PETER NOVITZKY

ETHICS OF AMBIENT ASSISTED LIVING TECHNOLOGIES FOR PERSONS WITH DEMENTIA

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DECLARATION

I hereby certify that this material, which I now submit for assessment on the programme of study leading to the award of Ph.D. is entirely my own work, that I have exercised reasonable care to ensure that the work is original, and does not to the best of my knowledge breach any law of copyright, and has not been taken from the work of others save and to the extent that such work has been cited and acknowledged within the text of my work.

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ACRONYMS

AAL	Ambient Assisted Living
AD	Alzheimer's Disease
ADL	Activity of daily living
AI	Artificial intelligence
AmI	Ambient intelligence

ART	Artificial Reproductive Technology
AT	Assistive Technology
CIOMS	Council for International Organizations of Medical Sciences
DAT	Digital Assistive Technology
DLB	Dementia with Lewy bodies
DSM-5	*Diagnostic and Statistical Manual of Mental Disorders: DSM-5* of the American Psychiatric Association
EDCON	European Dementia Consensus Network
FDA	Food and Drug Administration agency of the US Department of Health and Human Services
FTD	Fronto-temporal Dementia
FTDL	Fronto-temporal Lobe Degeneration
HTA	Health Technology Assessment
iADL	Instrumental activity of daily living
IBC	International Bioethics Committee
ICD	*The International Classification of Diseases* of the World Health Organization
ICT	Information and Communication Technology
IFR	International Federation of Robotics
MacCAT	MacArthur Competence Assessment Tool
MCI	Mild cognitive impairment
MMSE	Mini-Mental State Examinations
NCD	Neurocognitive Disorder
NGO	Non-governmental organisation
NICE	National Institute for Health and Care Excellence – United Kingdom
NIH	US National Institute of Health
PDD	Parkinson's disease dementia
PwD	Person with Dementia
R&D	Research & development
REC	Research Ethics Committee
UN	United Nations
UDBHR	Universal Declaration on Bioethics and Human Rights
UNECE	United Nations Economic Commission for Europe
UNESCO	United Nations Educational, Scientific and Cultural Organization

VR	Virtual Reality
WHO	World Health Organization
WMA	World Medical Association
WT	Welfare Technology

ABSTRACT

PETER NOVITZKY: ETHICS OF AMBIENT ASSISTED LIVING TECHNOLOGIES FOR PERSONS WITH DEMENTIA

Ageing populations worldwide are leading to an increasing incidence of dementia. Ambient Assisted Living (AAL) technologies are seen as one of the solutions to tackle a variety of problems posed by dementia. In this thesis, the ethical challenges and opportunities of AAL technologies for Persons with Dementia (PwDs) are identified through a systematic literature review. The three most prominent ethical issues are informed consent, special vulnerability of PwDs, and the value of the goals of AAL technologies. These key issues are comprehensively analysed in dedicated normative chapters as they arise during research & development (R&D) and clinical application of AAL technologies for PwDs. The analysis is performed using a methodological framework based on the principles of the *Universal Declaration on Bioethics and Human Rights* (2005) developed by UNESCO. Each normative chapter concludes with a set of recommendations for the effective management of the ethical issues.

1

INTRODUCTION

In this introductory chapter, the research objectives of this dissertation are presented, together with the methodology describing how these research objectives are met, followed by a section about the relevance of the research topic, and the outline of this thesis.

1.1 RESEARCH OBJECTIVES

The intention of this research is to contribute to the responsible development, clinical research, and application of Ambient Assisted Living (AAL) technologies for Persons with Dementia (PwDs). This demands substantial analysis of the ethical issues that might arise during research & development (R&D), clinical trials and eventual clinical application (Emanuel, Wendler, and Grady 2000; Emanuel, Wendler, Killen, et al. 2004). Accordingly, this dissertation aims to meet the following research objectives:

1. *Ethical Challenges and Opportunities* – The identification of the ethical challenges and opportunities associated with the development and application of AAL technologies for PwDs, and the selection of the most prominent ethical issues. These prominent ethical issues are identified from the systematic literature review presented in Chapter 3 and are as follows:
    - Values of the goals of AAL technologies.
    - Special vulnerability of PwDs.
    - Informed consent of PwDs.
2. *Interpretation of Universal Declaration on Bioethics and Human Rights (UDBHR) Principles* – The interpretation of the UDBHR principles related to the most prominent ethical issues. This interpretation is based on the overview of the related essential literature and policy documents.
3. *Normative Analysis of Ethical Issues* – The normative analysis of the most prominent ethical issues in specifying the UDBHR principles to the context of PwDs and AAL technologies.

4. *Conclusions of the Ethical Analysis* – The analysis is concluded with recommendations regarding how to tackle the ethical issues related to the application of AAL technologies for PwDs.

1.2 METHODOLOGY

1.2.1 *First Research Objective: Ethical Challenges and Opportunities*

The first research objective is the identification of the ethical challenges and opportunities involved in the various stages of R&D, clinical experimentation, and clinical application of AAL technologies for PwDs. These are identified by conducting an extensive systematic literature review.

The systematic literature review is a well-established instrument that in this case provides the means to identify the ethical challenges and opportunities of AAL technologies for PwD. The literature review also makes it possible to systematically categorise the variety of the ethical challenges and opportunities specific to the realm of AAL technologies and PwDs. The methodological details of the literature review are explained in Chapter 3.

The most prominent ethical issues are selected by screening all of the ethical challenges and opportunities in the literature review. The screening selects ethical issues that are important and have yet to be addressed sufficiently in academic debate.

1.2.2 *Second Research Objective: Interpretation of UDBHR Principles*

The most prominent ethical issues are specified using the principles of UDBHR. In the subsections below, the rationale for selecting the UDBHR framework is presented. This is followed by an explanation of how the principles of the UDBHR are to be interpreted.

1.2.2.1 *The Universal Declaration on Bioethics and Human Rights*

The *Universal Declaration on Bioethics and Human Rights*[1] is deeply embedded in the human rights tradition[2] that has been developed and adopted since World War II by a

1 For the whole text of the *UDBHR* (2005) see Appendix A on p. 267.

2 The historical development of the concept of human rights involves the emergence and subsequent moulding of various philosophical, moral, and political ideas (Fagan 2015). At least four stages of this development can be identified:

1. The first stage is a formulation of the theory of *(objective) natural rights*: an ideal world built upon rational principles of nature as a point of reference, and the universality of the rights common to every society (Vincent 1986). These classic natural right teachings include Plato's, Aristotle's, and the Stoics' accounts. Plato refers to 'nature,' or 'according to nature' (e. g. Plato 1997b, pp. 808–809, 464b–465d; p. 851, 506d–507a; Plato 1997c, p. 130, 1.626a; p. 1322, 1.627d; p. 1326, 1.631d; for a more comprehensive list see Lewis 2011) to represent a rule of reason, which is universally nor-

variety of international, intergovernmental organisations, as well as the European Council, the World Health Organization (WHO), the Council for International Organizations

mative for human affairs. Since the Sophists, the term 'convention' referred to something that is a consequence of human arrangement. With the introduction of the reference to 'nature' and its law, Plato aims to question the conflict between convention and nature, by highlighting that there is something permanent and not human-made in politics (Lewis 2011; d'Entrèves 1970). Aristotle, by defining every human as a member of a wider community by nature (Aristotle 1959, p. 9, 1253a3), advances the concept of natural law by stating three premises. Firstly, individuals are naturally subject to law (Aristotle 2009, p. 92, V.6 1134b10). Secondly, there are unchangeable and universal natural laws (Aristotle 2009, pp. 92–93, V.7 1134b20–1135a10; this thesis has been recently questioned, cf. Corradetti 2009, pp. 113–115). Thirdly, Aristotle also acknowledges that the good of an individual is secondary to the state by its very nature (Aristotle 1959, p. 11, 1253a20). Although Aristotle holds primacy in formulating an account, where the conventional and natural becomes compatible with each other (Corradetti 2009), the opposition of these concepts has been again revived by the Stoics, e. g. Cicero (1999, pp. 71–72, 3.33 and pp. 115–117, 1.29–33) or Seneca (2010, p. 89, 6.1.12; p. 114, 6.32.12).

2. The second stage towards the development of human rights may be identified with the emergence of *natural law theories*. These attempts tried to synthesise and harmonise the relationship of natural rights with other laws. One of these attempts is in the *Digest* of the *Corpus Iuris Civilis*, the compilation of legal materials completed in 534 AD by Byzantine lawyers of Emperor Justinian. The Roman law with its distinction between *ius civile*, *ius gentium*, and *ius naturale* preserved the idea of universal and rational justice (Vincent 1986; d'Entrèves 1970). A detailed and full account on natural law is developed by Thomas Aquinas, when he identifies God as a source of natural law (Dyson 2002, pp. 89–90, IaIIae q.91 a.4), and natural law can be used to evaluate the reasonableness of any human action (Dyson 2002, p. 119, IaIIa q.94 a.3). Persons acting on the basis of natural law are participating in the eternal law of God, which represents God's rational plan of providence (Dyson 2002, pp. 101–113, IaIIae q.93).

3. The third stage towards the development of human rights was the formulation of a doctrine of *(subjective) natural rights*. The formulation of this doctrine by John Locke is traditionally considered to be a decisive break from the natural law tradition, although this view has recently been challenged by Tierney (2005). The doctrine of natural rights is based on every person's duty of self-preservation towards God (Locke 2003, p. 28). The duty for self-preservation translates into natural rights of every human being to be free from threats of life, the right for liberty, and right for personal property. Due to Locke's interpretation that any political community is artificial, in the state of nature people provide consent for the formation of the political society to protect their natural rights (Locke 2003, pp. 101–106; Fagan 2015; Tierney 2005). Additionally, the emphasis on individual rights and liberties became the key concept of the Enlightenment, especially in the documents like the *US Declaration of Independence* (1776), or the *Déclaration des droits de l'homme et du citoyen* (1789) in the First French Republic.

4. The fourth stage of the development of human rights is its *codification*. The initial steps toward an international peace were made at the Hague Peace Conference (1899, Normand and Zaidi 2008, also called First Hague Conference). Despite the ratification of the *UDHR* (1948), Moyn (2010) highlights the fact that human rights did not play a central role in wartime and postwar rhetoric. Moreover, the Holocaust consciousness did not trigger the human rights movement in this period. Instead, the human rights movement emerged during the 1970s, gaining momentum from the collapse of other universalistic doctrines (Moyn 2010, pp. 7–8). Since the 1970s, United Nations Educational, Scientific and Cultural Organization (UNESCO) has been increasingly interested in issues regarding life sciences. This led, first, to the formation of the International Bioethics Committee (IBC) in 1993, which has been granted Statutes, and later in 1998 its mandate has been confirmed. Since 2002 UNESCO has been coordinating activities of international bodies in the area of bioethics. Simultaneously, the earlier intensive work resulted in the expressed interest of 191 Member States to elevate ethics to the priority-list of UNESCO in 2002 (ten Have, Jean, and Kirby 2009).

of Medical Sciences (CIOMS; Gordijn and ten Have 2014; ten Have, Jean, and Kirby 2009).[3]

The UDBHR consists of: a) the *reasons* noted in the *Preamble*, which led the General Conference towards elaborating upon the UDBHR, with explicit reference to related United Nations (UN) documents, such as the *Universal Declaration on the Human Genome and Human Rights* (1997) or the *International Declaration on Human Genetic Data* (2003); b) *general provisions*, which define the scope and aims of the declaration; c) a list of fifteen *principles*; with guidelines for d) the *application* and e) the *promotion* of these principles; together with f) the *final provisions* of the declaration (*UDBHR* 2005).

The UDBHR constructs three types of relationships between the human rights tradition and bioethics. These are (Gordijn and ten Have 2014, pp. 833–834):

- Human rights as a foundation and context of bioethics – UDBHR refers to human rights as the frame within which bioethical issues should be analysed.
- Human rights as a fundamental principle of bioethics itself – the initial principles, according to Gordijn and ten Have (2014), suggest that human dignity and basic human rights have a fundamental role in the way we understand and apply the other principles of the UDBHR.
- Human rights as a limitation and definite authority for bioethics – every specification and any application of the principles should be compliant with human rights laws.

Gordijn and ten Have (2014) list certain positives[4] of the close connection of UDBHR and human rights tradition. Such a connection is beneficial because many ethical issues have to be dealt with on a worldwide level. Ethical questions that humanity encounters do not stop at the national borders (e. g. pandemics, international drug trials, migration of healthcare professionals, pollution, etc.). Moreover, a development on one side of the globe unavoidably affects the developments on the other side of the globe because

3 The human rights tradition applicable to bioethical issues also includes documents such as *The Universal Declaration of Human Rights* (1948), "Declaration of Helsinki" (1964), the Proposed International Guidelines for Biomedical Research involving Human Subjects (1982), the *Universal Declaration on the Human Genome and Human Rights* (1997); the *Convention on Human Rights and Biomedicine* (1997); *International Declaration on Human Genetic Data* (2003); and *Universal Declaration on Bioethics and Human Rights* (2005; Gordijn and ten Have 2014; ten Have, Jean, and Kirby 2009).

4 Tierney (2005) highlights, referring to the publications of Glendon (2004) and Glendon (1993) that despite the limitations and abuses of 'rights talk,' these abuses are not intrinsic to the human rights discourse. Additionally, the *UDHR* (1948) does not follow atomistic and selfish individualism but reaffirms the role of a family as a fundamental unit of every society (Tierney 2005). This motif is noted also by Fagan (2015), referring to Nickel (1987). Nickel (1987), according to Fagan (2015), provides two additional positives of the human rights tradition. One of these is that the human rights tradition provides much greater engagement with the issue of the realisation of equity in the positive actions of the state compared with natural rights theories. The second positive manifests itself in the greater engagement in international advocacy for active promotion and protection of human rights compared with natural rights theories (Fagan 2015).

of interconnected societies worldwide. With its established nature, the human rights tradition seems nowadays to be one of the most effective means for addressing the demand for such international solutions. Among the positives of the UDBHR and its close links with the human rights tradition, therefore, are (Gordijn and ten Have 2014, pp. 834–837):

- *Familiarity and reputability* – everybody on the globe has heard about human rights, unlike other ethical theories (utilitarianism, deontology, virtue ethics, etc.), which remain the preserve of a few academics. Human rights are a well-tested and long established common language, and are present in international institutional practice.

- *Affinity between bioethics and human rights* – both have the same motivation of promoting human rights and public health, having been founded by similar social and historical forces and events. This closeness of the two may eventually develop in the future into a synthesis.

- *Universalism* – there is no special requirement needed to enjoy the rights, being a human is the only requirement. This universalism can overcome issues of cultural diversity.

- *Flexibility* – although the human rights claim universality, it is at the same time not blind to cultural and local diversities, in which specific rights and articles are interpreted and implemented. It acknowledges cultural diversity as a source of exchange, innovation and creativity, up until the point the cultural specificities violate the basic human rights and fundamental freedoms (esp. Art. 12 of the UDBHR).

- *Effectiveness and enforceability* – the human rights movement enjoys great support from international organisations, as well as non-governmental organisations (NGOs). These may effectively influence the definition of policies. With this characteristic, human rights reinforce the link to law-making and policy-making.

Despite all the positives, various critical comments[5] have also been expressed regarding the UDBHR and its close links with the human rights tradition (Gordijn and ten Have 2014, pp. 837–839):

- *Problems of human rights theory* – the origins of the human rights theory can be found in the 17th–18th century philosophical and religious reflection on 'natural rights,' 'unalienable rights' or 'rights of man.' These were related mostly to the concept of God-given rights, which at the present time does not provide an acceptable premise in modern secular societies, or societies with different religious traditions. Referring to the concept of human dignity does not provide enough support in the argumentation of human rights theory because it has also its origins in a religious concept. Moreover, the Kantian understanding of human dignity does not include individuals who have lost their rational capacity. Additionally, the anthropocentric approach that is embraced in the human rights theory is problematic, claiming an exclusive position for the human species on the Earth.
- *Impotence* – human rights theory focuses predominantly on rights but fails to define the necessary corresponding obligations, without which the rights are meaningless.
- *Activism's deleterious effects on academic work* – the human rights movement, which focuses on social change, can negatively affect, with social activism, the area of scholarly work. There is a fear that such activism can instrumentalise academic debates for its goals.

5 One of the major criticisms of the human rights tradition was formulated by the philosopher, Alasdair MacIntyre, who in his book, *After Virtue*, criticised both the 19th century philosophers' reference to self-evident truths in relation to natural rights, and 20th century philosophers' reference to moral intuition regarding human rights. MacIntyre (2007) thus states that the existence of human rights cannot be demonstrated, and the belief in them is comparable with the "belief in witches and in unicorns" (MacIntyre 2007, p. 69). Another criticism is formulated by Rorty (1998), who refers to any foundationalist approach towards human rights as "outmoded and irrelevant" (Rorty 1998, p. 170). Instead of grounding the shared human attributes on rationality, and searching for ahistorical foundations of human nature, one should focus on historical and cultural facts that distinguish human beings from animals. These facts lead in the post-Holocaust world to human beings culturally 'naturalised' in human rights (Rorty 1998). The third criticism of human rights comes from cultures that accuse human rights of being based on the Judeo-Christian tradition (Littman 1999). These include islamic countries with governments based on Sharia (e. g. Iran, Sudan, Saudi Arabia, Pakistan; Price 1999), or signatories of the *Bangkok Declaration* (1993), who stress the universality, objectivity, and non-selectivity of human rights with the need to avoid double standards in Asian countries, while at the same time emphasising the "respect for national sovereignty, territorial integrity and non-interference in the internal affairs of States" (*Bangkok Declaration* 1993, p. 1). The latter demand of Asian countries is congruent with the criticism of Ignatieff (2005). He criticises the US in three aspects. Firstly, as one of the leading countries involved in drafting the *UDHR* (1948), the US continues to exempt itself from international human rights and humanitarian law conventions. These include the formulation of explicit reservations (e. g. handing over US nationals to the International Criminal Court; ratifying *International Covenant on Civil and Political Rights* with the exemption on death penalty on juveniles), non-ratification or ratification of negotiated treatises after extended delays (e. g. *Convention on the Rights of the Child*), or non-compliance with the agreed treatises (e. g. stipulations that international rights provisions cannot supersede US domestic law). These issues render any criticism against countries for poor adherence to international agreements questionable, due to accusations of practicing double standards (Ignatieff 2005).

- *Western imperialism* – Hyakudai Sakamoto emphasises the difference between Eastern and Western bioethics, which have very little in common. The importance of human rights in Asia is appreciated in a culturally different way. In addition, it has triggered many conflicts in Asian societies (Sakamoto 1999).

The UDBHR has been unanimously adopted by UNESCO in its 33rd General Conference on 19th October 2005 (*Explanatory Memorandum on UDBHR* 2005; ten Have, Jean, and Kirby 2009).[6] The purpose of the Declaration was to satisfy the growing need for a set of rules and principles for national and international guidelines covering bioethical issues. The goal of the Declaration is to help scientists, practitioners, law-makers and citizens in general set the actual standards regarding human dignity, human rights and freedoms, and provide benchmarks for evaluating these norms.

The particular rationales, in this dissertation, for applying the principles of the UDBHR in the analysis of the ethical issues surrounding AAL technologies and PwDs are as follows:

- The UN today is the only existing platform that provides nations with the means to share and discuss their values or principles internationally, with the possibility to negotiate and agree on certain normative instruments. The UDBHR is a result of such an international standard-setting effort (ten Have and Jean 2009). Standard-setting is a process whereby universal agreements are made. Such agreements can be reached as a result of a delicate balance between developing universal principles grounded in shared values, and promotion of pluralism through the recognition of diversity. For this purpose, the platform of the UN—according to ten Have and Jean (2009)—provides a necessary framework for reflecting on the standard-setting process, especially at the global level (ten Have and Jean 2009).

  There are certain global issues, which the UDBHR framework may be especially helpful in solving. One of them is the issue of growing portions of the population which suffer from dementia. This poses increasingly great challenges in the fields of healthcare and bioethics. A further issue is the world-wide experience of ageing

6 The Director-General was requested by the General Conference on its 31st session in 2001 to submit a report on "the technical and legal studies undertaken regarding the possibility of elaborating universal norms on bioethics" (*Explanatory Memorandum on UDBHR* 2005, p. 1). The initial document, entitled 'Report of the IBC on the Possibility of Elaborating a Universal Instrument on Bioethics' was drafted and finalised at the request of the Director-General by the IBC on 13th June 2003, which was then discussed at the 32nd session in October 2003 of the General Conference. Member States, international organisations and relevant national bodies were invited for this discussion. The Director-General was requested to continue the preparatory work on the declaration in order to submit a draft of the future declaration at the 33rd session (32 C/Res. 24). The Director-General then entrusted the International Bioethics Committee with initiating the drafting of the declaration. The Executive Board of UNESCO then on its 169th session in April 2004 approved the timetable of the declaration. Again, many discussions were conducted with Member States, specialised agencies, intergovernmental organisations, NGOs and various national bodies and specialists (*Explanatory Memorandum on UDBHR* 2005).

societies, including those nations, which are currently at the stage of their population boom but later will face the same problem of ageing societies. These two issues together demand a global approach to the ethical standard-setting regarding dementia. Therefore, using a global framework from the very beginning of the ethical analysis could be beneficial and particularly effective in the standard-setting process. Additionally, the principles of the UDBHR make it possible to include the specificities of local cultures as well, until such standards violate basic human rights. This should also mean that the framework is more acceptable at a worldwide level.

- The source of the principles is not purely the product of academic scholarly discourse; it is also the result of the active contributions made by political and intergovernmental bodies that have contributed to the development of the UDBHR (Andorno 2007). The UN Member States expressed their need for regulation and legislation of bioethical issues. Furthermore, the whole procedure of reaching an agreement is a result of a multiple steps: elaboration, examination, adoption, and follow-up, all agreed and accepted by the Member States in consensus. This means that the resulting Declaration is also a product of political negotiation, expressing commitment and willingness of the Member States to gradually incorporate these principles into their legal systems.[7]

  This condition also promotes effectiveness. Thus, the resulting legislation a) can be informed about the experiences and results of the application of these principles in other Member States; b) can be easily adopted from other Member States, if they fit into the particular cultural framework of the country; c) is, instead of a limited scholarly discussion, open to the widest democratic public debate; d) provides the individual citizen of a Member State with the possibility of enjoying the benefits of ethical reflection as entitlements adopted in the new legislation within the legal system.

- The principles defined in the UDBHR are not only the result of collaboration between intergovernmental, governmental, and non-governmental bodies, but also of religious representatives (Buddhist, Catholic, Confucian, Hindu, Islamic, and Jewish) who were invited to express their viewpoints during the drafting process (ten Have and Jean 2009). This fact suggests that the UDBHR is one of the most widely discussed and accepted frameworks on the global level.

7 The legal status of the UNESCO UDBHR declaration is as an officially non-binding, so-called soft law, instrument. Unlike conventions, soft law declarations have weaker effect because they do not oblige states to enact the formulations based on common standards. However, the states are encouraged to enact them (Andorno 2007). Such an approach, according to Andorno (2007), motivates the states to take on commitments they would normally not take. Furthermore, soft law instruments make it possible for the countries with various cultural and political settings to become familiar with the proposed standards, and prepare the grounds for a development of binding convention in the future (Andorno 2007).

The conferring process adopted in the UN not only ensures a thorough discussion of the proposals. The UN also sees to it that the proposals are being discussed between a variety of governmental, non-governmental, and religious representatives. Such a process, during which the widest possible debate is being held among a multitude of political, philosophical and religious world-views, declares the willingness of the UN to provide a) the most universal frameworks for adoption, while at the same time it expresses also b) due respect towards these world-views.

- The UDBHR principles are necessarily minimalist, open to various interpretations and applications within the framework of human rights and freedoms (ten Have and Jean 2009). Therefore, it follows that when it comes to interpreting the principles no particular definitions are being preferred exclusively. Furthermore, the principles remain open to new interpretations and specifications, so long as they do not violate the basic human rights. Thus, the principles can be universally applied to any bioethical issue; they remain open to new interpretations and cultural differences globally.

- The principles of UDBHR have not yet been applied to the challenges of AAL for PwDs, at least not in the scholarly literature. The aim of this dissertation is to develop an ethical analysis in this field employing the principles of the UDBHR. This is in accordance with the overall spirit of the Declaration, which encourages the further specification of principles to particular cases (ten Have and Jean 2009).

By employing the principles of the UDBHR, this dissertation omits systematic discussion of the legal issues that arise during technological research. The application of legal standards and regulations specific to particular countries are already acknowledged through Art. 27 of the UDBHR. References to various legal regulations are made throughout the thesis whenever it is relevant to the interpretation of the UDBHR principles. However, legal documents in this dissertation are not reviewed systematically in this regard.[8] Similarly, other related aspects such as issues arising regarding patents and biobanks are not discussed systematically. This dissertation also considers the 15 principles of the UDBHR as a sufficient amount of principles for the purposes of normative ethical analysis of AAL technologies for PwDs. Extending this number of principles by other additional principles,[9] defined either by the UN or other expert bodies, would undesirably increase the complexity of the proposed normative analysis while the benefit of

8 These topics were already more systematically reviewed, for example, by B. D. Mittelstadt (2013), Stanberry (2001), Chan, Estève, et al. (2008), or Ahonen et al. (2010a).

9 Additional principles refer to principles of later declarations or conventions, e. g. *Convention on the Rights of Persons with Disabilities and Optional Protocol* (CRPD; 2006). As the UDBHR was published in 2005, it cannot refer to the *CRPD* (2006). The *CRPD* (2006) does not refer to the UDBHR. Only documents that are referred to by the UDBHR (cf. footnote 10), or documents that directly refer to the UDBHR are considered in this dissertation.

such a step would remain questionable. The UDBHR with its set of principles is considered as a complete document, along with its explanatory memorandum (*Explanatory Memorandum on UDBHR* 2005).

1.2.2.2 *Interpretation of Principles*

Every normative chapter (Chapters 4–6) provides an in-depth overview of the related UDBHR article(s). This overview is provided, firstly, by presenting the interpretation of the essential literature concerned by the UDBHR articles. The sources for this interpretation include the corresponding chapters of *The UNESCO Universal Declaration on Bioethics and Human Rights: Background, Principles and Application* (ten Have, Jean, and Kirby 2009), *Handbook of Global Bioethics* (ten Have and Gordijn 2014), and the related reports of the International Bioethics Committee (e. g. IBC 2008, and IBC 2013).

Secondly, the interpretation of the UDBHR principles is followed by the overview of the important policy documents, along with national and international guidelines. These include for example "The Nuremberg Code (1947)" (1996), *Belmont Report* (1978), "Declaration of Helsinki" (1964), *Convention on Human Rights and Biomedicine* (1997), CIOMS (2002) and many others.[10]

Thirdly, the interpretation also provides an overview of the academic literature of leading scholars, whose contributions are relevant for the appropriate interpretation of the general principles provided in the UDBHR.

1.2.3 *Third Research Objective: Normative Analysis of Ethical Issues*

The third research objective is to provide a detailed analysis of the most prominent ethical issues identified regarding the application of AAL technologies to the care of PwDs. These selected ethical issues undergo a deeper normative analysis. For this purpose, this study applies the UNESCO *Universal Declaration on Bioethics and Human Rights* (*UDBHR* 2005). The normative analysis involves first a specification of the UDBHR principles to the context of PwDs and AAL technologies, and secondly, if required, a balancing of conflicting UDBHR principles.

10 As noted in the *Preamble* of the UDBHR, other relevant principles from the *Universal Declaration on the Human Genome and Human Rights* 1997, the *International Declaration on Human Genetic Data* 2003 should be mentioned as well. *Explanatory Memorandum on UDBHR* (2005, p. 2) lists three especially important internationally accepted instruments, whose principles may be helpful in the normative analysis of ethical issues: a) the "Declaration of Helsinki" (1964) developed by the World Medical Association (latest version: "Declaration of Helsinki" 2013), b) the *Convention on Human Rights and Biomedicine* 1997 of the Council of Europe, and c) the *International Ethical Guidelines For Biomedical Research Involving Human Subjects* by the Council for International Organizations of Medical Sciences (CIOMS 2002). Also, the *Explanatory Memorandum on UDBHR* (2005) requires the use of other relevant international instruments for bioethical issues from the WHO or Food and Agriculture Organization. Ultimately, because of the indisputable foundations of modern bioethics on *The Universal Declaration of Human Rights* (*UDHR* 1948), references to this document are made where necessary.

1.2.3.1 *Specification of Principles*

Any *general* principle, like those in the UDBHR, demands a specification for its application in *specific* contexts. The principles of the UDBHR undergo a process of specification (i. e. the understanding of a general principle in a specific context), as a result of engagement with the three sources of the interpretation (e. g. UDBHR-related literature, policy documents, and academic literature). Wherever needed, additional literature will be provided in order to support the arguments provided during the specification of the general principles of UDBHR for the cases of PwDs and AAL technologies.

1.2.3.2 *Balancing of Principles*

By employing the principles of the UDBHR, this methodology adopts a pluralist principlist approach. Unfortunately, these approaches are susceptible to the possibility of clashing principles. In order to maintain the coherence of the ethical framework, there are three possible ways of resolving a conflict of principles:

1. The first option is to provide a hierarchical order of general principles, which consistently and sufficiently ranks the rules in order of priority (Richardson 1990).[11]

2. The second option is specification. During specification, the meaning, range, or scope of a general principle, narrowed by its application to a specific case, is reduced to a level at which the application of that principle no longer conflicts with any of the other principles. As such, the principles that do not or no longer conflict may then become action guides (Childress 2009).[12]

3. The third option is to provide a balancing with constraints to reduce excessive intuition, partiality, and arbitrariness. During the balancing process, the conflict between general principles that are applied to the special case is resolved by defining which principle is more plausible under the given circumstance (Childress 2009).

The UDBHR provides a tenuous hierarchical, ranked order of principles, which one may call a 'weak hierarchy.' Such a categorisation is apparent from the text of the Declaration (*UDBHR* 2005). The weakest of the principles within the Declaration is the principle of respect for cultural diversity (Art. 12). It is emphasised that this principle should never infringe upon any of the other principles. Conversely, Art. 3—respect for human dignity and human rights—is the strongest principle of the Declaration. It is stressed in Art. 28 that nothing from UDBHR should be interpreted or applied to violate this principle.

11 An example of such an approach has been explored by Veatch (1981).
12 Such an approach has been elaborated by Richardson (1990). DeGrazia (1992) interprets and designates Richardson's approach as 'specified principlism.'

The Declaration does not provide any further hierarchical ordering of the remaining principles. Therefore, in various circumstances, these remaining UDBHR principles might clash. This conflict of principles is analogous to the conflict of *prima facie* duties described by Ross (2002). Ross' definition of *prima facie* duties is applied to the interpretation of the UDBHR principles for the purpose of this study. For Ross, a duty might be either a *prima facie* duty (i. e. a consideration that *tends* to amount to a duty)[13] or an actual duty (duty proper; Ross 2002).[14] *Prima facie* duties are such generally promotable self-evident duties, which provide the agent with guidance for performing a morally right action.[15] However, these guidelines are not absolute. A *prima facie* duty may be outweighed by another *prima facie* duty. However, when a *prima facie* duty is outweighed by another *prima facie* duty, the more important *prima facie* duty becomes the actual duty of the agent (Ross 2002, p. 19).

From Ross' description it is clear that *prima facie* duties are not duties, nor are they anything illusory, as the term *prima facie* might initially suggest.[16] Instead, for Ross (2002), *prima facie* duties reflect some features of the situation (and characteristics of the act) that are related to the (proper) duty in a special way (Ross 2002, p. 20). These features inform the moral agent about the reasons why certain actions would be morally right in a given situation. These moral features are related to the objective fact involved in the particular elements of the nature of the situation. In case of conflict these features provide genuine (and not only apparent) reasons for the omission of one *prima facie* duty in favour of respecting another *prima facie* duty, which forms the basis of the performance of an act that is morally right (Stratton-Lake 2002, p. xxxiv).[17] As a result, the agent

13 "We have to distinguish from the characteristic of being our duty that of tending to be our duty. [...] In virtue of being the breaking of a promise, for instance, it tends to be wrong; in virtue of being an instance of relieving distress it tends to be right. Tendency to be one's duty may be called a parti-resultant attribute, i. e. one which belongs to an act in virtue of some one component in its nature. *Being* one's duty is a toti-resultant attribute, one which belongs to an act in virtue of its whole nature and of nothing less than this." (Ross 2002, p. 28).

14 Ross (2002) sometimes referred to actual duty as absolute duty, in the sense defined by Kant (for example, see Ross 2002, p. 28).

15 Ross lists the following as *prima facie* duties: a) fidelity, b) reparation, c) gratitude, d) justice, e) beneficence, f) self-improvement, g) non-maleficence (Ross 2002, p. 21).

16 While one might interpret Ross' '*prima facie* duties' as one's duties 'at first sight,' and the proper duties are one's 'real' duties, this is not so. Ross (2002) himself struggled with the correct terminology, and at the time of writing his book, he failed to find a better term than *prima facie* duties, for which he apologised (Ross 2002, p. 20). Kagan (1989) therefore proposes renaming Ross' *prima facie* duties as *pro tanto* duties, since they are 'most of the time' our action guides, unless, exceptionally, the general reason to promote good is outweighed by other morally acceptable reasons (Kagan 1989, p. 17). Philip Stratton-Lake in his *Introduction* to Ross (2002) mentions an alternative term suggested by Broad (1930, pp. 164–165, 219, 278), referring to a specific 'fittingness' of a situation and the moral action, which might be used instead of '*prima facie* duty' (Stratton-Lake 2002, pp. xxxiv–xxxv). Alternatively, these features may be also called dispositions, tendencies, or certain responsibilities towards oneself and to others for acting (Stratton-Lake 2002, pp. xxxiv–xxxv).

17 According to Philip Stratton-Lake, these definitions appeared first in Ross' book *Foundations of Ethics* (Stratton-Lake 2002, referring to the reprinted version of Ross 2008).

recognises the actual duty (duty proper) that emerges from the totality of the nature of the situation (Ross 2002, p. 20; Ross 2008, p. 81).[18]

From the weak hierarchy of UDBHR principles, it follows that Art. 4–11 and Art. 13–17, interpreted as *prima facie* duties in the Rossian sense, may occasionally conflict. To tackle these possibly conflicting *prima facie* duties, this dissertation uses Bernard Gert's approach of two-step procedure for justifying violations of moral rules (Gert 2004; Gert 2005).

The rationale for using Gert's procedure is that it can provide a more conclusive method to addressing the ambiguities inherent in pluralist principlist approaches. Ross' moral system relies solely on the agent's moral intuition in resolving the conflict of *prima facie* duties (see previous footnote 18 and in particular Ross 2002, pp. 29–30 and Stratton-Lake 2002, p. xliii). However, in certain cases, reference to one's moral intuition might result in inconclusiveness in moral judgements. Especially in conflicts of *prima facie* duties that are equally weighted, it might be irresolvable to decide which of the conflicting duties is more applicable under the given circumstances.

The desirable conclusiveness in moral judgements (and their possible consequences) can be introduced by the categorisation based on whether the judgements can be publicly allowed, as defined by Gert (Gert 2004; Gert 2005). His two-step procedure of justifying the violation of moral rules can be applied to any plural principlist approach that refers to common morality (Gert 2005, p. 116).[19] For Gert every moral rule should be obeyed "except when a fully informed, rational person can publicly allow violating

18 The definition of *prima facie* duties reflects basic aspects of Ross' moral theory, namely, his moral realism and non-naturalism. The realism means that the rightness and goodness described in moral theories are objective qualities of the moral order, which are perceived as properties of the existing world. The non-naturalism means that the aforementioned moral properties cannot be fully understood by psychological, sociological, evolutionary or other (empirical) scientific terms without falling into a reductive, naturalistic fallacy (Stratton-Lake 2002, pp. x–xii). The third attribute of Ross' moral theory follows from the non-naturalist interpretation of the moral order: our moral knowledge is partly based on derivative moral evaluation, and partly on deontic truths (e. g. one should not kill, etc.). The moral evaluation is based on the determination and appraisal of self-evident premises, among which belong both the relevant moral and also non-moral facts. The deontic truths, however, cannot be derived from non-moral premises (they describe intrinsically good actions). Therefore, the realisation of the deontic truths must be based on the direct understanding of the moral properties. The most fundamental moral properties – of which *prima facie* duties are also part – are *a priori* self-evident, directly understandable truths, recognisable for moral agents by apprehension (Stratton-Lake 2002, p. xliii; Ross 2002, pp. 29–30). As much as one's moral intuition is clear about the recognition of *prima facie* duties, this does not extend to one's moral judgement. The agent's moral judgements cannot be so certain in particular cases (Stratton-Lake 2002, pp. xliii–xliv; Ross 2002, pp. 30–31). Additionally, although *prima facie* moral duties are self-evident, they are not instantly perceived as such by everyone (Ross 2002). As self-evident mathematical proofs are understood after reflection on their meaning, according to Ross, the same is applicable to the *a priori* moral duties. Hence, the self-evidence of *prima facie* duties does not necessarily mean that they are automatically palpable to the moral agent herself (Ross 2002, p. 12). The *prima facie* duties are thus recognised in considered moral judgements. Therefore, Ross' definition of *prima facie* duties is appropriate for the interpretation of the UDBHR principles, thereby facilitating a basic framework from which the balancing of principles can be initiated.

19 Morality for Gert is an informal public system, which applies to all rational persons. Morality governs behaviour by its moral rules, moral ideals, and virtues. Its main goal is to protect the persons from harms (Gert 2005, p. 14).

it" (Gert 2005, p. 203). Publicly allowing a violation of a moral rule can be justified only if the violation has far better results than compliance (Gert 2005, p. 208). The first step of the two-step procedure is to identify the morally relevant features of the particular case (Gert 2004, pp. 58–74).[20] In the second step, the consequences of the violation of the moral rule are forecasted, and the positive and negative consequences of the violations are weighted, based on the scenario that the public is informed that this kind of violation is allowed (Gert 2004, pp. 74–76).

By employing Gert's two-step procedure, this dissertation aims to balance any conflicting principles by first identifying which principles conflict in the specific context, along with which stakeholders are directly and indirectly affected, and any other morally relevant circumstances. This balancing process is then to focus on delineating the possible outcomes of each of the conflicting UDBHR principles being violated, with the violation being publicised as permissible within the particular context of PwDs and AAL technologies. The consequences of the violations are weighed based on the resulting amount of potential benefit for and harm to the PwD. The central role ascribed to the PwD in the weighing process is based on the fact that the whole development of AAL technologies is aimed at serving them, assuming that they are the most vulnerable group amongst the stakeholders involved. The normative analysis also includes an analysis of the available academic literature, to support the considered judgements and moral intuitions of the author of the dissertation in the process of weighting the violations of the UDBHR principles. Special attention is given to the published and speculative opinions of the stakeholders identified in the literature review in Chapter 3. These stakeholders are considered as reasonable and impartial moral agents, as defined by Gert (2004, pp. 53–57).

As in every pluralist principlist method, Gert's two-step procedure for justifying violations of moral rules cannot completely omit the use of moral intuition in the forming of

20 Gert for this purpose lists 10 questions (Gert 2005, pp. 226–236; Gert 2004, pp. 58–73):

1. What moral rules are being violated?
2. What harms are being caused, avoided, or prevented by the violation of the moral rule?
3. What are the relevant desires and beliefs of the people toward whom the rule is being violated?
4. Does the person, violating the moral rule, due to her special relationship towards whom the rule is being violated, have a duty to sometimes violate moral rules, independently of their consent?
5. What goods and benefits are being promoted by the violation of the moral rules?
6. Is, by the violation of a moral rule that is being prevented, an unjustified or weakly justified violation of a moral rule?
7. Is the rule being violated toward a person because he has violated a moral rule unjustifiably, or with a weak justification?
8. Are there any alternative actions that would be preferable?
9. Is the violation being done intentionally, knowingly, voluntarily, freely, or negligently?
10. Is the situation sufficiently rare that no person is likely to plan or prepare for being in it?

moral judgements (Tomlinson 2012, p. 79). Therefore, this is one of the methodological limitations of this study.

To summarise: in this dissertation, the principles of UDBHR are used systematically. These principles have a weak hierarchical order, singling out one principle (Art. 3) as the strongest and another one (Art. 12) as the weakest and leaving the 13 remaining principles on an equal footing. These remaining principles are understood as *prima facie* principles in the Rossian sense (Ross 2002). If the application of these principles to specific cases (e. g. the application of AAL technologies for the care of PwDs) shows any signs of conflict, the conflicting principles are balanced using Gert's two-step procedure (Gert 2004; Gert 2005).

1.2.4 *Fourth Research Objective: Conclusions of the Ethical Analysis*

Based on the normative analysis of the selected issues, lists of recommendations are developed on how to address the ethical issues present in the application of AAL technologies for the care of PwDs.

The summary at the end of each normative chapter (Chapters 4–6) should help address the presented ethical issues. These recommendations stand as a conclusion of the normative analysis of the main ethical issues of these chapters.

1.3 RELEVANCE

Due to increased life expectancy and a falling birth rate, the age distribution in developed countries is gradually shifting towards older populations. Even though the population on our planet is still increasing overall, the birth rate in some countries has decreased to such a level that it has become impossible for them to internally maintain the sizes of their populations. The cohort aged above 60 worldwide is expected to rise from 11 % to 22 % between the years 2000–2050 (*Global elderly care in crisis* 2014).

One of the first nations confronted with this trend was Japan. Its current demographics already demonstrate a high proportion of over-60 year olds, a result of repeated baby booms after World War II. In 1950, Japan's population pyramid was a standard slow growth (box) shape but by 2010, 23 % of its population was older than 60. Within the next 40 years, that percentage is predicted to almost double to 39 % (Statistics Bureau, Japan 2011).

Eurostat (2011) reveals that Europe is going through a similar process. Whilst in 1960, an average ratio of three young people to one elderly person existed, it is predicted that there will be more than two elderly people to one young person by 2060. For most of the 20th century, the country with the highest median age, at 36, was Sweden. This

was surpassed in the 1990s by Italy. It is predicted that in the next 30 years, Germany will become the oldest country in Europe, which will then be superseded by Latvia and Romania by the year 2040, at which time, Sweden will have one of the lowest median ages. The proportion of the 'oldest-old' elderly persons (aged over 80) in Europe's average population will be about 10 % by 2060, five- to ten-fold more than the 1–2 % at the beginning of the 20th century (Eurostat 2011).

From the *World Population Prospects* of the UN figures, revised in 2006, it is obvious that almost none of the countries in the world will avoid the consequences of the ageing population, over the next 50 years. By 2050, all developed countries, together with Latin America, the Caribbean, and most of Asia including China, are expected to have a median age of around 40 years. Most African countries will still have a median age of 30 years by 2050 compared to 25 years at the moment (UN 2006).

The *Care in Crisis 2014* (2014) report of Age UK, quoted by *Global elderly care in crisis* (2014), ascertained that public funding of social care systems in the United Kingdom fell between the years 2010–11 and 2013–14 by 15.4 %, that is a massive cut of £1.2 billion. The portion of elderly who received social care services dropped from 15.3 % in years 2005–6 to 9.9 % in 2012–13. This means that in the UK itself around 800 000 people did not receive any care support from agencies in the public, nor private sector (*Global elderly care in crisis* 2014).

A similar case is present in the United States, where an article from The Washington Post calls the situation a "caregiving cliff" (Harris 2014). Most of the caregivers in the US providing assistance are unpaid, one in four adults identifying themselves as family caregivers (*Global elderly care in crisis* 2014).

A much more dramatic situation could arise in middle-income or lower-income developing countries, for example China. As the *China Health and Retirement Longitudinal Study*[21] in 2013 reported, China comprises more than 185 million people aged above 60 years, from which 32 % are considered to have poor health, 38 % reported difficulties with their everyday living, 40 % showed symptoms of depression, with 23 % below the poverty threshold (*Global elderly care in crisis* 2014).

The authors of the editorial in *Global elderly care in crisis* (2014) request a cultural and political paradigm shift, which should include a more age-friendly approach, ensuring healthy and dignified ageing. Also more financial and human resources investments are required, supported by better coordination in healthcare, long-term care and social services. According to the editors elderly care is at the moment in crisis, and it has been at this stage for too long (*Global elderly care in crisis* 2014).

An earlier study by the Alzheimer's Disease International (2013) suggests also a dramatic growth of PwDs until the year 2050 worldwide.

21 `http://charls.ccer.edu.cn/en` (visited on 30/07/2015).

What all this evidence points to is an unavoidable, worldwide, increase in the age profile for humankind and therefore an increase in the prevalence of age-related diseases, including dementia. The ageing of the population and its consequences necessitate better and more effective healthcare systems and health technologies. In such a scenario a deeper and more detailed ethical analysis of the needs of PwD would be desirable, especially if their care is facilitated by novel technologies such as AAL technologies. These relatively recent and constantly expanding technologies in general neither received satisfactory ethical attention in the scholarly debate, nor have their consequences been examined in the application to the particular care for PwDs.

1.4 OUTLINE OF THE STUDY

In Chapter 2, the basic terminology and definitions related to dementia and AAL technologies and their classification are clarified. The importance of clarifying both of these areas appears to be essential for the appropriate identification of the contexts of PwDs and AAL technologies, which may at first seem rather distant from each other. In Chapter 3, a literature review with the selection of prominent ethical issues is presented. These issues undergo a normative ethical analysis in the subsequent Chapters 4–6. At the end of each normative chapter, a set of recommendations point out how to deal with the ethical issues in practice. In Chapter 7 the results are summarised and suggestions for future research are presented.

2

TERMINOLOGY

2.1 DEMENTIA

2.1.1 *History of Dementia*

A description of dementia would not be possible without the thorough and meticulous work of Alois Alzheimer (1864–1915) that was conducted at his research laboratory in Munich. Before joining the "Anatomical Laboratory" newly established by Emil Kraepelin at the Royal Psychiatric Clinic/Department at the Ludwig-Maximilians University in Munich in 1903, Alzheimer worked as a clinical assistant at the Municipal Mental Asylum[1] in Frankfurt am Main (from 1888 to 1902), and in the Psychiatric Department of Heidelberg University (1902). Maurer et al. (1997) note that although Alzheimer moved to Munich, he followed the course of his patients in Frankfurt even after the year 1903 (especially Auguste D's case until her death in 1906, as mentioned below). During his career Alzheimer worked with specialists like Emil Kraepelin, Franz Nissl, Camillo Golgi, Arnold Pick, Hans Gerhard Creutzfeldt, Alfons Maria Jakob, Fritz Lewy and many others (Zilka and Novak 2006; Maurer et al. 1997).

In November of 1906 at the 37th Meeting of Southwest German Psychiatrists in Tübingen, Germany Alzheimer presented a case of a woman (originally without identification), Auguste D (51), with various clinical and neuropathological findings. She was suffering of, as Alzheimer depicted it with the expression that became ever since then famous: "a peculiar disorder of the cerebral cortex."[2] Her condition caused Auguste memory loss, disorientation, depression and hallucinations. Pathological investigations revealed atrophy, and particular lesions characterised by Alzheimer as a "paucity of cells in the cerebral cortex and clumps of filaments between the nerve cells" (Zilka and Novak 2006, p. 344). The first publication of Auguste D's case, six months after her death, has been submitted in the form of a title and short abstract on the 1906 neurological meeting

1 Maurer et al. (1997) mention an institute where Alzheimer worked in Frankfurt as "Hospital for the Mentally Ill and Epileptics" (Maurer et al. 1997, p. 1546).

2 In original German: "eine eigenartige Erkrankung der Hirnrinde" (Müller et al. 2013, p. 129; Zilka and Novak 2006, p. 344).

in Tübingen. The abstract was deemed to be too short and insufficient for short presentation.[3] Therefore it was rejected for publication in the *Allgemeine Zeitschrift für Psychiatrie* after its presentation as a case study at the convention of psychiatrists in Tübingen in 1906 (Weber 1997).[4] The next version in a form of abstract was then published without any illustrations in 1907 (Zilka and Novak 2006). In 1909 Perusini examined four cases in his article (Perusini 1909), where the case of Auguste D was referred to as case no. 1 mentioning her given name 'Auguste,' the initial 'D' of her surname and the profession of her husband (Maurer et al. 1997). Another article based on Alzheimer's second case (Johann F) with the first drawings of the amyloid plaques and neurofibrillary tangles (based on the results from his first case of Auguste D) was published in 1911 (Maurer et al. 1997). In this later article Alzheimer provided a differentiation of the histopathological spectrum of Alzheimer's disease with various forms ranging from 'plaque only' to 'tangles and plaques' (Zilka and Novak 2006).

Alzheimer's findings were confirmed by the subsequent reports of similar cases published by other researchers. These have been summarised by Solomon Fuller (Weber 1997), the already mentioned Perusini (1909), Bonfiglio (1908), and Fischer (1907; Zilka and Novak 2006; Maurer et al. 1997; Weber 1997). The famous Handbook of Psychiatry (*Psychiatrie: Ein Lehrbuch für Studierende und Ärzte*) written by Emil Kraepelin in 1910[5] proposed the naming of these conditions after Alois Alzheimer as Alzheimer's Disease (AD). Alzheimer's attention was raised by the fact that although the anatomical findings suggested that the conditions were a serious form of senile dementia, in this case the disease started much earlier, around the late forties. Therefore the age became very important in the definition of the new brain disease. Therefore two categories existed at that time: senile dementia which usually developed in a later age of the patient, and a much rarer AD occurring at an earlier age (Zilka and Novak 2006).

There are various views on why Kraepelin made such a hasty decision[6] to separate the pre-senile form of dementia from the senile form and creating the eponym of Alzheimer's Disease:

- *Scientific* reasons – according to which Kraepelin believed that Alzheimer had discovered a new disease (Maurer et al. 1997; Weber 1997)
- *Political* reasons – the desire for prestige, based on an existing rivalry between the Munich laboratory, where both Alzheimer and Kraepelin worked, with the laboratory in the German part of the Charles University in Prague with scientists Arnold

3 Alzheimer's text was the 11th submission, with the title "*Über einen eigenartigen schweren Erkrankungsprozeß der Hirnrinde*" (Maurer et al. 1997, p. 1548).

4 Alzheimer's submission was followed with the comment "zu kurzem Referat nich geeignet" [not appropriate for a short publication] (Maurer et al. 1997, p. 1548).

5 Weber (1997) notes that the 8th edition of Kraepelin's textbook has been published in 1909.

6 Weber (1997) reminds that Kraepelin drafted his textbook between the years 1908–1909, when only two cases of AD have been reported by either Alzheimer or Bonfiglio (Weber 1997).

Pick and Oskar Fischer, who were also researching dementia in their laboratory. In the background of this argument was the wish of Kraepelin to demonstrate the superiority of his school over Pick's neuropathologic laboratory or Freudian psychoanalytical theories over dementia (Maurer et al. 1997; Weber 1997).

- Reasons related to *funding* – Kraepelin could have sought to acquire additional funding for the extension of his neuropathologic laboratory in Munich, a goal which would have been supported by the publication of new and original findings that could attract greater attention, funding, and resource allocation (Weber 1997).

- *Personal* reasons – close collaboration which lasted between Kraepelin and Alzheimer already for two decades, while being aware of Alzheimer's scientific work on pre-senile cases, demonstrating Alzheimer's influence in clinical teachings, and a wish to reward Alzheimer for being a selfless co-worker (Maurer et al. 1997; Weber 1997).

However, Maurer et al. (1997) are convinced, supporting the scientific explanation, that the reason why the disease is called after Alois Alzheimer is based on the first report on Auguste D's case from 1907 (Maurer et al. 1997). Weber (1997) favours the view that explains Kraepelin's act based on his personal reasons (Weber 1997).

Recently a group of scientists re-examined the histopathological specimen of one of the most famous patient of all times, Auguste D, with state-of-the-art methods and techniques. From modern medical knowledge we now are aware that dementia has a multifactorial cause: genetic markers and environmental factors which both contribute to the development and expression of the disease. The most predisposing genetic variant is $\epsilon 4$ allele of the apoliproprotein E gene (APOE). The most important environmental factor is advanced age. Mutations in any of the three genes of amyloid precursor protein (APP) on chromosome 21, presenilin 1 (PSEN1) on chromosome 14, and presenilin 2 (PSEN2) on chromosome 1 can cause autosomal dominant Alzheimer's disease, meaning that anyone living long enough with these mutations will develop Alzheimer's disease. These mutations are inherited in a very small number of people (less than 2 % of all the cases). The scientists found evidence that Auguste D had an autosomal dominant form of the disorder (although she had $\epsilon 3/\epsilon 3$ APOE genotype, so the $\epsilon 4$ genetic risk allele was not present, she had a mutation in her PSEN1 gene). With modern analytical methods it has been confirmed that Auguste D's case was consistent with the clinical findings of her histopathological specimen made by Alzheimer more than a hundred years ago. This re-examination also uncovered the cause of her disease (Müller et al. 2013). Moreover, the reason that we know so much about the case of Auguste D and Alzheimer's work is that Alzheimer's medical notes have been found in his birthplace in Marktbreit, Germany, in 1995. This finding allowed the detailed insight into the clini-

cal cases of Alzheimer's patients during his stay at the clinic in Frankfurt (Maurer et al. 1997).

2.1.2 *Diagnosis of Dementia*

Dementia has a relatively wide variety of scientific definitions that usually describe a set of symptoms and signs: memory problems, communication difficulties (apraxia), issues with organising and planning everyday tasks, changes in mood, changes in behaviour, gradual loss of control over physical functions (Hope et al. 2009). Further issues are loss of the ability to recognise objects (agnosia) and problems with abstract thinking and complex behaviour.

These symptoms may be interpreted as a consequence of damage to the brain, caused by a variety of diseases: AD, vascular dementia, Dementia with Lewy bodies (DLB), Parkinson's disease, Fronto-temporal Dementia (FTD), Huntington's disease, alcohol-related dementias (Korsakoff's syndrome), prion diseases, dementia from syphilis. There are approximately one hundred different types of dementias, out of which certain dementias are reversible. Alzheimer's disease is the most common one (62 % of the cases in UK), followed by vascular dementia (17 %), DLB (4 %), FTD (2 %), and Parkinson's disease (2 %). The contemporary research also focuses on the estimated 10 % that happen to be interpreted as dementias of mixed origin, incorporating symptoms of both AD and vascular dementia. However, the exact figures are not universally accepted and they are the subject of on-going scientific research (Hope et al. 2009).

2.1.2.1 *Types of Dementia*

ALZHEIMER'S DISEASE

AD can be described as a form of dementia during which excessive and abnormally folded proteins, so-called 'plaques' around the neurones and 'tangles' inside the neurone cells accumulate in the brain. These structures damage the brain causing the death of brain cells, predominantly in the region of memory. Neurotransmitter communications are also negatively affected. The factors contributing to the onset and further development of the disease include, as already mentioned before, environmental factors (mostly age), genetic inheritance, diet and overall general health condition (Hope et al. 2009).

VASCULAR DEMENTIA

Vascular dementia may be caused by a series of small strokes resulting in a damage of blood vessels within the brain. Such damage causes disruptions in the delivery of oxygen to the brain cells causing their death. The damage on the brain and its consequences

depends on the areas affected by the death of the brain cells. Scientists differentiate between a) single-infarct vascular dementia caused by one single stroke in one larger area of the brain, and b) multi-infarct vascular dementia caused by a series of small strokes over time causing the death of brain cells in many small areas. These strokes may remain unnoticed by the person affected. Vascular dementia can be a result of small vessel disease (sub-cortical vascular dementia or Binswanger's disease), which causes damage in the deeper layers of the brain's vessels. The risk factors for vascular dementia are: high blood pressure, heart issues, high cholesterol, diabetes.

DEMENTIA WITH LEWY BODIES, PARKINSON'S DISEASE DEMENTIA

DLB and Parkinson's disease dementia (PDD) are caused by Lewy bodies, which are spherical protein deposits building up in the brain cells, interfering with the neurotransmitters. The detailed mechanism of a disruption is not known yet precisely. The higher amount of Lewy bodies are also found in the brains of people suffering from Parkinson's disease, which results in a higher prevalence of dementias in this group of people. PDD may be related to DLB, described as a result of the same continuum, but with two different set of signs and symptoms (conditions) caused by differing distribution of Lewy bodies in the brain (Hope et al. 2009).

FRONTO-TEMPORAL DEMENTIA

FTD is a rarer form of dementia, covering various conditions (Pick's disease,[7] frontal lobe degeneration,[8] motor neurone disease related dementia). The damage in this case happens in the frontal lobe or temporal lobe areas of the brain. Around 50 % of the cases have an hereditary component. Various genetic mutations are involved too, causing abnormalities in the production of proteins (tau, progranulin, TDP-43, ubiquitin). In these cases the symptoms may vary between different individuals, but the damage in most cases happens in the front part of the brain. This affects more the behavioural and mood areas of the individual, rather than causing problems with memory (Hope et al. 2009).

OTHER DEMENTIAS

Other rarer causes of dementia include progressive supranuclear palsy, Huntington's disease, prion diseases (e. g. Creutzfeld-Jakob disease), alcohol-related dementia, HIV, multiple sclerosis (MS), syphilis. A possible relationship has been suggested between

7 A former name of a typical form of dementia linked to frontal abnormalities (Brand and Markowitsch 2008, p. 29).

8 Brand and Markowitsch (2008) mention Fronto-temporal Lobe Degeneration (FTDL) as a heterogenous category, linked to atrophy of frontal and temporal areas of the brain. According to this source the group of FTDL consists of three syndromes that are rather subsumed to this category, which means that the categorisation is opposite to what is published in Hope et al. (2009): FTD, semantic dementia, and primary progressive aphasia (Brand and Markowitsch 2008, p. 29).

head injuries and a later development of dementias. However, this explanation is still a subject of scientific debate (Hope et al. 2009).

INHERITED DEMENTIAS

Inherited dementias in the most common forms could be described as 'sporadic,' meaning that they do not have any particular pattern. Most likely they are a result of environmental factors and the genetic inheritance of the individual. As mentioned above, a small amount of dementias have a strong genetic component (e. g. FTD with Parkinsonism-17, familial British/Danish dementia, Gerstmann-Straissler-Scheinker disease; Hope et al. 2009).

2.1.2.2 *Identifying Dementia*

Different symptoms tend to express themselves at various intervals, progressing with time. Therefore a more formalised description has been introduced, defining various stages of progress. This has been reached by the use of Mini-Mental State Examinations (MMSE),[9] also called Folstein test, in the case of Alzheimer's disease, in which case eleven questions are being asked of the person assessing five different areas of cognitive ability. With a maximum score of thirty the stages of Alzheimer's disease could be defined as (Hope et al. 2009):

- Mild dementia – reaching the score 20–24/26.
- Moderate dementia – reaching 10–19.
- Severe – 0–10.

Other tests are also being used. Examples are: Abbreviated Mental Test Score (AMTS, Hodkinson 1972); Modified Mini-Mental state examination (3MS, E. L. Teng and Chui 1987); Cognitive Abilities Screening Instrument (CASI, Evelyn L. Teng et al. 1994); Trail-making test (TMT, for general mental functioning; Tombaugh 2004); Clinical Dementia Rating (CDR, Morris 1993); Clock Drawing Test (CDT, Sunderland et al. 1989; Tuokko et al. 1995); Mini-Cog test (CDT expanded by a short-term recall test, Borson et al. 2000); National Adult Reading Test (NART, Fazel et al. 1999); Cambridge Mental Disorders of the Elderly Examination Revised (CAMDEX-R, for global cognitive evaluation; Roth et al. 1999); MacArthur Competence Assessment Tool (MacCAT; Appelbaum and Grisso

9 The Mini-Mental State Examination test has been originally distributed for free (Folstein et al. 1975). However, Psychological Assessment Resources (PAR), the current copyright holder, "will not grant permission to include an entire test or scale in any publication, including dissertations and theses". For more details see `http://www4.parinc.com/Faqs.aspx?FaqCategoryID=31#e-Manuals` (visited on 25/05/2015).

1995; Grisso, Appelbaum, et al. 1995; Grisso and Appelbaum 1995); Measure for assessing Awareness of Financial Skills (MAFS, Van Wielingen et al. 2004); Financial Competence Instrument (FCI, Marson et al. 2000); Testament Definition Scale (TDS, Fountoulakis and Despos 2008); and Hopkins Competency Assessment Test (HCAT, Hughes 2008).

It is relatively easy to measure physical autonomy of the Persons with Dementia (PwDs) by scales. They are both used in clinical trials and clinical practice worldwide (Soto and Vellas 2008). Amongst the most widespread assessment tools are the activities of daily living (ADLs) created by Katz et al. (1963), and instrumental activities of daily living (iADLs) developed by Lawton and Brody (1969), which examine the activities listed in Table 2.1 (Soto and Vellas 2008).

Table 2.1 – Comparison of ADL and iADL Scales' Items

ADL	iADL
Bathing	Shopping
Dressing	Preparing meals
Toileting	Travelling
Transferring	Doing housework
Continence	Doing laundry
Feeding	Using telephone
	Taking medications
	Managing money
Katz et al. (1963)	Lawton and Brody (1969)

Table 2.1: Comparison of ADL and iADL Scales' Items

The use of the ADL/iADL scales is not only to confirm the diagnosis of dementia, but they should be repeated at every visit of the specialist. This will provide (Soto and Vellas 2008, p. 36):

- An objective in physical therapeutics, defining which activities can be still performed by the PwD, trying to avoid failure situations.
- A help to set up medical and non-medical support, by having an overview of the alterations to ADLs/iADLs.
- Help evaluating the severity and the prognosis of the disease.

The National Institute for Health and Care Excellence – United Kingdom (NICE) guidelines for diagnosis of dementia is preferred to be made after a thorough assessment of (Hope et al. 2009):

- Medical records of the individual.

- Examination of cognitive and mental state, physical examination, assessing factors affecting person's cognitive and functional performance (mental and physical illnesses, disabilities, educational level and comparing these with the former levels).
- Reviewing existing medication.

When the results yield mild symptoms (or the symptoms are still questionable), the aforementioned assessment should be followed by formal neuropsychological tests. Magnetic resonance imaging (MRI) and computer tomography (CT) are the usual forms of structural imaging techniques. Various forms of single-photon emission computer tomography (SPECT) are used for differentiating the various forms of dementias (Hope et al. 2009). In certain cases further diagnostic tools and methods such as electroencephalography, amyloid imaging by positron emission tomography (PET scanning), tests of the cerebrospinal fluid (CFS), genetic or other diagnostic techniques might be found useful (APA 2013, pp. 599–643).

2.1.2.3 *Definitions of Dementia*

NUFFIELD COUNCIL ON BIOETHICS

The definition of the term 'dementia' by the Nuffield Council on Bioethics reflects rather the effects of all the different damages of the brain. Hence the Council's understanding of dementia does not follow its explanation as a mental disorder. It explains dementia rather as a physical condition which affects mental capacity. The Council defines dementia this way despite the actual definition in the mental health legislation in UK (Hope et al. 2009, p. 4).

AMERICAN PSYCHIATRIC ASSOCIATION

A different approach is taken by the 5th version of the *Diagnostic and Statistical Manual of Mental Disorders: DSM-5* of the American Psychiatric Association. The goal of DSM-5 is to be a standard reference for clinical practice in the field of mental health (APA 2013, p. xli). Compared with the earlier version of DSM-IV,[10] after a 12-year process of working on it, DSM-5, amongst others, introduces a more specific distinction of major and mild Neurocognitive Disorders (NCDs), where dementia is listed, based on the advances in neuroscience, neuropsychology and brain imaging in the past 20 years. It also incorporates a better compatibility with the future 11th Revision of *The International Classification of Diseases* (ICD) of the World Health Organization (WHO), which is due in 2017.

A mental disorder is defined in DSM-5 as a

10 Although the actual 5th version of DSM-5 uses an Arabic numbering in its title, the previous version of DSM-IV used a Roman numbering.

> "[...] syndrome characterized by clinically significant disturbance in an individual's cognition, emotion regulation, or behavior that reflects a dysfunction in the psychological, biological, or developmental processes underlying mental functioning. Mental disorders are usually associated with significant distress or disability in social, occupational, or other important activities. An expectable or culturally approved response to a common stressor or loss, such as the death of a loved one, is not a mental disorder. Socially deviant behavior (e. g., political, religious, or sexual) and conflicts that are primarily between the individual and society are not mental disorders unless the deviance or conflict results from a dysfunction in the individual [...]" (APA 2013, p. 20)

This definition of mental disorder was developed for the purposes of clinical, public health, and research. As already mentioned, dementia is listed under the heading of *Neurocognitive Disorders*. Earlier in DSM-IV NCDs has been referred to as "Dementia, Delirium, Amnestic, and Other Cognitive Disorders." The use of the word 'dementia' is retained in DSM-5 for continuity and because physicians and patients may be accustomed to it. However, a more precise term of 'neurocognitive disorder' is often preferred because it involves conditions affecting not only elderly but also younger individuals. Also the term of NCD may include cases of substantial decline in a single domain (e. g. complex attention, executive function, learning and memory, language, perceptual-motor, social cognition) of a diagnosis, for which the term 'dementia' would not be used (APA 2013, p. 591).

Under NCD DSM-5 understands a group of disorders in which the primary clinical deficit is cognitive. Furthermore, it is more an acquired rather than a developmental condition. There are few mental disorders in which cognitive deficits are being expressed (e. g. schizophrenia, bipolar disorders, etc.), however, only disorders with core cognitive features are included into the category of NCDs. Therefore NCDs are those disorders in which the impaired cognition was not present at birth or early life, and they represent a true decline from the previously reached functional level (APA 2013).

The classification of NCDs in DSM-5 starts with delirium, which is then followed by the major and mild (less severe cognitive impairment, which still can be a subject of care)[11] NCD syndromes and their etiological subtypes (APA 2013, pp. 596–643):

- Delirium
- Major or mild NCD
  - NCD due to Alzheimer's disease
  - Vascular NCD

11 Formerly listed under the heading "Cognitive Disorder Not Otherwise Specified" in DSM-IV.

- NCD with Lewy bodies
- NCD due to Parkinson's disease
- Frontotemporal NCD
- NCD due to traumatic brain injury
- NCD due to HIV infection
- Substance/medication-induced NCD
- NCD due to Huntington's disease
- NCD due to prion disease
- NCD due to another medical condition
- NCD due to multiple etiologies
- Unspecified NCD

The diagnostic criteria of major NCD consist of evidence of significant cognitive decline compared with the previous attained levels in at least one of the cognitive domains mentioned above. This evidence can either be expressed by the affected individuals themselves, or a knowledgeable informant or clinician; or it can be a result of a standardised neuropsychological testing or other quantified clinical assessment documenting substantial decrease in cognitive performance. These identified cognitive deficits furthermore must interfere with the independence and everyday activities of the affected person. Finally, the cognitive decline must not occur exclusively in the context of delirium, and it must not be amenable to better explanation by other mental disorders (e. g. depressive disorder, schizophrenia, etc.; APA 2013, pp. 602–603). The diagnosis of major NCD should specify also whether the person has or does not have any behavioural disturbances (e. g. psychotic symptoms, mood disturbance, agitation, apathy, other behavioural symptoms), as well as the severity of the symptoms (APA 2013, p. 605):

- Mild – difficulties with iADL (e. g. housework, managing money, etc.).
- Moderate – difficulties with basic activities of daily living (e. g. feeding, dressing, etc.).
- Severe – fully dependent.

The evidence of modest cognitive decline that is not occurring exclusively in delirium, while it does not interfere with the capacity for everyday activities and independence should be diagnosed according to DSM-5 as mild NCD. Of course, this is true under the condition that these deficits cannot be better explained by another mental disorder (APA 2013, p. 605).

WORLD HEALTH ORGANIZATION

A very similar definition of dementia is present in the 10th Revision of the ICD, which describes dementia as a

> "[...] syndrome due to disease of the brain, 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 judgement" (WHO 1992a)

In this case consciousness is not clouded, and the symptoms must be present at least for a duration of six months to avoid confusion with other possible diagnoses (WHO 1992a; WHO 1992b). The only definitive method of confirming dementia is that by autopsy (Epple 2002).

Various approaches of defining dementia have been presented in this section. While DSM-5 and ICD-10 approached dementia from its neurocognitive decline, the definition provided by the Nuffield Council of Bioethics understands dementia primarily as a physical condition, which affects, amongst other functionalities, also the mental capacity of the person. The question arises, which of these definitions would be more appropriate to use for the ethical analysis of assessing the consequences of using assistive technologies for PwDs. Given the fact that Ambient Assisted Living (AAL) technologies do not limit their support solely on the empowerment of mental capacities but aim for the support of physical and other faculties (cf. Chapter 2), it seems appropriate to consider the Nuffield Council of Bioethics' definition of dementia as a standard for the purposes of this ethical analysis. This choice is further supported by the recent developments in the healthcare practice that respect the PwD as a person, as recommended by T. Kitwood (1997). The understanding of dementia as a physical condition affecting mental capacities of the person is also in accordance with the spirit of the methodology of this dissertation (section 1.2), which is based on the United Nations Educational, Scientific and Cultural Organization (UNESCO) Universal Declaration on Bioethics and Human Rights (UDBHR), and the human rights tradition, respecting basic principles of human dignity and fundamental rights and freedoms of human beings. Therefore, the definition of dementia provided by the Nuffield Council of Bioethics is employed throughout the proposed ethical analysis and recommendations regarding AAL technologies for PwDs in this dissertation.

2.1.3 *Care and Treatment of Dementia*

In the early stages, a PwD needs memory support, help with regular daily activities and social contact. In the mild stage of the disease, special medication and medical care

become necessary. Care and management continue and are progressively more intensive as the disease progresses until it reaches the most severe stages. One of the symptoms of AD is a tendency to wander from the home and at some point sleep eventually enters a phase shift with wakeful nights leading to night-time wandering, which is usually the precursor to institutionalisation.

Care and management of PwDs are multi-faceted, and can include prevention, enablement and treatment once the disease presents. The prevalence of the disease and the heterogeneity of the age cohort affected means that there are a variety of needs that have to be recognised (Gaul and Ziefle 2009; Grönvall and Kyng 2012; Jeffrey Kaye 2010; Lynch et al. 2009; Mordini et al. 2009; Oppenauer et al. 2007; Remmers 2010; Salces et al. 2006), which can often only be fulfilled at significant economic, personal, organisational, social and managerial costs (Mandell and Green 2011).

There are a few medical treatments approved by the Food and Drug Administration (FDA) agency of the United States Department of Health and Human Services (such as Tacrine, Donepezil Hydrochloride) temporarily improving the symptoms. However, there is no known medical treatment to stop, nor cure the progression of dementia at the moment. Many experimental treatments are under development (like the experimental vaccine AN-1792, etc.). Brain imaging techniques (CT, MRI, PET, and SPECT) are also being recently used for either monitoring the progress of the disease, or for clinical research purposes (O'Brien 2005).

The care and management of dementia by AAL technologies attempt to address multiple areas of PwDs' needs, either by empowering them in their ADLs, or by providing various solutions for support, monitoring, therapy, and comfort. These classifications of treatment by AAL technologies are detailed in the following section, especially in section 2.2.1. Conventional treatment options will not be discussed in a systematic manner in this dissertation because it is outside the scope of the research objectives defined in Chapter 1.

2.2 AMBIENT ASSISTED LIVING

AMBIENT INTELLIGENCE

In this subsection a basic definition and description of the main characteristics of ambient intelligence (AmI) will be provided. Due to the recent development within this field of Information and Communication Technology (ICT), as well as the plans for applying these technologies to the healthcare practice, and PwD in particular, various terms and definitions are available regarding AmI and its use within the healthcare realm in the scholarly literature. The purpose of this subsection is to list these definitions, describe their historical, conceptual roots, and to clarify the differences within the nature, purpose and aims of such technologies.

The idea of AmI is relatively recent, the reference to the technologies expressed by the term AmI vary in academic and popular publications considerably. First, the term of AmI have to be clarified. Weiser (1991), then head of the Computer Science Laboratory at Xerox Palo Alto Research Center, first proposed the idea of a technology that is present and at the same time disappears into the background of everyday life. According to Weiser the most profound technologies are those that vanish into the background, do not require special attention of their user(s) and are ready for immediate use when required. He called such a technology "ubiquitous computing" (Weiser 1991, p. 95).[12] The attribute 'ubiquitous' covers this disappearance-into-background in an invisible, interconnected and non-intrusive way (Duquenoy and Whitehouse 2006; Duquenoy 2004). Due to the invisibility, given the definition of ambient intelligence (disappearance-into-background), Kosta, Olli Pitkänen, et al. (2010) notes also partial uncontrollability as one of the consequences of such ambience. Amongst the attributes of AmI is its integration into everyday objects (Kosta, O. Pitkänen, et al. 2008; Kosta, Olli Pitkänen, et al. 2010).

The term 'pervasive,' often used in relation of AmI, refers to ICTs that are available "everywhere, for everyone, at all times" (Duquenoy and Whitehouse 2006, p. 293). This pervasive, ubiquitous and non-intrusive nature is often also called 'calm computing' (Spiekermann and Pallas 2006; Wallace et al. 2010). The term "calm technology" has been proposed by Mark Weiser and his colleague John Seely Brown (Weiser and J. S. Brown 1996, p. 7), and describes a widespread distributed form of computing that slowly imbeds itself into the world, and becomes ubiquitous. However, it stays calm. This calmness is a requirement of the fact that computers are present everywhere, people want to compute, stay informed while doing something else, so computers have to stay in the background to allow people to be more fully human. Weiser and J. S. Brown (1996) regarded in 1996 calmness of technology (e. g. ubiquity, non-intrusiveness, pervasiveness) as the fundamental challenge of the next fifty years. The benefit of calm technology would be that it would be able to move to the centre of our attention, and back to the periphery automatically when needed. Such an approach will ensure that the technology is under control and information is brought to the attention of its users without dominating their lives. As a result calm technology will comfort users by putting them "at home, into a familiar place" (Weiser and J. S. Brown 1996, p. 11).

In the healthcare arena the term Digital Assistive Technologies (DATs) is being used by Francis et al. (2009) for any item that assists persons with their disabilities (Francis et al. 2009). DATs are a kind of AmI, which involves intelligent computing, with elements of pervasiveness and ubiquity with the focus on assistance. Similarly, Appleyard (2005) defines Assistive Technology (AT) as "any item, piece of equipment, or product system, whether acquired commercially, modified, or customized, that is used to increase, main-

12 The edition of this article in Scientific American due to multiple reprints has various page numbering available. This is the reason why e. g. Portet et al. (2011) and others often refer to the same article with differing page numbers.

tain, or improve functional capabilities of individuals with disabilities" (Appleyard 2005, p. 134).

The term 'intelligence' refers to the adaptability of a system to the presence of human beings (hearing, vision, language, knowledge) and to the needs of the user (Cook et al. 2009).

According to Cook et al. (2009) the term 'ambient intelligence' (AmI) refers to

> "a digital environment that proactively, but sensibly, supports people in their daily lives." (Cook et al. 2009, p. 279)

This definition of AmI is a result of their literature review. According to this literature review AmI usually include technologies that are: sensitive (S), adaptive (A), transparent (T), responsive (R), ubiquitous (U), and intelligent (I). These technologies are a part of context-aware computing (Cook et al. 2009, p. 279).

Zaad and Ben Allouch (2008) list five key features of AmI: 1) embedded network devices, which are 2) context aware, 3) personalised, 4) adaptive, and which 5) anticipate the needs of their users (Zaad and Ben Allouch 2008).

WELFARE TECHNOLOGY, UBIQUITOUS COMPUTING

B. Hofmann (2012) calls the usage of AmI for actual help in everyday-tasks a Welfare Technology (WT). According to the definition, formulated by the Information Society and Technology Advisory Group (ISTAG) of the European Commission, AmI is a convergence of three major key technologies: ubiquitous computing, ubiquitous communication, and interfaces that adapt to the users (A. Darwish and Hassanien 2011). According to B. Hofmann (2012), its aim is to provide better and more specific care and to reduce risks and therefore increase safety, making it possible for the vulnerable to increase their ability to cope and thus improve their capacity for self-determination, as well as enabling them to stay at home for longer before being institutionalised.

Cook et al. (2009) referring to Maeda and Minami (2006) emphasises a major difference between AmI and ubiquitous computing, namely that the former often provides support for hearing, vision, language and knowledge related to human intelligence. Therefore, such an understanding of AmI diverges from the definition of ubiquitous computing, which is supposed to disappear into the background (Cook et al. 2009).

Ubiquitous computing in the context of (elderly) care is also sometimes referred to as *health telematics* (Friedewald and Raabe 2011). Health telematics could be categorised as a form of *telemedicine*, which is defined by Maheu and Allen as

> "the use of audio, video, and other telecommunications and electronic information processing technologies for the transmission of information and data relevant to the diagnosis and treatment of medical conditions, or to provide

> health services or aid health care personnel at distant sites." (Chan, Estève, et al. 2008)

TELEMEDICINE, *e*HEALTH

Telemedicine, going back to the early days of the use of ICT within the healthcare settings, originally supposed to provide distant consultation services through video, and this communication is usually restricted to interactive patient-physician teleconsultations (Maheu et al. 2002). The term first appeared in the publication of Willemain and Mark (1971). However, this area in recent decades advanced so much due to clinical decision databases, electronic patient records, artificial intelligence (AI), administrative support, etc., that a new term *telehealth* has been recently introduced, as noted by Moore (1999):

> "the full array of technologies, networks and healthcare services provided through telecommunication, including delivery of educational programs, collaborative research, meetings,[13] patient consultation and other services provided with the purpose of improving health" (Chan, Estève, et al. 2008)

Telehealth towards the end of 1990s gained big popularity, and the term is often used synonymously to the older term of telemedicine (Maheu et al. 2002). Since then a new term of e*Health* has been also introduced by Eysenbach (2001) that is defined as

> "[A]n emerging field in the intersection of medical informatics, public health and business, referring to the health services and information delivered or enhanced through the Internet and related technologies." (Chan, Estève, et al. 2008)

Chan, Estève, et al. (2008) explain that the term *e*Health in a broader sense is a state of mind, that can be characterised as a new paradigm of commitment and global, networked thinking about the use of information and communication technology to improve healthcare locally, regionally and worldwide. It refers to all forms of electronic healthcare delivered via the Internet, while embracing concepts called 'the five C's': content, connectivity, commerce, community and clinical care, often with the addition of the sixth: computer applications in the form of application service providers (ASPs).[14] The main differences of *e*Health from telehealth or telemedicine, according to Maheu et al. (2002) are:

13 The word 'meetings' is missing from the definition provided by Chan, Estève, et al. (2008), however it is present in the original article of Moore (1999), to which Chan refers to.

14 Eysenbach (2001) lists in his article, based on a speech delivered at UNESCO in June 2001 in Paris, ten E's in *e*Health: efficiency, enhancing quality, evidence based, empowerment, encouragement, education, enabling, extending, ethics, equity.

a) that *e*Health is not professional-centric, it is not lead by health professionals but rather by consumers;

b) *e*Health services are motivated by financial gain, while telehealth and telemedicine were not.

The term *telehomecare* is a special form of telemedicine that uses a mixture of telecommunication and video-conferencing technologies to connect the physician and the patient situated at home (Chan, Estève, et al. 2008). Consequently the concept of *home-based* e*Health*, introduced by Demiris (2004), includes both telehomecare and smart-homes (Chan, Estève, et al. 2008). The definition of the latter is the following:

> "unobtrusive disease prevention and monitoring of residents who may not receive other forms of home care, such as the disabled or elderly" (Chan, Estève, et al. 2008)

TELECARE

S. Brown et al. (2004) and S. Brown et al. (2006) define *telecare* as the application of ICT "to support elderly people who live alone" (S. Brown et al. 2004, p. 56; S. Brown et al. 2006, p. 65).

DOMOTICS

The term *domotics* is sometimes used as a synonym term to smart-homes in Latin languages (Chan, Estève, et al. 2008). Stip and Rialle (2005) also mention the term *immotics*, which refers to the technical means allowing the adaptation of equipment into the house for the domotic technology (especially its computer network architecture; Stip and Rialle 2005).

SAFETY TECHNOLOGIES, SAFETY DEVICES

Daniel et al. (2009) defines a broader term of *safety technologies* and *safety devices* as technologies and modifications of the environment of its users, the purpose of which are to improve the safety of the inhabitants by lowering the risk of injuries. Safety technologies may be categorised in five different groups: 1) general adaptive technologies, 2) passive environmental sensors, 3) assistive technologies, 4) wander management systems, and 5) appliance technologies (Daniel et al. 2009).

AMBIENT ASSISTED LIVING TECHNOLOGIES

Finally, the term AAL refers to innovative technologies (relying on the field of AmI), intelligent systems of assistance that help elderly people (including those with disabilities,

such as PwDs) in all stages of their life in order to extend their stay in their preferred environment, and to support systems that maintain the person's health and functional capabilities. This might promote a healthier lifestyle, thus allowing the elderly to continue an active and creative participation in their communities, and ultimately maintain or improve their quality of life. Moreover, AAL technologies may provide useful data that can be used to yield increased efficiency in care systems and care management. They may also provide remote mobile support for caregivers, thus alleviating the caregivers of certain tasks that can be automated (e. g. services for dressing, personal hygiene, drug intake reminder, etc.), or delivered at a more affordable cost (Broek et al. 2010).

The goals of AmI, smart homes, and AAL often overlap; therefore it is sometimes hard to provide clear contours of their borders. Both, AAL and smart-home environments try to provide empowerment for their (somehow but not necessarily disabled) user, trying to prolong the stay of such a person in his or her preferable natural home environment, instead of being institutionalised.

In this dissertation the term AAL technologies will be used persistently in relation to PwDs, if the phrasing does not require the use of the much more general terms of AmI and ICT.

2.2.1 *Classification of Ambient Assisted Living Technologies*

The introduction of ICT in the home environment dates back at least twenty years, since the publication of the article about ubiquitous technology by Weiser (1991), if not longer. In the 20th century the homes of people underwent a dramatic revolution by the introduction of domestic technologies. One of the main drives of this change was the introduction of electricity to homes, which provided a clean and always-ready source of energy. The next major development for homes was the introduction of information technologies, which allowed the quick exchange of information between people, appliances, and various systems within and outside of the homes. Finally, the 20th century technological development also adopted different 'time-saving' and 'time-using' technologies that shortened the time spent on housework, but extended the time spent on the users' entertainment.[15] According to Aldrich (2003) these factors were the seedbed for the development of the smart-home concept (Aldrich 2003).

For the interlace of modern technology and home environments the researchers provide various terms. Zaad and Ben Allouch (2008) refer to the expression 'home automation,' which, according to their view, is a provision of technology and services in home. Its main aim is the improvement of the quality of life of its users (usually with AmI) by enhancing safety, comfort and better communication (Zaad and Ben Allouch 2008).

15 For a much more elaborate description of this process see Aldrich (2003, pp. 19–21).

Another terminology is used by Bamigboye (2009) who defines Digital Homecare as (Bamigboye 2009):

> "any combination of Digital Technologies installed in a home environment to enable delivery and management of health care. [...] Digital Technology means any combination of software, hardware and communications configured to provide the appropriate functionality for the patient and the carers who support them." (Bamigboye 2009, p. 97)

This category of support is usually provisioned in environment that are commonly described as smart-homes, often called domotics.[16]

S. Martin et al. (2010) provide a further overview of the hierarchical classes of smart homes, based on the publication of Aldrich (2003, pp. 34–35) as follows:

1. Homes containing intelligent objects – usually single stand-alone appliances, intelligent objects;
2. Homes containing intelligent communicating objects – same as above but with an option of exchanging information between devices for increasing functionality;
3. Connected homes – presence of internal and external networks, allowing remote control of systems, access to services, information, from within and beyond the home;
4. Learning homes – homes that are able to accumulate data about the patterns of activities, resulting in a possible anticipation of user needs and therefore it is also able to control the technology based on these needs (e. g. adaptive heating and lighting usage patterns);
5. Attentive homes – constant recording of activity and location of people within the home, the information is used for anticipating the needs of the users.

According to Aldrich (2003), each level of this classification represents an increase in functionality of its user, hence the hierarchical attribute. Each level therefore depends on the presence of a previous system level being in place (Aldrich 2003).

The introduction of smart-home technologies for PwDs is based on the special needs that are being represented by this group of population. The provision of smart homes belongs to the general technological development of our times. However, PwDs have special needs and requirements for their care, for which the appliances and other services of smart homes have to be adjusted. An insightful overview of the needs of PwDs regarding ICT based services has been identified by Steve Lauriks et al. (2010) as follows (Steve Lauriks et al. 2010):

16 See the definition of smart-home in section 2.2 on page p. 34.

- Need for general/personalised information (on dementia; service, care, and support provision; personal condition; care planning, appointments; legal and financial issues).
- Need for support of dementia symptoms (ICT compensation for disabilities (memory, ADL, iADL); ICT supporting the carer; ICT support for psychological, behavioural, and emotional changes).
- Need for socialisation of PwDs (keeping connections with family, friends, social environment; feeling of usefulness).
- Need for health monitoring and safety for PwD (need to be cared for; need for safety).

F. Meiland et al. (2010), from the same project called COGKNOW[17] identified various areas (memory; social contacts; daily activities; feelings of safety) and inventoried needs regarding these areas (need for being reminded; need for support for conversations; need for support with finances, shopping, and hobbies; need for security and safety cooking, house appliances, etc.; F. Meiland et al. 2010).

The aforementioned needs may be then linked with the services provided by the application of ICT in general, but also in a form of smart homes. An overview of AAL technologies is provided by Chan, Estève, et al. (2008) with their functions for their users (PwDs included). These involve (Chan, Estève, et al. 2008):

- Provision of support for disablement (hearing, visual disablement).
- Lifestyle monitoring.
- Delivering of therapy.
- Delivering of comfort (intelligent devices, smart objects, communication, activities and leisure equipment, etc.).

The support and empowerment attributes of AAL technologies project the possible application of these technologies not only for PwDs exclusively but also to a wider cohort of (vulnerable) elderly, or every possible user in the future. Therefore, where the context of AAL technologies can be extended to the empowerment of the elderly in general, the terms PwD and elderly are used synonymously.

17 The project COGKNOW – Helping people with mild dementia to navigate their day was funded under The Work Programme 2005–2006 of the IST Priority in the European 6th Framework Programme (FP6) for Research and Technological Development, which included an eInclusion Strategic Objective. More information: `http://www.cogknow.eu` (visited on 23/07/2014).

SUPPORT PROVISION

Into this category Chan, Estève, et al. (2008) include wheelchairs, specialised interfaces for disabled users. For visually impaired users here belong synthetic voice generation (Text-to-Speech) for control and command, tactile screen, sensitive remote control, and audible beacons. For hearing impaired users visible alarms, teletype machines (transferring audible information into written text), display screens for hearing, etc. All these co-morbidities might be present in the case of elderly and PwDs. Therefore, the relevance of these technologies in the home environment of PwDs is self-explanatory.

Chan, Estève, et al. (2008) list in this regard also rehabilitation robots and companion robots. The term 'robot' has been first used in the notable drama of the Czech playwright and littérateur Karel Čapek in 1920 (Čapek 1920), where it represents artificial people made out of synthetic organic matter. Their role was to perform the manual work of human beings, however a rebellion of the robots leads to the extinction of the human race as such. By contemporary definition, these creatures would be called rather androids or cyborgs.

Decker et al. (2011) differentiate two main types of robotic systems, based on their evolution during the history (Decker et al. 2011):

- *Industrial robots* – usually present in the manufacturing industry, with very little exposure to human beings.
- *Service robots* – all non-production robots, usually present for defence, rescue, and security purposes, usually present in environments populated by people.

Robots, as a joint effort of United Nations Economic Commission for Europe (UNECE) and International Federation of Robotics (IFR) since 1995 has been working on a preliminary definition of service robot, which have been adopted and resulted in a new ISO-Standard 8373[18] effective since 2012:[19]

> "A service robot is a robot that performs useful tasks for humans or equipment excluding industrial automation application."[20]

Decker et al. (2011) refer to the attributes of service robots, that may be defined as: intelligence, autonomy, and cooperation. Especially one might notice the quick advances in the development regarding the last group. Companion robots, also called social robots (and the field of social robotics respectively) may be identified as a subgroup of service

18 ISO 8373:2012 – Robots and robotic devices – Vocabulary http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=55890 (visited on 23/07/2014).

19 For more information see: http://www.ifr.org/service-robots/ (visited on 23/07/2014).

20 Decker et al. (2011) in their article refer to the preliminary definition of service robots provided by IFR: "A service robot is a robot which operates semi- or fully autonomously to perform services useful to the well-being of humans and equipment, excluding manufacturing operations." (Decker et al. 2011, p. 27).

robotics. They may be further categorised as a type of domestic robots (D. Lee et al. 2010). The main feature of companion or social robots is their friendliness. They are capable of creating an emotional link with their user (e. g. elderly, etc.). Hence, their users feel more comfortable during the period they use them. Next to the friendliness, companion robots may provide other effective services like that of informing, educating, reminding, or analysis of the user's feelings, thoughts or needs (D. Lee et al. 2010). With these specificities we reach another terminology of service robots, which often refers to the term carebots (i. e. caring robots). Carebots are defined by van Wynsberghe (2012), citing the article of Vallor (2011), as follows:

> "Carebots are robots designed for use in home, hospital, or other settings to assist in, support, or provide care for the sick, disabled, young, elderly or otherwise vulnerable persons." (Vallor 2011, p. 252; van Wynsberghe 2012, p. 3)

Their functions can be defined as (based on the list provided by A. Sharkey and N. Sharkey 2012 and Vallor 2011):

- Performing or providing assistance in caregiving tasks.
- Monitoring the health or behavioural status of care receivers.
- Monitoring the provision of care by caregivers.
- Providing companionship to care receivers.

The definition of carebots directly refers to their introduction to smart homes. For example, the GeckoSystems CareBot™ provides cost-effective constant remote monitoring of elderly people; automatic reminders for drug-intake; an alerting system of doctor's visit, unexpected visitors or intruders; companionship for the care receiver by holding conversations with the elderly person on various levels; and notifications of caregivers of a possibly harmful event (e. g. fall, fire, person cannot be located, etc.).[21]

A randomised control trial performed by Moyle et al. (2013) proved a moderate to large positive influence of companion robots to the quality of life of nursing home residents with dementia in Australia (Moyle et al. 2013).

MONITORING

Another element of smart homes is the monitoring of the environment and the human being present in this environment. This usually happens by using sensors, providing

21 For more information see: `http://www.geckosystems.com/markets/CareBot_benefits.php` (visited on 23/07/2014).

assistive technologies for PwDs, monitoring and tracking the movements and locations of the persons, and providing reminders.

A. Darwish and Hassanien (2011) define sensor networks as

> "irregular clusters of communicating sensor nodes, which collect and process information from onboard sensors, and they can share some of this information with neighbouring or surrounding nodes or even with nearby data collection stations" (A. Darwish and Hassanien 2011, p. 5565)

Chan, Estève, et al. (2008) differentiate fixed and wearable sensor systems. While the former group is usually installed on a fixed location within the home of its user, the latter group of sensors might be wearable. These might use either infrared waves, or, in the case of wearable devices, accelerometers, active badges (RFID[22] or NFC[23] chips), etc., (Chan, Estève, et al. 2008). Here belong also the *in vivo* implantable systems, for example a drug delivery system of endoradiosonde, which is a microelectronic transmitter device recording physiological data otherwise not obtainable from within its user's digestive tract (Chan, Campo, et al. 2009). As expected, the purpose of these sensors is usually collection of physiological data (EMG, EEG, heart rate, blood oxygen saturation, blood pressure, glucose level,[24] temperature, etc.) about the person (Chan, Estève, et al. 2008).

The provision of functionalities of these micro-devices with sensors (micro-electro-mechanical systems – MEMS) is usually established via some wireless technology (wireless sensor network – WSN). Therefore specific protocols (ZigBee, Bluetooth, etc.) and networks (wireless body area network – WBAN, body area network – BAN, personal area network – PAN, body sensor network – BSN, wearable wireless body area network – WWBAN, implantable wireless body area network – IWBAN) have to be developed that will allow the reliable communication between these devices and their super-nodes (A. Darwish and Hassanien 2011).

Scanaill et al. (2006) list amongst the sensor technologies available for smart homes pressure sensors, pressure mats that can detect movement of a person. Smart tiles can detect footsteps and the direction of the walking of a person. Passive infrared sensors, sound sensors in cooperation with magnetic switches can detect the type of the activity performed by the user. Active infrared sensors and optical/ultrasonic systems can detect the direction and size of a person passing through the doorway.

22 Radio-Frequency Identity Chip.

23 Near-Fieald Communication.

24 Google and Novartis recently introduced a smart contact lens project, which will contain sensors for making measurements of blood-glucose levels through the tears of its user. More information: `http://googleblog.blogspot.hu/2014/01/introducing-our-smart-contact-lens.html` (visited on 20/07/2014).

Mihailidis et al. (2008) use the term of Cognitive Assistive Technologies[25] for technologies that strive to support cognitive disorders. As a result Cognitive Assistive Technologies enhance the user's autonomy (Mihailidis et al. 2008). The Ambient Trust Cube has been developed in the US that helps elderly computer users to identify a trusted website (glowing green) from an untrusted site (glowing red) while browsing the Internet, which may therefore preserve the functional level of an elderly user of computers (Lorenzen-Huber et al. 2011).

One of the significant issues of PwDs is their wandering, which results in them not being able to remember their way home. Sometimes such a scenario ends tragically, when the person gets lost in a hostile environment of wilderness and starves to death or freezes in cold, or causes herself an injury. Therefore camera monitoring, location tracking and wandering detection play an important role in the smart home environment functionalities.

Regarding wandering usually some GPS tracking solution is proposed in cooperation with other services like RF[26] watches, or hybrid land-based tracking devices (Assisted GPS system using the GSM network). Within the KITE Project[27] a device in the form of an armband has been developed that provided location tracking while the PwD was carrying on her hobby – running (Louise Robinson et al. 2009).

In the Netherlands the Unattended Autonomous Surveillance (UAS)[28] system has been developed, which aims to support the ageing-in-place by detecting the persons present in the dwelling of its user, tracking their location and providing wandering detection (J. van Hoof et al. 2011).

A distributed accelerometer, accompanied with reed contact, light and temperature sensors have been found to be effective in detecting ADL of PwDs in the smart home system established within the Living Lab Schwechat project in Austria (Diermaier et al. 2008). In the same lab an e-Shoe has been developed, creating a wearable embedded system, which was able to detect the fall of the person in her home environment. The e-Home system further extended this functionality with a wireless monitoring and guidance system, allowing the caregivers to identify the level of activities of PwDs in different areas of the flat (Panek and Zagler 2008).

A 3D position detector imaging system has been developed for fall detection of the elderly without the cooperation of its user in smart homes within the FP6 Project Netcarity (Weimar et al. 2009). Such a system may avoid the necessity of wearing a wearable device during the day, and therefore avoid limiting the mobility of a possibly frail elderly person.

25 Cognitive Assistive Technologies are abbreviated as CAT. This should not be confused with Competence Assessment Tool, which is also abbreviated as CAT.

26 Radio-Frequency.

27 The Keeping In Touch Everyday (KITE) Project has been funded by the Centre for Excellence and Life Sciences (CELS), Newcastle upon Tyne, 2007–2008.

28 More information: `http://www5.vilans.nl/smartsite.dws?ch=&id=135331` (visited on 23/07/2014).

The introduction of any form of tracking and video-surveillance technology involves an issue of user's privacy. For maintaining the privacy of the users a 3D fall detection system has been developed within the project CARE,[29] where the representation of the person's fall does not reveal for the observer a complete picture of the person, but the system is still able to recognise such an event. Using similar technologies, when the person's picture is in an unwanted and possibly embarrassing situation, the privacy of the users in their dwellings can be maintained together with their safety (Belbachir et al. 2010).

THERAPY

Chan, Estève, et al. (2008) list in this section therapeutic devices that help for example in drug delivery to the user.

The FP6 MINAmI Project[30] developed a drug intake monitoring device. Their pillbox prototype was able to record the date and time when the pillbox has been opened, and it transferred the gathered data to a mobile phone. When the user forgets to take the pills due to the effect of the medication, she received a call from the care centre to remind her of the drug intake (Niemelä et al. 2007; Kosta, Olli Pitkänen, et al. 2010).

There are also plans for developing a mobile phone application promising the possibility of remote and automated diagnosis. An example of such an effort can be the start-up company Akili Interactive Labs[31] that with its Project:Evo tries developing a computer game for iPads, through which it will be possible to identify people with the risk of developing AD. Through the game it will be able to harvest data thirty times per second for remote monitoring and analysis of its player (Strickland 2014).

The COACH System[32] by using computer vision and AI techniques attempts to provide its users with verbal and visual reminders necessary to perform their ADL. Such a system has been used to ensure that PwDs, for example, were supported in their personal hygiene, where LCD screen and speakers with a video-based prompt supported its users with visual and audio guides of how to wash their hands properly (Mihailidis et al. 2008).

29 The project CARE – Safe Private Homes for Elderly Persons was a Ambient Assisted Living Joint Programme project between 2009–2011. More information: http://www.aal-europe.eu/projects/case/ (visited on 20/07/2014).

30 MINAmI – Micro-Nano integrated platform for transverse Ambient Intelligence application has been supported by the European Commission's Sixth Framework (FP6) Programme for Research and Technological Development. The project finished in 2010. More information: http://www.fp6-minami.org (visited on 23/07/2014).

31 Akili Interactive Labs: http://www.akiliinteractive.com (visited on 23/07/2014).

32 The COACH (Cognitive Orthosis for Assisting Activities in the Home) System has been developed in the Intelligent Assistive Technology and Systems Lab (IATSL) at the University of Toronto, Canada. More information: http://web.cs.toronto.edu/research/profiles/coach.htm (visited on 23/07/2014).

The Dem@Care Project,[33] run by the consortium of partners from industry and academia, aims for contributing to the timely diagnosis, assessment, maintenance and promotion of self-independence of PwDs. The objective of the research project is a deeper understanding of how the disease affects the PwDs' everyday life and behaviour. By implementing a multi-parametric closed-loop remote management service, the PwDs are able to provide their informal caregivers with adaptive feedback, while at the same time enables clinicians remote follow-ups in order to gain and maintain comprehensive insight of the health status of the persons concerned (Newman et al. 2012).

COMFORT

Amongst the comfort-providing technologies in smart homes belong intelligent household devices, smart objects (mailbox, closet, mirror, TV, etc.), and intelligent house equipment (Chan, Estève, et al. 2008)

One of the important categories of comfort-providing technologies are those provisioning active ageing. Active ageing can be supported by technologies that motivate the users to do more physical activities. Such technologies may also provide smart leisure equipment, for example in the form of digital gaming for the elderly. Gaming consoles and technologies are both used for brain training of PwDs (McCallum and Boletsis 2013).

Virtual Reality (VR) technologies are also reported to be helpful in various training scenarios in computer games.[34]

Technologies of autonomous robot cars (for example Google Self-Driving Car[35]) may provide support for PwDs mobility, to be able to visit their family members, friends, to socialise, or attend a lecture or play at the local theatre.

The Amazon Prime Air Project's[36] aim is to provide delivery services with drones. Such a service may also have a beneficial effect for the frail elderly population, who are unable or incapable of going out to do their shopping.

Another available technology that empowers people to stay at home for longer, is the i-Stay-@-Home Project.[37] Their website involves housing providers and technical partners in the North and West of Europe which are willing to identify, test, and select affordable ICT solutions that can help elderly to continue to live independently in their homes. Their motivation is that being able to stay home for an older person should

33 The Dem@Care Project – Dementia Ambient Care: Multi-Sensing Monitoring for Intelligent Remote Management and Decision Support has been supported by the European Commission's Seventh Framework (FP7) Programme. The project finishes in 2015. More information: `http://www.demcare.eu` (visited on 30/11/2015).

34 See for example: The Rehabilitation Gaming System (RGS): `https://ec.europa.eu/digital-agenda/en/news/rehabilitation-gaming-system-rgs` (visited on 23/07/2014) or Seppala (2014).

35 Google Self-Driving Car Project website: `https://plus.google.com/+GoogleSelfDrivingCars/` (visited on 23/07/2014).

36 Amazon Prime Air Project website: `http://www.amazon.com/b?node=8037720011` (visited on 23/07/2014).

37 i-Stay-@-Home (ICT SoluTions for an Ageing societY) official website: `http://wiki.i-stay-home.eu/index.php/Main_Page` (visited on 23/07/2014).

not be a luxury. So far they have identified more than sixty ICT solutions in various European countries (France, Germany, UK, Netherlands, Belgium, etc.).

3

A REVIEW OF CONTEMPORARY WORK ON THE ETHICS OF AMBIENT ASSISTED LIVING TECHNOLOGIES FOR PERSONS WITH DEMENTIA

In 2013, in a team with other researchers, the author of this thesis conducted an extensive literature review of the ethical issues present in the academic debate regarding Ambient Assisted Living (AAL). The results have been published in 2014 (Novitzky et al. 2015).[1] In this section I present the scope, methodology, results and the discussion of this review.

3.1 SCOPE OF REVIEW

Responsible development of AAL technologies demands substantial analysis of the ethical issues, which might occur during research & development (R&D), clinical trials or eventual clinical application (Emanuel, Wendler, and Grady 2000; Emanuel, Wendler, Killen, et al. 2004). During these stages of development, various claims and interests emerge from different stakeholders. Therefore, the question we address in this review is: what are the ethical issues involved in the stages of R&D, clinical experimentation, and clinical application of AAL technologies for Persons with Dementia (PwDs) and related stakeholders? We limit the scope of our investigation to this area and pose questions like how well-known are these issues, and are there any accepted resolutions. We do this by carrying out a literature review and organising and categorising the information we have found, and in the next section we describe the methodology we have followed in carrying out this review.

3.2 METHODOLOGY

A literature review is the most commonly-used methodology to survey an area, especially an emergent area which has many stakeholders and for that reason that is the methodology we adopted. For our review, we used the following available medical,

1 The final publication is available at Springer via http://dx.doi.org/10.1007/s11948-014-9552-x as Novitzky et al. (2015).

legal, sociological, engineering and computer science databases, which also cover the fields of philosophy and applied ethics: Web of Knowledge (containing: Web of Science, BIOSIS, MEDLINE, and Journal Citation Reports)[2] with sources since 1945, SpringerLink[3] with sources ranging from 1832 to the present, and the meta-database Scirus (Elsevier),[4] which contains twenty databases (including major scientific databases such as BMJ Group, IOP Publishing, MEDLINE/PubMed, Nature Publishing, Royal Society Publishing, SAGE Publishing, ScienceDirect, and Wiley-Blackwell), with sources since the year 1900. The searches were undertaken using a combination of terms in ten search phrases, listed in Table B.1. The searches were adjusted according to the manuals of the particular databases and their filters (using wildcards, regular expressions, etc.), which varied slightly according to their required syntax.

Ten searches[5] of the three databases produced a total of 1,720 hits (including possible overlaps). These included a variety of sources such as articles in journals, literature reviews, abstracts and conference proceedings, chapters of books and edited volumes. Figure B.1 shows the number of identified sources in each database and demonstrates a major increase in sources dealing with the ethics of AAL. The first article identified in the search was from 1965.

A more detailed diagram of the search results per database shows that the largest number of identified sources comes from SpringerLink, followed by Scirus, then Web of Knowledge (Figure B.2).

Following this initial trawl of the literature, the relevance of the sources was judged manually on the basis of title and abstract. Articles whose abstracts focused on very general and broad topics of *technology* and *ethics*, and not directly connected to the ethical issues of AAL technologies, smart homes, sensor technologies, elderly persons, persons with dementia, etc., were excluded. An article was deemed relevant if it appeared to focus on ethical issues relating to new (ambient-, sensor-, smart-) technologies for the elderly or PwD. Due to the large number of results and for reasons of practicality, sources without available abstracts were excluded.

This initial analysis of the search results yielded 350 relevant sources. The majority (341) of the relevant articles were in English, 6 in German, 2 in French, and one in Norwegian. The number of duplicates within the group of relevant articles was 177, resulting in 173 unique relevant sources from the 10 searches. Thirteen other sources

2 Accessible through: `http://www.webofknowledge.com` (visited on 27/7/2012).
3 SpringerLink website: `http://www.springerlink.com` (visited on 27/7/2012).
4 Scirus website: `http://www.scirus.com` (visited on 27/7/2012).
5 In the meta-database Scirus (Elsevier), the search was refined to Abstracts, Articles, Books, Conferences, only PDF articles, with subject areas: Computer Science; Engineering, Energy and Technology; Law; Life Sciences; Medicine; Social and Behavioral Sciences; Sociology. When the individual search phrase returned more than 500 results, the expression *ethic** was added. If the results then yielded more than 200 results, the additional word *dementia* was added, further specifying the search phrases and subject matter of the literature review. The search was conducted in 2012, and therefore restricted to the end of 2012. The overview of newer or unlisted relevant literature is provided in the normative Chapters 4–6 of this dissertation.

were added, which were not present in the chosen databases; they were either listed in the references of relevant articles, or they were found during the unsystematic search for authors well-known in the field of AAL technologies, and which were seen as clearly relevant for this review. However, they were not included in the 173 results of the original 10 searches. As a result, we had 186 relevant sources. From reading and systematically classifying the content of these articles, a clear trend can be observed in the increasing number of relevant articles addressing the ethics of AAL technologies, over time (Figure B.3).

3.2.1 *Terminology*

According to the literature reviewed, the term Digital Assistive Technology (DAT) can be used for any item that assists persons with their disabilities (Francis et al. 2009). DAT are a category of ambient intelligence (AmI), which involves intelligent computing, with elements of pervasiveness and ubiquity. The term 'intelligence' refers to the adaptability of such a system to the presence of human beings and to the needs of the user. The term 'pervasive' refers (in the literature) to Information and Communication Technologies (ICTs) that are available "everywhere, for everyone, at all times" (Duquenoy and Whitehouse 2006, p. 293). 'Ubiquitous' – the term introduced originally by Weiser (Portet et al. 2011) – covers the disappearance-into-background of the technology in an invisible, interconnected and non-intrusive way (Duquenoy and Whitehouse 2006; Duquenoy 2004). This pervasive, ubiquitous and non-intrusive nature is often also called 'calm computing' as referred to earlier (Spiekermann and Pallas 2006; Wallace et al. 2010). Due to the invisibility of ambient intelligence, Kosta, Olli Pitkänen, et al. (2010) emphasise its partial uncontrollability. Amongst the attributes of ambient intelligence is its integration into everyday objects (Kosta, O. Pitkänen, et al. 2008; Kosta, Olli Pitkänen, et al. 2010). As Cook et al. (2009) present it, the term 'ambient intelligence' refers to

> "a digital environment that proactively, but sensibly, supports people in their daily lives." (Cook et al. 2009, p. 279)

B. Hofmann (2012) calls the usage of ambient intelligence for actual help in everyday-tasks a Welfare Technology (WT). According to the definition formulated by the Information Society and Technology Advisory Group (ISTAG) of the European Commission, ambient intelligence is a convergence of three major key technologies: ubiquitous computing, ubiquitous communication, and interfaces that adapt to the users (A. Darwish and Hassanien 2011). According to B. Hofmann (2012), its aim is to provide better and more specific care and to reduce risks and therefore increase safety, making it possible for the vulnerable to increase their ability to cope and thus improve their capacity for

self-determination, as well as enabling them to stay at home for longer before being institutionalised.

Ubiquitous computing in the context of (elderly) care is also referred to as health telematics (Friedewald and Raabe 2011).

The term Ambient Assisted Living (AAL) refers to innovative technologies (relying on the field of ambient intelligence), intelligent systems of assistance that help elderly people (including those with disabilities, such as PwDs) in all stages of their life in order to extend their stay in their preferred environment, and to support systems that maintain the person's health and functional capabilities. This might promote a healthier lifestyle, thus allowing the elderly to continue an active and creative participation in their communities, and ultimately maintain or improve their quality of life. Moreover, AAL technologies may provide useful data that can be used to yield increased efficiency in care systems and care management. They may also provide remote mobile support for caregivers, thus alleviating the caregivers of certain tasks that can be automated (e. g. services for dressing, personal hygiene, drug intake reminder, etc.), or delivered at a more affordable cost (Broek et al. 2010.

The support and empowerment attributes of AAL technologies project the possible application of these technologies not only for PwDs exclusively but also to a wider cohort of (vulnerable) elderly in the future. Therefore, where the context of AAL technologies can be extended to the empowerment of the elderly in general, the terms PwD and elderly are used synonymously.

3.2.2 *Frequency of Occurrence of Most Ethically Relevant Terms*

The usage frequency, namely, the number of different papers in which these terms occurred from our set of 186 papers, was measured.

The most frequent term used in the selected sources was 'home' (140 occurrences), which is understandable given that the purpose of AAL technologies is that of allowing PwDs to stay at home for longer. A complete list of the usage frequencies of ethical terms is presented in Figure B.4.

Various ethical theories were applied in the publications for the analysis of AAL technologies: John Rawls' theory of justice (Doorn 2010),[6] Amartya Sen's capability ap-

6 Doorn (2010) attempts to develop a procedural model that contributes to the alleviation of conflicts of responsibilities within professional settings of R&D. Based on the approaches of wide reflective equilibrium and overlapping consensus (Rawls 1993), this model has been applied to the development of an in-house monitoring system involving AmI. The procedural approach developed by Doorn (2010) may contribute to the definition of various responsibilities within a research project, as it may also clarify what a fair responsibility distribution in such large projects are. In addition, the Rawlsian idea of the veil of ignorance (Rawls 1999) may be further employed in a procedural approach for defining an acceptable and fair design for PwDs, as noted by Duquenoy and Thimbleby (1999).

proach (Coeckelbergh 2010; Coeckelbergh 2012; Toboso 2011; Vallor 2011),[7] ethics of care[8] of Carol Gilligan (Stapleton 2008), Nel Noddings (Vallor 2011), Joan Tronto (van Wynsberghe 2012), and a criticism of evolutionary theories (Foddy 2012).

3.3 RESULTS

This results section presents an overview of the ethical issues raised by the usage of AAL technologies in the case of PwD. These are presented here from the point of view of the stakeholders involved: the PwD, formal and informal caregivers (nurses, family proxies), researchers and clinicians, (software/hardware) engineers, designers, and technicians. These stakeholders involved in our ethical analysis had been previously defined by various authors (Allen et al. 2008; Duquenoy and Whitehouse 2006; Duquenoy 2004; B. Hofmann 2012; R. Sparrow and L. Sparrow 2006; Sponselee et al. 2008; J. van Hoof et al. 2011). For all these stakeholders we have listed the ethical issues present in the group of relevant articles that occur in three different stages of the technology: R&D, clinical trials,[9] and clinical application. The complete set of ethical issues mentioned in

7 The capability approach have been developed by Martha Nussbaum and Amartya Sen (M. Nussbaum and Sen 1993; M. C. Nussbaum 2007; Sen 2009) as a reaction to the incomplete measure of Gross National Product (GNP) for estimating quality of life. Instead of the sole provision of formal freedoms, material goods, technologies, etc., quality of life should be measured by the 'real freedoms,' and how the human dignity of individuals can be empowered to enhance their capability to live better lives (Coeckelbergh 2012). Coeckelbergh (2012) extends the idea of the capability approach to elderly care in order to enhance their well-being and agency. By this approach, he expects a shift from focusing solely on the technology to a much wider emphasis on what people can do with technology (Coeckelbergh 2012).

8 Ethics of care emphasises solidarity and the ideal of human relationship. This approach also considers these issues as important from a communitarian viewpoint. Ethics of care stands in opposition with a more prevalent ethics of rights approach with its emphasis on universal standards, professional codes, moral rules and impartiality (Stapleton 2008). The approach of ethics of care has been developed by Gilligan (2009), who—by challenging Kohlberg's view (Kohlberg 1958; Kohlberg and R. H. Hersh 1977; Kohlberg 1981) from a feminist perspective—differentiated three stages of female moral development: preconventional, conventional, and postconventional stages. These represent a moral development from selfishness towards selflessness (i. e. universal care; Gilligan 2009). The normative framework of ethics of care has been applied to Assistive Technologies (ATs) and PwDs in relation to ethics of nursing. These sources do not limit their investigations only to nursing homes, but also focus on topics of reducing the burden of care, maintaining human contact between the caregiver and the person needing care, role of carebots in the caregiving process, and the implication of these issues on R&D (Vallor 2011; van Wynsberghe 2012).

9 Clinical trials usually refer to "[a]n experiment done involving persons as study subjects for the purpose of assessing the safety and/or efficacy of a treatment, especially such an experiment involving a clinical event as an outcome measure, done in a clinical setting, and involving persons having a specific disease or health condition" (Meinert 2012, p. 34). Clinical trials are subject not only to ethical standards (e. g. "Declaration of Helsinki" 2013; *Convention on Human Rights and Biomedicine* 1997; etc.) but also legal regulations. In the US, clinical trials are regulated by the Food and Drug Administration (FDA) and its *21 CFR* (2009); in Canada, it is Health Canada; in the EU, it is regulated by *EU Clinical Trials Directive (2001/20/EC)* (2004) and the European Medicines Agency (EMA); and in Japan, the Ministry of Health, Labour and Welfare, to mention few. Device trials are trials designed to test medical devices (Meinert 2012, p. 71). Research with medical devices are regulated in the US centrally by the FDA and its *21 CFR H* (2009). In Europe, it is regulated by a series of Medical Devices Directives: *Active Implantable Medical Devices Directive 90/385/EEC* (1990) regulating implantable devices, *The Medical Devices Regulations* (1994) covering most of the medical devices except *in vitro* diagnostics, and *Council Directive 93/42/EEC of 14 June 1993 concerning medical devices* (1993; Eckstein 2003). Under the provisions of these directives, no medical device can be introduced to the EC market

the literature is presented in Table B.2, which is inspired by Mepham's methodology of ethical analysis[10] with the help of an ethical matrix, adjusted to the needs of this literature review (Mepham 2008). As Mepham's ethical matrix is fundamentally a checklist of concerns (Mepham 2008, p. 63), we use it to provide in Table B.2 a checklist of ethical issues, which are present during the various stages of R&D, clinical trials and clinical application of AAL technologies. The matrix was then modified. Whenever an ethical issue was applicable to the sections both in the group of stakeholders or group of various stages of research, this was scored in the matrix.

As stated earlier, we structured our analysis of the field in terms of the stakeholders (PwDs, formal and informal caregivers, researchers and clinicians, engineers, designers, and technicians) and for each of these we categorised the literature in terms of issues to do with R&D, clinical trials, clinical application. Table B.3 shows the distribution of the literature across this categorisation and in the remainder of this section we examine each of the issues for each of the stakeholder groups, in turn.

3.3.1 *Persons with Dementia*

3.3.1.1 *Research & Development*

USER INVOLVEMENT IN R&D

Persons with mild cognitive impairment (MCI) have special needs and requirements, which may not be immediately apparent to developers and researchers (Wallace et al. 2010). Wallace et al. (2010) emphasise the importance of providing feedback from the user to reduce possible errors in the product while Francis et al. (2009) suggest that a new technology might be rejected and abandoned by its potential users, if they have not been directly involved in the R&D process from the very beginning.

without the CE marking (Eckstein 2003). Clinical investigations involving medical devices in the EU must be reported to the Competent Authority of the individual Member State where the research is performed. In the UK, for example, the Competent Authority is the Medical Devices Agency of the Department of Health (Eckstein 2003). The regulations regarding clinical trials involving human participants are described in Chapter 6 in further detail.

10 Mepham's methodology of ethical analysis is a practical framework that is designed to guide ethical analysis and discussion, which can lead to rational decision-making regarding competing requirements. However, the framework was not designed for prescriptive decision-making but rather as an ethical map. The framework involves the construction of a matrix, which first lists the interests of the various stakeholders (agents), then identifies the ethical requirements of these interests (based on three relevant *prima facie* principles: well-being, autonomy, fairness; representing the major traditional ethical theories: utilitarianism, deontological tradition, and modern social contract theory). Finally, the importance of each ethical requirement is rated (Mepham 2008).

ACCEPTANCE OF ICT

Panek and Zagler (2008) report that the user needs are usually ill-understood during the processes of R&D and implementation, and according to S. Lauriks et al. (2007) and Steve Lauriks et al. (2010), there are several unmet needs (general and personalised information; support with regarding symptoms of dementia; socialisation; health monitoring and perceived safety). Users' cultural differences and backgrounds play a significant role in the acceptance of ICT (Duquenoy and Whitehouse 2006). A very important aspect for the acceptance of ICT amongst the elderly, according to many authors, is the motivation of the user (Gaul and Ziefle 2009; Grönvall and Kyng 2012; Holzinger et al. 2008; Remmers 2010; Salces et al. 2006; J. van Hoof et al. 2011). With correct motivation, a greater intention to use the ICT devices can be reached by the elderly (Zaad and Ben Allouch 2008) who are willing to accept technology if it is worth the effort (Wallace et al. 2010). It has been reported that designers are usually less successful than relatives in motivating users to use ICT devices (Sponselee et al. 2008). Relatives can have a major impact on PwD's subjective norms for ICT acceptance (Steve Lauriks et al. 2010; Zaad and Ben Allouch 2008). Training and education also play an important role in ICT acceptance (Mordini et al. 2009; Oppenauer et al. 2007).

Authors disagree on the functionalities of ICT devices, with some proposing that they should be reduced (Wallace et al. 2010) and others proposing that they should be extended by providing more alarms and more functions (Zaad and Ben Allouch 2008). It should be borne in mind that the elderly (even those with mild dementia) are still able to learn, albeit in a different way than usual (Wallace et al. 2010). Nevertheless, overly complex systems with multiple-step procedures that place high learning requirements on the diminished capabilities of PwDs have a greater likelihood of failure (O'Neill, Mason, et al. 2011; Wallace et al. 2010). For instance, blinking LEDs or vibrating sounds (J. van Hoof et al. 2011), a screw head looking like a button (O'Neill, Mason, et al. 2011), or an amount of newly installed cables (J. van Hoof et al. 2011) can cause confusion or frustration and can also have a major impact on the overall acceptance of the technology for the user. PwDs will also have to learn to cope with AAL technologies, when employing these assistive tools (Portet et al. 2011). A further way of enhancing the acceptability of a system for the user is by the provision of sufficient customisation, adaptation possibilities or high quality products (Abascal and Azevedo 2007; Francis et al. 2009).

Fairclough (2009) recommends the use of a 'titration' approach while defining the needs of a vulnerable ICT user, which employs subjective self-reports to standardise and personalise the various experiences of each participant, to provide a more objective and scientific evaluation. Moreover, Francis et al. (2009) propose using the recommendations of the The Autism Simplex Collection (TASC) project (1998), which involves using visual communication tools for less-verbal users during the interview questions, thus helping

to introduce these participants actively into the process of R&D, without recourse to using abstract and complicated concepts.

3.3.1.2 *Clinical Trials*

INFORMED CONSENT, INDEPENDENCE AND SELF-DETERMINATION

During the clinical trial period, the vulnerability of the PwD could raise certain questions regarding informed consent as the hi-tech nature of AAL technology may make it difficult for a PwD to fully understand what their consent is being sought for. PwDs could become dependent on AAL technology to such an extent that it reduces their autonomy (e. g. a user who is over-dependent on a system may wait for the system to report a complication on her behalf, instead of reporting it directly herself; Scanaill et al. 2006). This dependence on the (hi-tech) pseudo-intelligence provided by AAL technologies means that, while they empower very specific faculties, they can reduce people's autonomy. Consequently, they could also dramatically infringe the validity of informed consent given by PwD at the more advanced stages of their AAL usage (B. Hofmann 2012). Also, the ambient functioning of the AAL technology in the private homes of PwDs would mean that additional informed consent would be needed from co-habitants (B. Hofmann 2012). Moreover, Kosta, Olli Pitkänen, et al. (2010) criticise the opt-out policy, which weakens personal autonomy and thereby the decision-making of the user.

Remmers (2010) points out that the reduction of independence does not automatically result in an incapacity of self-determination.[11] According to him, the longest possible preservation of self-determination is the main normative background legitimising the usage of ATs in the home. Reciprocal dependency on other humans is unavoidable because it is impossible for any human being to lead a completely independent, self-determined life without at least once in their lifetime (e. g. childhood, teenage years, etc.) needing support and aid. The use of ATs is mostly justified when the need for such support emerges and the compensating functions of technologies are intended, resulting in a regained personal self-determination. Thus, the form and consequences of dependency linked with the use of ATs extend only to the dependency on a technical instrument (Remmers 2010).

Picking et al. (2012) mention that researchers welcome the development of a certain amount of dependency on a product, if the product provides support for independent living. After all, according to Remmers (2010), such self-induced dependencies on artefacts are typical of modern civilisation.

11 Remmers defines self-determination, based on the traditions of the Stoics, Cicero, later Thomism, the natural law tradition of Pufendorf, and Kantian philosophy as: 'freedom from constraint.' Self-determination tightly linked with human dignity is normatively a basic right, however it is acquired on a genealogical level (biographical development of personal abilities; Remmers 2010).

CONTROL OF ICT, CUSTOMISATION

Wallace et al. (2010) emphasise the different perception of technology by PwDs, who might consider technology as not meant for them: the system is not of any use to them, or not even relevant to them at all.

One of the major worries expressed by Kosta, Olli Pitkänen, et al. (2010) is that the PwDs, when dealing with ambient technologies, will lack necessary control, becoming prisoners of AAL technologies in their own homes. J. van Hoof et al. (2011) reported that a high number of false alarms resulted in annoyance in some users, partially because the falsity of the alarm needed to be verified through confirmation by the user, otherwise it was automatically considered to be a true alarm.

During clinical trials, certain users reported fears about these technologies having a 'life of their own.' There is a risk that users might find the technologies obtrusive (Portet et al. 2011). During trials, it has been observed that some persons with physical or mild cognitive impairment prefer using voice commands to touchscreen control of the devices (Portet et al. 2011), while others found the touchscreen control equally beneficial (Wallace et al. 2010). In a discussion of the use of robots, Decker (2012) emphasises that although it is recommended that a veto function should exist to allow users to stop the robots' actions, this view has been challenged where persons with cognitive impairment are concerned. Also, some authors point out that during a trial, the participants had to be protected against information overload (Duquenoy and Whitehouse 2006; Kang et al. 2010).

Zaad and Ben Allouch (2008) also mention the possible 'compassionate interference' between the user and caregiver. While users expressed their wishes for more direct control over ICT devices, the caregivers, however, wanted to prevent a user having control over the supporting system (in some cases). Often, at first glance, it is not clear who the real user of the system is. Therefore, user controllability and user-centredness does not overlap in all cases (Zaad and Ben Allouch 2008).

PREVENTION OF HARM, PERVASIVENESS, MEDICALISATION OF HOME ENVIRONMENT

One of the major positives of AAL technologies is their ability to prevent certain harms resulting from the frailty of PwDs (i. e. accidental falls; B. Hofmann 2012; Sponselee et al. 2008). This can have the positive benefit of reducing anxiety (B. Hofmann 2012). However, Kosta, Olli Pitkänen, et al. (2010) emphasise the fear about the laboratorisation of the home, which is supported by J. van Hoof et al. (2011) and Landau and Werner (2012), when they use the expression the 'medicalization of home.' The pervasiveness of AAL technologies poses certain challenges to user privacy, due to the sometimes intrusive nature of these ICT devices. Technologies with privacy-preserving video-sensing are

also being developed (Belbachir et al. 2010). These technologies, following the principles of privacy-by-design (Ahonen et al. 2010b; Batchelor et al. 2012; Cavoukian et al. 2010; Friedewald and Raabe 2011; Kosta, Olli Pitkänen, et al. 2010), do not infringe on privacy during their use (e. g. due to strong data encryption on the physical layer, Chan, Estève, et al. 2008; or because they are based on wearable technologies, Piasek et al. 2013).

3.3.1.3 *Clinical Application*

AGEING AT HOME, AUTONOMY, AND DEPENDENCE ON A SYSTEM

Almost every publication we encountered in our analysis of the field emphasises the benefits of ageing at home instead of institutionalisation: *inter alia* more privacy, personal integrity, dignity and a positive impact on the self-image (Harrefors et al. 2012; Kosta, Olli Pitkänen, et al. 2010). However, certain authors are sceptical whether the actual autonomy of the PwD is really increased through AAL technologies. Enhanced dependence on ICT might result in greater inactivity, promoting a lazy lifestyle instead of a true and desirable independence (Portet et al. 2011; Maguire et al. 2011). Moreover, dependence on technology requires us to put a certain amount of trust (Kosta, O. Pitkänen, et al. 2008; Kosta, Olli Pitkänen, et al. 2010) and confidence in these systems, despite potential problems e. g. regular false alarm warnings, incorrect notifications or even failures of the technology (J. van Hoof et al. 2011). Portet et al. (2011) report a certain fear that growing user dependence on AAL technology could expose them to danger in the case of emergency (i. e. if the technology were to breakdown). For example: an automated bed that deflated during a blackout hindered communication with the external world (J. van Hoof et al. 2011). In addition, sensors, battery-driven devices, and external devices should avoid causing problems for the mobility of users (A. Darwish and Hassanien 2011), either when worn or when installed in their homes.

EMBARRASSMENT, STIGMATISATION, SOCIAL ISOLATION

Ageing at home could have a positive impact on PwDs, especially when counterbalancing the negative aspects of institutionalisation (especially in the case of couples, who are used to living together and have done so autonomously and privately for decades (J. van Hoof et al. 2011). However, the use of AT or leakage of disease data—associated with the diagnosis of dementia —may cause embarrassment (Kumar and H.-J. Lee 2011) or even stigmatisation (Chan, Campo, et al. 2009; Dishman and Carrillo 2007; J. van Hoof et al. 2011; Kleinberger et al. 2007; S. Martin et al. 2010; O'Neill, Mason, et al. 2011; Oppenauer et al. 2007; Palm 2012; Louise Robinson et al. 2009; Salces et al. 2006; A. Sixsmith and J. Sixsmith 2008; Sponselee et al. 2008; Wright 2011; Wright and Wadhwa 2010; Zwijsen et al. 2010). Some AAL technologies evoked resistance in certain persons with MCI because of their 'handicapped-look' design (Francis et al. 2009) so

the design of the devices should be aesthetically pleasing for the users (Francis et al. 2009; Louise Robinson et al. 2009). Fairclough (2009) warns that an explicit feedback of information of a delicate nature coming from an assistive device in front of others or in public spaces can be embarrassing for its user. Stigmatisation can have major effects on the isolation of the user (Kosta, Olli Pitkänen, et al. 2010; Portet et al. 2011; Salces et al. 2006; Sorell and Draper 2012; Zwijsen et al. 2010), which can be followed by ghettoisation (Camarinha-Matos and Afsarmanesh 2011) or victimisation (A. McLean 2011) of the user.

MONITORING, SURVEILLANCE

AAL technologies raise security issues due to risks of surveillance (Kosta, O. Pitkänen, et al. 2008; Kosta, Olli Pitkänen, et al. 2010), when monitoring of the activities of daily living (ADLs) of PwDs. B. Hofmann (2012), discussing surveillance during the beneficial use of monitoring, questions whether it is possible to define a standard of normal daily activities that can be used in relation to WTs. The heterogeneity of the PwD cohort (Gaul and Ziefle 2009; Grönvall and Kyng 2012; Jeffrey Kaye 2010; Lynch et al. 2009; Mordini et al. 2009; Oppenauer et al. 2007; Remmers 2010; Salces et al. 2006) greatly complicates the differentiation between normal and abnormal ADL. Moreover, it is unclear who should define normal and abnormal ADL (B. Hofmann 2012).

SOCIAL EXCLUSION, DIGITAL DIVIDE, FAMILIARITY WITH ICT, AFFORDABILITY

Kosta, O. Pitkänen, et al. (2008) and Kosta, Olli Pitkänen, et al. (2010) ask whether the use of AAL technologies promotes social exclusion, rather than inclusion. Francis et al. (2009) demonstrate this issue using an example: the use of technology for persons with autism/Asperger's syndrome enables them to communicate better, thus seemingly promoting their social inclusion; however it can actually enforce their social exclusion and cause more intense anxiety by increasing their interactions with others.

The relevant literature also lists another form of social exclusion that is caused by technology, between users of ICT and non-users, namely the digital divide. The digital divide, according to Francis et al. (2009), has arguably similar effects on stakeholders as those of exclusion from ICT design cycles. The digital divide, as a form of social discrimination (B. Hofmann 2012), drives society to elitism (Kosta, O. Pitkänen, et al. 2008; Kosta, Olli Pitkänen, et al. 2010; Satava 2003). ICT devices can also widen the digital divide (Wright and Wadhwa 2010) and any existing divisions for example, between the quality of care (Walsh and Callan 2011) of those already familiar and those unfamiliar with ICT. Batchelor et al. (2012) differentiate younger and older generations based on familiarity with ICT devices, characterising them as 'digital natives' and 'digital immigrants.'

Francis et al. (2009) and B. Hofmann (2012) both mention that the prevalence of technology for certain people can cause feelings of alienation. Whilst Katz and Rice characterise the role of communication technology as primarily interaction, this interaction can be negative, for example where people cheat, exploit or hurt each other (Francis et al. 2009). Therefore, education and training from an early age on how to properly use ICT should be emphasised, enhancing the motivation to use, familiarity with and overall acceptance of, the ICT systems (A. McLean 2011; Mordini et al. 2009; Oppenauer et al. 2007). This could help address the aforementioned issue of digital divide and social isolation.

Wright and Wadhwa (2010) point out that eInclusion (digital inclusion of a person) might not be beneficial to everybody and that there will be certain social groups who will self-willingly exclude themselves from ICT technologies. The group of people classed as 'lapsed users' despite their familiarity with ICT, lack genuine interest in computers (Wright and Wadhwa 2010).

Other issues for the user, closely related to social discrimination and digital divide, are the overall affordability (Niemelä et al. 2007; Satava 2003; Wright and Wadhwa 2010; Zaad and Ben Allouch 2008; Zwijsen et al. 2010), feasibility (Kosta, Olli Pitkänen, et al. 2010), or cost (Daniel et al. 2009; Zaad and Ben Allouch 2008) of ICT systems. Economic barriers can lead to isolation too (Abascal and Nicolle 2005).

3.3.2 *Formal and Informal Care-Givers (Nurses, Family Proxies)*

3.3.2.1 *Research & Development*

WHOSE BENEFIT?

The basic interest for caregivers in the development of AAL technologies lies in the possibility of continuous monitoring of PwDs (A. Darwish and Hassanien 2011). An important question here is whether AAL technologies mainly benefit the PwD or the caregivers (B. Hofmann 2012). B. Hofmann (2012) points out that whilst many papers mention benefits of welfare technologies, there is a lack of empirical evidence from documented studies substantiating these claims.

3.3.2.2 *Clinical Trials*

DATA COLLECTION

According to Fairclough (2009), during clinical trials, the caregivers, together with the PwD, have the right to know what data are collected about them; the right to access the data if required; the right to provide/refuse their implicit/explicit prior consent; and finally, the right to some benefit for permitting data collection.

PREVALENCE OF TECHNOLOGICAL RATIONALITY IN HUMAN CARE

Several scholars are sceptical of AAL technologies because of their ability to replace human proximity and care (B. Hofmann 2012; R. Sparrow and L. Sparrow 2006). Moreover, there are reports of concerns regarding the deception of vulnerable people by the substitution of human emotions or relations by technologies (Oost and Reed 2011) and insecurity (Sponselee et al. 2008) during the use of technology by the caregivers.

B. Hofmann (2012) questions whether all the stakeholders of the AAL technologies are ready to translate the technologies of hospitals into the home (and private) environments. A home has a special symbolic meaning as a place of confidence, trust, comfort, safety and privacy (Dekkers 2009), meanings which can be disrupted by hospital technology. B. Hofmann (2012) also questions the prevalence of technological rationality in the care provided because it might reduce the potential to support and enhance patients' agency.

3.3.2.3 *Clinical Application*

INSTRUMENTALISATION OF CARE, THE VALUE OF HUMAN CARE

Care-givers, especially proxies, tend to welcome allowing PwD to remain at home, e. g. helping couples to live their lives together for longer at home, even with a moderate-dementia diagnosis instead of the institutionalisation of these persons. However, B. Hofmann (2012) reports that caregivers are increasingly concerned about the ethical responsibility and legal liability for any possible misuse of the technology in the home setting. He also stresses the possible risks of using ICT, which by its nature emphasises instrumental values, such as productivity and efficiency instead of important relational aspects of human welfare. This criticism is based on the assumption that values such as hope, coping, vulnerability, dignity, meaningfulness or proximity, which are essential core aspects of the human caregiving activity, cannot yet be meaningfully replaced with technologies (B. Hofmann 2012). The person-to-person interaction is emphasised as very important (Walsh and Callan 2011) as opposed to the drives towards replacement of human care with ICT devices (Borenstein and Pearson 2010; Coeckelbergh 2010; Oost and Reed 2011; Portet et al. 2011; R. Sparrow and L. Sparrow 2006; Vallor 2011).

Vallor (2011) expresses her concerns about the lack of academic discussion on the question of value of caregiving for caregivers themselves. Whilst being aware of the strenuous work during caregiving, she points out that in most of the literature about ATs (or as she calls them 'carebots'), the practice of caregiving *per se* is usually suggested as "nothing except a burden" (Vallor 2011, p. 255). According to her, emotional and social support is considered as a 'task' (R. Sparrow and L. Sparrow 2006), or caregiving as simply a 'burden,' which technologies can help reduce (Borenstein and Pearson 2010). Stip and Rialle (2005) mention the threat that artificial intelligence poses in replacing

the physician/caregiver by a pure data-manager of a database, transforming the notion of patient to a disembodied and virtualised user that is manageable from a distance. A. Sharkey and N. Sharkey (2012) highlight the danger of objectification of the elderly by the caregivers via technology (Vallor 2011).

OVERPROTECTION, PATERNALISM, PREVIOUS WORK HABITS, RIGID APPLICATION OF PROTOCOLS

Although caregivers are known for their general protective character and for trying to protect the remaining privacy of the elderly (Sponselee et al. 2008), cases of overprotection by caregivers have been reported (L. Robinson et al. 2007), which could be understood as a form of paternalism (S. Martin et al. 2010).

Moreover, the literature emphasises the needs of users, which are not always in accordance with the needs of caregivers. This is often the case when caregivers are reluctant to use ICT devices in human care and stick to their previous work habits, irrespective of the needs of the care receivers (Sponselee et al. 2008). Where the application of assistive devices is utilised, the prescribed protocols are reportedly often rigidly followed by caregivers, regardless of the needs or requests of the user (e. g. patient lifts, etc.) (Sponselee et al. 2008).

NOT-INVENTED-HERE SYNDROME

In caregiving institutions a 'not-invented-here syndrome' has been noticed, which means that the formal caregivers tend to be less willing to adopt an AAL system, which was developed outside their caregiving institution or was not solely designed for care purposes only (Sponselee et al. 2008).

3.3.3 *Researchers and Clinicians*

3.3.3.1 *Research & Development*

MOTIVES FOR PARTICIPATION IN RESEARCH, EAGERNESS TO PLEASE, POWER-RELATIONSHIP BETWEEN THE RESEARCHER AND PWD

Elderly persons reported various attitudes and motives as reasons for taking part in research: a wish to contribute to the development of AAL technologies, a feeling of obligation to participate in research that could result in progress in the field of study, feelings of curiosity and loneliness, and a desire to find somebody willing to listen (Grönvall and Kyng 2012).

During R&D and clinical trials, users tended to be eager to please the researchers or feared offending them somehow (Wallace et al. 2010) or of 'causing some problem by

doing something wrong' (Oberzaucher et al. 2009). They often blamed themselves for causing problems (Wallace et al. 2010).

Moreover the physicians'/researchers' relationship to a (vulnerable) user could be a power relationship. The elderly tend to have less confidence in their own judgement (Wallace et al. 2010) and regard researchers as people with higher status and expertise (Maier and Kempter 2009). Therefore, they tend to defer to their opinion and ideas. According to Maier and Kempter (2009), such power inequalities can negatively affect the whole R&D process and its results. In cases like this, the elderly person should be reassured that the researchers are performing the research in order that they may learn from them (Maier and Kempter 2009).

3.3.3.2 *Clinical Trials*

MEANINGFULNESS AND PRIORITISATION OF DATA

Despite the physicians' declared lack of motivation to learn how to use new ICT technologies (Sponselee et al. 2008), the interest that clinicians and medical researchers take in AAL technologies partially overlaps with that of the caregivers in the continuous monitoring of the PwD. During the clinical trials, an important aspect for medical researchers is the meaningfulness of the data gathered, both from a scientific and a medical point of view, in order to be able to translate it into valid knowledge (Allen et al. 2008; Conley et al. 2008; Cook et al. 2009; A. Darwish and Hassanien 2011; Kang et al. 2010; Jeffrey Kaye 2010; Noury et al. 2011; Romdhane et al. 2012; Viswanathan et al. 2012; Wherton and Monk 2008). The accuracy and reliability of such data has to be prioritised, according to their relevance, importance and urgency (A. Darwish and Hassanien 2011; Viswanathan et al. 2012).

SAFETY AND SECURITY OF PWDS

With various technologies and their functions (location tracking, drug intake monitoring, social interaction detection, etc.), the reduction of fear and insecurity amongst the elderly has been documented, as well as an increase in both, genuine and perceived safety (B. Hofmann 2012; S. Lauriks et al. 2007).

3.3.3.3 *Clinical Application*

HUMAN-CENTRED APPROACH

The clinical application of AAL technologies should incorporate two considerations with regard to a human-centred approach. Firstly, a human-centred computing approach should consider the health- and technology-orientation of an ambient system, along with the need for comfort of the PwDs (i. e. their special needs as persons; the need

for empowerment living in their homes; etc.; Portet et al. 2011; Zaad and Ben Allouch 2008). Secondly, a consideration of whether the need for AAL technologies is in the best interest of the individual PwD (Scanaill et al. 2006). The aforementioned considerations pose decision-making challenges linked with the responsibilities and competencies of both the clinical researchers and clinicians (B. Hofmann 2012).

ALLOCATION OF RESOURCES

Duquenoy (2004) stresses the question of who decides about the prioritisation of information, bandwidth, machine power, storage and, more generally, the allocation of resources and trade-offs.

ICT AND DIAGNOSIS, AUTOMATED MACHINE DIAGNOSIS

The use of ICT devices in healthcare is divided between the services- and information-related forms of telehealth (tele-care and tele-rehabilitation) for end-users, and telemedicine, which is defined by Plaza et al. as ICT devices used for diagnosis (Plaza et al. 2011). Behind the introduction of ICT into the arena of healthcare is the shift from the traditional reactive approach, namely diagnosis and treatment or cure, towards the preventive approach, namely, monitoring and early detection of diseases (Palm 2012). Regarding PwDs, the focus in diagnosis is on the preclinical state, when the symptoms provide enough variances during monitoring to enable the projection of the possible later loss of independence and physical functioning (Merilahti et al. 2012). The role of ICT in diagnosis is to predict and track the progression of the disease (Dishman and Carrillo 2007), often doing so remotely (B. Hofmann 2012).

The automated diagnosis via ICT technology is welcomed by a few authors (Camarinha-Matos and Afsarmanesh 2011; A. Darwish and Hassanien 2011; Friedewald and Raabe 2011). In addition to the current difficulties with fidelity and trustworthiness of such systems (Fairclough 2009; Gaul and Ziefle 2009; Kleinberger et al. 2007), there are also legal constraints. In the context of EU laws, persons have a right not to be subjected to significant decisions based on any such automated processing (European Commission *Data Protection Directive 95/46/EC* 1995; Kosta, O. Pitkänen, et al. 2008; Kosta, Olli Pitkänen, et al. 2010). Similar regulation is present in Japan's Doctor's Act no. 20, which prescribes that diagnosis should be provided only by direct examination of a patient, not by a machine (Chan, Estève, et al. 2008).

3.3.4 *(Software/Hardware) Engineers*

3.3.4.1 *Research & Development*

USER-INVOLVEMENT IN R&D

It may be detrimental if engineers and designers of AAL technologies do not involve PwDs in the customisation and co-design of these assistive technologies (Francis et al. 2009; Gaul and Ziefle 2009).

SECURITY OF MEDICAL AND PERSONAL DATA

A significant number of articles raise concerns about security (see Figure B.4), which in the case of medical and personal data necessitates the provision of strong data security, even automatic encryption (e. g. encryption in the physical layer Chan, Estève, et al. 2008). The encryption of personal data is stipulated by both international and national legislation (e. g. *21 CFR 11* 2009; or *Data Protection Directive 95/46/EC* 1995). Kumar and H.-J. Lee (2011) stresses the importance of protection against Denial of Service (DoS) attacks on the whole system because of their potentially tragic consequences. Moreover, the Quality of Service should be evaluated together with the security of the system (Kumar and H.-J. Lee 2011).

SAFETY OF AAL SYSTEMS

The installation of assistive technologies, as previously mentioned, should not reduce the mobility of their users (A. Darwish and Hassanien 2011). This also holds true for implantable (*in vivo*) sensors (Chan, Estève, et al. 2008). These should also not overheat or harm their user (A. Darwish and Hassanien 2011).

TASKS NOT SUITABLE FOR ICT

During the R&D, according to B. Hofmann (2012), engineers should be aware of, or be warned by other stakeholders about certain tasks, which are not suitable for ICT solutions. R. Sparrow and L. Sparrow (2006) point out that, in future, different types of assistive robots are supposed to provide either physical services, such as lifting, turning, monitoring; or caring and emotional labour, such as conversations, social interactions, sympathy, emotional support, etc. By introducing these solutions, we may also be withdrawing the only regular human social contact for the elderly, namely the people providing physical care for them (professional caregivers, cleaners, household maintenance assistants, etc.; R. Sparrow and L. Sparrow 2006). R. Sparrow and L. Sparrow (2006) therefore emphasise that the human companionship provided by caregivers is at least as important as the physical duties they perform.

TECHNICAL OR 'QUICK FIX,' R&D FOR PWDS AS LOW PRESTIGE ENDEAVOUR

The danger of regarding AAL technologies as 'quick and easy fixes' or a 'technical fix' to grave psycho-social and societal problems is still present (B. Hofmann 2012; Mordini et al. 2009).

Moreover, researchers see the development of technologies for the elderly as a low-prestige endeavour (B. Hofmann 2012; compared with other technologies, e. g. diabetic insulin pumps, artificial cardiac pacemakers, wearable EEG systems, or wearable dialysis machines, etc.), although the need for these technologies is increasing.

MISMATCHED EXPECTATIONS OF USERS AND ENGINEERS

The literature warns about mismatched expectations of engineers/researchers and actual users of a system (Allen et al. 2008). For example, video-telephony is often understood as enhancing the social inclusion of a user but according to van Hoof's empirical study, it did not always reduce feelings of loneliness or improve the social contacts of the users (J. van Hoof et al. 2011). Therefore, an analysis of the broader social context is required (Duquenoy and Whitehouse 2006; Duquenoy 2004).

INTEROPERABILITY AND COMPATIBILITY OF SYSTEMS

During R&D the longevity of AAL technologies requires that they must be developed with the possibility of extending and integrating their use with other future systems and sensors (Chan, Estève, et al. 2008; A. Darwish and Hassanien 2011; Román et al. 2009).

SPECIAL STATUS OF HUMAN EXPERIMENTATION

The engineers should be aware of the dangers and issues linked with human experimentation (Mordini et al. 2009).

3.3.4.2 *Clinical Trials*

INDISPENSABLE THIRD PARTIES

The responsibilities of indispensable third parties, without any direct health responsibilities (electricity-, heating-, gas-providers, technical service, etc., B. Hofmann 2012; J. van Hoof et al. 2011) for the application of assistive technologies in home environments, must be considered critically from the clinical trials stage onwards. An unexpected power-cut or loss of internet connection by an Internet service provider could have tragic consequences in a smart home and for a PwD using wearable life- and health-logging sensors. Furthermore, privacy and confidentiality could be infringed (B. Hofmann 2012). The question at stake is the allocation of the responsibility.

Kosta, Olli Pitkänen, et al. (2010) express that the liabilities can be strict, meaning that if, for example, from the clinical trials stage onwards, an unauthorised person gains access to sensitive data, the controller should be held responsible for the damage regardless of culpability. This view of liability could be applied to the indispensable third parties as well.

Wright mentions the notion of "overlapping responsibilities" (Wright 2011, p. 211), originally defined by Vedder and Custers (Wright 2011). In the development of new technologies the stakeholders at various stages of the development have only limited insight into the opportunities and risks involved, while at the same time having only very limited means to respond. As it is undesirable to assign all the responsibilities of a highly complex system to only one group of stakeholders, overlapping responsibilities are favourable in cases when there is usually a responsibility gap (Wright 2011).

Finally, Decker (2012) calls for legal accountability of damages caused by service robots themselves. In principle, the owner of a service robot is liable for the damages caused only if he or those assisting him are personally responsible. Mistakes in the production or instructions of a product are the responsibilities of the manufacturer (Decker 2012). However, the liability of the owner is again questionable, if such a robot adapts autonomously to various situations, or can react to human beings, other robots or the environment. Therefore, its behaviour is not predictable in detail. Decker et al. (2011) ask whether, for such cases, an independent legal 'liability' and new rules of accountability should be called for.

TESTING OF AAL TECHNOLOGIES

B. Hofmann (2012) further expresses the need for more intensive testing of AAL technologies. Compared with the testing of drugs in healthcare, the regulation of ambient technologies seems to be lax (B. Hofmann 2012). Portet et al. (2011) clarify that in principle, there are three possible venues of testing: a) *in situ* (in the real environment of the user), b) *in vitro* (in laboratories), and c) *in-sitro/in-simu* (in a simulated environment, reproducing the users' home environment). Against this background, Portet et al. (2011) point out that there are very few instances of *in-situ* testing. He also remarks that although the *in vitro* tests are more affordable and possibly more objective, the *in situ* tests provide more realistic data, although at a higher cost and possibly with an observers' subjective bias. The *in-sitro/in-simu* experiments are able to identify most of the usability problems found in other conditions, though not as precisely as the *in-situ* experiments, hence *in-sitro/in-simu* experiments are particularly suitable for prototyping (Portet et al. 2011).

3.3.4.3 *Clinical Application*

DATA SAFETY AND PROTECTION

During clinical application, demand is placed on the engineers to deal with the issue of data protection (Kosta, O. Pitkänen, et al. 2008), involving its secure storage for a requisite amount of time, and its subsequent secure removal (Abascal and Azevedo 2007). Duquenoy (2004) emphasises that the bandwidth, processing power, memory, etc., necessary for transferring and processing medical data is a scarce resource and therefore, an adaptive and on-going negotiation about operational space and its prioritisation should be applied.

PRINCIPLE OF PROPORTIONALITY

B. Hofmann (2012) indicates that the proportionality principle, should be applied during the application of welfare technology,[12] especially surveillance technologies. Accordingly, the harm and burden caused must be appropriate in relation to the benefits yielded. For example, a tracking system should not impose physical restrictions or mobility surveillance on its user by limiting his or her activities but rather, should apply less obtrusive subjective barriers, with labels, mirror doors, RF[13]-coded access points, etc. However, the benefit of these alternatives could also be questioned (B. Hofmann 2012).

EASY TO LEARN, ERROR FREE ICT

Assistive technology should be easy to learn for future users. Also, it should be as error-free as possible (Portet et al. 2011).

DIFFERENT LIFE-CYCLE OF TECHNOLOGY AND SERVICE, TECHNOLOGY PUSH

The engineers of ambient assisted solutions should bear in mind the differences between the life-cycle of a device (technology), and the life-cycle of the healthcare service providing it, as they are usually not identical. The health service begins with the person going to see the clinician, and it ends when the clinician resolves the person's problem. The technological life-cycle is different: it is developed, produced in large quantities, and distributed to selling points. From an ethical point of view, a service life-cycle is more human-centric, while that of a product is more technology-centric. According to Kosta, O. Pitkänen, et al. (2008) and Kosta, Olli Pitkänen, et al. (2010) the former should be

12 Hofmann defines welfare technology as a heterogeneous group of technologies which are "supposed to give better and more focused care, reduced risk and increased safety, increased coping and self-determination, make it possible to stay at home longer, avoid harm (from falling, fire, robbery), make more just resource allocation, and to promote technology development, commercialization and growth." (B. Hofmann 2012, p. 391)

13 Radio-frequency.

highlighted. Furthermore, because the difference between life-cycles is not clear, how much ethical analysis is transposable from earlier product study, and how much new ethical analysis is required in a new model of ambient intelligence (Kosta, Olli Pitkänen, et al. 2010) is an open question. Related to this, Chan, Campo, et al. (2009) point out that the technology push from the industry is usually greater than the demand pull from the users' needs, which can cause user disappointment.

THE ROLE OF AAL TECHNOLOGIES

Rapoport (2012) notices that the role of ICT devices regarding the human body facilitates a new perception of the body itself: mediated through technologies. Moreover, beyond merely detecting, the technologies do currently also take on agency, make choices, assume the intentionality allotted to human beings while performing actions in a purposeful, goal-oriented manner. Such a technology thus turns into a proxy (Rapoport 2012).

3.3.5 *Designers*

3.3.5.1 *Research & Development*

DESIGN-FOR-ALL APPROACH AND HETERONOMOUS GROUP OF PWDS

For the designers, the literature emphasises the user-centred approach to design (Wallace et al. 2010), which means a universal design for users with various needs and requirements. The design-for-all, universal design, and inclusive design approaches are characterised by encouragement of designers to extend their designs to include older and disabled people in all phases of R&D (Newell et al. 2011), despite the higher cost, extra work (Abascal and Azevedo 2007; Sponselee et al. 2008) and greater attention required from the designers (Wallace et al. 2010). However, according to Portet et al. (2011), the design-for-all approach may be inappropriate for PwDs because of their specific individual needs and pathologies. They emphasise that "no smart home application is going to be successful if the intended users are not included in the design" (Portet et al. 2011, p. 132). It is imperative to focus on safety during the design process. This may be achieved by employing the privacy and security by design model (Kosta, O. Pitkänen, et al. 2008; Kosta, Olli Pitkänen, et al. 2010), and maintaining privacy (Portet et al. 2011) and user-friendliness (A. Darwish and Hassanien 2011; Duquenoy and Whitehouse 2006).

USER INVOLVEMENT IN R&D

As stated before, the active involvement of users in the process of design is necessary for the overall usability and success of AAL technologies (as is the case with the user-

centred Participatory Design Approach during the design of disability assistive technology for people with autism/Asperger's syndrome (Francis et al. 2009). This approach could also be referred to as 'proactive design' (Duquenoy 2004), as a holistic approach or perspective (Kosta, Olli Pitkänen, et al. 2010), as value sensitive design (Wright 2011), ergonomic design (Wallace et al. 2010), or simply as ethical design (Kosta, O. Pitkänen, et al. 2008). The involvement of (vulnerable) users in the design process can be maintained by means such as role-playing (Picking et al. 2012), drama (Sponselee et al. 2008) or acted performance (Newell et al. 2011), and interviews (Maier and Kempter 2009).

The feedback from users for design is crucial because every target user is a domain expert (Allen et al. 2008). Borenstein and Pearson (2010), quoting Oosterlaken, emphasises that the details of design are morally significant. Details such as a step-by-step design (Aarts et al. 2007; Burleson et al. 2012; Pulli et al. 2012), or large and coloured buttons (O'Neill, Parente, et al. 2011; Picking et al. 2012), and the overall intuitiveness (Maguire et al. 2011) of a system are preferred if these are helpful for the end-users. The reported difficulties of elderly users of ICT are usually about hardware issues, inconsistent interface, screen size, height mobility, information interpretation or the overall mental (rather complex) model applied (Lorenzen-Huber et al. 2011; Wallace et al. 2010). M. Hersh et al. (2003) would also welcome financial payments for users providing feedback.

DEFINITION OF DISABILITY

Since the development of the classic functional model by Nagi in 1965 (Lynch et al. 2009), the design-for-all approach tries to address the paradigm shift from understanding disability solely from a medical perspective to understanding disability in a social context. In this approach, the biological and pathological characteristics of the impaired individual are less important compared with the social context (functional limitations and disability; Appleyard 2005; Darzentas and Miesenberger 2005; Lynch et al. 2009).

According to Abascal and Nicolle (2005), instead of being rigid, the design should be adaptive, dynamically adjusting itself to the needs of its user, and consequently reducing potential user's anxiety. Bad design facilitates more handicaps through less accessible systems (Abascal and Nicolle 2005).

RELATIONSHIP OF DESIGNERS WITH PWDS

As the caregivers could be technophobic (Sponselee et al. 2008), the designers are in general the opposite, technophiles (Wallace et al. 2010). In addition, the age gap between PwDs and designers can be an issue (Wallace et al. 2010), triggering communication difficulties in introducing ICT (Sponselee et al. 2008). The power relationship, between the (formal) caregivers/researchers and the PwDs is, as mentioned above, possible be-

tween the PwD and designers as well (eagerness to please, Francis et al. 2009; deferring to the opinion of the researcher as a person with higher status and competence, Maier and Kempter 2009; etc.). Hence, the use of focus groups, where the users share their ideas with the researchers/designers in an interactive, open, and friendly manner, is welcomed in most of the literature (S. Brown et al. 2004; S. Brown et al. 2006; Maier and Kempter 2009; Walsh and Callan 2011). Wallace et al. (2010), however, find focus groups unsuitable due to efforts to utilise as many participants as possible, resulting in less useful discussion.

3.3.5.2 *Clinical Trials*

TESTING, IMPACT ASSESSMENT

Although some untested systems could be reportedly beneficial for the users (Steve Lauriks et al. 2010), as already mentioned, very little *in situ* testing was reported by Portet et al. (2011), with a lack of more general socio-economic impact studies (Chan, Estève, et al. 2008), and a lack of studies of gender differences (Chan, Campo, et al. 2009). Cahill et al. (2007) emphasises that pre-testing in the care of PwD is critical to ensure the reliability and efficiency of the devices. According to Scanaill et al. (2006), very few impact assessment methodologies were developed and a relatively small number of them are able to enforce actions based on their results. Wright (2011) proposes a framework (ethical principles, values, issues, and questions) for impact assessment to ensure that responsibilities and considerations of the designers regarding technology are ethically adequate and not detrimental to the generally accepted social values.

3.3.6 *Technicians*

3.3.6.1 *Clinical Trials*

SENSITIVE INSTALLATION OF DEVICES

Technicians are the mediators between the technology, the PwD, and their homes. Their approach to the installation and removal of the technological equipment must be very sensitive, in order to avoid producing extra harm and anxiety for the PwD. J. van Hoof et al. (2011) mention the complaint of one of the participants of their research about the drill-holes left behind by technicians in their home. Also, research participants may be worried about the presence of 'strangers' in their home environment (J. van Hoof et al. 2011).

3.3.6.2 *Clinical Application*

Naturally, the remark above about sensitivity holds for the application stage as well. Furthermore, during a regular maintenance/check-up activity, technicians should consider the special status of PwD, for example by minimising repeated departure-and-returns to the easily confused patient's home during a single session. Due to the possible memory impairment of the PwD, technicians should work in pairs, in order to maintain a constant presence and connection with the PwD residents and to avoid losing touch with the PwD. They should also be able to listen and repeatedly explain their activities to the PwD and answer their questions (J. van Hoof et al. 2011). In this case, the indispensable third parties demand special attention because their staff may have different (technology) competencies (J. van Hoof et al. 2011), and could also have very little experience of working in healthcare.

3.4 DISCUSSION

In the current scholarly debate as identified in our study of the literature reported in the previous section, privacy, safety and security issues are major concerns in relation to AAL technologies for PwDs. It is also clear, however, that PwDs have persistent mobility issues and need support for their everyday living at home, which can be provided by AAL technologies. In addition to these issues, we wish to highlight the following ethical aspects that have not received enough attention yet in the scholarly debate: 1) the value of the goals of AAL technologies, 2) the special vulnerability of PwDs in their private homes, and 3) informed consent.

The frequency of ethical terms in the reviewed publications highlights a heterogeneous set of goals that provide reasons for the development of AAL technologies. However, these goals and reasons are assumed to be beneficial for PwDs, and are only rarely actually analysed from the ethical viewpoint. In some cases, ethical concerns related to AAL technologies are mentioned but the consequences for the R&D of these technologies are rarely discussed. Therefore, a dedicated section aims to map the values associated with the various goals, which AAL technologies aim to achieve.

The involvement of PwDs in the R&D process introduces additional ethical issues related to the vulnerable status of these research participants. Ethical standards require that due attention should be provided to the special vulnerabilities of PwDs for safe and successful conduct of R&D, as well as the clinical deployment of AAL technologies for their users. The section below highlights aspects related to special vulnerabilities of PwDs with regard to the development and clinical application of AAL technologies.

A third section highlights additional ethical challenges that arise during research with PwDs. The specific condition of PwDs with their MCI poses serious challenges and

complications for the fulfilment of the requirement for valid informed consent. This issue is one of the leading concerns in the reviewed literature, as well as being one of cornerstones of medical ethics.

3.4.1 *Value of the Goals of AAL Technologies*

Here we consider whether the a) motives for the development and b) the ambitious goals promised by the AAL technologies are really valuable. Our focus on the value of the goals in this section will be exclusive. We will omit the assessment of the feasibility of the goals of AAL technologies because such an assessment is subsidiary to an assessment of the value of the goals, and does not focus solely on the ethical aspects.

Many of the articles we reviewed accept the benefits of using AAL technologies (e. g. better care, 24-hour non-stop care, staying at home longer for PwDs, cheaper option than a nursing home, maintenance of independence and autonomy of PwDs, etc.). Very few articles critically question this presumption.

Firstly, one should consider the question of who will primarily benefit from the application of AAL technologies. B. Hofmann (2012) predicts that the use of assistive technologies (which he calls 'Welfare Technologies') will benefit the caregivers more than those in need of care. This criticism raises serious questions about the justification of using AAL technologies for PwDs, as it might turn out that the biggest share of benefits are for third parties, whilst those most in need of care bear the brunt in terms of risks and harms from their use. Therefore, the motivation of the R&D of AAL technologies has to be clearly stated because different ethical considerations apply, particularly if such a system benefits the caregivers more than those in need of the care.

Secondly, regarding the issue of motives for developing AAL technologies, Sorell and Draper (2012) stress the fact that by definition, AAL technologies set as their main priority, the provision of independent living and staying longer at home (as Sponselee et al. (2008) call it 'extramuralization') for persons with chronic diseases. The policy changes in the UK for telecare serve as an example of the cutting back of institutionalisations and the shortening of hospital stays, indicating that the goals of AmI can align with governmental policy. However, Sorell and Draper (2012) note that although this policy coincides with the motivations of the elderly, this does not mean that the governmental motivations are the same as those of the elderly and not solely economic. Using an economic angle for policy, telecare (including AmI, AAL technologies) maximises self-financing. In the light of telecare having a cost-cutting effect, the presentation of it solely as a means for prolonging independent living may be disingenuous. Similarly, although increasing the default retirement age has a cost-cutting effect on pension benefits, this governmental policy is often presented with the rhetoric of an anti-ageist approach (Sorell and Draper 2012). Hence the motivation for cost-cutting has to be care-

fully assessed. We agree with the finding of Holzinger et al. (2008) that the benefits of using technology in the arena of healthcare (including care of PwDs) must be clearly appreciable, either on physical, medical or emotional grounds. The recognition of these values provides not only acceptance from its users but also motivation and justification for its research (Holzinger et al. 2008).

The varied pathologies linked with dementia are currently the object of scientific research, which investigates their biological nature as well other (phenomenological, behavioural, etc.) aspects. Consequently, one of the goals of the development of AAL technologies, from a medical point of view, is the recording of health-related scientific information. The collection of data *in-situ*, i. e. within the home-settings of the PwD, is very challenging for researchers. In addition, the presence and intrusive nature of the AAL technologies in the home environment of a PwD, with their possibly harmful effects, raises serious ethical issues (surveillance and continuous monitoring, pervasive nature of the technology, data safety, etc.). That being said, it might open up the horizons for establishing better scientific foundations for more sensitive diagnosis and treatment or management of dementia. The perspective of better diagnostic techniques could be a valid justification for the introduction of AAL technologies to PwDs. However, this benefit, as such, may be too small to justify the serious potential harms and risks thus posed to this very vulnerable segment of the population. Similarly, the application of sensor-systems, mainly for research data collection could also go against the proportionality principle.

Let us look at an example: One of the major fears of PwDs is falling, as reported by B. Hofmann (2012) and J. van Hoof et al. (2011). However, even the most advanced and complex ambient technology would be undesirable, if the benefit could also be provided by a more lightweight, simpler, cheaper and easier-to-use system. Currently, despite the immense efforts of research in the area of AAL technologies, the smart-home full of sensors does not provide greater help in preventing or assuaging the fear, not to mention coping with the situation of a PwD falling than a much simpler one-button, danger-reporting alarm worn around the neck. AmI should provide much more benefit than being just another solution for reporting complications for PwDs. The obtrusiveness of AmI demands proportional benefits in the well-being of their actual users.

In addition to the issue of proportionality, B. Hofmann (2012) asks who will define, and on what basis, what constitutes the average everyday normal activity for a PwD under the control of surveillance technology? As mentioned before, the cohort of the elderly, including PwDs is a heterogeneous group (Gaul and Ziefle 2009; Grönvall and Kyng 2012; Jeffrey Kaye 2010; Lynch et al. 2009; Mordini et al. 2009; Oppenauer et al. 2007; Remmers 2010; Salces et al. 2006). Different users have different needs, behavioural expressions and habits. Therefore, the goals of AAL technologies should be defined alongside the provision of a high level of customisation and adaptability of the

system to the activities and needs of every individual user. Introducing an AAL system to a private home should avoid forcing users into performing activities, which are considered to be unpleasant and burdensome, and are required solely by the introduction of assistive technologies into the healthcare process. For example: users reported problems with false alarms, which are, because of the sensitivity of the ambient technology, somehow inevitable (J. van Hoof et al. 2011). AAL technologies should not give the PwD unreasonable extra burden of taking care and managing the technology. The aim of AAL technologies is to provide support and empowerment and a feeling of safety and security, not the burden of performing extra tasks. Researchers cannot expect that a person with MCI and with fading memory capabilities will defer to the requirements of a system, which is not intuitive and easy to use. Such a scenario contravenes the very definition of AAL technologies, which are supposed to disappear into background without any undue need for human interference. Therefore, efforts should be made during R&D to ensure that the technology fulfils the 'ambient' attribute of its definition. As Abascal and Nicolle (2005), quoting Thimbleby (1994), remarked, "badly designed systems handicap all users" (Abascal and Nicolle 2005, p. 491), not only PwDs but also caregivers, family members and physicians.

The heterogeneity of the group of PwDs includes geographical and cultural differences too. However, there is a dearth of literature regarding the possible labelling of AAL technologies. The development of AAL technologies should, in the future, discard the label of being developed in highly industrialised and computerised Western societies. Therefore, in order to fulfil – globally – the goals of beneficence and value, the variety of culturally influenced characteristics to be found between different countries and cultures, deserve deeper analysis.

Also, when ambient technologies are widely used, the freedom to refuse assistance from AAL technologies has to be considered. It is not known, whether, in the future, compulsory introduction of AAL systems at home could be refused by a PwD, for example, if they were offered by her insurance company. Also, it is not known whether a proxy of a PwD would have a right to refuse the deployment of AAL technologies. More empirical research is needed regarding the acceptance, usage and overall personal and social impact of AAL technologies upon their users.

In summary, the value of the goals of AAL technologies is generally positive: according to the literature, they aim to give assistance, support, empowerment, a sense of security to vulnerable persons, and aim to facilitate them staying longer at home whilst maintaining their comfort, social connections and security. However, extra attention should be given to attempts to reduce the possible harms and risks for the vulnerable PwDs. Researchers should bear in mind that the provisioning of AAL technologies for PwDs is non-therapeutic, thus the justification of possible harms involved requires an outweighing amount of benefits to make the assistance of AAL technologies favourable. Still, due

to a lack of sufficient empirical evidence, the feasibility of achieving all the beneficial goals of AAL is still very much an open question and requires more research.

3.4.2 *Special Vulnerability of PwDs in Their Private Homes*

Although modern hospitals and care- and nursing-homes currently use a plenitude of technologies, for which partial responsibilities are held by various stakeholders (engineers, designers, etc.), there is usually a 'safety net' of human caregivers (nurses, clinicians, proxies) present in case of any malfunction of the technology. AAL systems by their nature try to reach a level where such assistance should not be needed, thus enabling users to live at home for longer. Moreover, assistive technologies are not present in clinical settings but rather in the private homes of PwDs. A misunderstanding with technology at home can cause extra harm, instead of providing support for the PwDs, compared with settings in hospitals or nursing homes. These facts introduce a need for a much higher level of safety and reliability in AAL technologies than in technologies used in hospitals and nursing homes.

Furthermore, where the interactivity of AAL technologies is necessary, the system should also provide measures that allow the reporting of false alarms by the users themselves. The cognitive condition should not disqualify PwDs from a certain amount of control, self-determination and evaluation of the applied AAL technology. The seemingly contradictory requirements of AAL technologies, of being ambient and interactive at the same time, necessitate a careful design process and empirical research about the needs and habits of the users, while maintaining their safety and security in their preferred environment.

Besides, although debated by some (Decker et al. 2011), it would be ethically unacceptable that in case of fault or malfunction, the responsibility is allotted to the 'system' and not to somebody, who designed, engineered, applied, or (mis)used it. Therefore, there is a serious need for guidelines for the R&D of the AAL technologies, where the liability and accountability of a developed technology is preserved throughout the whole process of R&D, trial, application and ensuing continuous use of the AAL technology.

In the R&D stage, designers should actively involve PwDs as they will be the end-users of the technology. In addition, during the R&D procedure, a correct balance should be struck between cost-effectiveness on the one hand and the quality of the methodology to obtain feedback from the participants of ambient technologies on the other. Such a balance needs to be emphasised because methodologies to obtain quality feedback (*in vitro*, *in-sitro/in-simu*, *in situ* scenarios) can significantly increase costs. Depending on the costs involved, participant feedback methodologies are differently optimised and can provide different results for the R&D process (Portet et al. 2011). These differences may be crucial and could cause serious issues later on, during the final introduction

of the AAL technologies to a wider group of PwDs. So the quality of the feedback methodology directly affects the quality of the feedback from the PwD participants. Therefore, as the introduction of the PwDs into the R&D process is vital, the quality of the feedback itself must also be considered as essential for the entire project of the use of ambient intelligence for PwDs.

However, the vulnerability of PwDs imposes serious requirements on the quality and quantity of data collected during the R&D procedure (how many sensors can a research participant with dementia wear, for how long, how many sensors are necessary to be installed in the *in-situ* private home environment, etc.). Therefore, judiciousness from the researchers is required in their approach to the PwDs as human beings and at the same time, in their assessment of the quality of data gained from the PwDs as research participants. A more comprehensive human-centred approach from researchers and caregivers can be extremely beneficial for all the stakeholders, especially during the R&D process. With a human-centred approach, all the processes of introducing and maintaining the AAL technologies could be made more successful by being stress-free and goal-orientated, while also avoiding the dangers of technical/technology-based and economic biases. This will very likely ensure a better applicability of the AAL technology in the final clinical application period.

B. Hofmann (2012)'s comparison of the complexity and profundity of the testing of pharmacological drugs and their introduction into the healthcare system with the relative lack of rigorous testing and regulation when it comes to medical devices in healthcare is noteworthy. Dishman and Carrillo (2007) find the approach of review boards regarding everyday technologies for Alzheimer's Disease (AD) care ill-equipped and worthy of criticism because their members may be unfamiliar with the technology, and often evaluate the risks of ICT devices on the basis of drug trials, while they involve "little to no participant risk" (Dishman and Carrillo 2007, p. 232). However, despite the lax regulation for testing medical devices, we are obliged to state that the impaired condition of PwDs requires rigorous ethical considerations during research, testing and application periods.

Finally, one of the expressed hopes of researchers is the future use of continuously operating (ambient) machines for diagnostic purposes (Camarinha-Matos and Afsarmanesh 2011; A. Darwish and Hassanien 2011; Dishman and Carrillo 2007; Friedewald and Raabe 2011). However, in various countries, such a scenario is already subjected to regulation and is legally prohibited (Beyleveld 2011; Chan, Estève, et al. 2008; Kosta, O. Pitkänen, et al. 2008; Kosta, Olli Pitkänen, et al. 2010).

In short, the special vulnerability of PwDs with their declining cognitive abilities should put the researchers on guard regarding the research and testing of AAL technologies on this group of participants. Researchers should also be more alert due to the

lack of 'safety nets' in private home environments, which are usually present in hospital and nursing home scenarios.

3.4.3 *Informed Consent*

Informed consent is considered crucial for the application of any research or treatment with technology in healthcare. The importance of the notion of informed consent has become more apparent since the Nuremberg trials and has accordingly been legally embodied in many modern jurisdictions. Hence, the notion of informed consent has a strong legal dimension. According to the definition of Beauchamp & Childress, informed consent is an "individual's autonomous authorization of medical intervention or of participation in research" (Beauchamp and Childress 2009, p. 119).

The present justification of informed consent is based on considerations of autonomy. Not being treated as mere means but always as ends, means that people must have an opportunity to choose to participate in research or to undergo a treatment (Beauchamp and Childress 2009).

According to Árnason et al. (2011), the modern understanding of valid informed consent consists of three parts: a) competence (ability to do what is needed to perform a task), b) understanding (disclosure of relevant information is a precondition of adequate understanding of the information about a treatment/research), and c) voluntariness (being aware of the possible outcomes).

The logic of *competence* means that even a healthy person is not globally competent because no one has the ability to do all mental and physical tasks. Therefore, Árnason et al. (2011) propose that competence should be understood as a task-specific notion, rather than a global notion. This task-specificity is based on a person's abilities to understand and perform a particular decision-making task in a particular situation (Árnason et al. 2011).

Regarding *understanding*, Árnason et al. (2011) stress that no one has a pure and abstract understanding of clinical treatments/research. A professional's duty is to find a correlation between the personal background knowledge of the participant and the information about the treatment/research, in order to reach an adequate level of comprehension of the relevant information. This correlation has to be reached with the usage of comprehensible (plain) language, while the participant is neither overloaded with the information, nor under-informed (Árnason et al. 2011). These principles pose challenges to the researchers when requesting informed consent from a PwD with gradually developing MCI or memory impairment.

Finally, a valid informed consent has to be *voluntary*. This means that in order to be able to make a decision, one has to be aware of the possible relevant outcomes of the research. In addition, informed consent had to be requested while not being under the

influence of coercion, deception, persuasion, or manipulation. The assessment of the voluntariness of consent usually is the responsibility of the researcher (Árnason et al. 2011) with oversight from the research ethics committees. As already mentioned, the eagerness to please the researcher or a proxy, higher status and trust in the competence of the researcher, family relationships can influence the voluntariness of consent of the participant negatively. Cultural influences can play a specific role here, since certain cultures prefer to make collective decisions (Árnason et al. 2011). In addition, voluntariness should incorporate the possibility for a participant to opt-out of the research at any time without necessarily giving a reason.

PwDs with MCI and memory issues pose a serious challenge regarding informed consent. The developing MCI and progressive memory and communication issues of the PwD may affect the quality of the aforementioned requirements of informed consent considerably. During the progression of dementia, the task-specificity of competence and the understanding of PwD may change. These require the introduction of a concept of informed consent that is adapted to the altering conditions of PwD, which we call 'rolling informed consent.' Rolling informed consent involves: a) the necessity of repeatedly providing information on an iterative basis (i. e. not only when requested), and also asking for consent during the various stages of the treatment/research; b) listening to the content and nuances of the speech of PwD and continuously assessing whether her participation is voluntary and not subjected to coercion, persuasion, manipulation, or simple distress, which if so subjected, would be sufficient reason to end the session for the researcher without needing the expressed request of the participant (Astell et al. 2009); while also c) communicating the possibility of opting-out or withdrawing from treatment/research at any given stage. Rolling informed consent in the case of PwD does not result in a single-event legal act but rather, is a continuous consideration of the choices made by the vulnerable person. The need for a concept of rolling informed consent is also supported by Árnason et al. (2011), when they define informed consent, not as a unique (legal) event but rather, as a communicative process between the relevant parties (Árnason et al. 2011). In practice, however, rolling informed consent could cause issues for the caregivers, clinicians, and researchers regarding considerations of its validity and its being time-consuming to obtain. Rolling informed consent might prolong the whole treatment/research process, hence caregivers might see it as an impediment to their work.

The responsibility of the researcher in assessing the changing competence of the PwD during the R&D increases within the context of rolling informed consent. Such an assessment may be considered very subjective. However, the assessment may be based on the special, often long-standing relationship and bond, which is usually shared between PwDs and their clinicians/researchers. It is not clear whether researchers have a more

objective means of assessing the changing competence of PwDs. The development of such a protocol promises to be challenging and worthwhile.

Despite the difficulties of obtaining informed consent from PwDs, the introduction and application of rolling informed consent is inevitable in the case of PwDs, given the empirical characteristics and progressive nature of dementia, while at the same time taking seriously the participant's autonomy. The principles of respect for the participant's autonomy and respect for potential enrolled subjects are broadly accepted as pivotal ethical requirements in research and healthcare settings, especially when dealing with vulnerable persons (Emanuel, Wendler, and Grady 2000).[14]

3.5 CONCLUSION

AAL technologies are said to provide assistance and support to vulnerable persons and those with dementia by allowing them to live for longer at home whilst maintaining their comfort and security. However, the R&D, clinical trials and the application of AAL technologies also pose serious ethical challenges. The ethical challenges mostly focused on in the literature to date are concerns about safety, security and privacy.

Although these issues are undoubtedly relevant, further ethical issues need to be addressed as well. They involve the value of the goals of AAL technologies, the special vulnerability of PwDs in their private homes, and the complex issue of informed consent from PwDs. These issues urgently need further analysis in order to ensure that R&D, clinical trials and the application of AAL technologies take place only in accordance with the highest ethical standards.

14 The topic of informed consent and the ethical issues related to PwDs are further analysed in Chapter 6 on p. 183.

4

VALUE OF THE GOALS OF AAL TECHNOLOGIES

In the current chapter, the concepts of benefit and harm are examined in relation to Persons with Dementia (PwDs) and Ambient Assisted Living (AAL) technologies. The chapter focuses on addressing the following questions:

1. What does the literature interpreting Art. 4 of the Universal Declaration on Bioethics and Human Rights (UDBHR) say about the benefit and harm evaluation, the maximisation of the first, and minimisation of the second, and how should respect for these principles be fulfilled?
2. How are benefit and harm interpreted in policy documents and academic literature?
3. How should Art. 4 of the UDBHR be understood in its application to the circumstances of PwDs and the context of AAL technologies?
4. Which principles of the UDBHR need to be balanced with the principle of benefit maximisation and harm minimisation?

In order to answer the first question, the notions of beneficence and harm, present in the UDBHR, are clarified. This step will utilise handbooks that directly interpret the UDBHR principles, including dedicated sections referring to benefit and harm. This literature mainly includes *The UNESCO Universal Declaration on Bioethics and Human Rights: Background, Principles and Application* (ten Have, Jean, and Kirby 2009), and *Handbook of Global Bioethics* (ten Have and Gordijn 2014). Unfortunately, the International Bioethics Committee (IBC) has not issued an explanatory report on Art. 4 of UDBHR.[1]

Addressing the second question of the descriptive part of this chapter involves an overview of the international and national policy documents, along with notable academic literature relevant to the interpretation of the issue of vulnerability and personal integrity.

1 The IBC has issued explanatory reports on other UDBHR articles, namely IBC (2008) and IBC (2013), which are referred to in Chapter 6 and Chapter 5.

In the normative part of this chapter, the previously interpreted UDBHR principle of benefit maximisation and harm minimisation are first specified to the specific context of PwDs and AAL technologies. The specification will focus both on clinical research with PwDs, and clinical practice with PwDs.

Then, other UDBHR principles that may conflict with Art. 4 are identified, examined, and balanced, utilising the balancing process described in section 1.2.

At the end of this chapter, a dedicated section summarises the results of the specification reached with outcomes of balancing, providing a brief overview of the normative analysis of the requirement to benefit maximisation and harm minimisation of PwDs. This summary will adhere to the spirit of the principle as stipulated in Art. 3 of the UDBHR, applied to the cases of PwDs and AAL technologies.

4.1 INTERPRETATION OF THE PRINCIPLE

4.1.1 *Principle of the UDBHR*

Art. 4 of the UDBHR refers to the requirement related to clinical research, medical practice, and the utilised technologies to maximise the direct and indirect benefits of patients, research participants and other involved individuals, while at the same time minimising the possible harms.

Article 4
In applying and advancing scientific knowledge, medical practice and associated technologies, direct and indirect benefits to patients, research participants and other affected individuals should be maximized and any possible harm to such individuals should be minimized.

Art. 4 uses the notions of benefit and harm. In the following sections, these notions are first, separately described, and secondly, their relationship with each other is interpreted.

4.1.1.1 *Benefit*

This section presents the concept of benefit, as founded upon the concept of human dignity, a concept to which it is closely linked. This connection forms one of the crucial notions of Art. 4 of the UDBHR. This is followed by the historical development of the UDBHR formulation of Art. 4. The interpretation of the notion of beneficence concludes with an overview of whether various levels of beneficence can be identified, and if so, in what hierarchical order.

FOUNDATION OF THE PRINCIPLE OF BENEFIT IN HUMAN DIGNITY

The achievement of adopting the UDBHR at the United Nations (UN) level is interpreted as a logical and timely extension of *The Universal Declaration of Human Rights* (1948). Therefore, the principle of benefit maximisation (and harm minimisation) formulated in Art. 4 cannot be interpreted independently from the requirements to respect every human beings' dignity and equality (*UDBHR* 2005, Art. 1–3; *UDHR* 1948, Art. 1). Due to the inherent dignity of every human being, their equality, and possession of reason render human beings responsible for their actions. According to Pellegrino (2009), the possession of these attributes obligates every human being to direct their actions towards achieving good (Pellegrino 2009).

DRAFTING OF ARTICLE 4

During the drafting process of the UDBHR, representatives of 27 UN member states, 13 national bioethics committees, 10 personal commentators, and one permanent observer participated in the formulation and adoption of the declaration. Representatives of the world's main religions were also invited to comment upon the draft of the Declaration. The UDBHR thus constitutes one of the most widely adopted international agreements on the principles of bioethics, including the requirements of benefit maximisation and harm minimisation (Pellegrino 2009).

The original title of the Fourth Outline of this article[2] was *Beneficence and Non-Maleficence*. However, at a joint session held in January 2005, a general consensus was reached to avoid the use of these terms. One of the reasons was that these terms are not commonly used by either policy-makers and the general public in many languages and cultures. The other reason was that the original ancient meaning of the two separate maxims of 'do good' and 'do no harm' (*primum non nocere*) have a different meaning when joined together. As a result, the formulation of the principle has been altered to reflect the standpoint of seeking a benefit and minimising the possible harm resulting from a decision or practice (*Explanatory Memorandum on UDBHR* 2005).

Additionally, Andorno (2007) expresses personal regret that during the drafting of the UDBHR, the recognition of the precautionary principle as a tool for public health risk management was removed from the final version (Andorno 2007).

LEVELS OF BENEFICENCE

The requirement for doing good and avoiding harm can be further categorised, based on the necessity and desirability of beneficence. Such a categorisation of beneficence has

2 The *Explanatory Memorandum on UDBHR* (2005) lists this principle as Art. 6. However, in the final Declaration it is listed as Art. 4. This difference in the numbering may be the result of the editing and discussions during the drafting of the document. This may also be the case with other differing article numbers, which are explained by the *Explanatory Memorandum on UDBHR* (2005) document.

been proposed in Frankena (1973), starting with the most important *prima facie* duty and moving towards the least important one (Frankena 1973, p. 47):

1. One ought not to inflict evil or harm (what is bad).
2. One ought to prevent evil or harm.
3. One ought to remove evil.
4. One ought to do or promote good.

It is, however, rather difficult to precisely define at what point a certain level of beneficence should be followed. It would depend greatly on the specific circumstances, details of the situation, as well as on the nature and course of the human interaction (Pellegrino 2009).

Pellegrino (2009) emphasises that special obligations (e. g. those of researchers, physicians, etc.) impose higher standards of beneficence.

4.1.1.2 *Harm and Non-maleficence*

THE NOTION OF HARM IN ARTICLE 4

Another key notion used in Art. 4 of the UDBHR is harm, which everyone is obliged to minimise in the healthcare setting. Not inflicting harm on patients (*primum non nocere*) is a requirement of the physician's professional code ascribed to the Hippocratic Oath (cca. 500 BC, Craik 2015).[3]

The issue with the identification of harms is similar to the issues of identifying benefits. It is hard to identify harms on a general level, without the context. As presented with examples by Evans (2014), an amputation of a leg can be perceived differently by a paranoid schizophrenic patient, who could not imagine a life without a leg and would prefer death above the amputation; while in the context of the World War I, a soldier in a trench, who valued his life more with one leg than dying in a war with both of his legs, would opt for the amputation (Evans 2014). A final example and an extreme case is that of Kevin Wright, who, while suffering from body dysmorphic disorder, never felt that his left leg was part of his body, and thus requested its amputation (Evans 2014).

Art. 4 uses the phrase 'possible harm.' The probability of causing harm by exposing patients or research participants to risks is a real and valid concern. Therefore, criteria for assessing risks, optimal applications of beneficence, and conditions of permitting risks in specific cases need to be defined. According to Pellegrino (2009), in Art. 4, what

3 The Hippocratic Oath, as such, does not precisely contain the non-maleficence requirement. In the *Hippocratic Corpus*, *The Oath* states "Into whatever houses I enter, I will enter to help the sick, and I will abstain from all conscious wrongdoing and harm, especially from sexual relationships with women or with men, slave or free." (Craik 2015, p. 145).

is without any doubt is the entitlement of everybody to be free from intentional harm. This claim has to be further qualified because nobody can be protected against all harms, and unintended harms are also possible, being sometimes required to be tolerated while aiming for a benefit of a treatment. Art. 4 introduces the requirement into these cases when it states that these exposures to risks are morally acceptable only if the benefits are maximised, while, at the same time, harms are being minimised (Pellegrino 2009).

Compliance with the ethical standard set out in Art. 4 requires more than technical competence and attention to moral content by physicians and researchers. Fulfilment of the spirit of the standard in Art. 4 requires the application of prudential judgements in the ethical assessment of circumstances. Prudential judgements, or the Aristotelian *phronesis* (Aristotle 2009, p. 110, 1142a 10–30) – practical wisdom, are necessary for the correct choice of the most practical means for reaching a good end in a particular situation. According to Pellegrino (2009), this is an intellectual virtue, in other words, a habit that requires continuous cultivation (Pellegrino 2009).[4]

DEFINITIONS OF HEALTH

The assessment of the exposure to harm (and benefit) cannot be provided without some notion of health (and health benefits). The intuitive interpretation of health is often described as freedom from disease. However, it may be questioned whether such an interpretation is correct. This is particularly relevant because, according to this narrow definition, people who are healthy have no possibility of health benefit (Evans 2014).

A narrow definition of health is counter-intuitive when one considers the following scenarios, when medical treatment is provided. Firstly, the provision of prophylactic treatment to healthy individuals (e. g. vaccinations). Secondly, not all physiological pathology stems from a disease; physical trauma such as that sustained in a traffic accident can result in pathology and ill health. Moreover, in cases of amputation (where full bodily function cannot be completely restored), healthcare professionals may still provide prostheses for retaining some bodily functions. Such a treatment by the physician may not be only partially restore bodily functioning but it is argued to address also social needs by alleviating burdens of dysfunctional body (less discrimination, stigmatisation, etc.). Thirdly, mental health problems may also not be categorised as disease in the narrow definition of health. Despite the narrow definition of health that may preeminently focus on physiological functioning, many would argue that psychological issues clearly belong to the topic of health (Evans 2014).

4 Aristotelian virtue ethics and the role of prudential judgements of healthcare professionals in medical ethics and ethics of nursing has been extensively discussed in Pellegrino and Thomasma (1993, especially pp. 84–91), Pellegrino (1995), Flaming (2001), Svenaeus (2003), Vanlaere and Gastmans (2007), and Sellman (2009). The importance of the promotion of risk assessment is again emphasised in Art. 20 of the UDBHR regarding the application of UDBHR principles, while the requirement for appropriate education of healthcare professionals is reiterated in Art. 23 of the UDBHR regarding the promotion of the Declaration.

A more nuanced definition of health has been proposed by the World Health Organization (WHO) in its Constitution accepted in 1946: "Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity" (Grad 2002, p. 984; *Constitution of WHO* 2006, p. 1). This definition was further extended by the formulation "to lead a socially and economically productive life" in 1977 at the 30th World Health Assembly (resolution WHA30.43, *Formulating strategies for health for all by the year 2000* 1979, p. 7). Despite this more nuanced and and more inclusive definition, criticism has been raised that even the definition of health by the WHO can disregard a significant group of people with medical conditions (Evans 2014). These patients are those that are temporarily or permanently unable to live an economically productive life. However, these people should also be allowed to benefit from research activities or therapy, despite the fact that they may not be recognised by the definition of health by the WHO as healthy individuals. Furthermore, the definition of health by WHO may bring an illusion of an existence of some universal objective measures of health and health benefits, which perception constitutes a reductionist view and would lead to oversimplification (Evans 2014).

Evans (2014) notes that any definition of health would tend to be either too narrow or too wide to apply to all cases. Therefore, sufficient effort to describe the details of the context must be made to ensure that the particular circumstances of each patient are considered. The result of such analysis would lead to a valid identification of the health needs of a patient (Evans 2014).

4.1.1.3 *Uncertainties*

During the benefit-harm assessment, two kinds of uncertainties are present: empirical and conceptual. According to Evans (2014), in the perspective of uncertainty in healthcare the administration of any drug is, in a way, an experiment. Adverse effects may occur, as attested to in the product information leaflets. Human beings are individuals, not only in a philosophical sense but also at a biological level. Thus, they may have different reactions to various therapies. Although serious efforts are being made to limit these adverse effect by the use of novel technologies, pharmacogenomics, etc., empirical uncertainty cannot be completely eliminated nor ignored (Evans 2014).

Another type of uncertainties people may face are conceptual uncertainties. For example, at intensive care units, people may be offered the chance to decide between retaining or withdrawing a person from life-prolonging machines, i. e. keeping her alive, or allowing her to die a 'dignified' death. The conceptual uncertainty in cases like these refer to the dilemma during the decision-making process as to which of the treatments are still beneficial and beneficent for the patient (Evans 2014). Evans (2014) remarks that in situations with conceptual uncertainties there is a tendency to consider any choices equally as beneficial or harmful (Evans 2014).

4.1.1.4 *Acuteness*

No healthcare system is capable of treating all patients immediately as symptoms arise. The lack of immediate treatment may incur risks of death or irreparable damage. Therefore, it is important to introduce effective categorisation of various cases based on their urgency. Differentiating between the need for immediate, urgent, semi-urgent, and routine care provides healthcare professionals with the possibility of ranking cases based on necessity (Evans 2014). A widely-known international classification of cases based on determining the priority of patients is the triage process, used during emergencies (including hospital accident and emergency departments), disasters, catastrophes, or wars.

Evans (2014) emphasises that the use of such classification is acceptable insofar as it is possible to grade the benefits and harms. Often, this is not possible due to the aforementioned empirical or conceptual uncertainties. However, the temptation to still grade relative harms and benefits (often required in resource-allocation management) may lead to the comparison between incomparable conditions (Evans 2014).

It is noteworthy that the person concerned may regard such categorisation of her condition as a sign of careless approach to her treatment. The patient may believe that good outcomes appear to be less attainable, and hence find the categorisation personally unacceptable (Evans 2014).

4.1.1.5 *Limits of Benefit Maximisation and Risk Minimisation*

Art. 4 requires more than the prevalence of benefit over risks in treatments and research. The phrasing of Art. 4 explicitly requires the maximisation of the benefits, and the minimisation of possible harms. This claim is understandable in a world of scarce medical resources. However, such claim may also echo an element of the utilitarian philosophy (Evans 2014).

The next sections provide a brief overview of some influential accounts that deal with the evaluation of risks and benefits. Although the related topics of these accounts presented raise significant ethical issues, they are only referred to in an abbreviated manner. These topics include: allocation of resources, qualitative approaches to health needs assessment, etc.

QUANTIFICATION OF HEALTH NEEDS

One of the key philosophers of utilitarian thought, John Stuart Mill (1806–1873), in his book *Utilitarianism* (Mill 2003), defines qualitative distinctions of pleasures. The concept of pleasures as a measure of happiness was originally introduced into philosophical thinking by Jeremy Bentham (1748–1832) in his *An Introduction to the Principles of Morals and Legislation* (Bentham 1780). Mill's principle of utility (also called the greatest happiness principle) states that "actions are right in proportion as they promote happiness,

wrong as they tend to produce the reverse of happiness" (Mill 2003, p. 186). By happiness, Mill means pleasure and the absence of pain (Mill 2003). Mill's differentiation of pleasures is based on whether the pleasure satisfies the 'higher faculties' (e. g. intelligence) of human creatures or only lower ones. Happiness at the level of lower pleasures is less satisfying for a human being than happiness due to higher pleasures.[5]

In conditions of scarce medical resources the principle of greatest happiness for the greatest number of people cannot be applied unconditionally. Mill himself was aware of the problems related to the application of his approach. Different people have different views on what happiness is, in theory. Nobody can claim that he or she is the ultimate expert on happiness (Evans 2014).

An attempt to find a common denominator for comparison and subsequent ranking of health needs is that of Norman Daniels (1942–). He defines normal opportunity range, extending Rawls' theory of justice as fairness (Rawls 1999), as "the array of life plans reasonable persons are likely to construct for themselves" in a given society (Daniels 2008, p. 45). This range of opportunities helps to identify healthcare needs and benefits, together with their aggregation and protection. Healthcare needs are an important part of basic needs that provide normal functioning (Daniels 2008).

A well-known quantitative approach of evaluation of health treatments is the Quality-Adjusted Life Year (QALY) method. One QALY represents one year of life expectancy in perfect health, and zero QALY represents death. By linking the quality of life with life expectancy, QALY provides a single measure for the comparison and subsequent cost-utility analysis of various treatments and their respective gain (Williams 1994). This method had been criticised for its utilitarian bias in health benefit and harm assessment, trying to quantify qualitative criterions that are *per se* immeasurable. Additionally, the QALY approach is also known for being biased against the sickest and oldest persons (Pellegrino 2009).

QUALITATIVE APPROACHES TOWARDS HEALTH NEEDS' ASSESSMENT

Instead of quantitative evaluations of benefit and harms, Pellegrino (2009) prefers qualitative evaluations. These can be described as probabilistic value judgements, which are conducted in an informal manner, involving all stakeholders. Qualitative evaluations are also broadly dependent on the personal values of the participants. Risk and benefit assessments cannot be conducted without first knowing what the patient deems worth living for, working for, or even dying for (Pellegrino 2009).

Evans (2014) favours this approach too, which he refers to as vertical aggregation. In his view, ranking is unachievable across dissimilar conditions, except distinguishing

5 By Mill's own words: "It is better to be a human being dissatisfied than a pig satisfied; better to be Socrates dissatisfied than a fool satisfied. And if the fool, or the pig, is of a different opinion, it is because they only know their own side of the question." (Mill 2003, p. 188).

between elective and acute cases. Vertical aggregation enables clinicians to weigh the severity of conditions, set priorities while calculating fairly the relative health needs of their patients. Non-acute cases can be weighed based on the degree of need. Additionally, vertical aggregation makes the incorporation of aspects beyond the range of quantitative methods (e. g. the ability to continue employment after the intervention, future family duties, etc.) also possible (Evans 2014).

Although the qualitative assessment of health needs is admittedly an inexact science, Evans (2014) remarks that without the knowledge of the particular patient's narrative, the patient's needs may be mistakenly disregarded. However, this approach does not involve the maximisation of benefits, as required by Art. 4. Evans (2014) considers the discrimination of minority groups (e. g. chronically ill, elderly, mentally ill, etc.), represented by quantified methods, as being more harmful than the harm incurred by failure to increase the health benefits. The overall lower level of benefits is compensated by the fairer allocation of resources without the exclusion of groups in need, allowing the prioritisation of cases that would otherwise be categorised as not acute (Evans 2014).

ARTICLE 4 AND BENEFIT MAXIMISATION, RISK MINIMISATION

Pellegrino (2009) sheds light upon the complexities of the criteria that need to be taken into account if one wants to evaluate the maximisation of beneficence and minimisation of harms. Amongst these criteria are: the domain of prevention, treatment, or research; the question of moral acceptability, reliability, or fairness; the nature of benefits in regard to advancement of patient's interests, finding new knowledge for future patients, or the development of policies enhancing common good; the nature of harm (financial, physical, emotional, spiritual, separately or in combination); or the probabilities of harms (risks; Pellegrino 2009).

However tempting a population-level benefit may be (e. g. statistical, economic, scientific, or social), the benefit-harm ratio for individuals can never be overlooked. Art. 4 of the UDBHR is safeguarded by the requirement formulated in Art. 3.2. This states that the interests and welfare of the individuals should be always prioritised, and cannot be disregarded by reference to the interests of the society or science (Pellegrino 2009).

4.1.1.6 *The Importance of Education*

It has been mentioned that clinicians, unlike economists, policy-makers, or health managers, prefer to make prudential judgements (in an Aristotelian or virtuous sense) regarding the health needs assessment of benefits and harms (Pellegrino 2009). Such assessment is dependent on personal and subjective values, where the role of education is valued. In this regard, Pellegrino (2009) makes in important distinction between beneficence and benevolence.

While beneficence is an "act that enables one to do good" (Pellegrino 2009, p. 106), benevolence refers to a character trait (virtue) that guides a person to habitually do good (Pellegrino 2009). As a virtue, benevolence needs to be cultivated by healthcare professionals. It is not sufficient to only define a principle of benefit maximisation and harm minimisation. In interpreting Art. 4 of the UDBHR, the distinction of beneficence from benevolence is remarkable as it thus also defines the kind of person required for the fulfilment of the principle. The development of the virtue of benevolence as a habitual act and practice should also motivate the education of future healthcare professionals, and therefore, needs to be cultivated at all phases of the physician's development (Pellegrino 2009).

4.2 POLICY DOCUMENTS AND ACADEMIC LITERATURE

4.2.1 *Policy Documents*

4.2.1.1 *The Nuremberg Code (1947)*

Following the Doctors' Trial in 1946 (one of the twelve trials before the Nuremberg Military Tribunals held between 1946–1949, after World War II) a Code was proposed and accepted by the Counsel for War Crimes. As a reaction to the unregulated experimentation on humans, mostly in concentration camps, "The Nuremberg Code (1947)" defined in ten principles the requirements for conducting research on human beings. Most of these paragraphs relate to the risks and possible harms of research with human beings.

The first principle requires, amongst others, the proper provision of information about all the inconveniences and hazards that can be expected during a participation in a research. This information should be disclosed along with the effect of the research upon the participant's health ("The Nuremberg Code (1947)" 1996, § 1).

The second principle defines the requirement regarding the objectives of the investigation, which need to aim towards the benefit of society. The objectives of the research study must not be achievable by other methods, thus ensuring that the research is not being conducted unnecessarily or randomly ("The Nuremberg Code (1947)" 1996, § 2).

The third principle requires that the research study and objectives be justified and supported by, first, animal experimentation, and secondly, the anticipated results ("The Nuremberg Code (1947)" 1996, § 3).

The fourth principle defines that any physical and mental suffering of the research participant has to be avoided ("The Nuremberg Code (1947)" 1996, § 4).

The fifth principle ensures that no research is conducted, which may involve death or disablement of the research participants. A single exception can be (with the clause

'perhaps'), if the participant is, in fact, also the researcher ("The Nuremberg Code (1947)" 1996, § 5).

The sixth principle attempts to define a principle of proportionality, by stating that the risks of participating in a research study should not exceed the 'humanitarian importance' of the research objectives ("The Nuremberg Code (1947)" 1996, § 6).

The seventh principle requires from researchers to provide the research participants with adequate protection against—even remote—exposure to injuries, inflicting disability, or causing death ("The Nuremberg Code (1947)" 1996, § 7).

4.2.1.2 *Documents of the United States*

BELMONT REPORT (1978)

The *Belmont Report* (1978) provides an extensive account of the topic of risk-benefit assessment.

The first mention of the assessment of risks and benefits in the Report occurs in relation to the protection of vulnerable populations, who deserve extensive protection. The extent of this protection should depend upon the estimate of benefit, and the assessment of the risk of being harmed (*Belmont Report* 1978, B.1).

One of the three basic ethical principles of the *Belmont Report* (1978) is beneficence. Beneficence is understood as a two-fold obligation to, first, not do harm, and second, maximise the possible benefits while minimising the possible harms (*Belmont Report* 1978, B.2). The former is part of the Hippocratic Oath, which requires that physicians avoid causing harm to their patients, while also learning what is harmful, and acting in accordance with what is beneficent for their patients, based on their best judgement as physicians. This sometimes also involves exposing patients to risks, for their subsequent benefit. The *Belmont Report* (1978) also recognises more challenging ethical situations, such as the exposure of research participants (in this case, children) to more than minimal risks, when no immediate prospect of direct benefit can be expected. Arguments remain unsettled whether such research studies should be regarded as unacceptable, or whether they should be permitted in order not to rule out research benefits for future patients. The *Belmont Report* (1978) does not provide any definitive answer in this regard, rather it indicates conflicts of the principle of beneficence with other principles presaging difficult choices to be made (*Belmont Report* 1978).

In the third part, Part C, about the application of the principles, § 2 describes the procedure and requirements for the assessment of risks and benefits. The risk in this regard "refers to a possibility that harm may occur" (*Belmont Report* 1978, C.2). While benefit represents a positive value that is anticipated, risk refers to the chance (probability) and severity (magnitude) of the harm. The *Belmont Report* (1978) provides a list of examples about the types of benefits or harms: psychological, physical, legal, social, and economic.

During the assessment of benefits and risks, the *Belmont Report* (1978) notes the ambiguous nature of such a balancing process. It is only in rare cases when quantitative techniques of balancing can be applied. However, this complication should not endorse the capitulation of the assessment of benefits and risks. Rather the opposite; a systematic assessment of benefits and risks in research is much needed, in order to enable circumvention of misinterpretations and misinformations between Research Ethics Committees (RECs) and researchers. Therefore, the validity of the research objectives should first be rigorously and precisely reviewed, then followed by the identification of the nature, probability, and the magnitude of the harms. The analysis of the risks should explicit and its modalities made as clear as possible (*Belmont Report* 1978).

The justifiability of research is also affected by other considerations, such as: how inhumane a treatment is; whether the risks are reduced to the minimal level in order to achieve the research objectives; whether the involvement of human participants is necessary at all; whether the research carries significant risks of impairment, and whether the risk of the impairment are sufficiently justified; whether vulnerable populations are involved; and whether the research participants were properly informed about the risks in the informed consent (*Belmont Report* 1978).

4.2.1.3 *Documents of International Biomedical Communities*

DECLARATION OF HELSINKI (1964–2013)

The "Declaration of Helsinki" (1964), in its newest edition "Declaration of Helsinki" (2013), dedicates a whole section (Section III) to the topic of risks and burdens, and the assessment of risks.

Paragraph 16 acknowledges that most medical interventions involve risks and burdens. These risks extend both to the areas of treatments and research studies ("Declaration of Helsinki" 2013, § 16).

Medical research cannot be started without a careful assessment of the possible risks involved. This assessment must involve the research participants but should also extend to the groups involved, and the individuals and groups that may may be affected by the results ("Declaration of Helsinki" 2013, § 17).

The "Declaration of Helsinki" (2013) also contains a rule of evaluation, which is known as the principle of proportionality. However, it is split between § 16 and § 18. The former states that research with human subjects may be performed only if the importance of the research objectives outweigh the possible risks of participation. The latter specifies cases when the risks outweigh the prospective benefits of the research study. In such cases, the physicians (or researchers) should consider whether it is acceptable to continue the study, or whether it needs to be modified, or even whether the study must be stopped immediately ("Declaration of Helsinki" 2013, § 18).

Other requirements of the "Declaration of Helsinki" (2013) demand active engagement in minimisation of risks of research studies. These risks should be continuously monitored, continuously assessed, and properly documented by the investigators ("Declaration of Helsinki" 2013, § 17).

4.2.1.4 *Documents of the European Union and the Council of Europe*

CONVENTION ON HUMAN RIGHTS AND BIOMEDICINE (1997)

In Art. 16.ii, the *Convention on Human Rights and Biomedicine* (1997) introduces the rule based on the principle of proportionality, stating that the persons undergoing research should not be exposed to disproportionate risks compared with the potential benefits of the research study (*Convention on Human Rights and Biomedicine* 1997, Art. 16.ii). Persons who are not capable of providing valid informed consent can be involved in research, as with other people with other applicable conditions, if there are potential benefits of the research study, and its risks are only minimal (*Convention on Human Rights and Biomedicine* 1997, Art. 17.1.ii and Art. 17.2.ii). Otherwise, any therapeutic interventions on incapable persons must provide direct benefit to the patient (*Convention on Human Rights and Biomedicine* 1997, Art. 6.1). According to the *Explanatory Report to the Convention on Human Rights and Biomedicine* (1997) there are only two exceptions from this latter rule, which are: participation in research (based on the *Convention on Human Rights and Biomedicine* 1997, Art. 17), and the removal of regenerative tissue (based on the *Convention on Human Rights and Biomedicine* 1997, Art. 20.2; *Explanatory Report to the Convention on Human Rights and Biomedicine* 1997, pp. 11–12).

The articles of the *Convention on Human Rights and Biomedicine* (1997) are legally binding for the European Council Member States that signed the Convention (by 2015 it is 25 Member States) and ratified it (29).[6]

4.2.2 *Academic Literature*

This section focuses on three areas related to the benefit-harm assessment regarding Art. 4 of the UDBHR, as well as the application of AAL technologies for PwDs. The first is the reception of Art. 4 in the academic literature, and the relevance of the criticism formulated by Macklin (2005).

Secondly, the attempt for a more elaborated categorisation of benefits and harms is presented, an account of King (2000), which distinguishes various levels of health benefits, and strictly separates between the reasonable chance to benefit and the reasonable choice of a research participant to join a study.

6 For more details visit: `http://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/164/signatures?p_auth=ifD69f0C` (visited on 30/11/2015).

Thirdly, the value of the technology in healthcare is critically interpreted, using the analysis provided by B. M. Hofmann (2015), Hoffmann and Chris (2015), and Fisher and Welch (1999).

4.2.2.1 *Non-maleficence and Beneficence of Beauchamp & Childress*

Tom L. Beauchamp and James F. Childress in their popular textbook, *Principles of Biomedical Ethics*, argue that the distinction provided by Frankena (1973), cited above, mistakenly combines the obligations of non-maleficence with the obligations of beneficence. With such conflation, important distinctions are missed, in their opinion (Beauchamp and Childress 2009).

Therefore, Beauchamp and Childress propose the separation of Frankena's hierarchical list into two principles, where the principle of non-maleficence comprises intentional refrain from causing harm (e. g. avoiding inflicting evil or harm), and the principle of beneficence comprises acts of help (e. g. the prevention of harms, removal of harms, and the promotion of good; Beauchamp and Childress 2009, pp. 149–151).

The structure of the principles of non-maleficence and beneficence within the framework of common morality does not exhibit any hierarchical ordering (Beauchamp and Childress 2009).

PRINCIPLE OF NON-MALEFICENCE

The obligations posed by the principle of non-maleficence are often interpreted as more stringent than the obligations of beneficence. However, as highlighted by Beauchamp and Childress, this need not to necessarily be so. There is no rule in ethics that favours abstaining from inflicting harm at all costs and under all circumstances over the provision of benefit to the person concerned (Beauchamp and Childress 2009).

The principle of non-maleficence is closely linked to the concept of harm, which has both normative and non-normative use. Harming is distinguished from wronging, where the latter incorporates the violation of somebody's rights, which is not necessarily the case for the former concept. Therefore, the concept of harm in medical ethics represents the non-normative sense of "thwarting, defeating, or setting back some party's interests" (Beauchamp and Childress 2009, p. 152). However, even if harm is not understood in a legal way, harmful actions that justifiably limit a person's interests need not to necessarily be wrong (Beauchamp and Childress 2009).

The principle of non-maleficence in medical ethics can be specified by the following *prima facie* (i. e. not absolute) moral rules: not to kill; not to cause pain or suffering; not to incapacitate a person; not to cause offence; and not depriving others of the goods of life (Beauchamp and Childress 2009).

Physicians and researchers, by the principle of non-maleficence, are not only obliged to not inflict harm but also to not impose risks of harms. This obligation is specified in the standard of due care, related to the principle of non-maleficence. Due care is defined as "taking sufficient and appropriate care to avoid causing harm, as the circumstances demand of a reasonable and prudent person" (Beauchamp and Childress 2009, p. 153). If this standard is violated, the absence of due care is called negligence. Negligence can occur in two forms: either as the intentional act of imposing unreasonable risk upon a person; or the unintentional but careless exposure of a person to risks (Beauchamp and Childress 2009).

The rules of non-maleficence are negative prohibitions of actions; they must be followed impartially (i. e. not distinguishing between people who are close to the moral agent and people who are not); their violation may result in a legal prosecution (Beauchamp and Childress 2009).

PRINCIPLE OF BENEFICENCE

The principle of beneficence in the *Principles of Biomedical Ethics* obliges physicians and researchers to contribute to the welfare of persons. The authors differentiate between positive beneficence and utility. The former requires the provision of benefits to others (without mentioning benefits to oneself). The latter requires balancing between the benefits, risks, and costs for providing the best overall results for everybody (Beauchamp and Childress 2009).

Beneficence

Beauchamp and Childress define beneficence as "a statement of moral *obligation* to act for the benefit of others" (Beauchamp and Childress 2009, p. 197). Some forms of beneficence are not obligatory, others are. Although some philosophical traditions of the Scottish Enlightenment (e. g. Hutcheson 2014, Hume 1960) defined beneficence as the cornerstone of their theories, Beauchamp and Childress do not ascribe the highest priority to the principle of beneficence (Beauchamp and Childress 2009).

Furthermore, in common morality, obligatory beneficence can be distinguished from ideal beneficence. While the former defines moral rules of obligation, the latter is more a moral ideal than an obligation. It has been argued that beneficence may be reduced to the category of moral ideals. This is however under debate (Beauchamp and Childress 2009).

Beauchamp and Childress define an array of moral obligations related to the principle of beneficence: to protect and defend the rights of others; to prevent harm; to remove conditions causing harm; to help people with disabilities; and to rescue persons in danger (Beauchamp and Childress 2009).

The rules of beneficence are clearly distinguishable from the rules of non-maleficence. The rules of beneficence represent positive requirements for action; they may not necessarily be followed impartially; and in general, they do not provide reasons for legal punishment in cases where they have not been adhered to (Beauchamp and Childress 2009).

Beneficence may also be specified as general beneficence, which includes the obligation to act to benefit every human being. Specific beneficence aims for beneficence of specific parties, e. g. children, friends, patients, vulnerable, etc. (Beauchamp and Childress 2009).

Finally, the principle of beneficence is distinguishable from the virtue of benevolence, where the latter refers to a specific character trait that disposes the moral agent to act for the benefit of others (Beauchamp and Childress 2009).

Utility

The principle of beneficence requires a moral balancing between benefits, risks, and costs, for which Beauchamp and Childress employ the principle of utility. The principle of utility, however, is not identical with the classic utilitarian principle, where the principle of utility stands above every other moral principle and is the ultimate and most prominent action guide. Within the framework of common morality, Beauchamp and Childress view the principle of utility as one of many *prima facie* principles, which can be constrained by other conflicting principles (Beauchamp and Childress 2009).

4.2.2.2 *Categorisation of Benefits and Harms*

The attempt of King (2000) to develop categories of benefits and harms is particularly related to conducting research. According to her, both low risk of great harm and high risk of small harm has to be disclosed appropriately to the research participant, in a way that the participant is able to comprehend and enable her adequately weigh the consequences of participation (King 2000).

THERAPEUTIC MISCONCEPTION

The role of RECs in this process cannot be taken frivolously. In the last few decades, the role of RECs was to define a clear-cut line between research bearing no benefit for the (often healthy volunteers) research participants, and research bearing benefits by developing effective treatments. Gradually, it has been assumed that *all* research with patients somehow directly contributes to the development of treatment with reasonable direct benefits for the participants. This understanding is ethically incorrect and is known as therapeutic misconception (King 2000).

Therapeutic misconception is widespread because of technological optimism, and popular public relation news about prospective preclinical (and partial) research results, which lead to confusion and erosion of trust. People involved in research studies may automatically assume that the investigational intervention is the best (state-of-the-art) treatment option available, especially if they reason that they would not be offered an ineffective treatment (King 2000).

This misconception, according to King (2000), was even encouraged, in recent times, by researchers and RECs who devoted substantial effort to exaggerating or even inventing benefits for research participants, in order to ensure that research proposals were approved. Extensive lists of potential benefits in research studies have already been identified in research with children, pregnant women (and foetuses), persons with questionable levels of capacity, and prisoners. King (2000) refers to this as 'benefit creep' (King 2000).

ROLE OF RESEARCH ETHICS COMMITTEES IN CATEGORISATION OF BENEFITS AND HARMS

The functions of RECs can be, according to King (2000), improved in the following three ways (King 2000):

1. By keeping the different types of benefits separate.
2. By thoroughly examining any claim of potential benefit.
3. By discussing the dimensions of benefit.

According to King (2000), these three dimensions often overlap with each other. Investigators may find it difficult to specify direct benefit for the research participant because this issue may be the content of the research question itself. Uncertainty factors also play a significant role in the assessment of benefits and harm. However, benefits need to be properly categorised for their correct assessment (King 2000).

Types of Benefits (and Harms)

Regarding the first claim, i. e. the different types of benefits need to be defined in separate categories, King (2000) identifies three types of benefits. *Direct* benefits pertain to the participants and arise from receiving the intervention that is being examined. *Collateral* or indirect benefit occurs from being a part of the research study, even though one may not necessarily receive the experimental intervention. *Aspirational* benefits are the benefits aimed at future patients, or the wider society. In research proposals and informed consent forms, it is quite common that the direct and aspirational benefits are confused. This occurs mostly in early-phase trials, when the project proposal of a single

study may describe aspirational benefits expected from an entire research programme (consisting of multiple research projects; King 2000).

Examination of Benefits (and Harms)

The second claim, which requires the proper examination of claims about potential benefits, aims at identifying research studies that do not offer any prospective direct research benefits for the participants. According to King (2000), it is quite normal that some research studies, for example, early-phase clinical trials, Phase I oncology trials, and other early-stage research studies, cannot foresee whether participants will gain any benefits. These study proposals and documents should therefore not contain overly optimistic views; rather, they should contain cautions that admit that direct health benefits may be unlikely. Moreover, statements about the realistic probability of any benefits for the participants should also be clearly stated (King 2000).

The other issue revolves around the question of what constitutes a reasonable chance of benefit for a research participant? According to King (2000), guidelines like the *Belmont Report* (1978), and *IRB Guidebook* (1993) are more successful in presenting the complexities in this area, rather than in actually providing clear guidance. A more successful account has been provided by the The National Commission For the Protection of Human Subjects of Biomedical and Behavioral Research, which, in its report *Research Involving Those Institutionalized as Mentally Infirm* (1978), describes direct benefit as one that has to be "fairly immediate" for the research participant (*Research Involving Those Institutionalized as Mentally Infirm* 1978, p. 13).

A more recent attempt in this regard is the account of Edward W. Keyserlingk (1995), who defined direct health benefits for PwDs as "a short- or long-range improvement, or a slowing of a degenerative process, in the specific medical condition of the relevant subject, whether in the patient's condition of dementia, a medical symptom associated with dementia, or another physical or mental condition unrelated to dementia" (Edward W. Keyserlingk 1995, p. 327). However, Edward W. Keyserlingk (1995) admit that PwDs as research participants have little likelihood of direct benefit, due to the lack of knowledge about the development of dementia, and hence also the lack of effective preventions, therapies, and cures (Edward W. Keyserlingk 1995).

The direct and indirect (collateral) benefits do not have the same weight, when the possible consequences of participation in the research study are being described to the prospective participants and/or proxies. Moreover, it seems acceptable to grant the altruistic wish of a competent PwD to participate in a research study. Nevertheless, according to Edward W. Keyserlingk (1995), it is unethical to seek the participation of incompetent PwDs in a research study where only indirect benefits may be expected, unless the individuals express their wish to do so. This wish may be expressed in the advance directive of the PwD, who may state her willingness to participate in a research study despite the

likelihood of no direct personal benefit, and also in studies that involve higher levels of risk than minimal risks. A PwD, who provides evidence that she has previously undergone similar levels of physical or psychological discomfort in a different therapeutic or research setting, is entitled to accordingly raise the cap of allowable risk for prospective research participation in her advance directive (Edward W. Keyserlingk 1995). However, reasonable chances of possible benefit must be evident; only the reasonability of the choice can be subjective and open to discussion (King 2000).

According to King (2000), RECs need better guidance in this area, for the evaluation of the potential benefits for participants. RECs should also improve the way in which information is disclosed and discussions are lead about the potential benefits and reasonable choices for participants (King 2000).

Dimensions of Benefits (and Harms)

The dimensions of potential benefits (and harms) for the participants can be described in three aspects, based on their nature, magnitude, and likelihood (King 2000).

The *nature* of potential benefits and harms is difficult to specify because it relies on the purpose of the research study itself. This condition, however, does not alleviate researchers from needing to clearly list all the uncertainties, unknowns, and unproven statuses of the interventions being studied (King 2000).

Regarding the *magnitude* of benefits and harms, the purpose of this information is to provide particulars about the size and/or duration of potential benefits and harms (e. g. quality, time, etc.). These should include information about whether the benefits or harms are temporary or permanent, or whether the effects of these benefits are obvious or less obvious. This information is unfortunately rarely provided in consent forms (King 2000).

Finally, the *likelihood* of benefits and harms can be based on the results of research. Research provides information on the effectiveness and safety of a treatment, and thereby, the likelihood of benefits and harms (King 2000).

UNCERTAINTY IN RESEARCH

King (2000) advocates that uncertainty is an organic part of any research and therefore, it should be acknowledged without any ambiguity. Potential benefits should always be reasonably claimed, and adequately supported by evidence that has already been recognised. Potential benefits should never be overstated, either by excluding the harms from the disclosure of information, or by referring to aspirational benefits as direct benefits (King 2000).

Furthermore, a much stricter separation between the status of a patient and the status of research participant is necessary. The prospective participant needs to know that entering a research study brings consequences that are different from that of undergoing

treatment as a patient. The risks may be higher, and a general statement about the possibility that one may eventually not benefit from the research study is insufficient (King 2000).

REASONABLE CHANCE OF BENEFIT

To introduce a clearer category of what constitutes a reasonable chance of benefit, King (2000) attempts to define it as:

> "A reasonable chance of direct benefit exists when a reasonable person under all the circumstances would consider the nature, magnitude, and likelihood of direct benefit sufficient to reasonably choose to participate in research in anticipation of the benefit." (King 2000, p. 336)

By "a reasonable person," she means "all reasonable people" (King 2000, p. 336), which she argues is implicit.[7] Without this implicit understanding, it might be misunderstood that only a single reasonable person would be sufficient to state the likelihood of direct health benefit (e. g. the researcher herself). There are other implicit claims in this definition. One of them is that evidence must be presented in all the three dimensions of direct health benefit (i. e. nature, magnitude, likelihood of benefits). For this purpose, human data and evidence from animal research can be utilised. A theory, however plausible or logically convincing, is not sufficient to fulfil this claim. Another claim is that this information needs to be judged in support of the decision, where a reasonable choice is being made to gain a chance of benefit (King 2000).

As one may already expect, King (2000) strictly distinguishes between reasonable chances of direct benefit, and reasonable choices about participation. While the former belongs, strictly speaking, to the matter of disclosure, it is the latter which constitutes the proper risk-benefit assessment of the participant.

Matter of Disclosure

When talking about reasonable chances of direct benefit, the emphasis is always upon the correct presentation of all the evidence. The information about chances of benefit should always be interpreted with some scepticism. At this stage, although evidence claiming the beneficence of interventions are presented, it does not yet constitute the evidence of the beneficence of the treatment as such. The importance of this stage is that the proper disclosure of evidence supports the enrolment of participants in order to perform the research study (King 2000).

7 King (2000) refers to this condition as implicit and self-evident standard in the application to informed decision-making but she does not discuss it further (King 2000).

It is also noteworthy that a lack of reasonable chance does not mean that no participant may enrol (King 2000). In this statement, the importance of the difference between being a patient and being a research participant prevails, as was commented upon earlier.

Matter of Risk-Benefit Assessment

A reasonable choice of the prospective participant for participation in a research study is a choice that all reasonable people would endorse in order to attempt to secure the benefits of the study, after disclosure of sufficient information. However, the definition does not assume that it logically follows that when a sufficient level of information has been disclosed, a reasonable person would opt for participation. Reasonable minds differ, and even the rejection to participate in a research is a reasonable choice for a person. This is so, even if all the important information has been disclosed and there is a reasonable chance of direct benefit (King 2000).

Context-specific Threshold Requirements

The phrasing of the definition that refers to the assessment of direct health benefits "under all the circumstances" (King 2000, p. 336) introduces an additional level of qualification to the reasonable chance of benefit definition (King 2000). There are context-specific conditions that are relevant for the benefit assessment, and that may divert the choice of the participant to other alternatives. Among these are, for example, the specificities related to the condition of disease, subject population, the degree of disease burden, other treatments available, etc. (King 2000).

King (2000) warns about two tempting simplifications that RECs need to avoid. The first is the assumption that every intervention offered to a participant carries a reasonable chance of benefit. RECs may assume that if a research proposal is acceptable by many prospective participants, it expresses the reasonableness of that choice. However, it is easy to recognise that a choice made under time-pressure or other stress (e. g. desperation, etc.) may involve therapeutic misconception (King 2000).

The second assumption relates to the presence of clinical equipoise. Clinical equipoise refers to a difference of reasonable minds about what will be the better treatment between the various arms of the research study (e. g. research arm v. standard treatment, or research arm v. no treatment). Clinical equipoise does not focus on the assessment of potential direct benefits. The focus is rather on the overall risk-benefit calculus with specific interest of aspirational benefits. Therefore, clinical equipoise fails to assess the benefit-harm ratio for current research participants in a particular research study (King 2000).

RECs should pay significant attention in assessing the particular benefits and risks of the research participants actually involved in research studies.

4.2.2.3 *The Value of Technology in Healthcare*

The other extensively discussed topic related to the introduction of technology into healthcare is the value of health technologies for its users and for the society. In this section, various views and reflections are presented. First, the transforming factor of technology is critically described, along with the expectations by, and impact on, the stakeholders who use it (e. g. professionals, patients). Secondly, the negative consequences that should be avoided in the application of health technology are focused upon. Thirdly, how technology and our perceptions can together negatively influence medical judgements about impairments, and how the realisation of the issues behind these misconceptions can lead to risk-minimisation of harms will be discussed.

TRANSFORMING FACTOR OF TECHNOLOGY

The transforming factor of technologies upon medicine is manifold. Recent history has shown that health technologies have unquestionably provided great advances and better care overall for patients. However, these new methods and technologies have also introduced some new issues, that challenge the effectiveness of their application. Among these issues is the fact that technology increases and contributes to over-diagnosis. Subsequently, it increases over-treatment, and thus, unfavourably influences the benefit-harm ratio by intensifying the harms that are already present during most of the testing and screening activities (B. M. Hofmann 2015; Hoffmann and Chris 2015). Another negative effect that technology induces is the tendency towards medicalisation (B. M. Hofmann 2015).

Half of the increase in overall healthcare costs is accredited to technologies, and researchers warn that such an extensive use of technologies may go beyond benefits, and actually cause more harm. The ever increasing implementation of health technologies evidently affects every stakeholder (B. M. Hofmann 2015).

Technology Sought by Patients

The use of technologies in healthcare is actively sought by the patients. They usually believe general social myths, for example, that new things are better than the old ones, complicated things are better than simple ones, or more action is better than less action (B. M. Hofmann 2015).

Patients are also more prone to exhibit some sort of optimistic bias. This is understandable given the particular disease for which they seek remedy. Patients naturally demonstrate more hope, as well as a greater need for safety, sense of control, action, or reassurance. It is also known that regarding expectations about benefits and harms, patients rarely provide an accurate estimation of interventions. Overall, patients tend to overestimate benefits, and underestimate harms (Hoffmann and Chris 2015).

The overly positive patient expectations are further multiplied by the lack of direct questions addressed to the healthcare professionals. Patients tend to avoid confrontation with their physicians, even though discussion with them may provide an opportunity for the correction of misbeliefs, and misperceptions about the effectiveness of interventions (Hoffmann and Chris 2015).

Technology Sought by Professionals

The technology is also actively sought by the members of the medical professions. It catalyses not only the development of novel technologies but also the delivery of care, as it attracts patients who are willing to utilise the health service. There is also a technological arms race amongst healthcare professionals (B. M. Hofmann 2015).

Hoffmann and Chris (2015) emphasise that it is not only the patients who have overly optimistic ideas about technologies in healthcare. Clinicians also expect overly high benefits from technological interventions. The origins of such expectations may be linked with the belief held by professionals that doing something is always better than doing nothing. Additionally, beliefs in the pathophysiological effectiveness of a treatment may further encourage the willingness to intervene (Hoffmann and Chris 2015).

Clinicians may have poor knowledge about the possible harms, simply by being unaware of the true effectiveness of an intervention, and how it influences the overall benefit-harm ratio. Alternatively, clinicians may not be incentivised to discourage patients from continuously asking for more care. There may also be financial interests (e. g. fee for service) behind a clinician's failure to discourage a patient from opting out of an intervention (Hoffmann and Chris 2015). The knowledge deficit about the harms of interventions may also be due to the assumptions during research studies, based on which researchers disregard the data inconsistent with the hypothesis. Also, it is rather common in research studies that an identified source of harm is perceived as an isolated finding (Fisher and Welch 1999), and as such harms, are less routinely evaluated than benefits (Hoffmann and Chris 2015).

Other Driving Forces Behind Implementation of Technology into Healthcare

Technology is increasingly implemented due to its own attributes. One of these is the ability of technology to compensate for human deficiencies. Technology is becoming increasingly autonomous, and its measurements more precise than those made by humans (B. M. Hofmann 2015). These characteristics enrich the dependance on and trust towards technologies.

Also, the push from the industry, which develops and implements technology into various areas cannot be ignored. The so-called technology-push is one of the driving forces behind their application in almost every aspect of our lives (B. M. Hofmann 2015).

Technology Changes the Meaning of Disease

It has been argued by B. M. Hofmann (2015) that the prevalence and ever increasing role of technologies is also noticeable in the perception of disease itself. Firstly, it influences the *definition* of diseases because modern diagnostic methods are all reliant on devices. Secondly, it influences the *knowledge* about the disease because most of the necessary measurements are made by employing technological devices. Finally, through *manipulation* by technologies, we can modify or diminish diseases (B. M. Hofmann 2015).

NEGATIVE CONSEQUENCES OF TECHNOLOGY IN HEALTHCARE

The pervasiveness of the application of technology and its influence upon healthcare provision can lead to the loss of focus on important goals of healthcare. This issue has been called by B. M. Hofmann (2015) a self-perpetuating loop of diagnostics. The influence of technology is continually increasing in healthcare due to the positive feedback loop in diagnostics: the advances in technical performance lead to better diagnostic techniques; better diagnostic techniques lead to the diagnosis of an increased number of diseases; increased numbers of diagnosed diseases catalyses the need for therapeutic interventions; and the increased need for therapy leads to the treatment of milder cases (i. e. those, that were not treated before); by enhancing the feeling of success inherent in the increased numbers of treatments, the technological innovation is boosted (B. M. Hofmann 2015).

The positive feedback loop in diagnostics leads to some particular negative consequences, which, according to B. M. Hofmann (2015) need further attention.

Enhanced Leaps of Beliefs

The positive feedback loop in diagnostics may induce unwarranted enthusiasm on the side of healthcare professionals, patients, and those who develop the technology. Patients are then especially prone to developing unrealistic expectations regarding their conditions, and how they can be treated. For all the stakeholders, the benefits of the ever increasing use of technologies may seem so evident that its downsides are simply ignored, or actively suppressed (B. M. Hofmann 2015).

Good Tests Become Poor

The higher sensitivity of diagnostic devices results in an overall decrease in positive results. B. M. Hofmann (2015) demonstrates this scenario, when the sensitivity of a diagnostic technology is increased from 0.80 to 0.95, such an increase of specificity may lower the chance of valid positive test result from 0.80 to 0.16, if the prevalence of the diagnosis decreases, for example, from 50 % to 1 %. A technical improvement in this case would lead to a lower threshold and alertness about a disease, and thus, such improvement does not promise any clinical improvements (B. M. Hofmann 2015).

On the systematic-scale, Fisher and Welch (1999) reminds us of the law of diminishing returns. This holds that although the first input provides significant benefits, the amount of benefits declines with every additional input, a tendency which would, at some point, reach a point when any additional input would result in more harm than benefits (Fisher and Welch 1999).

Detecting More Does Not Help

B. M. Hofmann (2015) also emphasises that a greater number of detected cases may not necessarily result in increased levels of patients being treated. The only immediate result of the increased sensitivity of diagnostic technologies would be the greater number of mild cases detected. High levels of over-diagnosis would subsequently result in physicians having to devote less time to individual patients (B. M. Hofmann 2015).

Even if healthcare professionals were able to cope with such an increase in the number of mild cases, it would not be possible to avoid an increased threat of over-treatment. More medical care at times may produce more harm than benefit on, at least, three levels. Firstly, it may result in a change of the diagnostic definition to be more inclusive. Secondly, it enforces labelling by forcing physicians to disclose to patients that they are not well, when they would otherwise be asymptomatic and feel well. Thirdly, more medical care boosts the development of pseudo-diseases, that is, diseases that would not become apparent during the lifetime of the person were they to have eschewed the diagnostic test. A further consequence of pseudo-diseases are the disagreement of physicians about which patient has priority in the consecutive treatment. Pseudo-diseases lead to greater anxiety for patients and increased numbers of people with disability (Fisher and Welch 1999).

Increased Activity

The prevalence of technology in healthcare also leads to the increased activity of physicians. The more testing is done on the side of diagnostics, the higher likelihood that some incidental findings will be noticed (B. M. Hofmann 2015). At the system-level, this leads to tampering, which occurs when an intervention is adjusted to correct for random rather than systemic variations. The result of addressing random deviances is that it leads to unstable systems (Fisher and Welch 1999).

On a diagnostic level, the increased need for activity generates more work for physicians but with less measurable outcomes (B. M. Hofmann 2015). Behind this incentive for activity is the belief that doing more is better than doing less or doing nothing. However, as highlighted by Fisher and Welch (1999), this approach ignores the possibility of causing harm. Harm can occur at any level of the intervention, at the particular discrete level, or the general systemic level. According to Fisher and Welch (1999), there is a dearth of studies that examine systemic-level harms in medical care. For exam-

ple, it is notable that a system with free healthcare provision provides 40 % more care than co-payment systems, which yields beneficial results in high-risk groups of patients. However, the group randomised to receive more care showed no improvement in their functioning, along with more pain, more worry, and more restrictions in their everyday activities (Fisher and Welch 1999).

Increased activity on the physician's side introduces more complexity to the tasks. Greater complexity appears to be dangerous, not only on the systemic-level (i. e. more steps needed to finish a task) but also on a particular discrete level, due to the higher likelihood of being distracted during a more complicated task (i. e. missing an important detail because other tasks need to be performed; Fisher and Welch 1999).

Increased Health Anxiety

On the side of the patients, greater activity may raise more concerns about their health, causing individuals to become more worried and anxious about their health condition. These concerns may increase the demand for testing and screening even more, and thus, intensify all the aforementioned issues (B. M. Hofmann 2015).

Increased Costs

The convergence of the consequences of more intensive use of technology in healthcare also results in increased costs. With greater testing and screening, more incidental findings, and more follow-ups demanded by patients, resources may be directed away from other healthcare areas, where they could be used more effectively. Ultimately, resources may be withdrawn from areas like the development of innovative technologies (B. M. Hofmann 2015).

Reduced Value

Another effect of over-diagnosis and over-treatment is the creation of medical labels (or pseudo-diagnosis), the usefulness of which is deflated, according to B. M. Hofmann (2015). The value of prescribed treatments for symptoms that are not troublesome may be considered wasteful. Fisher and Welch (1999) also highlight that the near-term risks of a treatment may prevail over long-term benefits. Additionally, a distinction between efficacy (i. e. outcomes of treatment in ideal settings), and effectiveness (i. e. outcomes in community practice) also plays an important role in the benefit-harm assessment (Fisher and Welch 1999).

Undermining Trust

Finally, all the consequences together may result in the loss of trust by the general public, which would be detrimental for clinical practice and also research (B. M. Hofmann 2015).

Also, it should always be borne in mind that uncertainty plays a significant role in medicine, and is simply unavoidable in practice (Fisher and Welch 1999).

NEGATIVE INFLUENCES ON MEDICAL JUDGEMENTS

As it may be apparent for any valid benefit-harm assessment, a correct medical judgement is necessary. However, medical judgement may be flawed. The negative impact of the medical judgement can only be partially blamed on technology. Fisher and Welch (1999) lists four other conditions that may negatively influence medical judgement, and thus, the assessment of the benefit-risk ratio.

Missing Check on Reality

Firstly, the idea of disease may often be inconsistent with reality. It is tempting to perceive the human condition as a dichotomous model, as either sick or healthy. This affects not only the thinking of physicians but also the conduct and performance of medical interventions. Such simplistic interpretations fail to consider wide-ranging variations in outcomes. Moreover, many diseases inevitably progress to the worst possible stage. Therefore, healthcare professionals should consider an approach that better encompasses the full spectrum of disease when making decisions (Fisher and Welch 1999).

Results Extrapolated Too Broadly

Secondly, there is a noticeable tendency to apply particular findings to a wider area than that investigated in the study. This occurs especially in cases when results of highly-controlled studies are extrapolated to lower-risk patients than those studied, expanded to include similar or related interventions, or providers with unknown capabilities. This poses an increased risk of harm. Moreover, the attempt to introduce such extrapolation carries also the burden of proof (Fisher and Welch 1999).

Missing System-level Research

A wide range of research studies investigated the implementation of changes made to increase capacity (e. g. increasing visit frequency, hire additional personnel, purchase new diagnostic technology); changes which also incur increased costs. However, it is unknown whether these changes affect the outcomes of the interventions. Fisher and Welch (1999) emphasise that not only costs but also outcomes (their benefits and harms) should be precisely measured. The measurement should not focus on discrete groups of patients but should extend to the wider population that is affected by the system-level changes (Fisher and Welch 1999).

Looking For More to Be Better

It is argued that findings that are inconsistent with the underlying beliefs of the researcher(s) are often simply ignored or disregarded. Harms in studies are perceived as isolated findings because it is believed that only benefits are expected with more care, not harms. Little effort is invested in defining what not to do, as well as into the evaluation of clinical practice. Moreover, stakeholders are increasingly market-oriented and profit-driven, leaving very little room for the exploration of the potential harms of technologies. Fisher and Welch (1999) note a danger in industry-sponsored research studies, which carry a higher likelihood of publication bias and/or conflicts of interests. These dangers, in their view, will only escalate in the future (Fisher and Welch 1999).

REQUIREMENTS FOR REDUCING HARM FROM HEALTHCARE TECHNOLOGIES

To minimise the dangers of influences that have negative impact on medical judgement, along with the greater likelihood of harms in interventions instead of expected benefits, it is insufficient to note these dangers and harms when they occur. The true challenge is to actively look for these dangers and purposely identify them (Fisher and Welch 1999).

B. M. Hofmann (2015) adds that the medical community should halt the uncritical implementation and use of health technology that endorses excessive medicine/medication. This can be done, for example, by eliminating all the traces of truism: that doing more is better than doing less, that new is always better than old, and that advanced is always better than simple (B. M. Hofmann 2015).

Responsible actions cannot be based upon the vague concepts linked with health technology, which are a sort of technological imperative of progress alongside of uninformed patients' demands (B. M. Hofmann 2015).

The dual role of technology has to also be acknowledged. Technology cannot be understood as a neutral, value-less means for human ends. It is at the same time an artefact and an actor (B. M. Hofmann 2015, referring to Latour 2005).

Finally, health technology needs to be critically assessed with the same rigour as that with which drugs are assessed (B. M. Hofmann 2015).

4.3 SPECIFICATION OF ARTICLE 4

This section specifies the requirement of Art. 4 to maximise benefits and minimise risks of PwDs while using AAL technologies. The section is divided into the standard areas of clinical research and clinical practice. This specification of Art. 4 also takes into account the highest requirement of UDBHR, i. e. assessing the protection of the human dignity of the PwDs, and extending to the interests and motives of other stakeholders (e. g. formal/informal caregivers, researchers, etc.) participating in the care of PwDs.

4.3.1 *Clinical Research*

The maximisation of benefits in clinical research, required by Art. 4 of the UDBHR, is much more difficult to achieve than in clinical practice. Participants may be limited by their disease, and may be overly eager and willing to try novel (and potentially dangerous) experimental treatments. Investigators should never take advantage of this kind of vulnerability, nor should this vulnerability be exploited for the sake of research (Pellegrino 2009).

Evans (2014) points out the inner incoherence of Art. 4 regarding clinical research. The requirement to maximise research benefits appears impossible, since, due to the nature of any experiment, no benefits can be assured (Evans 2014). This inconsistency may be somewhat mitigated by the motives and justifications for conducting the research study. The ultimate motives for conducting research studies is search for amelioration of physical and/or psychological distress, pain, and disturbance. The justification for conducting research studies with possible risks, besides all the efforts made to minimise these risks and burdens, is based on the potential of discovering treatments, the benefits of which will prevail over its dangers or discomforts.

It may be further argued that the phrasing of the Art. 4 requirements is extreme and unbalanced. The maximisation of benefits and minimisation of risks are conditions at opposing ends of the spectrum of research results. As such, they omit any mention of proportionality, as defined by the principle of proportionality. The next section sheds more light on this issue. The subsequent section specifies the reasons and benefits of involving PwDs in research studies of AAL technologies and the needs of researchers.

4.3.1.1 *Principle of Proportionality and Article 4*

Hermerén (2012) argues that the principle of proportionality should be used more in a plural form because there are many versions of principles of proportionality. Originating in legal form in German case law, the principle of proportionality also appeared in the Amsterdam Treaty in 1997 (*Treaty of Amsterdam* 1997; Hermerén 2012). It is mostly applied in areas of terminal care, crime and punishment, and military interventions (Hermerén 2012).

The aim of the principle is to set-up a connection between the aims of an action and the means used in order to reach it. According to the principle of proportionality, this relation must be adequate and appropriate. Hermerén (2012) lists four constitutive elements, which are required in the (various versions) of the principle of proportionality: importance of objective, relevance of means, the most favourable option, and non-excessiveness (Hermerén 2012).

IMPORTANCE OF OBJECTIVE

In order to make the risks placed on persons acceptable and justifiable, the principle of proportionality requires that the objectives of the action are important. Without important goals, any risky action that carries the possibility of harm is irrational.

However, the focus on the importance of the objectives may introduce additional issues. In some cases, the importance of the aims is transient, e. g. what is important on day 1 is not important on day 99, or what is important from a theoretical point of view is not so significant from a practical point of view. The importance of an objective is not a static entity; there may be many objectives with conflict and have different priorities (Hermerén 2012). In medical circumstances, these may be the fast pain management and alleviation of suffering; the middle-term goal of mitigating the disease; and the long-term goal of restoration, maintaining or improving of the quality of life.

RELEVANCE OF MEANS

The means used for reaching the goals, according to the principle of proportionality, have to be adequate and relevant to the risks taken and the benefits expected. Thus, relevant means are also proportionate in terms of causality between the means and the ends (Hermerén 2012).

There are two interpretations about what constitutes the relevance of means. According to the stronger interpretation, the means have to be sufficient or necessary to reach the objectives. The weaker interpretation requires only that the means bring about, or help to bring about, the objectives. The weaker interpretation assists in the criticism of excessive expectations of novel and emerging research studies (Hermerén 2012).

The assessment of means is important because they also identify goals that may be achievable. A goal cannot be reached with unsatisfactory or inadequate means; thus, the means shape and limit which goals are achievable (Hermerén 2012).

THE MOST FAVOURABLE OPTION

The requirement of the most favourable option appears to be the most problematic aspect in the application of the principle of proportionality. There is a distinction between what constitutes risky treatment, and controversial treatment (Hermerén 2012). As the phrases might suggest, risky treatment is considered by all those involved (as well as, possibly, by the wider population) on a consensual basis as bearing the danger of possible harm, while the latter term refers more to treatments that introduce an element of controversy (e. g. religious or political views). This poses additional issues related to the interpretation of what constitutes favourable options, and of how they can be measured or justified (who decides, on what grounds, etc.). All these issues demonstrate that the

difference between risky and controversial favourable options cannot be equivalent, and these terms cannot be interpreted as synonymous terms (Hermerén 2012).

NON-EXCESSIVENESS

Hermerén (2012) argues that a fourth condition applies, for the effective application of the principle of proportionality, which is the non-excessiveness of the means. This is defined as: "[t]he means used should not be excessive in relation to the intended goal" (Hermerén 2012, p. 377). Assessing the non-excessiveness requirement means considering the measures, restrictions, and proper forces that may be used in a given situation. These become an issue when they are exceeded (Hermerén 2012).

The benefits and harms need an explicit estimate that reflect the specific context. For such an estimate, circumstances like the type of harm or interests at stake need to be considered. What may be considered as an appropriate type of harm in one situation, may be considered as excessive in another situation (Hermerén 2012).

VARIOUS INTERPRETATIONS OF THE PRINCIPLE OF PROPORTIONALITY

Hermerén (2012) argues that the issues related to all the above-mentioned conditions of the principle of proportionality suggest that there is no single principle of proportionality but many. He distinguishes between extended, standard, and minimal interpretations (Hermerén 2012).

The extended interpretation involves all the conditions mentioned earlier: the requirement of the important objective, relevant means, choosing the most favourable and non-excessive option. This interpretation is the most useful in considering applications within research ethics (Hermerén 2012).

The standard interpretation involves the requirement of the importance of means, choice for most favourable option, and non-excessiveness of the chosen means for reaching the objective (Hermerén 2012).

The minimal interpretation of the principle of proportionality embraces only two requirements: the relevance and non-excessiveness of the means. These two versions of the principle of proportionality may be useful, mostly in bioethical evaluations of harms and benefits (Hermerén 2012).

Hermerén (2012) concludes that the principle of proportionality can be considered as a principle that helps raise additional questions in the ethical assessment of benefits and harms. The principle of proportionality cannot be considered a basic ethical principle because it produces various outputs in the context of a multitude of ethical theories (e. g. utilitarian, human rights based, dignity oriented theories). Additionally, its results may not necessarily be always conclusive, involving significant levels of grad-

ing (whether the interests are fundamental, strong, or weak; or the harm involves the majority, minority, or only few persons; Hermerén 2012).

IS THE PRINCIPLE OF PROPORTIONALITY MISSING FROM ARTICLE 4?

On closer inspection, there is no reference to a principle of proportionality in the UDBHR. However, in earlier drafts of the UDBHR, reference was made to this principle. As the *Explanatory Memorandum on UDBHR* (2005) notes, earlier drafts of the Declaration, in Art. 30 on the restrictions on the principles (content-wise this article in the final version is under Art. 27), declared that restrictive measures in choosing between various (conflicting) principles should be made proportionally. A necessary restriction of any of the principles of the UDBHR (and the rights derived from it) should have been restricted in the least limiting manner, and "only to an extent proportional to the legitimate end of the restriction" (*Explanatory Memorandum on UDBHR* 2005, p. 16)

The *Explanatory Memorandum on UDBHR* (2005) makes another link to the principle of proportionality, referring to the *Additional Protocol to the Convention on Human Rights and Biomedicine* (2005). The *Convention on Human Rights and Biomedicine* (1997) refers to the principle of proportionality only in two occurrences. In Art. 6.2, in relation to a consent of a minor, the opinion of the minor needs to be weighed in proportion to her age (*Convention on Human Rights and Biomedicine* 1997, Art. 6.2); and in Art. 16.ii, stating that the risks for persons participating in research studies should not be disproportionate to the benefits (*Convention on Human Rights and Biomedicine* 1997, Art. 16.ii). These requirements are again confirmed in Art. 15.iv and Art. 6.1 of the *Additional Protocol to the Convention on Human Rights and Biomedicine* (2005) respectively. It is this latter document that the *Explanatory Memorandum on UDBHR* (2005) refers to when it describes the meaning of Art. 6 on benefit and harm, in the preliminary draft of the Declaration. According to this statement, both documents require, in their principles, the search for benefit for the person concerned in the research, while minimising the possible harms (*Explanatory Memorandum on UDBHR* 2005).

However, the final accepted text of the UDBHR does not refer to the principle of proportionality. The phrasing of the UDBHR does not require a simple proportionality balanced in such a way that the benefits outweigh the harms but rather, it demands the widest gap possible between the benefits and harms. As the text of *Explanatory Memorandum on UDBHR* (2005) suggests, the dismissal of any reference to the principle of proportionality is a result of both conceptual and political decisions during the drafting of the UDBHR (*Explanatory Memorandum on UDBHR* 2005).

4.3.1.2 *The Involvement of PwDs into the Design of AAL Technologies*

The literature review (Chapter 3) highlighted the requirements and beneficence of involving PwDs in the research & development (R&D) and design process of the AAL technologies. Such an involvement is expressed by many terms: holistic approach or perspective (Kosta, Olli Pitkänen, et al. 2010), value sensitive design (Wright 2011), ergonomic design (Wallace et al. 2010), proactive design (Duquenoy 2004), or ethical design (Kosta, O. Pitkänen, et al. 2008).

A similar framework has been developed during the European Rosetta project,[8] called user participatory design. The user-friendliness and usefulness of the system has been achieved by the active involvement of PwDs in the design process. Amongst the needs of the PwDs were the support for memory, behaviour, and activities of daily living (ADLs). The more inclusive involvement of research participants in the design process resulted in fruitful and better targeted results. The PwDs reported better support in cases of emergency. The informal carers were able to provide additional valuable feedback about the usefulness (or the lack thereof) of the technology (e. g. difficulties in using buttons, vision problems of PwDs, losing the mobile devices, etc.; F. J. M. Meiland et al. 2014).

Indeed, the involvement of PwDs into the R&D process is likely to increase in the future, and should be actively encouraged in order to fulfil the requirements defined in Art. 4 of the UDBHR. F. J. M. Meiland et al. (2014) highlight a few issues in the R&D of AAL technologies, which may be avoided through a more inclusive approach towards PwDs in the research of AAL technologies. Among these is the drawback of the fragmented functionalities of AAL technologies, i. e. they aim to support only a single need of the PwDs. Instead, AAL technologies should be designed in a way that will enable them to support various needs of PwDs, over the different stages of the development of the disease. Also, more inclusive and participatory involvement of PwDs into a research project provided engineers with the practical knowledge that modular systems serve PwDs better. Unfortunately, some technologies used by PwDs were developed without their active involvement, or were initially developed for younger generations (F. J. M. Meiland et al. 2014).

INHERENT RISKS OF LIVING WITH ICT

Coeckelbergh (2015b) highlights an additional and important aspect that goes beyond the purely pragmatic approach of Information and Communication Technology (ICT) design. This overall aspect of living with ICT, in Coeckelbergh's view, is an ethics of vulnerability coping. The introduction of ICT, according to him, does not introduce 'external' harms. ICT is a part of our lives and as a consequence, their vulnerabilities are all our vulnerabilities. Life with ICT inadvertently shapes our existence; it is our form

8 Project website: `http://www.aal-europe.eu/projects/rosetta/` (visited on 27/11/2015).

of life with ICT, which is therefore a life lived with risk. During the development of ICT, human beings evaluate the (inherent) risks with which they are willing or unwilling to live (Coeckelbergh 2015b).

Coeckelbergh's interpretation opposes the view held by the Dutch design-oriented philosophy of technology (Coeckelbergh 2015b, referring to Verbeek 2011; Verbeek 2005; and van de Poel 2005). According to this design-oriented interpretation, living with technology is a matter of choice. The way we live with technology is within our control; it is a lifestyle (Coeckelbergh 2015b). It is not tightly linked with our social and cultural nature of living. Therefore, through the approach called 'designing the morality of things' (Coeckelbergh 2015b referring to Verbeek 2011), it is possible to shape human behaviour and thus, human existence, through the interfaces of the technology. The design-oriented approach interprets lives with ICT as a market, where individuals make choices between various lifestyles, suggesting a consumer-like concept of morality and human existence (Coeckelbergh 2015b).

Coeckelbergh (2015b) finds this interpretation misleading, as it fails to reflect upon the importance of moral habits and moral cultures. Just as using a language, being part of a society or culture is a style of living that is extremely hard to change. Changing the style of living with ICT is similarly impossible on an individual level.

The conclusion that may be drawn, based of Coeckelbergh's interpretation of living with ICT, is that any use of technology carries an inherent risk of harm for its user. It is impossible to completely circumvent these risks. Additionally, these risks cannot be effectively minimised on an individual level. Living with ICT involves being in the fabric of societies, the minimisation of the risks posed by ICT (i. e. with which risks we are willing to live with, and which not) can be decided upon at the level of the wider public and through the involvement of the relevant stakeholders.

4.3.1.3 *Needs of Researchers*

The unknown factors behind the pathology and the pathogenesis of dementia forms a justifiable set of needs for researchers who wish to develop better and novel diagnostic and monitoring means. As mentioned by König et al. (2015), in 2015, there were approximately 2500 trials listed in the official `clinicaltrials.gov` registry that studied mild cognitive impairment (MCI), Alzheimer's Disease (AD), and other dementias. It is argued that the development and use of AAL technologies (especially their monitoring abilities), and ICT devices for capturing and recording physiological and other data may provide the researchers with these valuable data (Robert et al. 2013; König et al. 2015). The appropriate assessments for diagnosis, in particular of cognition, behavioural, psychological, and ADLs essentially provide the user-needs data for researchers regarding this type of technology (Robert et al. 2013).

ICT services are used for automated speech analysis, non-invasive 2D video recordings and video signal analysis, for computer games and actigraphy. In the future, it is expected that ICT may provide researchers with a non-invasive, objective, and inexpensive way of recognising and identifying the decline of various cognitive or functional abilities in patients. This may facilitate the early detection of these impairments (König et al. 2015).

Robert et al. (2013) defined the requirements and wishes that ICT should fulfil in order to be of use in clinical trials. One of these requirements is that ICT needs to be accepted as a valid clinical study endpoint by health authorities. Robert et al. (2013) argue that introducing ICT into clinical practice is particularly important because it would encourage this acceptance, thereby allowing the application of ICT to move beyond the clinical trial setting alone. Another requirement is the establishment of a correlation between the data recorded by ICT and that obtained with various other clinical assessment tools. ICT must also be able to record long-term data (frequency, intensity, etc.) on a wide range of behavioural and psychological symptoms related to dementia (Robert et al. 2013).

Beside these essential requirements, Robert et al. (2013) also defined wishes and user-needs that the ICT services might fulfil for researchers. Amongst these are the reduction of the number of research participants dropping out, the elimination of the need for repeat study visits to the research centre; the improved blinding about the evolution of PwDs in order to reduce bias; the development of a more objective and homogenous assessment of behavioural disturbances, the derivation of more precise insight regarding behavioural disturbances; and the need for games in order to rate and manage PwDs' behavioural issues (Robert et al. 2013)

Undoubtedly, the aforementioned aims, if achievable, would provide future PwDs with notable benefits. However, it must be recognised that these goals are only aspirational benefits, according to the categorisation of King (2000). This means that the disturbances and risks of PwDs participating in these research studies may be greater than the direct benefits required by Art. 4 of the UDBHR. Moreover, Art. 3.2 places the interests of individual PwDs above the needs of science. Therefore, the user needs of researchers regarding ICT (e. g. to increase participants' admission rates; to improve sensitivity of detection of settle changes that would result in an improved accuracy of the research objectives; or the reduction of required visits on the research centre and consequently reducing the dropout rate; König et al. 2015) should be defined as secondary to those needs of the PwDs and their caregivers regarding AAL technologies.

4.3.2 *Clinical Practice*

The principle of benefit and harm of Art. 4 of the UDBHR defines that in medical practice and therapy, physicians are obligated to cure their patients whenever possible, amelio-

rate their disease, relieve their pain, and provide care. According to Pellegrino (2009), these requirements go beyond the simple removal, avoidance, or prevention of harm. Art. 4 demands much more than these negative obligations. Art. 4 poses positive obligations of beneficence upon healthcare professionals, i. e. that positive good must be provided to patients. What the UDBHR states in Art. 4 is that the healthcare professional carries the responsibility of weighing the potential risks and benefits. In Pellegrino's view, this weighing should be prudential (Pellegrino 2009).

The assessment of benefits and risks related to the application of AAL technologies cannot be successfully conducted without a precise knowledge of the user-needs. In the clinical application of AAL technologies, there are at least three different types of users, with various user-needs: PwDs, formal and informal caregivers. The following sections will specify their respective needs, and how AAL technologies can be help meet these these. This will be followed by the specification of the risks that AAL technologies may introduce in the care for PwDs.

4.3.2.1 *User-needs*

AAL technologies need to fulfil the expectations of three different groups of users and their needs. This has implications for the benefit and harm assessment of the AAL technologies that is required by Art. 4 of the UDBHR.

PERSONS WITH DEMENTIA

As argued in the literature review (Chapter 3), PwDs exhibit a great deal of heterogeneity. Therefore, two types of user-needs can be defined: those that are required by all PwDs as persons, and those that can differ significantly between PwDs, e. g. needs that differ depending on the stage of the dementia.

General Needs of PwDs

The book, *Dementia Reconsidered: The Person Comes First* (T. Kitwood 1997) provides a definition of the general needs of PwDs. Kitwood's initial encounter which dementia prompted him to reconsider the overall paradigm present in dementia care. Kitwood refers to this as a "standard paradigm" (T. Kitwood 1997, p. 2) or the "old culture of care" (T. Kitwood 1997, p. 77). This standard paradigm is based on a medical model, in which dementia is referred to as an 'organic mental disorder.' This reference is based on the results of neuropathological investigations of 1960s. According to this approach, the phenomenon of dementia must be understood in a 'technical way.' As a result of this (objective) interpretation, namely, that behind dementia must be a structural failure of the brain, a technical approach must also be the decisive element of dementia care (T. Kitwood 1997, pp. 1–3).

In contrast to this standard paradigm, Kitwood, during his initial research, focused on how personhood is undermined in the various stages of dementia. He found that there had been no attempt to interpret dementia from a subjective perspective. Therefore, he proposed a hypothesis for defining dementia care (based on the psychological and neurological basis of dementia) as requiring respect for a PwD's personal emotions and feelings in a more substantial and profound way (T. Kitwood 1997, pp. 4–6).

The main element of Kitwood's approach is the concept of personhood. His understanding of the concept of the person cannot be interpreted as a mere synonym for 'human being.' Accepting Quinton's criteria of personhood,[9] T. Kitwood (1997), along with other authors such as Post (1995), criticises the overt emphasis on rationality and autonomy in the concept of personhood. Instead, the concept of personhood should be more closely linked to feelings, emotions, and relationships, i. e. to areas in which people with dementia are still often highly competent (T. Kitwood 1997, p. 10).

Therefore, against the background of the aforementioned criticism, T. Kitwood (1997) defines personhood as

> "[. . .] a standing or status that is bestowed upon one human being, by others, in the context of relationship and social being. It implies recognition, respect and trust." (T. Kitwood 1997, p. 8)

The understanding of personhood is inspired by the philosophy of Martin Buber (1878–1965) and his seminal work *Ich und du* (Buber 1923; in English Buber 1970).[10] The recognition of relational terms of human beings led Kitwood to redefine the understanding of dementia care. He argues that, despite the severity of the cognitive impairment, Buber's I-Thou relationship between a PwD and a person unaffected by dementia can still be established. The essence of the caregiving act is missing, if the I-Thou meeting never takes place. This is unfortunately often the case, despite the efforts made to ensure the most accurate assessment and diagnosis, and the most thorough care plan within pleasant surroundings (T. Kitwood 1997, p. 12).

Kitwood calls his approach to the care of PwDs "person-centred care" (T. Kitwood 1997, p. 4). He and his colleagues also developed Dementia Care Mapping (DMC), a method that helps evaluate the quality of provided care, usually in formal settings (e. g. nursing homes). This method involves the use of empathy and observational skills. The framework is based on trying to understand the caregiving process from the point

9 T. Kitwood (1997) refers to Quinton (1973) when listing the five criteria of personhood, as the possession of a) *consciousness* (the idea of the self); b) *rationality* (the capacity for abstract thinking); c) *agency* (forming intentions, considering options, direct actions); d) *morality* (accountability for one's actions, living according to principles); and e) *relationship* (identify and understand the desires and needs of others) (T. Kitwood 1997, p. 9).

10 There are two standard translations of Buber's *Ich und Du* (Buber 1923) into English. In 1937, Ronald Gregor Smith published his translation (Buber 1937), and later, in 1970, Walter Kaufmann provided another translation. The latter includes Buber's own, previously unpublished, comments on the English translation of *Ich und du*. For details, see Buber (1970, p. 5).

of view of the person with dementia. It helps to assess the levels of deterioration for introducing possible improvements (T. Kitwood 1997, p. 4).

Kitwood's person-centred care tries to overcome the widespread tendency to depersonalise those who are having some kind of noticeable physical or mental disability (T. Kitwood 1997, p. 12). T. Kitwood (1997) refers to research conducted by Meacher (1972) who found out earlier that the general arrangement and conditions present in residential homes were alone sufficient to "drive people demented" (T. Kitwood 1997, p. 46). Therefore, every time Kitwood noticed any depersonalising tendencies during the caregiving activity, he took notes of such episodes and included them into the topics of his research. He referred to these depersonalising tendencies as "malignant social psychology" (T. Kitwood 1997, p. 46). Kitwood admits that this term need not necessarily imply evil intentions of caregivers because their work is usually led by kindness and good intentions. He defined and listed these malignant approaches in Table 4.1 (T. Kitwood 1997, pp. 46–47).[11]

Table 4.1 – Malignant approaches to PwDs by T. Kitwood (1997, pp. 46–47)

Approach	Description
Treachery	Forms of deception to manipulate or distract the PwD, or to force them into compliance.
Disempowerment	Not allowing a person to use her remaining abilities and failing to help them to complete their initiated actions.
Infantilisation	Patronising treatment of the person.
Intimidation	Inducement of fear in a person via threats or physical power.
Labelling	Using categories (e. g. dementia, 'organic mental disorder') as a main basis for interaction with a person and explanations of their behaviour.
Stigmatisation	Treating a person as a diseased object, an alien or outcast.
Outpacing	Information overload when presenting choices, providing information, mostly in too high a rate, putting the person under pressure by the speed they cannot deal with.
Invalidation	Ignoring the subjective reality and feelings of persons.
Banishment	Excluding a person either psychologically, or physically (e. g. sending PwDs away).
Objectification	Treating a person as mere object, as a lump of dead matter (e. g. pushing, lifting, filling, pumping, draining).
Ignoring	Carrying on an activity (e. g. conversation) as if a PwD were not present.
Imposition	Forcing a person to conduct certain activities without the possibility of choice, overriding their desire.
Withholding	Refusing to provide requested attention, or to fulfil an evident need.
Accusation	Blaming a PwD with failures because of their lack of ability to finish certain actions, or their misunderstanding of the situation.
Disruption	Sudden intrusion or disturbance of a person's action or reflection. Crude breaking of their frame of reference.
Mockery	Making fun of person's inability, making remarks, teasing, humiliation or joking on their expense.

11 The original list contained 10 approaches (Tom Kitwood 1990), which were later expanded with 7 additional approaches (T. Kitwood 1997, p. 47).

Table 4.1 – continued from previous page

Approach	Description
Disparagement	Expressing the incompetency, uselessness, worthlessness, etc. of the person, damaging their self-esteem.

Table 4.1: Malignant approaches to PwDs by T. Kitwood (1997, pp. 46–47)

Many elements from this list will never be possible to be mimicked by AAL technologies and ICT. Among these are stigmatisation, banishment, accusation, or mockery by AAL technologies. However, other malignant approaches are indeed relevant, even for the development of AAL technologies. Badly designed AAL technologies may disempower the PwDs, as they may infantilise, intimidate, label, or outpace them. ICT may also be ignorant of the subjective reality of the PwD, and is almost unimaginable that technology would ever be able to eradicate their objectifying approach to human beings. The former issues may be avoided by more sensitive R&D processes, greater inclusion of PwDs into the design process, etc. Unfortunately, the latter characteristics of technology will be harder to eliminate.

Aspects of the malignant social psychology are part of the 'old culture of care' criticised by Kitwood. This is often followed with pervasive neglect from caregivers. Caregivers often interrogate already confused PwDs with questions and tasks, the purpose of which are never fully explained to the PwDs, because the PwDs are not taken seriously. Such an approach results in PwDs feeling as if they have been "left in chaos," are under "oppression," experiencing "naked terror," and feeling "abandoned for ever" (T. Kitwood 1997, p. 77).

Besides the minimal requirements for the care of PwDs, technology should also fulfil certain psychological needs of PwDs, which are defined as "[those] without the meeting of which a human being cannot function, even minimally, as a person" (T. Kitwood 1997, p. 81). These include comfort, attachments, inclusion, occupation, and identity (T. Kitwood 1997, pp. 80–84). Under *comfort* is meant the greater need of PwDs for tenderness, closeness, security, and support. This need is even greater than in the healthy elderly person due to the diminishing cognitive and other abilities of a PwD, or their fear of losing a preferred lifestyle. The need for *attachment* assures the necessary safety nets, feeling of security, and reassurance for PwDs. *Inclusion*, as opposed to social exclusion, is aimed at preventing the decline and retreat of PwDs. Isolation in the history of humanity has often been used as a form of punishment, therefore inclusion emerges as an understandable and justifiable need of PwDs. The need of PwDs to avoid boredom, apathy, and futility is concluded in the requirement of *occupation*. PwDs often manifest this need in the form of eagerness to help, or participate in activities. Finally, PwDs need to know, feel, and preserve their *identities*. This provides continuity with their personal

histories, recollected not only by the PwDs themselves but also by their peers, friends, and family members (T. Kitwood 1997).

The fulfilment of any of the aforementioned needs may be achieved by fulfilling all of the other needs to some extent because they are interlinked. The fulfilment of these needs, in Kitwood's view, enables the PwD to realise her personality at least on a minimal level, despite the deficits and gaps present in her functioning (T. Kitwood 1997).

Kitwood's list of the malignant approaches during caregiving practice, and the psychological needs of PwDs are important when considering the provision of care by AAL technologies. If AAL technologies aim to provide only physical empowerment of PwDs, it will still have to fulfil the requirements of avoiding malignant social psychology. If the AAL technology aims to provide a wider spectrum of support than only those defined as ADL, it will then—to certain extents—have to also fulfil the special psychological needs of PwDs as well.

Special Needs of PwDs

Beside the general needs required by every PwD, additional special needs may be identified, depending on the actual situation and impairments of individual PwDs. These include support for memory problems, information about one's condition and about the adequate provision of care, social contacts and companionship, monitoring of health, safety, and daily activities (Wichert et al. 2012).

As noted by Wichert et al. (2012), some of these needs may be met by AAL technologies but many of these technologies are still in their infancy. The issue that emerges most often with PwDs is their difficulty in learning to use new aids, due to their problems with memory, concentration, and understanding instructions. These problems are then followed by others, like difficulties recognising objects or images, issues with verbal expressions, carrying out complex tasks, and psychological and behavioural problems (Wichert et al. 2012).

The research conducted by van der Roest et al. (2009) identified many needs of PwDs, which are currently met. Among these are professional assistance, assistance related to food (e. g. shopping, preparing, composing diet, eating), household activities, or activities related to memory health (coping with memory loss), financial assistance and appropriate care (van der Roest et al. 2009).

The unmet needs are related mostly to areas of information provision about dementia and its care (e. g. little or no available information, unclear printed information), issues related to companionship, psychological distress, and the requirement for more professional help. Higher demand for services were also reported in the areas of mobility, personal care, supervision, or behavioural problems (van der Roest et al. 2009).

Wichert et al. (2012) identified five areas where AAL technologies may be helpful for PwDs. The first is in assuaging the need for assistance. PwDs require compensation of

impairments. Here, technologies may provide PwDs with the necessary support, by way of reminders (Wichert et al. 2012).

The second area where AAL technologies may be helpful for PwDs is in the provision of information. There is high demand among PwDs for information about dementia, and the services available for the care of dementia. PwDs also require information about their personal condition (Wichert et al. 2012).

The need for social contacts forms the third area of need of PwDs, where technology may prove to be helpful, by keeping PwDs in contact with their social environment (Wichert et al. 2012).

The fourth area is the need for health monitoring, mainly for two reasons: to review the progression of the disease, and, more importantly, for safety reasons for the PwD (Wichert et al. 2012).

Finally, the fifth area in which PwDs have expressed specific needs is the support and monitoring of daytime activities. Although the monitoring of daytime activities was found to be less helpful for PwDs (van der Roest et al. 2009), the importance of relaxing or doing something useful was identified as a need of PwDs (Wichert et al. 2012).

CAREGIVERS

Alongside the needs of the PwDs, also the needs of the carers have to be considered. Carers are a group of people who spend most of their time with PwDs, and who often they have the greatest interest in providing the best care for PwDs.

Caregiver's needs are usually identified in the improvement and support of caregivers well-being (e. g. social, emotional, and information support), relieving of the caregiving burden (e. g. stress, tiredness, improving care work; Topo 2009).

However, Jennifer Bray et al. (2015) note that the understanding of needs of *informal* carers is often unknown. For this purpose, they developed a caregiver-passport, to complement the patient-passport (containing the recorded wishes of the PwD). These passports contain information regarding how informal caregivers wish to be involved in the assistance and care of a PwD (Jennifer Bray et al. 2015).

It has been reported that both the needs of informal caregivers and those of PwDs are met in the area of household activities, finances, or food preparation and provision. However, informal caregivers identified unmet needs for sufficient memory support, support in daytime activities, and companionship for the PwDs (van der Roest et al. 2009).

Informal caregivers on average reported more needs in total than PwDs themselves. Higher levels of unmet needs were reported by professional (*formal*) caregivers, especially when they had to provide care to a PwD with non-Alzheimer's dementia, and when they were highly burdened (based on subjective feelings of being burdened; in respect of low income; being at the early stages of the career; or caring about a person

with severe dementia). Formal carers also reported more unmet needs if they did not share the household with the PwD and in cases of severe dementia (van der Roest et al. 2009).

Low levels of agreement are usually reached between PwDs and their carers on issues of personal needs, accidental self-harm, abuse, or neglect. The best agreements between PwDs and their carers are achieved in physical domains. Most of the unmet needs reported by carers involve the lack of available services, or their distance, and their high costs (van der Roest et al. 2009).

What needs to be particularly emphasised, according to van der Roest et al. (2009), is the fact that the perspectives of both the PwDs and their carers need to be taken into account. This is true, not only for services and information available to the PwDs and their carers in general, but also for AAL technologies. For the successful development of AAL technologies, both the user-needs of the PwDs and their (informal and formal) carers need to be addressed. This poses specific technical and ethical challenges for the R&D and clinical application of AAL technologies. All these challenges can be addressed and put into the perspective, based on the requirements of Art. 4: the maximisation of benefit and minimisation of harm. It is meaningless to only maximise the benefit for PwDs, without maximising the benefit for their informal carers at the same time. Similarly, minimising risks for only PwDs would miss its full purpose if those risks were not also minimised for their respective informal and formal carers.

4.3.2.2 *Health Technology Assessment*

One of the approaches for evaluating the benefits and harms of health technologies[12] is Health Technology Assessment (HTA). HTA emerged as a reaction to the need for closer evaluation of biomedical developments and their justification, before these costly medical technologies and procedures are introduced into clinical practice (*Development of Medical Technology: Opportunities for Assessment* 1976).

Since its early days in 1970s, HTA has involved ethical analysis, along with cost evaluations. Various international and national networks and agencies employ HTA, such as the International Network of Agencies for Health Technology Assessment (INAHTA), the Health Technology Assessment international (HTAi), and the European network for Health Technology Assessment (EUnetHTA; B. Hofmann et al. 2014).

HTA is also used for the evaluation of the role of ICT in healthcare. A HTA model for assessing the effects and consequences of telemedicine was developed as a part of the EUnetHTA project by Kidholm et al. (2012).

12 Health technology is defined as "[a]n intervention that may be used to promote health, to prevent, diagnose or treat acute or chronic disease, or for rehabilitation" (*HTA Glossary* 2015). These include pharmaceuticals, devices, procedures, and organisational systems that are being used in healthcare (*HTA Glossary* 2015).

In relation to Art. 4 of the UDBHR, HTA using the Socratic approach may be interesting. It has been argued that many health technologies are not afflicted by the issues of human dignity, the persons' integrity, and human rights. Therefore, a revised list of the Socratic approach for HTA has been proposed (B. Hofmann et al. 2014). This not only reflects the ethically relevant benefits and harms of the technology (in question 8) but also assesses the challenges that technology may pose to the patient's autonomy, integrity, privacy, dignity, and human rights (question 5; B. Hofmann et al. 2014).

HTA tools, such as the aforementioned Socratic approach (B. Hofmann et al. 2014) or the Swedish Council on Health Technology Assessment (SBU) approach (Heintz et al. 2015), may also be valuable in assessing the risks and benefits of AAL technologies in relation to the care of PwDs.

4.3.2.3 *Doom Scenarios*

The literature review (Chapter 3) noted the criticism of AAL technologies regarding the value of their care, voiced by R. Sparrow and L. Sparrow (2006), Vallor (2011), and A. Sharkey and N. Sharkey (2012). These are identified as the instrumentalisation of care, which is introduced by AAL when it dehumanises the caregiving process, resulting in the objectification of the PwDs (Novitzky et al. 2015).

Coeckelbergh (2015a) recently provided valuable insights about the value of ICT in elderly care, which may also be extended to AAL technologies. He identifies in publications of R. Sparrow and L. Sparrow (2006) and A. Sharkey and N. Sharkey (2012) three elements, which address the above-mentioned criticism. These doom scenarios, as Coeckelbergh (2015a) calls them, are based on the following assumptions: deception is always morally unacceptable; ICT inevitably creates a 'virtual' world as opposed to the 'real' world; and that future generations of the elderly population will have the same low levels of ICT skills as the present one.

ACCEPTABLE DECEPTION IN HEALTHCARE

Coeckelbergh (2015a) refers to the article, also cited in the literature review in Chapter 3, of R. Sparrow and L. Sparrow (2006) that argues that good clinical care for the elderly is incompatible with any attempt to deceive. R. Sparrow and L. Sparrow (2006) further argue that the elderly should not be left in the hands of machines because good care is characterised by human care. Without the companionship of humans in the caregiving process, the elderly are not being provided quality care (R. Sparrow and L. Sparrow 2006).

According to Coeckelbergh (2015a), from the ethical point of view, this need not to be necessarily so. Good care, in his view, may involve deception. The duty to respect the persons' autonomy in healthcare may be defined as a *prima facie* duty. However, caregivers

often have to cope with the phenomenon that not all elderly persons are necessarily fully autonomous. Proper care for their condition may therefore involve enhancing their sense of autonomy, by convincing them that they are still capable of doing things, despite their cognitive impairments. This may be accomplished by setting up an illusion for them that they are fully autonomous, despite the fact that they are not. This approach is however, severely conditioned. According to Coeckelbergh (2015a), deception may be legitimate in relation to persons who have lost their autonomy due to their cognitive impairment, if such deception enhances their overall quality of life (Coeckelbergh 2015a).

Coeckelbergh (2015a) argues that the provision of the illusion of full autonomy with ICT may be one of the possible modes of treatment for elderly persons with compromised autonomy, if caregivers, family members, and other relevant persons involved in the caregiving process agree upon its beneficial effect. However, due to the fact that every form of paternalism is morally questionable, such an 'enhancement' should be introduced carefully and in small doses (Coeckelbergh 2015a).[13]

Behind the criticism of R. Sparrow and L. Sparrow (2006) based on the fear of deception in relation of dementia care with ICT may lie the phenomenon of disengagement, as Coeckelbergh (2015a) calls it. The caregivers, due to the ever increasing involvement of social robots, may feel disengaged from the caregiving process. This may manifest in the loss of meaningful relations, and the loss of connection with the concrete, bodily, and material realities that are involved in care. ICT devices may contribute to an atmosphere that caregivers already find burdensome, including aspects such as the overall speed of modern care, oriented to improve efficiency and cost-optimisations. As a result, PwDs may not receive the necessary amounts of attention, care, respect, and dignity that they deserve (Coeckelbergh 2015a).

Coeckelbergh (2015a), in response to these admonishments, emphasises that using the word 'deception' in relation of care with ICT is too strong. He distinguishes between the intention to deceive and 'pretend,' the latter describing the ICT action. Technology, in his view, does not deceive us but rather is an integral part of our lives; we interact and play with it. Just as prohibiting children from ICT would confine their world to a non-technological one, similarly, the limitation of ICT devices in care may prohibit PwDs from maintaining (or developing alternative) capabilities. Finally, if deception by ICT is a serious issue, then it is not constrained to the area of care but to every area of human life where ICT plays a role, and consequently would need to be addressed at that level (Coeckelbergh 2015a).

13 An additional issue may be raised in this regard, namely, the question of whether PwDs retain any social obligations to family to stay 'authentic,' meaning, authentic in coping with their cognitive impairment? The communication of informal caregivers, friends, or other family members with the deceived PwD may run ashore due to the inability to have more or less meaningful discussion about shared experiences. The AAL may provide the PwDs with experiences that the informal caregivers have not shared.

ICT AS THE 'VIRTUAL' WORLD

R. Sparrow and L. Sparrow (2006) also claim that the caregiving process should be based on realities of the real world, not on utopian/dystopian goals of some 'virtual' reality. Coeckelbergh (2015a) disregards this criticism as a narrow and dualistic interpretation of our world. The dichotomy, even if it were true, between the real world of human care and the virtual world of things fake, deceptive and illusory is too simplistic. Modern lives accompanied with ICT are already hybrid. People today live both offline and online lives, and the ever increasing issues of separating these two lives from each other demonstrate the complexity and the uneasiness of categorising the latter as something virtual and unreal. When using ICT, the user does not leave the real world; ICT remains the part of one's presence, existence, and embodiment. Moreover, ICT is still connected to our materiality. Just as our minds do not disconnect from our bodies by using material technologies, it follows that the disconnection of our bodies from our minds also does not happen when we use ICT. Additionally, ICT is social because it enables real social interaction. The only difference that ICT introduces into our lives is that most of the activities we used to perform on our own we now perform with a mediation of technology (Coeckelbergh 2015a).

Analogously, ICT-mediated care is not an unreal care. It is a different form of care (Coeckelbergh 2015a).

ICT-mediated care, moreover, demands special skills from its users. Such a skilled engagement with ICT enables the users to be more social with the prospect of developing other new skills. From this viewpoint, ICT may be characterised as an opportunity to develop novel approaches to (re-)engagement. This interpretation opens up new horizons for its user: it may empower engagement in different ways, even by developing new skills, or maintaining existing skills; it may render the users' lives meaningful by providing new opportunities, challenges, and incentives; and may contravene the disengagement of its user from activities (Coeckelbergh 2015a).

ICT SKILLS OF FUTURE GENERATIONS

The third misguided assumption originates from the interpretation of persons' capabilities as something independent from ICTs. Coeckelbergh (2015a) argues that these cannot be separated from each other. This would project into the higher computer literacy of the future generations of old persons. Moreover, they will demand the ICT that they have been using their whole lifetime, to stay connected to their peers.[14] Withholding the ICT from a generation, which was socialised with the increased level of ICT use, would lead to greater harm than benefit (Coeckelbergh 2015a).

14 Coeckelbergh remarks that discussions are being held about defining access to the Internet as a human right (Coeckelbergh 2015a).

ICT already left its imprint on our lives; a fact that definitely has normative consequences on how we think about rights, needs, and capabilities related to ICT (Coeckelbergh 2015a). Life with ICT will require, in Coeckelbergh's view, the art of living with vulnerabilities. While ICT will diminish certain risks, other risks will be introduced by ICT. ICT in this regard, only transforms the existential vulnerabilities of humans but it does not eradicate it completely. Thus, the morality of living with other human beings should be accompanied also by the morality of living with ICT (Coeckelbergh 2015b).

ADDITIONAL ISSUES

Besides the issues identified earlier regarding the overall value of ICT services, and AAL technologies in particular, that may expose their negative effect upon persons (also with dementia), there are other more concrete and imminent problems regarding the value of AAL technologies.

Blurring PwDs with the Group of Elderly

Membership of the elderly occurs when a certain age group is reached. According to the definition of the WHO, "[t]he age of 60 or 65, roughly equivalent to retirement ages in most developed countries, is said to be the beginning of old age" (*Definition of an older or elderly person* 2015).

PwDs, however, by definition have to exhibit specific symptoms that are characteristic to the syndrome linked with dementia (cf. the definition of dementia in Chapter 2). It is a clinical condition, which no longer includes age in its definition. Indeed, the elimination of age as a criterion in order to separate AD from senile dementia is considered to be one of the most important developments that has emerged from the scientific research (P. Fox 1989).

Unfortunately, this distinction is less rigorous in the context of the R&D of AAL technologies for PwDs. Numerous articles identify the applicability of AAL technologies for both the elderly and PwDs (e. g. Benoit et al. 2015; Mahoney et al. 2007; F. J. M. Meiland et al. 2014; B. Mittelstadt et al. 2011; Mok et al. 2014; van der Roest et al. 2009, and others). It may be argued that AAL technologies aim to fulfil the needs of both of these groups. This claim may be accurate in terms of providing increased levels of safety, security, and other forms of assistance. Nevertheless, many conditions of PwDs are specific to the diagnosis of dementia, which an average elderly person would not have. A typical elderly person may therefore not need to use certain AAL technologies (e. g. monitoring of wandering, extensive use of reminders, or recording of ADLs).

This differentiation between the elderly and PwDs is not based solely on the distinguished and specific user-needs. The vulnerability of PwDs, based on their MCI, requires higher than average standards and functionalities of service provision from AAL devices. For example, AAL technologies for PwDs should not increase the anxiety levels

of the PwDs. Increased vulnerabilities of PwDs impose higher risks of harms due to technology, which makes the requirement formulated in Art. 4 of the UDBHR to minimise harm and maximise benefit more important.

The distinction between the PwDs and the general elderly population in relation of the requirements of Art. 4 also has consequences on the distribution of AAL technologies. While the elderly may themselves recognise their need for an assisting device and actively seek it out, PwDs may not be aware of their need. Moreover, AAL technologies for PwDs must be introduced based on the recommendation of a physician. This poses a much higher demand on the adaptability and personalisation of AAL technologies, meeting much more specific needs of PwDs, who may have less capabilities than the elderly in general. The services offered by AAL technologies will not end simply at their deployment into the living environment of the PwD but they will need to be further fine-tuned, to reflect the specific needs of PwD concerned. Similarly, PwDs in nursing homes would require different functionalities and services from AAL technologies than PwDs living in their home dwellings, either alone or in companion with their families, and/or spouses.

Therefore, it would be beneficial for future R&D of AAL technologies to separate the functionalities and aims of technologies to those aimed at the general elderly population, and those aimed at achieving the high requirements of care for PwDs. This would reflect the historical development of the definition of dementia, namely that dementia is not a simple condition of ageing (Katzman 1976), and be more precise in accordance with it.

Lack of Justification of Research with PwDs

A clearer distinction between the goals of AAL technologies aimed at the elderly in general and PwDs as users would also be beneficial for the performance of further research in the field of dementia. It has been noted by Joost van Hoof, Wouters, et al. (2011) that behind the lack of success during the introduction of home automation systems in the early days was its focus on the persons demanding care (Joost van Hoof, Wouters, et al. 2011 who, in this regard, refers to the Dutch report of The Netherlands Institute for Telemedicine; Nispen 2004). The Dutch pilot projects often ignored the negative connotations that were linked with these technologies. Not only that, they were also usually labelled as 'grey,' 'old,' or 'elderly' technologies. The users also showed lower willingness for using these technologies. In the view of Nispen (2004), the focus of home automation systems should be shifted to younger generations in oder to achieve greater success with their application for older persons (Joost van Hoof, Wouters, et al. 2011).

However, there is a problem behind such a paradigm shift. The most obvious one is that great amount of research resources has been invested into the R&D of AAL technologies. If the focus of research with PwDs were to be shifted to achieve greater

success of AAL technologies for the elderly in general, the involvement of a vulnerable population in the research would be unjustified. It would mean that the aspirational benefits defined in the research project proposals were mistakenly granted. It would also mean that the exposure of PwDs as research participants during these research studies to possible harms were greater than minimal.

It may be argued that the harms encountered by the PwDs involved were not greater than those of an average user of ICT devices, or those that PwDs would have experienced anyway. However, evidence from various publications of different research projects suggest that this might not be the case. As highlighted in the literature review (Chapter 3), high levels of malfunctioning functionalities (Joost van Hoof, Kort, et al. 2007 citing Bronswijk et al. 2005), false alarms (J. van Hoof et al. 2011), the ICT's 'life on its own' (Portet et al. 2011), and other experiences that raised PwDs' anxiety levels were reported. If the results of these research studies were to be applied purely for the benefit of the general public, relegating the interests and benefits of PwDs to a lower level, the risk-benefit assessment of these research studies would need to be *ex post* reviewed. In fact, an additional review of the already approved and conducted research studies is unlikely to occur. However, it may be argued that the application of research results, obtained by the participation of PwDs exposing them to risks of harms, to a different target group than PwDs would also endanger the ethical approval of future research studies of AAL technologies involving PwDs as participants. Any future study that would refer purely to aspirational benefits should be deemed as scientifically unfounded. The consequence would then result in an even greater harm upon the growing group of PwDs, who prefer to stay longer in their homes instead of being institutionalised in nursing homes in the form of lack of approved research studies.

A proper differentiation between the groups of general elderly population and PwDs would also be beneficial to circumvent the adverse application of research results obtained with the participation of PwDs to the general population. A research study focusing on the needs of PwDs should focus solely on the benefits of PwDs. Consequently, research studies aiming to develop assistive technologies for the greater elderly population should be clearly distinguished from those aimed towards PwDs. Blurring the differences of these two groups would not only lead to confusing results but also to the lack of proper justification for conducting research with the involvement of PwDs.

4.4 BALANCING OF PRINCIPLES

4.4.1 *Principles Conflicting with Article 4*

Two possible conflicts between Art. 4 and other articles of the UDBHR may be identified. Conflict may arise between the respect for autonomy required by Art. 5 and the

requirement of providing direct and indirect benefits that should be maximised while the risks should be minimised in Art. 4. An additional conflict may also arise between the requirement of advancing scientific knowledge of Art. 14, and Art. 4 on maximising direct and indirect benefits, while minimising the possible harms.

4.4.1.1 *Conflict with Article 5*

A conflict of may arise between Art. 4 and Art. 5 of the UDBHR, when a patient demands a treatment before harms have been minimised, or willingly obstructs the attempt of the physician to minimise the harms (e. g. by not giving up behaviour that increase the likelihood of harms, non-compliant patients). However, the phrasing of Art. 5 does not prioritise the autonomy of any of the involved stakeholders. It only states that the autonomy of those making the decisions should be respected. In this regard, both decisions can be respected on the same grounds. The decision of the patient to act in a way that increases the possibility of harms is respected as equal to the decision of the physician to not treat the patient because of her conduct. Moreover, Art. 5 also requires that the decision-making parties take responsibility for their decisions, a condition which, in this regard, favours the physician not to expose the patient or participant to even greater risks than she is exposing herself already.

4.4.1.2 *Conflict with Article 14*

As noted in Macklin (2005), the responsibilities of researchers to advance scientific knowledge through the promotion of health defined in Art. 14 may conflict with the requirement of Art. 4 for maximising direct and indirect benefits, and minimising harms. The conflict may be characterised by the opposing responsibilities of advancing scientific knowledge on one hand, and the minimisation of possible harm acceptable to the research participant on the other hand. To resolve this conflict, Art. 3.2 may be useful. Art. 3.2 clearly states that scientific and social interests are second order interests to the interests (and dignity) of the individuals. Therefore, in this respect, the minimisation of harms for the research participants has priority over the advancement of scientific knowledge.

4.5 SUMMARY

In applying Art. 4 of the UDBHR on maximisation of direct and indirect benefits, while minimising the possible harms during the application and advancement of scientific knowledge, medical practice, and associated technologies for the care of PwDs using AAL technologies, the following recommendations can be made:

- The deep roots in the concept of respecting the PwDs' human dignity and basic human rights of Art. 4 requires not only the maximisation of the direct and indirect benefits and minimisation of possible harms of PwDs during medical treatments and research activities. Art. 4 also requires the maximisation of direct and indirect benefits during the R&D and application of medical technologies, including AAL technologies.

- Every health intervention for PwDs may, besides aiming for some benefit, carry a risk of causing some harm. Physicians and researchers are obliged to appropriately inform the PwDs about the possible benefits and risks of the intervention.

- Health benefits, according to the definition of health by WHO, involve the amelioration of disease and infirmity, as well as benefits that improve the physical, mental, and social well-being of the PwD. This is in accordance with the definition of dementia given by Hope et al. (2009).[15] Therefore, the benefits of AAL technologies should not focus solely on the mental well-being of PwDs but should provide support for the physical and social needs of PwDs.

- The assessment of health benefits should not be made employing a single quantitative criterion. Such an assessment carries inherent risks of misconceived benefits and risks of PwDs. It is beneficial to extend the assessment of health benefits and risks of PwDs to also include qualitative evaluations.

- The needs of scientific research should not supersede the dignity and human rights of PwDs.

- The highest level in the assessment of research benefits for PwDs are direct health benefits, followed by collateral (indirect) benefits. The lowest level of benefits in the research with PwDs are aspirational benefits. These levels of benefits should be clearly separated.

- Therapeutic misconception should be eliminated wherever possible. The most common form of therapeutic misconception in a research proposal is the dressing up of aspirational benefits as direct health benefits. Research need not necessarily involve any benefits for the PwDs, which must be clearly and honestly stated.

- Any claim of potential benefit from a research study involving PwDs should be thoroughly examined, and its nature, magnitude, and likelihood clearly identified. Whenever possible, for a clear conceptualisation of the likelihood of potential benefits, it is recommended that they be quantified in percentages.

15 (Cf. section 2.1.2.3, p. 26).

- A reasonable chance of benefiting in a research study does not automatically mean that is would be reasonable to participate and unreasonable not to join up the study. Both decisions, to accept or reject an offer to participate in a research study, made by a PwD (or her legal representative) might constitute a reasonable choice by that person. Such a choice should not automatically lead to questions about the competency of PwD, nor should be such a decision be overruled by the decision of the researchers.

- Health technology may negatively impact the medical judgements of physicians and/or informal caregivers about the PwD. Overemphasis on data provided by the health technology may result in the overriding of other information, particularly that from the PwD herself. This may lead to harm, which could undermine the trust between caregivers and PwDs. Therefore, healthcare professionals should not rely solely on the data provided by health technology but should also link the data with the feedback from the PwD, which would enhance trust between the PwD and the caregivers/physicians.

- Doing more with health technology need not necessarily mean it is better than doing less; a newer health technology need not necessarily mean it is better than the old technology; and more advanced technology need not necessarily mean it is more beneficial than the simple one. Health technology should be designed and provided to fulfil the needs of PwDs in order to enhance, empower and support them in their everyday activities.

- Physicians and caregivers should not make decisions based solely upon data from health technology, nor should they be unduly influenced by the push from industry (that doing more is better than doing less, B. M. Hofmann 2015), or by pressure from the patient (that more advanced is better than simple, B. M. Hofmann 2015).

- Technology is not a morally neutral, value-less means. Technology by its introduction to the healthcare of PwDs eliminates certain risks but also produces new vulnerabilities. Therefore, every introduction of AAL technologies should be adequately assessed, whether it fulfils its purpose, and whether it fulfils the needs of the PwD, without introducing more risks than benefits for its user.

- Health technologies, including AAL technologies, should be assessed by regulatory bodies as strictly and by the same level of authority as drugs.

- PwDs should be involved in the design process of AAL technologies from the very beginning of the R&D.

- Although the user-needs of PwDs may be distinct from those of their informal caregivers, they overlap in such a way that renders them inseparable as far as care

for the PwD is concerned, particularly as most caregivers share a dwelling with a PwD that they care for. Therefore, AAL technologies need to be designed to meet not only the user-needs of PwDs but also those of their informal caregivers. AAL technologies should address the general needs that all PwDs have, as well as be customisable to meet specific (personalised) user-needs of individual PwDs.

- The needs of the researchers are not at the same level of priority as the user-needs of PwDs and their informal caregivers. Every implementation of AAL technologies should prioritise the user-needs of PwDs, along with those of their caregivers, before fulfilling the specific needs of researchers.

- The needs of PwDs are different from the needs of the wider general elderly population. These needs should be strictly distinguished and reflected during the R&D of AAL technologies; otherwise, the involvement of PwDs in the development of AAL technologies may lack justification and cause greater harm. PwDs should not be involved in research studies the objectives of which can be achieved with non-vulnerable research participants.

5

SPECIAL VULNERABILITY AND PERSONAL INTEGRITY OF PERSONS WITH DEMENTIA AND AMBIENT ASSISTED LIVING TECHNOLOGIES

In the current chapter, the concept of human vulnerability and personal integrity is examined in relation to Persons with Dementia (PwDs) and Ambient Assisted Living (AAL) technologies. The chapter focuses on addressing the following questions:

1. What does the literature interpreting Art. 8 of the Universal Declaration on Bioethics and Human Rights (UDBHR) say about the concepts of vulnerability and personal integrity, and how should respect for these principles be fulfilled?
2. How is the principle of respecting vulnerability and personal integrity interpreted in policy documents and academic literature?
3. How should Art. 8 of the UDBHR be understood in its application to the circumstances of PwDs and the context of AAL technologies?
4. Which principles of the UDBHR need to be balanced with the principle of respecting vulnerability and personal integrity?

By answering the first question, the notion of vulnerability and the requirement of respect for personal integrity is interpreted in relation with PwDs. This step will utilise the available handbooks and reports that directly interpret the UDBHR principles, with their dedicated sections referring to the principle of vulnerability and respect for personal integrity. This literature mainly includes *The UNESCO Universal Declaration on Bioethics and Human Rights: Background, Principles and Application* (ten Have, Jean, and Kirby 2009), *Handbook of Global Bioethics* (ten Have and Gordijn 2014), *Explanatory Memorandum on UDBHR* (2005), and *The Principle of Respect for Human Vulnerability and Personal Integrity* (IBC 2013).

Addressing the second question this chapter provides an overview of the international and national policy documents, together with notable academic literature relevant for the interpretation of the issue of vulnerability and personal integrity.

In the normative part of this chapter, the previously interpreted UDBHR principles of respecting vulnerability and personal integrity are first specified to the specific context of PwDs and AAL technologies. The specification will focus both on clinical research with PwDs, and clinical practice with PwDs. Secondly, any possible conflicts between Art. 8 and other UDBHR principles are identified, examined, and balanced, utilising the balancing process described in section 1.2.

At the end of this chapter, a dedicated section summarises the results reached with outcomes of the specification and balancing, providing a concise overview of the normative analysis of the requirement to respect the vulnerability and personal integrity of PwDs. This summary will adhere to the spirit of the principle as stipulated in Art. 8 of the UDBHR, applied to the cases of PwDs and AAL technologies.

5.1 INTERPRETATION OF THE PRINCIPLE

5.1.1 *Principle of the UDBHR*

Art. 8 of the UDBHR refers to the requirements of respecting human vulnerability and personal integrity of the persons in biomedicine.

5.1.1.1 *Respect for Human Vulnerability and Personal Integrity*

Article 8

In applying and advancing scientific knowledge, medical practice and associated technologies, human vulnerability should be taken into account. Individuals and groups of special vulnerability should be protected and the personal integrity of such individuals respected.

VULNERABILITY

Art. 8 operates with the notions of vulnerability and personal integrity, which will be explained in detail in this section. Art. 8 also distinguishes between 'human vulnerability' and 'special vulnerability,' which distinction will be also explained in this section.

Etymology of Vulnerability

The etymological background of the concept of vulnerability comes from the Latin word *vulnus, -eris, n.*, which translates as wound, injury, or hurt (Glare 1968). The Latin infinite of the verb, *vulnerare* means to (inflict a) wound (on), or to damage (Glare 1968). Hence vulnerability can be understood as a certain susceptibility to being wounded (Neves 2009).

Approaches to Vulnerability

The definition of vulnerability has not proved to be an easy task for philosophers and researchers. Two main approaches can be identified regarding the definition of vulnerability throughout the academic literature: one, where a definition is provided; and one, where there is no definition provided nor any intention to provide one. The latter tends to provide only a non-exhaustive list of descriptive features of vulnerable groups and populations, instead of exposing itself to criticism by providing a definition. Such a list appeals to the intuition of the reader to evoke an idea of what it means to belong to a vulnerable group.

Defining Vulnerability

Those who have contributed to the definition of vulnerability are mostly international expert bodies and philosophers. In Europe, the partners of the BIOMED II Project advanced "The Barcelona Declaration" to the European Commission in 1998, which defines vulnerable persons as "those whose autonomy or dignity or integrity is capable of being threatened" (Kemp and Rendtorff 2009, p. 248; Rendtorff 2002, p. 243; for further information see Rendtorff and Kemp 2000a; Rendtorff and Kemp 2000b). Council for International Organizations of Medical Sciences (CIOMS) in cooperation with World Health Organization (WHO) in 2002, defined vulnerable persons as those "who are relatively (or absolutely) incapable of protecting their own interests [...] they may have insufficient power, intelligence, education, resources, strength, or other needed attributes to protect their own interests" (CIOMS 2002, Guideline 13). Finally, the World Medical Association (WMA) in the *Declaration of Helsinki* (2008) describe particularly vulnerable groups as "those who cannot give or refuse consent for themselves and those who may be vulnerable to coercion or undue influence" (*Declaration of Helsinki* 2008, Art. 9). Interestingly, this definition can no longer be found in the updated "Declaration of Helsinki" (2013). In summary, these documents define vulnerable persons as those persons, whose autonomy, dignity, and integrity is threatened due to various circumstances, which renders them unable to protect their own interests, and thus leaves them unprotected from coercion or undue influence.

Philosophers also provide definitions of vulnerability. For Emmanuel Levinas (1906–1995), vulnerability was equal to one's subjectivity. According to his understanding, the self always comes after the otherness because the self is always in relation with the other human being.[1] Levinas therefore interprets vulnerability as an intrinsic state of the human,[2] as well as the universal condition of humanity (Neves 2009).

1 Kottow (2005) translates from Levinas (1972): "vulnerability is the obsession for the other or the approximation of the other" (Kottow 2005, p. 283).

2 "The I, from head to foot and to the bone-marrow, is vulnerability" (Kottow 2005, p. 283).

Hans Jonas (1903–1993) attempted to define vulnerability based on ontological and natural terms, in his book *Das Prinzip Verantwortung* (Jonas 1979). Being vulnerable is a perishable characteristic of anything that exists, and consequently extending this perishable reality to the whole of nature (Neves 2009).

As a result of these philosophical investigations about the definition and nature of vulnerability, Neves (2009) herself defines vulnerability as a "human condition, inherent to existence in its radical finitude and fragility, so that it cannot be eliminated or surpassed. It requires the care of others, the responsibility and solidarity of others in the recognition and non-exploitation of that condition" (Neves 2009, p. 158). Other attempts at defining vulnerability from a philosophical perspective include definitions from political philosophy,[3] or anthropology.[4]

As well as the multiple approaches to vulnerability, the interpretation of it as a concept demonstrates great variety. Philosophers, like Thomas Hobbes (1558–1679),[5] John Stuart Mill (1806–1873),[6] Robert Nozick (1938–2002),[7] Alasdair MacIntyre (1929–),[8] and many others, have tried to provide their readers with a specific interpretation about the concept of vulnerability and what it consists of.

The concept of vulnerability was introduced into the field of bioethics alongside issues related to human experimentation. Particular sections of various populations have been defined as exposed to and unsatisfactorily protected against the maltreatment and abuse of others. These populations, based on historical circumstances, were identified as: institutionalised groups like orphans, prisoners, elderly; and Jews, Chinese, and other ethnic groups during World War II. The noun of vulnerable persons was later expanded to include populations such as ethnic minorities, socially unprivileged groups, or women (Neves 2009).

During the development of the concept of vulnerability within bioethics, two major interpretations were formed. One interpretation reflects the approach of philosophers

3 Zion et al. (2000) define vulnerability as a genuine lack of basic rights and liberties that make vulnerable populations particularly open to exploitation (Zion et al. 2000).

4 According to the care ethicist, Nel Noddings, "[w]hen citizens are defined by race, gender, adult rationality, and/or economic status, those who do not fit the definition become vulnerable" (Noddings 2002, p. 441).

5 Hobbes, in his book, *Leviathan*, defines the reason for people establishing the institute of the commonwealth as one founded on the premise: "to live peaceable amongst themselves, and to be protected against other men" (Hobbes 1998, p. 115). Hobbes ascribes the universal vulnerability of every person, and the role of the State as that of serving a protective function (Kottow 2005).

6 Mill, in his classic essay, *On Liberty* (Mill 2003), defends the protective role of the State, by stating: "the only purpose for which power can be rightfully exercised over any member of a civilised community, against his will, is to prevent harm to others" (Mill 2003, p. 94).

7 Nozick, being a libertarian philosopher who favoured the minimal night-watchmen state argues: "The state has means for the suppression of what the society considers to be wrongs or crimes: police, courts of law, prisons, institutions which explicitly and specifically function in this area of activity. Moreover, these institutions are stable within the frame of reference of the society, and permanent" (Nozick 1974, p. 116).

8 From his virtue ethics perspective, MacIntyre deals with vulnerability as part of the general human condition, which presents challenges and obstacles that are common to all and which can therefore ultimately enrich the development of each person's ability to recognise goods and reason independently (MacIntyre 1999, pp. 71–72; Kottow 2005).

mentioned above, that of the universal vulnerability of every human being. The other interpretation reflects the approach taken by International Bioethics Committee (IBC) in mentioning special vulnerabilities. The latter interpretation can be defined as an Anglo-American circumstantial interpretation, which ascribes adjectival function to vulnerability by qualifying groups or persons who are vulnerable, thereby limiting the definition and thus also the scope of inclusion of such groups. Vulnerability in this sense is contingent and only temporary, and is being used as a factor of differentiation (and potentially positive or negative discrimination). The Anglo-American approach is concerned mostly with issues related to human experimentation, which require high respect of principles of autonomy and informed consent. The former interpretation is referred to as the European theme-like interpretation, where vulnerability has a noun-function, characterising a genuine reality common to every human being in its broader meaning. In this sense, vulnerability is a universal and indelible condition, referring to the anthropological perspective of the foundation of ethics. Vulnerability therefore provides a rather equalising factor. The European interpretation of vulnerability is thus concerned mostly with clinical assistance and healthcare policies, which pose a high demand on the principles of responsibility and solidarity (Neves 2009). According to Neves 2009, both of these meanings of vulnerability are effectively incorporated into the Art. 8 of UDBHR.

The justification of defining vulnerable groups in biomedical ethics is based on the reason to reinforce the principle of autonomy. Autonomy is a capacity common to all persons, who hold certain world-views, make choices, and take actions based on personal values or beliefs. A continuous referral to the principle of autonomy creates not only effective conditions for liberty but also enables, encourages, and supports the person's autonomous acts as a moral agent (Neves 2009, referring to Beauchamp and Childress 2009, p. 100). The reinforcement of this principle of respecting one's autonomy is achieved by demanding the fulfilment of the requirements of informed consent (Neves 2009).

The differences between the Anglo-American and European interpretations of vulnerability can be useful in the categorisation of the concept of vulnerability. A key differentiator in the definition of vulnerability is in its transience. Vulnerability in this sense can be categorised either as a universal and inherent condition, or as a transient and contextual one (S. A. M. McLean 2014).

Another differentiator in the categorisation of vulnerability is based on the proactivity required in relation to it. In this sense, vulnerability is related *to* a specific threat. From this perspective, vulnerability transforms from a passive notion to an active one. Vulnerability, as an active notion, is then affected by different political systems, as well as by socioeconomic and health-related circumstances. As a result, one becomes vulnerable *to* disrespect, discrimination, and ultimately, lack of agency (S. A. M. McLean 2014). Con-

versely, vulnerability in a general sense may not require an active response to a specific threat.

Another differentiating factor, noted earlier, is that of traditional categorisation based on group characteristics. This is based mostly on the grounds of historical or contemporary realities. The potential downside of such a categorisation lies in the somewhat controversial overgeneralisation of discrete groups into being necessarily vulnerable, for example, children, pregnant women, females in general, and the elderly. S. A. M. McLean (2014) thus emphasises that the protections triggered by the status of being vulnerable should to be targeted, and should not be based solely on the grounds of a membership to a particular group (S. A. M. McLean 2014).

This categorisation of people based on group membership is problematic at the theoretical level (i. e. issues related with the definition of the concept itself) and the practical level. Defining who should be afforded protection because of a particular vulnerability is extremely complicated, as is the determination of the form such protection should take (Hurst 2008; S. A. M. McLean 2014). This critique is even more apparent when one considers Macklin's proposal for extending vulnerable groups to include whole communities and countries that may be exposed to exploitation and double standards in research (Macklin 2003; S. A. M. McLean 2014).

Not Defining Vulnerability

Some international and national expert bodies provide descriptive characteristics of vulnerable persons, groups, or populations, rather than particular definitions of vulnerability. From these characteristics, one is able to extend the attribute of vulnerability to other persons or groups by analogy. Examples of the formulation of vulnerability by listing specific groups and populations are included in the *Belmont Report* (1978), Hope et al. (2009), and IBC (2013).

The *Belmont Report* (1978), the first official document linked with medical ethics using this term, is discussed later in section 5.2.1.4 (p. 150).

The report *Dementia: ethical issues* (Hope et al. 2009) issued by the Nuffield Council on Bioethics describes the vulnerability of PwDs in relation to their declining capacity, sense of loss, fear of social embarrassment, and anxiety of being a burden for their relatives in the future. PwDs experience vulnerability in terms of their physical decline and general frailty but also through discrimination and stigmatisation. Their real vulnerabilities that manifest in memory problems and feeling of disorientation are followed by fears of neglect and abuse (Hope et al. 2009). The Report also associates the vulnerability of PwDs pejoratively with dependence. The Report's vocabulary utilises attributes like potential vulnerability, inherent vulnerability, potential high vulnerability, and particular vulnerability, in relation to the vulnerable condition of PwDs, without providing a direct definition about the nature and conditions of such a state (Hope et al. 2009).

The IBC Report on vulnerability (IBC 2013) also provides examples and a non-exhaustive list of situations for the description of vulnerability. The ultimate reason for not providing a particular definition of the concept of vulnerability is justified by the fact that any definition would either depict the concept too widely or too narrowly. As a result, it would only trigger disputes rather than resolve them (IBC 2013). Furthermore, according to S. A. M. McLean (2014), vulnerability is easy to recognise when it occurs because it is an essential feature of human nature.

By avoiding the definition of the concept of vulnerability, the Report of IBC (IBC 2013) provides a rather practical template for the implementation of Art. 8 of UDBHR, by focusing more on the outcomes than the definition (S. A. M. McLean 2014). The analysis given in the Report is neither exhaustive, nor prescriptive. Its examples extend to cases of people suffering from HIV/AIDS; impoverished people involved in clinical trials that fail to respect free and informed consent; and people disregarded in trials for the sake of profit. Additionally, IBC provides special attention to the gender-related vulnerabilities of women. The Report's examples in their case depends on the fact that women usually live longer; elderly women may find themselves abandoned by their families; they may be subject to inadequate healthcare; or disregarded by society (IBC 2013).

The IBC Report on vulnerability connects respect for personal integrity with the recognition of vulnerabilities, thus reinforcing the active need to protect vulnerable individuals and groups (IBC 2013; S. A. M. McLean 2014). Art. 8 of the UDBHR provides both negative and positive moral duties. The negative duties are the respect for human vulnerabilities and personal integrity of individuals. The positive duties necessitate the application and advancement of scientific knowledge, medical practice and associated technologies in order to protect individuals and groups with special vulnerabilities (IBC 2013).

According to the IBC, Art. 8 of the UDBHR requires an interpretative perspective, where the ultimate goal of scientific progress in compliance with bioethical standards cannot be solely based on profit. By underscoring the importance of other related principles (e. g. autonomy, beneficence, justice, dignity, equality, etc.) and enhancing the value of solidarity instead of sole individual interests, the concept of vulnerability might provide a bridge over the damaging gap between moral strangers, and pluralistic societies (IBC 2013).

Special Vulnerability

The IBC focuses its attention on special vulnerability in Art. 8, especially the scope and content of special vulnerability. The focus on special vulnerabilities takes into account conditions that undermine one's capacity to live as a free and autonomous individual. The attention paid towards special vulnerabilities reinforces the genuine right of every human being to live in the world, where, despite the breadth of significant inequalities,

everybody's basic needs are taken into consideration. Therefore, the purpose of the IBC Report on Art. 8 of UDBHR was to boost awareness of the various responsibilities of the States. These responsibilities apply to both domestic and international levels. The Report focusing on Art. 8 also demands the exercise of vigilance in the protection of well-being of individuals and groups in all sectors of the society (IBC 2013).

Although the approach of not providing a definition for the concept of vulnerability exposes the ethical analysis to criticism, Coleman (2009) remarks that the concept of vulnerability, as a general call for providing protection, has an "intuitive ethical appeal" and is unlikely to vanish (Coleman 2009, p. 14). In support of the approach coined by IBC, i. e. not defining the concept of vulnerability, S. A. M. McLean (2014) notes that even as a 'plastic' term, the discussions about vulnerabilities can trigger important protections for individuals (K. Fox 2002; S. A. M. McLean 2014).

Various conditions and situations confer special vulnerabilities, for example, age, disease type, lack of access to healthcare, lack of patient or physician education. Other determinants of special vulnerabilities may be their 'natural' characteristics (e. g. special temporary or chronic disabilities; limitations imposed by the stages of human life); or social, political, and environmental determinants (e. g. culture, economy, relations of power, natural disasters, etc.), which are fundamental matters of justice and basic human rights. Special vulnerabilities, according to the IBC, require special responsibilities (IBC 2013).

PERSONAL INTEGRITY

The other key concept present in Art. 8 is that of personal integrity. The IBC emphasises the close relationship between the state of vulnerability with the condition of violated personal integrity, by being 'touched' (IBC 2013). During such an invasion, one's freedom is hampered, whereby one has no capacity to refuse unwanted exposure to possible violation, harms and disadvantages. The elimination of these threats is at the core of human flourishing and self-fulfilment (IBC 2013).

Etymology of Personal Integrity

The etymological foundation of the word is from the Latin verb, whose infinitive is *tangere*, meaning to make physical contact or to touch (Glare 1968). The related Latin adjective, *integer*, describes a state of not being previously touched, tried or used, and the word, *integritas, -atis, f.*, translates as soundness, wholeness (of the body and mind), purity, and normality (Glare 1968). Neves (2009) describes the noun, integrity, as a "state in which all the parts are maintained and the quality of that which is unaltered, also functioning then as an adjective" (Neves 2009, p. 159).

Interpretations of Personal Integrity in Bioethics

The concept of personal integrity in bioethics currently appears in three variations. The first interpretation of personal integrity is based on the etymological sources of the word, namely, "the quality of that which is unaltered" (Neves 2009, p. 159). Personal integrity understood as wholeness, completeness, or a reference point to some original state is restated in documents like *Belmont Report* (1978), *Convention on Human Rights and Biomedicine* (1997), and Rendtorff and Kemp (2000a). Rendtorff and Kemp (2000a), by listing integrity amongst its four main principles, refer to the European humanist tradition in bioethics by emphasising the fuller and plural sense of personal integrity. This is defined as "an untouchable core, the personal sphere, which should not be subject to external intervention" by reference to the "coherence of life of beings with dignity that should not be touched and destroyed" (Kemp and Rendtorff 2009, p. 248; Rendtorff 2002, pp. 237, 243; Neves 2009, p. 161).

The second interpretation of personal integrity in bioethics is built upon the negative right of non-interference, to which all persons are entitled. Such a right abolishes disrespect from others, along with non-interference of others in the private sphere of the self (Neves 2009). Moreover, respect of personal integrity is integral to the attribution of human rights. Thus, this interpretation provides protection of negative rights, including freedom from discrimination and exploitation (S. A. M. McLean 2014).

The third interpretation of personal integrity in bioethics is based on virtue theory. Personal integrity in this sense is a disposition to act in a certain way, which is attributed to people, who remain unalterable and incorruptible, especially from external influences. This interpretation is reiterated in its common deontological sense in international documents like the *Universal Declaration on the Human Genome and Human Rights* (1997) and the *International Declaration on Human Genetic Data* (2003).

Philosophical Definitions of Personal Integrity

As with vulnerability, philosophers have also contributed to the definition of personal integrity. Maurice Merleau-Ponty (1908–1961), in his book *Phénoménologie de la perception* (Merleau-Ponty 1945), overcomes the traditional Cartesian dualist distinction of body and mind by the notion of incarnate subjectivity (Neves 2009).

Another influential philosopher on the topic of personal integrity is Paul Ricoeur (1913–2005), who in his article, "L'identité narrative" (Ricoeur 1988), examines the hermeneutics of the person by focusing on her narrative identity and history of life, encompassing past experiences, together with future fears and expectations. Ricoeur finds integrity in the totality and oneness of the person, where the coherence of one's life expresses itself in the plurality of dimensions throughout the person's existence (Neves 2009).

Personal Integrity in the Human Rights Tradition

Personal integrity is also guaranteed in *The Universal Declaration of Human Rights* (*UDHR* 1948), where Art. 1 states that every human being is born free and equal in dignity and rights. According to S. A. M. McLean (2014), the meaning of integrity, similarly with dignity, attain form and content from experience and implicit understanding. Art. 1 of *UDHR* (1948) requires that people develop brotherly cooperation through reciprocal respect, equality and solidarity (S. A. M. McLean 2014 quoting Sulmasy 2008).

Personal Integrity in Clinical Practice

Respect for personal integrity demands a new approach to the human body and disease in clinical practice. This means a transition from interpreting the body as an object, to a more subjective perspective of the human body as inseparable from the person. Also, the approach towards disease should be more nuanced and not simplified to an objective phenomenon. It should consider the accumulated reality of the lived body of a person, which has significance in the history of life of the self (Neves 2009).

In clinical practice, ethically sound activity, based on the respect of personal integrity, is entitled through the reinforcement of patients' rights by the healthcare professional. Just as in research, this means establishing symmetrical relationships, or requiring institutions to protect citizens even when no complaints are present (Neves 2009).

Personal Integrity in Research

In research, personal integrity mainly appears as an obligation that provides protection through the requirement of informed consent. However, it also encompasses the prohibition of the objectification of the body. Additionally, the protection of personal integrity is sought in order to enable the forming of a meaningful relationship, and eventually a partnership, between the participant and the researcher. This includes better and new forms of communication, a more focused approach towards the person rather than to her illness, a proactive involvement of the participant, the development of less invasive therapies, and a more respectful approach towards the person (Neves 2009).

In research, personal integrity is protected and autonomy respected by the application of the request for informed consent. None of these safeguards, however, eliminate vulnerability completely. The major violations of personal integrity occur through the exploitation of participants. In practice, such exploitation can take many forms, including presenting trials in an overly optimistic manner, offering (financial or other) incentives, exaggerating biomedical success in mass media, or aggravated medicalisation. Moreover, people also often consent to participate because of false ideas about biomedicine as panacea (Neves 2009).

Personal Integrity in Healthcare Policies

In healthcare policies, respect for personal integrity is interpreted as a general prohibition against the commercialisation of human body parts. It also extends to safeguarding the human genome by regulating human genetic manipulation, and even introducing patents on human matters (Neves 2009).

The protection of personal integrity in healthcare policies should mostly be applied at a social level, both nationally and internationally. The overarching rule in this area should be that the benefit of some people should not be secured by the exploitation of others, especially the weak. When only a minority of people receives the benefits of well-being, others are often excluded, resulting in vulnerable individuals becoming (even) more vulnerable (Neves 2009).

5.1.1.2 *Drafting of Article 8*

The content of Art. 8 was not originally part of any of the preliminary drafts of the UDBHR proposed by the IBC. The principle of respect for vulnerability and personal integrity was proposed and accepted during the 2nd and final Intergovernmental Meeting of Experts in June 2005, preceding the final adoption of the UDBHR (Neves 2009). Hence, the merit of the introduction of the reference to the principle of respecting human vulnerability can be exclusively ascribed to an amendment requested by governmental representatives (Andorno 2007).

For the interpretation of personal integrity in Art. 8, it is important to note that historically, in the early proposal of the principle, its requirements were considered in a restricted sense. In the initial drafts the requirements of the principle were applicable only to the most vulnerable. However, during the drafting process, this restricted interpretation transformed. Hence, personal integrity is represented in Art. 8 in a broader sense. Firstly, it necessitates the consideration of the inherent and universal vulnerability of all human beings. This is fulfilled by not being unnecessarily 'touched' by the other person, e. g. to be subject to diverse and often subtle forms of exploitation, subject to abuse, irrespective of one's level of autonomy. Secondly, it necessitates the prioritisation of groups classified as especially vulnerable. This is facilitated by providing protections against being 'wounded,' by respecting one's personal integrity, and by not being reduced to merely a part of oneself, or being considered too abstractly (Neves 2009).

Neves (2009) emphasises that Art. 8 is listed in the UDBHR after Art. 6, on Consent and Art. 7 on Persons without the capacity to consent, which strongly suggests that Art. 8 is aimed at addressing issues encountered in circumstances when the dignity of the individual is violated by Art. 6 and Art. 7. Moreover, Art. 8 is strongly linked to the Art. 3, on Human dignity and human rights, necessitating respect of the unconditional value of every human being and demanding their inviolability (Neves 2009).

5.1.1.3 *Relevance of Article 8 in Clinical Practice*

In the clinical setting, the respect for vulnerability and personal integrity described in Art. 8 concerns mostly individuals who are sick, especially if they are experiencing pain. The response to pain is usually discomfort, frustration, and potentially severely diminished physical and cognitive abilities. As a result, one's capacity for self-determination can be either limited, or non-existent at all (IBC 2013). Sick people are highly dependent on healthcare, therefore irrespective of the context, every sick person must be deemed vulnerable. The aim of any legislation in the context of vulnerability is to secure the protection of those with limited abilities to self-determine. Such protection should be defined in accordance with the principles of autonomy and personal integrity. Moreover, these laws should aim at redressing the imbalance between the (healthy) healthcare professional and the (sick) patient arising due to differences in knowledge, context, or authority (S. A. M. McLean 2014).

Universal and special vulnerability are also present as two distinct categories within the clinical setting. The first category, termed as 'average vulnerability' (S. A. M. McLean 2014),[9] acknowledges the unique vulnerability of average human beings when subjected to medical care. This vulnerability exposes itself against the backdrop of the greater expertise and social authority of the physicians (IBC 2013).

The second category, known as 'special vulnerability' (S. A. M. McLean 2014),[10] represents a group, to whom the laws provide insufficient protection. Especially vulnerable people are often exposed to systemic disrespect, inadequate funding, and are treated as 'second class citizens' (S. A. M. McLean 2014). According to Kottow (2005), due to their circumstantial deprivation, poverty, disease, and suffering, these people deserve a more specific ethical response. The reason for this response is based in double jeopardy: these people not only suffer from the elevated risk of health problems occurring but also from the greater likelihood of harm, once these problems occur. In addition to average vulnerability, individuals who are injured cease to retain their integrity and are no longer 'only' vulnerable. Thus, the state of being injured should be, according to Kottow (2005), clearly differentiated from universal vulnerability.

SUSCEPTIBILITY AS SPECIAL VULNERABILITY

Kottow (2005) proposes the employment of the term 'susceptibility,' which is clearly differentiated from average vulnerability. In his interpretation, vulnerability, as an essential attribute of mankind, can be reduced by the equal protection of all members of

9 Kottow (2005) calls this type of vulnerability 'essential vulnerability,' while also notes the term 'basic human vulnerability' coined by Onora O'Neill (Kottow 2005).

10 The exact terminology used in S. A. M. McLean (2014) is 'especially vulnerable' (S. A. M. McLean 2014, p. 107). Synonymous terms used in the scholarly literature are 'particularly vulnerable' (Kottow 2003), or as Onora O'Neill describes them: "more deeply, variably and selectively vulnerable" (Kottow 2005, p. 283).

the society under the principle of justice (Kottow 2003; Kottow 2005). Hence, universal vulnerability should be protected by human rights. Related to the principle of justice, human rights, as *in rem* rights should appeal to the community at large, thus possibly compensating for or eliminating vulnerability. Whenever such compensation is insufficient and citizens are susceptible to specific harm, further positive welfare rights should be added to the general human rights (Kottow 2003). This is represented by the term, susceptibility, which applies to specific accidental conditions that are diagnosed and treated. Susceptible individuals already suffered harm: they are no longer intact and have fallen from a state of integrity to one of damaged individuality, and are even therefore more vulnerable to further injury (Kottow 2005). This process of destitution can be reduced or neutralised by the effective and active application of measures that are specifically targeted against such destitution. This elimination of susceptibility should be the goal of positive *in personam* rights, which should be based on the principle of non-maleficence (Kottow 2003).

Blurring the distinction between average vulnerability and susceptibility is a dangerous euphemism. Kottow (2003) states that whenever the correct distinction between the vulnerable and susceptible is ignored, society then fails to address the indifference and neglect of others. This usually happens when the aged, the poor, women, ethnic minorities, etc., are wrongly labelled as vulnerable because they are left destitute and discriminated against, without the opportunity to address their own specific susceptibilities (Kottow 2003).

In conclusion, it is important to emphasise that from the phrasing of Art. 8, it is evident that both categories of vulnerability (i. e. average or universally vulnerable; and especially vulnerable, the susceptible) are represented in the UDBHR.

PRINCIPLE OF VULNERABILITY, PERSONAL INTEGRITY AND ITS RELATION TO TECHNOLOGY

A new context relevant for the protection of the vulnerable and respect for personal integrity relates to technologies. New discoveries opened up novel and potent techniques of exploitation (IBC 2013). S. A. M. McLean (2014) provides an example from the field of Artificial Reproductive Technologies (ARTs), where female patients from developing countries were enrolled in treatment on the condition that they also donated their eggs. Such an inclusion criterion may result in situations when the donor remains childless, while the egg recipient and ART company benefit from the donation. The validity of the donors' consent may further be questioned in certain situations: societal expectations and pressure to conform, stigmatisation due to childlessness, failure to achieve the status of a full member of the community if a woman fails to reproduce, unavailability of appropriate technology and treatment. These all render *prima facie* the willingness

to participate problematic, while at the same time open the opportunities for exploitation (S. A. M. McLean 2014).

Due to ARTs, a new vulnerable population may be born, namely, the children themselves. They might carry the psychological burden of being conceived in unconventional ways (e. g. surrogacy arrangements) or to unconventional (e. g. same-sex) couples, and hence stigmatised in their own societies (S. A. M. McLean 2014).

Novel technologies discovered in the field of genetics may produce medical or financial benefits. However, the very possession of genetic information may render people vulnerable, based on which they might be stigmatised and discriminated against by insurance companies, employers, or other groups. The sharing of this information also opens a separate issue. Although at present, technologies in medicine are mostly used for diagnosing, curing, palliating, or to circumvent established medical problems, in the future, technologies may also use the human body as a mere source of information (S. A. M. McLean 2014).

The IBC provides examples for avoiding vulnerability and protecting personal integrity during the use of technologies in cases indicating unfair pressure towards participants for volunteering, premature application of technologies, person's privacy, and stigmatisation (IBC 2013).

5.1.1.4 *Relevance of Article 8 in Research Context*

The second well defined context for the application of the principle of respecting vulnerability and personal integrity is research. The context of research is specific due to the very nature of research activity: to avoid biases, research requires a greater distance between the researcher and the participant than in purely therapeutic situations because in the centre of the activity is not the participant but the aims of the study. This results in a fracture of the beneficent relationship usually observed in clinical practice (S. A. M. McLean 2014).

Special vulnerability in research may exist on the individual level, the level of the quality of information, the socioeconomic level or on other levels specific to the type of research (S. A. M. McLean 2014). Grady (2009) points out that the categorical exclusion of vulnerable research participants at a group-level may be harmful, as it can lead to the cessation of research in a desired therapeutic area (Grady 2009; S. A. M. McLean 2014).[11] Exclusion from research may render people especially vulnerable (S. A. M. McLean 2014), by denying them access or the possible benefits of research (IBC 2013). Moreover, such exclusion may ultimately weaken the results of the research study (Grady 2009).

11 As an example of such a case serves the infamous thalidomide scandal. The drug, thalidomide, was prescribed off-label to pregnant women in the 1950s and 60s to fight morning sickness. However, the drug had very serious adverse side-effects (limb deformations, etc.) on the babies (McBride 1961). As a result of this controversy, the pharmaceutical industries pulled out completely from the research of drugs for pregnant women (S. A. M. McLean 2014).

The IBC lists further situations that can put research participants into especially vulnerable positions. Among these is the absence of the physician's general focus on restoring the patient's health. Also, the interests of the researcher and the participant may not to always be in accord, which may result in a tendency to under-protect the participant or foster ignorance of the participant's well-being (IBC 2013).

The vulnerability of research participants is not necessarily caused by the abovementioned direct circumstances. They may also emerge indirectly, in the form of certain pressures. These less salient pressures may lead individuals to act in a manner, which may potentially compete with their interests. An application of pressure may occur, for example, when a developed country is performing a research in a developing country. Another indirect pressure may occur when exploiting the socio-political vulnerability of the participants. Researchers may also render participants especially vulnerable by the abuse with therapeutic misconception (IBC 2013). Due to the possibilities of indirect pressures being exerted upon research participants, the guideline of CIOMS explicitly requires special justifications for the invitation of especially vulnerable individuals into research (CIOMS 2002, Guideline 13).

LEGAL PROTECTION OF VULNERABLE PERSONS

One of the strongest protections the law can offer especially vulnerable research participants is their protection through the requirement of consent. However, informed consent has its weak points (see Chapter 6). Firstly, it may be questioned, whether consent as it is defined in law provides appropriate and sufficient protection, especially for the most vulnerable individuals. Secondly, although appropriately informed of all the probable and possible adverse outcomes, people providing informed consent to participate in research may still experience adverse outcomes that were unforeseen. Therefore, the main protection for especially vulnerable potential participants in research should be an open, full and honest discussion about the possible benefits and harms of participating. This requires a very high level of trust between the participant and the researcher (S. A. M. McLean 2014).

The legal protection of consent may be more illusory than real, especially in light of the many research misconducts that have taken place, where trust was completely abused. Hence, the basic rules of protection have recently been extended, with the addition of new set of criteria. For example, the "Declaration of Helsinki" (2013, § 20) requires not only proper justification for research with vulnerable populations but also, the obligation to stay responsive to the health needs and priorities of such groups. These groups should also benefit from the research practices and interventions, as well as the knowledge and results gained by the research (S. A. M. McLean 2014).

Within the context of research, there are also cases where it is impossible to provide participants with special protections (e. g. population genetic research). Again, the spe-

cific population, due to the nature or design of the research study, may not benefit from the results. The participants may agree to participate due to misconceptions, pressure, and/or lack of awareness. Also, such a targeted population for research may at the same time be poor, ill educated, isolated, under the influence of cultural traditions, etc. However, laws may not only fail to protect the especially vulnerable, they may also fail to protect the personal integrity of research participants. Issues like lack of education, lack of healthcare resources, or poor understanding of research may all contribute to the otherwise avoidable violations of the integrity of research participants (S. A. M. McLean 2014). Individuals may have difficulties rejecting offers for research participation, if they do not recognise the unfairness of the offer provided. Potential participants may feel that the research does not offer anything, or simply that they are obliged to participate without being able to refuse (S. A. M. McLean 2014, citing Grady 2009).

THE RELATION OF PRINCIPLE OF VULNERABILITY, PERSONAL INTEGRITY, AND INTEGRITY IN RESEARCH

Paying careful attention to both vulnerability and personal integrity in research means that a possible future benefit of research—however promising—can never override the requirement of non-exploitation of participants. The generic rule of the more invasive the research, the higher standards of protection should be followed. Only in cases of less invasive research, with very high possible benefits, can the approach towards protection of participants be more casual. The goal of Art. 8, in such cases, is the protection of research participants against physical or emotional harms. Sacrificing the consideration of possible vulnerabilities, the fact that the research itself is an intrusion that may be harmful, and the actual impacts of research on the respect participant would conflict with the requirement defined in Art. 8 (S. A. M. McLean 2014).

Careful attention should also be paid to the protection of personal integrity. It is common in urgent situations that the argument about the greater good is used or abused, which results in circumvention of Research Ethics Committee (REC) approvals. When these situations occur in developing countries and the research is funded by developed countries, an added level of vulnerability is introduced. Therefore, it may be easier to circumvent best medical practice in developing countries, including the violation of personal integrity. It is paramount therefore that the protection of personal integrity should be ensured by the obligation for scientific validity in research, and by the direction of appropriate attention to, and respect for the rights of, participants at all times (S. A. M. McLean 2014).

SHIFT IN INCLUSION OF VULNERABLE POPULATIONS INTO RESEARCH

The greater willingness of inclusion of vulnerable populations into clinical research is a result of a recent development. As Mastroianni and Kahn (2001) note, since the *Belmont Report* (1978) was first published, until the late 1980s, the general approach towards the inclusion of vulnerable population into research was protection. However, as already mentioned, this approach resulted, in the cessation of research into essential medical conditions, due to the complicated and laborious requirement that needed to be fulfilled in order to include vulnerable individuals in research (pregnant women, children, prisoners, etc., S. A. M. McLean 2014). Thus, since the 1990s, research shifted and focused more on how vulnerable groups could be included in research. The justification for this is based on the direct and potential medical benefits, and the imperative to provide access to these goods (Mastroianni and Kahn 2001).

THE ISSUE OF DOUBLE STANDARDS

The IBC provides some examples of special vulnerabilities in research. These relate to double standards employed during research (usually between developed and developing countries), or various forms of social vulnerability (e. g. poverty, gender discrimination, hierarchical relations, etc.; IBC 2013).

5.1.1.5 *Vulnerability is Not an Isolated Ethical Issue*

The IBC admits that vulnerability seldom exists in isolation. It notes that lack of education, lack of social authority, and limited access to healthcare independently make individuals vulnerable, and can collectively have greater negative effects. Respect for personal integrity can also be negatively affected by complex social, cultural and political *status quos*. Therefore, vulnerability cannot be fully abolished. The purpose of constant reference to the protection of the vulnerable and the respect of the personal integrity is to support the determined quest towards eradicating their causes and contexts of vulnerability. Securing the protection of these groups is fostered by the idea of equal human rights and the dignity of every person (IBC 2013).

As such, the responsibility of protecting vulnerable people and their personal integrity must manifest the joint effort of all the healthcare providers and agencies, private companies and industry, as well as countries (S. A. M. McLean 2014). This requirement should be applicable for the development of AAL technologies for PwDs.

5.2 POLICY DOCUMENTS AND ACADEMIC LITERATURE

5.2.1 *Policy Documents*

5.2.1.1 *Universal Declaration on Human Rights (1948)*

Art. 1 of *UDHR* (1948) refers directly to the principles of human dignity. It also refers to one of the key elements of solidarity, by driving individuals' actions "towards one another in a spirit of brotherhood" (*UDHR* 1948, Art. 1). Connecting these two elements into a single article reinforces the foundation of human solidarity on the grounds of universal human dignity.

5.2.1.2 *Documents of International Biomedical Communities*

This section specifies two documents of the international biomedical communities that are explicitly referred to in the preamble of the UDBHR: the "Declaration of Helsinki" (1964), and CIOMS (2002). The descriptive characterisation of vulnerability and personal identity, in the perspective of the above-mentioned documents, has also been confirmed during the discussion at the World Congress on Bioethics in Brasilia in 2002.

DECLARATION OF HELSINKI (1964–2013)

The first document is the "Declaration of Helsinki" (1964). The WMA, the issuer of this set of principles, is an international organisation that represents physicians. Since its first adoption in 1964, this document has been amended nine times in total (two of these amendments were only notes of clarification), with the latest version of the "Declaration of Helsinki" being published in 2013.

As the number of amendments may suggest, the development of the "Declaration of Helsinki" (1964) is not particularly linear or gradual. When reviewing the differences between the individual amendments, one may discover at least three major changes, both in the structure of the Declaration itself and in its content. These changes are particularly noticeable between the versions of 1964–1975, 1996–2000, and 2008–2013. And yet, the continuous (and some would say, excessive) changes are also one of the reasons for the Declaration is not being a legally binding document. Some countries have rejected the current version, preferring to use an earlier version of the Declaration (e. g. US), despite the WMA considering these versions as no longer valid.

Vulnerability

The concept of vulnerability was not mentioned in the first version of the "Declaration of Helsinki" (1964). It first appeared in the *Declaration of Helsinki* (2000), which states in its *Introduction* that "[s]ome research populations are vulnerable and need special

protection" (*Declaration of Helsinki* 2000, § 8). The subsequent sentences suggest that the Declaration at this point considers mostly two particular groups: those economically and medically disadvantaged, and those who are incapable of providing valid informed consent. While in the case of the first disadvantaged group, their needs must be respected, in the case of people unable to consent, special attention is required (*Declaration of Helsinki* 2000, § 8). This distinction becomes more well defined contours in the *Declaration of Helsinki* (2008), where the Declaration clarifies "particularly vulnerable" populations as either "those who cannot give or refuse consent for themselves" or "those who may be vulnerable to coercion or undue influence" (*Declaration of Helsinki* 2008, § 9). This distinction is again confirmed in *Declaration of Helsinki* (2008, § 17), which states that medical research on these vulnerable populations is justified only if it is "responsive to the health needs" of the population concerned, and if this group is likely to "benefit from the results" of such research (*Declaration of Helsinki* 2008, § 17).

The last *Declaration of Helsinki* (2008) underwent a major review, which resulted in the addition of whole new section fully dedicated to *Vulnerable Groups and Individuals* in the current "Declaration of Helsinki" (2013, § 19–20). In this version, being vulnerable means having "an increased likelihood of being wronged or of incurring additional harm" ("Declaration of Helsinki" 2013, § 19). Regarding research with vulnerable populations, the "Declaration of Helsinki" (2013) introduces additional criteria to those presented in the earlier version of the *Declaration of Helsinki* (2008): research cannot be carried out on the non-vulnerable part of the population, and in addition, the vulnerable group should benefit from the "knowledge, practices or interventions that result from the research" ("Declaration of Helsinki" 2013, § 20).

Personal Integrity

The requirement of respecting personal integrity is, unlike vulnerability, present since the first version of the "Declaration of Helsinki" (1964). It states that each individual's right to protect her personal integrity must be respected, especially if the person resides in a dependent relationship to the researcher ("Declaration of Helsinki" 1964, III. 4a).

This statement in the *Declaration of Helsinki* (1975) was moved to the first section of the Declaration concerning *Basic Principles*. Moreover, it was linked with the requirement of respecting one's privacy, minimising the possible negative impact of the research study on the participant. This impact may affect negatively either the physical or mental integrity, or the personality of the research participant (*Declaration of Helsinki* 1975, I. 6), thus they need to be protected. The *Declaration of Helsinki* (2000) extended the original scope of respect of the research participant's privacy also by the confidentiality of the patient's information.

The *Declaration of Helsinki* (2008) refers to integrity in two occasions. Firstly, integrity is listed together with the protection of the life, health, dignity, right to self-determination,

privacy, confidentiality of research participants. The protection of these are the duty of the physician(s) conducting the research (*Declaration of Helsinki* 2008, § 11). Secondly, integrity is again referred to in relation to the protection of privacy and confidentiality of personal information in the research study, minimising the negative impact of participation. The reason for this is the protection of the participants' physical, mental, and – newly – social integrity (*Declaration of Helsinki* 2008, § 23).

The "Declaration of Helsinki" (2013) reduces the reference to the protection of personal integrity of the research participant to one single occurrence. Furthermore, it clarifies that the only responsible person for protecting the participants life, health, dignity, right to self-determination, privacy, etc., is the physician or other healthcare providers involved in the study. The research participant can never be solely responsible for the protection of these. This requirement is not affected by the eventual provision of valid consent by the participant in any way ("Declaration of Helsinki" 2013).

THE COUNCIL FOR INTERNATIONAL ORGANIZATIONS OF MEDICAL SCIENCES (CIOMS) GUIDELINES (2002)

The CIOMS (2002), regarding research with vulnerable persons, notes that "[s]pecial justification is required for inviting vulnerable individuals to serve as research subjects and, if they are selected, the means of protection their rights and welfare must be strictly applied" (CIOMS 2002, Guideline 13; S. A. M. McLean 2014). The document refers extensively to the issue of vulnerability, consistently using the word as an adjective while describing classes of vulnerable individuals, subjects, persons, groups, populations, and communities (Neves 2009). As such, CIOMS (2002) defines vulnerability as a "substantial incapacity to protect one's own interests" (CIOMS 2002, p. 12; Neves 2009).

Finally, during 6th World Congress on Bioethics in Brasilia (2002), it was agreed upon that the principle of vulnerability must necessarily also refer to the principles of integrity and dignity. Together, all three constitute the descriptive features of humanity, with its subsequent normative implications (Kottow 2005).

5.2.1.3 *Documents of the European Union and the Council of Europe*

THE CONVENTION ON HUMAN RIGHTS AND BIOMEDICINE (1997)

The countries of the EU agreed upon a *Convention on Human Rights and Biomedicine* (1997). Art. 1 of this Convention directly refers to the protection of dignity, integrity, and other fundamental rights of all human beings during the application of biology and medicine (*Convention on Human Rights and Biomedicine* 1997, Art. 1; Neves 2009).

THE BARCELONA DECLARATION (1998)

A second important document regarding vulnerability and personal integrity in biomedicine within the European context is the Barcelona Declaration (1998). This Declaration provides a definition of the following four key ethical principles:

1. *Autonomy* – is defined as capacities of a) creating ideas and goals of life; b) moral insight, self-legislation, and privacy; c) rational decision and action without coercion; d) political involvement and personal responsibility; e) and informed consent. Autonomy, however, remains an ideal (Kemp and Rendtorff 2009).

2. *Dignity* – a principle that should not be reduced to autonomy, and which refers to an intrinsic value of every individual on one hand, and to the inter-subjective value of every human being on the other hand (Kemp and Rendtorff 2009).

3. *Integrity* – is defined as inviolability of human being. Originally it meant the virtue of an uncorrupted character, uprightness, honesty, and good intentions. Today integrity, similarly to dignity, refers rather to the quality of a person as such. Integrity, thus, means one's coherence of life in time and space on one hand, and a coherence of memory and corporeal life expressed in remembrance and narrative on the other hand. Integrity is closely related to the respect for one's privacy, and therefore it is the most important principle for the creation of trust (Kemp and Rendtorff 2009).

4. *Vulnerability* – expresses, firstly, the finitude and fragility of life. Secondly, it refers to the object of a moral principle requiring care for the vulnerable (Neves 2009). These two basic ideas, i. e. finitude and suffering, describe together the universal human condition (Kemp and Rendtorff 2009). Vulnerability, however, does not concern human beings exclusively but animals and all self-organising life (Kemp and Rendtorff 2009). The essential difference regarding the provision of protection against vulnerability depends on the interference. For non-human beings, the protection should be passive, i. e. by non-interference, or sustainable interference. For human beings, the protection requires active involvement in preventing or avoiding harm (Kottow 2005). Furthermore, vulnerability provides a necessary bridge between moral strangers in pluralistic societies (Kemp and Rendtorff 2009). Finally, respect for vulnerability should encourage outlining a right balance between the struggle for immortality, and the finitude and suffering of human beings (Kottow 2005).

The four principles described in the Barcelona Declaration should always be promoted within a framework of solidarity and responsibility (Neves 2009).

5.2.1.4 *Documents of the United States*

THE BELMONT REPORT (1978)

In the US, the initial impulse to acknowledge the need for protection of vulnerable populations began with the publication of the *Belmont Report* (1978). In the section dealing with informed consent for research purposes, the Report lists certain groups of people, who might be subjected to undue influences during research activities (e. g. racial minorities, the economically disadvantaged, the very sick, the institutionalised (*Belmont Report* 1978, C.1–3; Neves 2009).

THE IRB GUIDEBOOK (1993)

The Institutional Review Board (IRB) Guidebook of the Office for Human Research Protections (OHRP), published in 1993, regularly refers to vulnerable populations. However, it avoids providing an exact definition of these groups (OHRP 1993; Levine et al. 2004b).

US CODE OF FEDERAL REGULATION 45 CFR 46 (2009)

The third important source of information on vulnerability in the US is the legislation incorporated into the US Code of Federal Regulation (*45 CFR 46* 2009). Although this regulation also does not define vulnerability, it does specify the requirement for special protections of vulnerable populations (e. g. pregnant women, human foetuses, neonates, prisoners, children, handicapped, mentally disabled, economically and educationally disadvantaged) during research (*45 CFR 46* 2009; Levine et al. 2004b). This protection is required because of the likelihood of "coercion or undue influence" being exerted on these vulnerable populations (*45 CFR 46* 2009, 111b).

5.2.1.5 *Documents of the UNESCO*

Alongside to the UDBHR, two other documents of the United Nations Educational, Scientific and Cultural Organization (UNESCO) refer in detail to the concept of vulnerability and personal integrity.

UNIVERSAL DECLARATION ON THE HUMAN GENOME AND HUMAN RIGHTS (1997)

Art. 17 of the *Universal Declaration on the Human Genome and Human Rights* (1997) demands respect for and the promotion of solidarity, especially with vulnerable groups affected by disease or genetic disability. In Art. 24, the Declaration requires that RECs organise consultations with representatives of vulnerable groups about the dissemination of the Declaration's principles and the application and evolution of technologies related to genetic research (*Universal Declaration on the Human Genome and Human Rights* 1997).

INTERNATIONAL DECLARATION ON HUMAN GENETIC RESEARCH (2003)

According to Art. 15 of the *International Declaration on Human Genetic Data* (2003), integrity, along with meticulousness, caution, and intellectual honesty should be practiced in the conduct of research (*International Declaration on Human Genetic Data* 2003, Art. 15). This can take the forms of responsibility or virtue, which can be enhanced by either the investigator herself, or a demand from society (Neves 2009). This requirement is also expressed explicitly in the *Universal Declaration on the Human Genome and Human Rights* (1997, Art. 13).

5.2.2 *Academic Literature*

Due to the recent technological developments, the topic of vulnerability has gained significant importance within the scholarly debate in the recent years. The academic literature either tried to propose alternative ways of describing vulnerability, often fine-tuning the actual definitions; or it tried to challenge various aspects of the actual definitions.

In the following sections, this debate is presented. This consists, firstly, of presenting the papers of Kipnis (2001) and Kipnis (2003), whose scientific input to the debate of vulnerability is still very influential. Kipnis challenged the unsatisfactory subpopulational view of vulnerability by proposing an analytical categorical view.

Secondly, the view of Levine et al. (2004b) is presented, who extensively criticised the whole scholarly debate of vulnerability. Although this criticism was recognised by others as a valid one, other members of the scientific community argued that the concept for protecting vulnerable populations remained relatively useful.

Thirdly, as a result of these discussions, further contemporary approaches to redefine (or refine more precisely) the actual definitions are presented, from Kottow (2003), Luna (2009), Luna and Vanderpoel (2013), Lange et al. (2013), and Hurst (2008).

5.2.2.1 *Analytical Approach to Vulnerability*

Whenever an official document (i. e. international declaration, or statement from professional communities) intentionally avoids the provision of a clear definition of vulnerability, it provides instead a non-exhaustive listing of possible vulnerable populations. Besides the lack of a clear definition, such approaches also tend to be impractical. Researchers must often exclude individuals due to their affiliation to the groups of population listed as generally vulnerable. Researchers are forced to do this, even if these individuals are not necessarily vulnerable if they participate in a research study (Kipnis 2003).

These reasons lead Kipnis (2003) to abandon the subpopulational view. Instead, his approach is more analytical. Kipnis asks what vulnerability consists of exactly, when this

concept is applied in research. He, firstly, identifies a difference between the everyday use of vulnerability, and the special use of this concept in research ethics. Secondly, vulnerability is not the only reason for declaring a research proposal impermissible. Lastly, participation in research should not always be considered burdensome for the participant (Kipnis 2003).

As a result of his analytical approach, Kipnis introduces seven distinct varieties of vulnerability that may affect the permissibility of participation in research (Table 5.1). Although Kipnis' initial focus was in paediatric research, his approach has, since its publication, been successfully applied to other biomedical fields, both in research and clinical practice (e. g. Horn 2007).

Table 5.1 – Overview of Kipnis' Vulnerability Taxonomy (Kipnis 2003, p. 110)

Vulnerabilities	Description
Incapacitational	whether participant lacks the capacity to deliberate about and decide whether to participate in the study
Juridic	whether participant is liable to the authority of others who may have an independent interest in that participation
Deferential	whether participant is given to patterns of deferential behaviour that may mask the underlying unwillingness to participate
Social	whether participant belong to a group whose rights and interests have been socially disvalued
Situational	whether participant is in the situation of medical condition that prevents the information and deliberation needed for the participation in the research
Medical	whether participant has been selected because of the presence of serious health-related condition for which there are no satisfactory remedies
Allocational	whether participant or proxy is lacking subjectively important social goods that will be provided as a consequence of participation in research

Table 5.1: Overview of Kipnis' Vulnerability Taxonomy (Kipnis 2003, p. 110)

Based on the description provided by Kipnis (2003), along with the development of the application of this taxonomy by Horn (2007), one can define the following vulnerabilities regarding PwDs and AAL.

INCAPACITATIONAL VULNERABILITY

The condition of PwDs by its nature renders them vulnerable in this respect. PwDs, due to the slow and irreversible deterioration of cognitive functioning, become progressively vulnerable, deteriorating from a fully or partially competent state to a fully incapacitated one.

JURIDIC VULNERABILITY

PwDs may be exposed to juridic vulnerability, by questioning their competency. This may happen, if the informal caregivers use surveillance technologies to monitor the activities of a PwD. Such monitoring opens up the possibility of overriding or influencing the free choices of a PwD, which otherwise would not be possible for the caregiver. Also, researchers during the research & development (R&D) and clinical trial period may have vast and hidden interests, which are not disclosed properly to PwDs. The conflict and motivations for research between the researchers and caregivers may also render the PwDs vulnerable.

DEFERENTIAL VULNERABILITY

This type of vulnerability may, firstly, be present mostly in nursing homes, where, for example, the financial dependence of PwDs on proxies may result in deference. Secondly, applications of Information and Communication Technology (ICT), due to faulty or inappropriate ways of functioning (e. g. erroneous interpretation of the situation; continuous and/or repeated nudging from ICT to perform an action), may mislead or pressurise PwDs to defer in response to the ICT. Finally, cross-cultural differences in the interpretation of autonomy may further expose PwDs to deferential vulnerability.

SOCIAL VULNERABILITY

Stigmatisation, and social exclusion of PwDs both belong to this category. PwDs may become more vulnerable because of hidden agendas of researchers, or due to various conflicts of interests and motivations that may exist between researchers and caregivers. Finally, the subordination or ignorance of the PwDs' limited decision-making capability by AAL technologies may further extend this category of vulnerability.

SITUATIONAL VULNERABILITY

Situational vulnerability may occur in the case of PwDs when they are temporarily incapacitated and thus unable to make a decision, although this may rarely occur in the early stages of dementia.

MEDICAL VULNERABILITY

This type of vulnerability is present from the moment that mild dementia develops. Medical vulnerability may increase after the removal of AAL technologies from PwDs at the completion of a research study. Finally, a specific type of hopelessness and thus medical vulnerability may be present due the fact that AAL technologies do not provide any therapeutic remedies for the condition of PwDs.

ALLOCATIONAL VULNERABILITY

PwDs may be vulnerable, in this regard, due to the fact that AAL technologies would be a less affordable tool compared with the more cost-effective option of traditional institutionalisation of PwDs in nursing homes offered by healthcare systems. The principle of fairness is also questionable due to the fact that PwDs participate in research that may not result in any direct benefit.

Kipnis remarks that despite the variety of available definitions, the main themes of vulnerability show "remarkable universality" (Kipnis 2003, p. 119). Additionally, Horn (2007), as a result of her analysis of vulnerability by applying Kipnis' approach, recommends the formation of Community Advisory Boards, whose role should be to provide general guidance and protection to vulnerable populations (Horn 2007). This could be reasonably understood as being applicable to PwDs. Also, the delegation of Occupational Health Practitioners may be helpful during research or therapy in mediating requests between the researchers/caregivers and vulnerable individuals (Horn 2007).

5.2.2.2 *The Critique of the Concept of Vulnerability*

The taxonomy of various vulnerabilities provided by Kipnis (2003) gained significant attention amongst researchers. Along with the positive reception, in the form of application in specific cases (e. g. Horn 2007), Kipnis' approach has also been extensively criticised (e. g. Levine et al. 2004b).

Levine et al. (2004b) note three crucial weaknesses that profoundly limit the concept of vulnerability: a) its broadness, b) its narrowness, and c) tendency of stereotyping.

VULNERABILITY – TOO BROAD

The concept of vulnerability has become so broad that one finds it difficult to identify a group of people that is not vulnerable. According to Levine et al. (2004b), potentially every human being is today considered in one way or another vulnerable somehow. The "Declaration of Helsinki" (2013) does not define vulnerability at all, although it states that "some groups" are particularly vulnerable ("Declaration of Helsinki" 2013, p. 2192, § 19). Similarly, the CIOMS (2002) refers to vulnerable groups as juniors, subordinate members of hierarchical groups, elderly, or other groups or classes that may be considered vulnerable (CIOMS 2002, Guideline 13). Levine et al. (2004b) remark that the most affected by being excluded from research due to their vulnerable status are those, who may benefit from the research the most. She further emphasises that most clinical research is combined with clinical care. The basis of her criticism of the overly broad concept of vulnerability is the fact that if everybody is considered to be potentially vulnerable, the concept itself becomes meaningless. Additionally, she questions the general

requirement for 'special consideration' by RECs to balance the vulnerability of research participants. In Levine's view, every research protocol requires special attention. Moreover, RECs have no effective guidelines on how to effectively focus the limited attention and resources of researchers on cases requiring such special consideration (Levine et al. 2004b).

VULNERABILITY – TOO NARROW

Levine et al. (2004b) criticise the concept of vulnerability as (also) being too narrow. This materialises in the requirement of informed consent. Groups that are not competent to provide consent are considered vulnerable. However, such inflated focus on the obtaining of valid consent diverts the researchers' attention from the essential features of the research, and from the social, economic, and institutional contexts. This diverted attention may, in fact, result in more harm for the research participants. On the one hand, although consent is unquestionably a serious concern, it is not the only concern that should be focused upon while investigating vulnerability. On the other hand, despite the fact that modern bioethical discourse identifies vulnerability in being harmed or being wronged,[12] the risks that research participants must bear are far greater than those of being a member of one of the vulnerable groups (Levine et al. 2004b).

VULNERABILITY – PRONE TO STEREOTYPING

The concept of vulnerability, according to Levine et al. (2004b), enforces thinking in terms of stereotypes. Whole categories of populations are stereotyped by not making distinction between those, who might have special characteristics and requirements that need to be taken into account, and those, who don't have such a need. Not all members of a group are necessarily vulnerable, just as not all vulnerable persons are vulnerable to the same extent. While the US National Institute of Health (NIH), based on the recommendations from the Institute of Medicine (IOM) in 1994, recommends to include pregnant women into research, the current US regulation (*45 CFR 46* 2009, Subpart B) of conducting research still consider pregnant women as vulnerable (Levine et al. 2004b). Such inconsistencies within regulations and recommendations make the already complex picture of vulnerability even less discernible.

SPECIAL SCRUTINY AND OTHER RECOMMENDATIONS

Levine et al. (2004b) therefore propose the following recommendations regarding the interpretation of vulnerability. Firstly, it is crucial to consider certain aspects of research, such as timing, the participants' need for special protections, the nature of the study, and the environment in which the study takes place. This is mainly due to the fact that some

12 See the etymological origins of the word 'vulnerability' (p. 130).

people are vulnerable in certain situations but not in others. Secondly, the definition of participant groups included in research should be as narrow as possible. Their inclusion should extend to a period that is justifiable and not beyond. Thirdly, if necessary, special protections should be considered for research participants with permanent cognitive impairments (e. g. Alzheimer's Disease (AD), etc.). Finally, a closer collaboration of researchers, sponsors, study coordinators, ethicists, REC members, policy makers, etc., is necessary. Their role is to implement and administer more targeted forms of protections for participants.

In this regard, Levine et al. (2004b) propose a scheme called "special scrutiny" (Levine et al. 2004b, p. 48).[13] This scheme consists of more thorough review triggered by the following three criteria: a) initial translation of new scientific advances to studies in humans, especially when the intervention is novel, irreversible, or both; b) risk of significant harm, or no prospective direct medical benefit; c) ethical questions about research with no consensus (Levine et al. 2004b; Levine et al. 2004a). Special scrutiny, triggered by the fulfilment of these criteria, should result in an intensive review by REC (Levine et al. 2004a).

In reaction to Levine's criticism of the concept of vulnerability, Horn (2007) admits the validity of the criticism. However, Horn (2007) argues that the taxonomy proposed by Kipnis remains valuable. It proves helpful in identifying conditions that may expose research participants to undue influence. Kipnis' taxonomy successfully highlights and calls to attention instances when the best interest of research participants is not being respected, therefore exposing them to potential harm (Horn 2007).

5.2.2.3 *Contemporary Alternative Approaches to Vulnerability*

THREATS TO SUSCEPTIBILITY

One of the alternative approaches to vulnerability is, as already mentioned earlier in section 5.1.1.3, Kottow's distinction between vulnerability and susceptibility. Vulnerability is universal and describes every human being, while susceptibility is specific and an accidental condition to diagnosis and treatment. The former is linked with the principle of justice, being thus the responsibility of the State, the latter is linked with the principle of non-maleficence (Kottow 2003).

Kottow identifies three fields in which the concept of vulnerability is usually ignored (Kottow 2003).

13 The deaths of research participants, Hoiyan Wan, Elaine Holden-Able, and Ellen Roche, stimulated the development of this novel framework by Levine et al. (2004a). Its purpose is to avoid causing serious harms to research participants. Although these participants were not initially considered vulnerable, the consequences on their health of participating in a research trial were fatal. The framework aims to enable RECs to provide prospective participants with better protections (Levine et al. 2004a).

Double Standards

In Kottow's view, bioethicists throughout history have all too often defended *double standards* in multinational research studies. Participants from developing countries are in a more vulnerable position compared with more developed countries where the research funding originates. Participants are clearly in an immersed state of frailty that is deplorable but which some regard as not needing any improvement in care and protection beyond that which is available in the host country (Kottow 2003).

Exploitation

The *exploitation* of research participants is named by Kottow as the second domain where vulnerability is ignored. This is manifested in taking advantage of the weak and utilising them for selfish purposes (e. g. for profit; Kottow 2003).

Paternalism

The third threat to the respect of the vulnerability of research participants comes from *paternalism*. Paternalism is, according to Kottow paraphrasing Kant (Kant 1991, p. 250, § 34), an insulting kind of benevolence. Paternalism may be exceptionally acceptable when decisions are made for a disautonomous person by an authorised person. However, the issue is that often paternalism originates from unauthorised sources (Kottow 2003).

LAYERED VULNERABILITY OF LUNA

Luna (2009) proposes a different classification of vulnerability. For her, the subpopulational view is a form of labelling of people with vulnerabilities. The issues with such labelling are manifold: it fails to describe the complexities of human vulnerabilities; individuals may be vulnerable on more than one level and due to more than one reason; belonging to a subpopulation may not represent an individual's vulnerabilities correctly; it carries the risk of stereotyping and hence undue stigmatisation (Luna 2009).

Instead of the subpopulational and labelling view, Luna (2009) proposes the layered view. The layered view of vulnerability is relational (i. e. inessential). It does not consist of identifying one single origin or feature of vulnerability but considers as many layers of vulnerability as possible (Luna 2009; Luna and Vanderpoel 2013; Lange et al. 2013). Furthermore, a layered view closely examines the context of vulnerability, by not focusing solely on a single category or label of vulnerability. This view acknowledges that it is not that a person is vulnerable but rather, that a particular situation renders the person vulnerable (Luna 2009; Lange et al. 2013). Thus, as the circumstances change, so do the presence and layers of vulnerability. This makes the layered approach to vulnerability more dynamic (Lange et al. 2013).

Based on the application of the layered view presented by Luna and Vanderpoel (2013), the application of AAL technologies for PwDs carry the following layers of vulnerabilities.

Home-layer

While AAL technologies promise PwDs the ability to stay longer at home, it unavoidably introduces the threat of medicalisation of the home environment. Home is considered a place, which provides shelter from the external and public world, where the individual has freedom to choose what belongs to his private sphere. However, AAL technologies may turn the private sphere of home into a place equipped with hospital technology.

AAL technologies can be beneficial in continuous monitoring of dangerous situations for the vulnerable PwDs. At the same time, such technology may also introduce dangers of surveillance and loss of privacy, thus making PwDs vulnerable.

Home is also a place where the individual has control over her extent of privacy. Although the introduction of AAL technologies can provide better information for the clinical staff, even remotely, it can also introduce threats. For example, it is unclear how the PwDs' decisions about their privacy will be respected and protected in case of a conflict with the clinical staff.

Information-layer

Another layer of vulnerabilities for PwDs in relation to AAL technologies is linked with the information that the technology gathers. AAL technologies may empower PwDs by keeping them informed and requesting their consent for actions. However, a great amount of requests may be considered disruptive as, some PwDs may be overwhelmed by the sheer volume of information, which can cause higher levels of confusion. Additionally, such requests for interaction from the technology may interrupt the PwDs activities, making them impossible to finish. This may result in more stress and anxiety for the PwDs.

Technology-layer

While AAL technologies enable PwDs to perform various activities in their homes, they pose a threat, not only through the possibility of deceiving or manipulating its user, but also through coercion. PwDs may thus become vulnerable if their choices, preferences, and wills are overridden by the software of the AAL technology.

Although the definition of AAL technologies requires their disappearance into background (i. e. ambient intelligence (AmI)), they can also be very intrusive. By enabling PwDs to do something, AAL technologies must provide incentives, repeatedly reminding and making suggestions to their users about tasks in order to reach the goal of the started activity.

Despite the potentially beneficial assistive nature of AAL technologies, these technologies may also manipulate and coerce their users into performing actions that she, the PwD, no longer wants to perform. There is a danger that the technology will be unable to recognise a change of mind by its user. It may happen that the user is performing tasks recommended by AAL technologies because they want to perform it. It may also be that a PwD does so because she is nudged into performing it because the easiest way of satisfying the requests of the AAL technology is to perform them.

The incapability of interpreting the information may be pertinent in another field. AAL technologies may be helpful in recording the fragmented wishes, advance directives, statements, or preferences of PwDs. However, these technologies as lifelogs may be insensitive to the recording of adverse events, failures, or other negative issues that a person prefers to be forgotten (Jacquemard et al. 2014).

While AAL technologies can provide clinical staff with relevant and important information about the PwDs' condition, the technology itself may be ignorant towards the personal preferences of PwDs about the disclosure, use, and handling of such information.

Societal-layer

AAL technologies are being introduced to provide PwDs with the opportunity for active ageing. However, this opportunity may be interpreted by some as a requirement, resulting in the demand for elderly people (and PwDs) to not be physically frail. The application of AAL technology may thus result in the questioning of the universal vulnerability of human beings, rendering people especially vulnerable in this regard.

Although AAL technologies promise that they will be financially more affordable than human caregivers, while providing better management of time and resources, this claim may be questionable. PwDs, mostly during retirement or while unable to work full-time, may be financially unable to afford AAL technologies, which raises questions about the accessibility of AAL technologies for every PwD.

AAL technologies increase the chances for socialisation with distant family members, friends, etc. However, as pointed out by R. Sparrow and L. Sparrow (2006), in the end, PwDs may be stripped of human care, rendering them more vulnerable to loneliness.

Due to the prospect of better care, health insurance companies may prefer the widespread deployment of AAL technologies to larger groups of PwDs. This raises the question of whether PwDs will have the choice to refuse such an offer, and whether they are not risking any penalisation if they do so due to their personal preferences.

VULNERABILITY AS A CLAIM TO SPECIAL PROTECTION BY HURST

Hurst (2008) finds the subpopulational view philosophically unsatisfying. She identifies the purpose of vulnerability in protecting research participants with the need of special

protections. Therefore, the concept of vulnerability is useless if it is defined too broadly and universally. A restrictive definition of vulnerability is required (Hurst 2008; Lange et al. 2013).

Hurst (2008) categorises the alternative analytical definitions of vulnerability in three categories: consent-based, harm-based, and combined approaches. The first group representing consent-based vulnerability considers as vulnerable those who are at risk of not being competent to giving consent or are prone to exploitation (Hurst 2008). This group, according to Hurst (2008), is represented with documents like *ICH Harmonised Tripartite Guideline* (1996), or CIOMS (2002). Consent-based definitions of vulnerability are, according to Hurst (2008), too narrow because they do not consider issues of harm, disrespect, or injustice (Hurst 2008).

The second group are affiliated with definitions of vulnerability, whose focus is on the added harms. This group is represented, for example, the definition of susceptibility by Kottow (Hurst 2008). It is unclear, however, how harm-based definitions sufficiently cover those groups, which are exposed to greater risk of harms. Harm-based definitions include vulnerable or susceptible persons only after an actual harm occurred to them (Hurst 2008).

Both of these approaches carry insufficient comprehensiveness in their definitions of vulnerability. The third group of the combined approach aims to overcome this drawback, by covering three areas: a) vulnerability of those with compromised capacity to protect their interest by either informed consent or the possibility of refusal of treatment; b) vulnerability of those more likely to take on the burdens of participation in research, especially if their increased risk-taking is not compensated by other benefits; c) vulnerability of those less likely to gain benefits by participation in research, especially if their participation is not compensated by other benefits (Hurst 2008). As a result, the combined approach defines vulnerability as "increased potential that one's interests cannot be protected" (Hurst 2008, p. 194, citing Agrawal 2003, S26).

Based on this definition, Hurst (2008) defines vulnerability as "an identifiably increased likelihood of incurring additional or greater wrong" (Hurst 2008, p. 195). This definition allows Hurst (2008) to apply the concept of vulnerability to persons as a claim for special protection. Firstly, there must be an identifiably greater likelihood or likely degree of wrongs that may occur. Secondly, researchers share the duty to avoid previously identified wrongs. Both of these conditions require increased attention from researchers to avoid wrongs from happening (Hurst 2008).

This definition does not generate new obligations because it is restricted only to wrongs that happen when the research participant has a valid claim, and it is denied from her (Hurst 2008; Lange et al. 2013). These obligations already persist but sometimes special efforts need to be made to fulfil them (Lange et al. 2013).

Hurst (2008) proposes a 4-step approach that helps identify the vulnerability of research participants, based on the proposed definition. This approach includes answers to the following 4 questions (Hurst 2008, p. 197):

1. Is there an identifiable potential wrong?
2. If yes, are some people identifiably more likely than others to incur this wrong, or likely to incur it to a greater degree?
3. Who shares in the duty to minimize, or avoid, this wrong, and does it include us in any way?
4. What should we do to minimize this increased likelihood or degree, or to compensate for it in ethically justifiable ways?

The definition does not include examining the responsibility of those who can be held accountable for the avoidance or minimisation of wrongs. Therefore the question 3 is included (Hurst 2008).

From the set of questions, it is evident that the ethical issues identified in the literature review (Chapter 3) may all be used. The first problem with this approach may be that applying it to every ethical issue occurring in the application of AAL technologies for PwDs may make the results exceptionally long. Additionally, the answers to the questions 3 and 4 can be harder to determine. One of the reasons for this obstacle may, for example, emerge during a multinational research study, with various overlapping specialists, and with their various respective expertise. Another reason is that in many cases, AAL technologies should perform some action, which may have ethically relevant consequences. However, in such cases, it is very hard to identify the person responsible when a harm occurs.

TAXONOMY OF VULNERABILITY OF LANGE

Lange et al. (2013) review both of the aforementioned proposals for redefining the concept vulnerability. They find Luna's approach insufficient, in its specification of how the different layers of vulnerabilities define the obligations attendant on researchers or RECs. The only 'recommendation' is to carefully consider the context of research. Although the subpopulational labelling may be flawed, this flaw does not automatically mean that all taxonomy-based approaches are flawed. Moreover, these flaws can be mended in subsequent and improved versions of these frameworks (Lange et al. 2013).

Lange et al. (2013) consider the definition of Hurst (2008) valuable because it provides clear categories for the parties involved. However, RECs can still, while using the 4-step approach, fail to correctly identify the risks involved in complex phenomena. Therefore,

the danger of labelling persists, while the approach still fails to produce clear action guides (Lange et al. 2013).

Due to the insufficient reflection of complexities of previous definitions of vulnerability, Lange et al. (2013) propose their own taxonomy of 'more than ordinary' vulnerability. Every kind of vulnerability can be captured in one of the 3 main categories. Each vulnerability can further belong to short-term or long-term subtypes (see Table 5.2). This approach, according to Lange et al. (2013) provides their users with concrete guidance for recognising, reacting, and minimising vulnerabilities in research (Lange et al. 2013).

Table 5.2 – Taxonomy of 'More Than Ordinary' Vulnerabilities (Lange et al. 2013)

Vulnerabilities	Subtypes	Description
Inherent	Occurrent (immediate/present)	age, health, gender, disability, capacities for resilience
	Dispositional (latent/background)	
Situational	Intermittent, short term	social, political, economical, environmental situation
	Enduring	
Pathogenic[14]	Occurrent	prejudice, abuse, neglect, disrespect, political situation–injustice, persecution, political violence, exacerbating feelings of embarrassment, shame, isolation, inability to care for one's family
	Dispositional	

Table 5.2: Taxonomy of 'More Than Ordinary' Vulnerabilities (Lange et al. 2013)

General Rules for Researchers

The general rules for every researcher consist of an obligation not to impede the autonomy of vulnerable participants. The reason behind this requirement is instrumental: autonomous individuals are usually better in protecting their interests than those with weakened agency.[15] This is granted not only by seeking informed consent but also avoiding any forms of paternalism. This duty includes the promotion of participants' understanding, duty to work with target populations, or provision of additional support or advice from external and independent expert bodies (Lange et al. 2013).

Under no circumstances should well-intended extra protections exacerbate or create additional vulnerabilities during research. The researchers have a special duty to not create additional pathogenic vulnerabilities via design or conduct of research. By being part of the research context, researchers are an unavoidable source of novel vulnerabilities, or of their exacerbations (Lange et al. 2013).

14 According to Lange et al. (2013), pathogenic vulnerability is a subtype of situational vulnerabilities, which emerges from dysfunctional social or personal relationships (Lange et al. 2013).

15 Lange et al. (2013) state in the article that the reason behind this requirement is purely instrumental. However, later in the article, they acknowledge 'intrinsic reasons', i. e. valuable aspect of human life, as an additional basis to foster the participants' autonomy (Lange et al. 2013, p. 337).

Lange et al. (2013) emphasise that the procedures that create additional pathogenic vulnerabilities in clinical application usually create the same vulnerabilities during clinical research.

Application of the Taxonomy

Lange et al. (2013) provide an application of their taxonomy to research with participants with AD. Inherent vulnerabilities consist of, for example, the cognitive deficits of PwDs, their vulnerability to harm and exploitation, and general physical vulnerabilities of the elderly people (frailty). Situational vulnerabilities consist of mismanaged affairs (e. g. financial vulnerability, fraud, costly mistakes, etc.), and being prone to accidents. Pathogenic vulnerabilities in the case of PwDs are characterised by their dependency on an incompetent or abusive caregiver, institutionalisation, and psychological vulnerabilities (e. g. isolation, coping with unfamiliar surroundings, loneliness, disorientation, etc.; Lange et al. 2013).

The suggestions stemming from this categorisation of vulnerabilities of research participants with AD, according to Lange et al. (2013), focus on a few aspects. Firstly, PwDs should be involved in research at the early stages of their disease. Secondly, the clinical trials should not focus solely only on comparative drug testing but the tests should include comparisons with no-drug interventions too. The reason behind this suggestion is based on the physical frailty of PwDs, whose existing medication can negatively interact with the drugs tested in the trial. Thirdly, researchers should assess the effects of the trial on the participants' daily lives. The research study should not exacerbate already existing situational or pathological vulnerabilities for the participant. Fourthly, PwDs as research participants will already have a higher level of dependency on their current caregivers for their health management. Followed by their limited abilities to consent, research studies should be designed to minimise any additional dependencies the study may impose on the participant. Additionally, the assessment of the competency of PwDs to participate in a research study should not be allowed to be exploited by third parties (Lange et al. 2013).

Evaluation of the Taxonomy

The taxonomy proposed by Lange et al. (2013) clearly identifies some crucial aspects of research with PwDs. However, there are certain areas that are overlooked by this approach. The categories of the taxonomy of vulnerabilities (inherent, situational, pathogenic) only partially reflect the vulnerabilities introduced by the application of assistive technologies. The biggest issue is the apparent autonomy of AAL devices, which may be categorised as environmental situational vulnerability but at the same time may not. Just as the place of researchers in the taxonomy of vulnerabilities is unclear, the situation is similar with partially or fully autonomous AAL technologies.

The second issue with the taxonomy presented by Lange et al. 2013 is the questionable additional value of the distinction of occurrent/dispositional vulnerabilities beyond the main types of vulnerabilities. Lange et al. (2013) themselves do not appear to employ these subtypes of vulnerabilities, thus the added value of introducing such a distinction is unclear.

Thirdly, the focus of the taxonomy on preserving the autonomy of a research participant justified at times by instrumental value, and at other times by intrinsic value referring to human dignity, is unclear. The claim to preserve a research participant's autonomy based on instrumental purposes may also trigger certain instrumental reasons (e. g. for the beneficial results of the research study) to suppress her autonomy. The autonomy of research participants, especially with a condition like dementia, is easily questioned. In such a context, referring to goal-oriented reasoning, the drive towards achieving results, which is inherent in every research project, may result in increasing the vulnerabilities of participants, or even in their abuse.

Compared with the 4-step method proposed by Hurst (2008), the taxonomy of Lange et al. (2013) lack a clear reference to any identification of who is responsible and liable for actively minimising or conversely, exacerbating the vulnerabilities of research participants during and after the study. This issue is even more relevant if AAL technologies eventually become partially or fully autonomous.

5.3 SPECIFICATION OF ARTICLE 8

The vulnerability of PwDs consists of two elements. First, PwDs are vulnerable by being part of the human family. Every human being is in a constant intrinsic state of vulnerability, and as such, universal vulnerability is the universal condition of humanity and existence. Secondly, PwDs, due to their frailty, growing mild cognitive impairments (MCIs), memory issues, and other progressively worsening dementia-related conditions can be rendered especially vulnerable.

Therefore, the PwDs' special vulnerability is based on the definitions provided by CIOMS (2002) and Kemp and Rendtorff (2009): PwDs are especially vulnerable in their (relative or absolute) inability to protect their own interests (e. g. lack the power, intelligence, resources, strength, etc.); and PwDs are especially vulnerable regarding to the threat of violating their autonomy, dignity, and personal integrity.

The personal integrity of PwDs is much harder to define. PwDs unquestionably may exhibit certain behavioural changes, which are noticed either by others (e. g. relatives, friends, etc.) or by the PwD herself. It remains unclear, whether the personality, personal identity (and hence integrity of a PwD) during the progress of dementia alters

dramatically or not.[16] Therefore, instead of a positive definition, which would set certain requirements towards the (virtuous) development of PwDs, a negative definition of personal integrity of PwDs appears to be more appropriate. A negative definition of respecting PwDs' personal integrity sets requirements towards every other stakeholder involved except the PwDs themselves. The content of the negative definition of the principle of the PwDs' personal integrity consists of the requirement of avoiding disrespect to their personal sphere (irrespective of the changes of 'consistency' within the PwD's personality), supported by the standard of non-interference requiring the avoidance of any undue external interventions to the person concerned. This respect, as required by Art. 8 of the UDBHR, is based upon the universal dignity of every human being.

Due to the fact that vulnerability in the biomedical sphere is always related to a specific threat, the violation of one's personal integrity occurs either during clinical practice, or during participation in research. These two contexts are specified in the following sections in detail.

5.3.1 *Clinical Research*

In research settings, the vulnerability of PwDs reveals itself as special vulnerability, or as an indicator of susceptibility to future harms. Although the universal vulnerability of PwDs during research is also present, it is, however, only as a background issue (i. e. not so obvious), which is present alongside any more serious concerns about the special vulnerability of PwDs.

The types of vulnerabilities of PwDs during research of AAL technologies may be categorised based on their three sources: a) vulnerabilities from researchers and from participation in research studies itself; b) vulnerabilities related to close relatives and proxies; and c) vulnerabilities from developing AAL technologies.

5.3.1.1 *Vulnerabilities of PwDs from Researchers and from Participation in Research Studies*

Due to the nature of research, PwDs are especially vulnerable to being treated with greater distance and smaller levels of empathy. Researchers, while trying to eliminate their subjective biases, focusing on recording meaningful and objective data may find

16 A recent paper published by Strohminger and Nichols (2014) examines which traits of the mind are constitutive for the definition of one's self. The authors suggest that distinguishing features (e. g. authentic experiential memories) seem to be more important for the person herself, than to her close relatives/friends. The authors examined in five conducted studies the reaction to changes in the constitutive elements of the self: personality traits, memories, desires, perceptual faculties, cognition, and morality. Supporting the essential moral self hypothesis, the studies concluded that the changes in one's morality are considered as a more dramatic change in the person's personality, than any other of the aforementioned traits. For example, if one's episodic memories fail to restore but his moral traits are seemingly unchanged, the person is likely to be considered more as herself than a different person whose moral traits changed significantly to her previous self (Strohminger and Nichols 2014).

themselves lacking genuine interest in curative or supportive activities, which may render PwDs especially vulnerable during their participation in research studies. This special vulnerability may be exacerbated by the questioning of the remaining (limited) competencies of PwDs by researchers. This may result in researchers ignoring the wishes, interests of PwDs, and their potentially important insights and feedback.

PwDs should not be categorically excluded from research activities. However, their inclusion into research should be duly considered and supported by strong justification. The justifications need to be even stronger for the inclusion of PwDs in moderate or severe stages of dementia. It may be worth considering research study inclusion to only those PwDs at the early stages of dementia.

The inclusion criteria should be reviewed by appropriate RECs. Recruiting participants with dementia for research studies should only be allowed if the study focus is directed at addressing their condition. Research studies may try to recruit research participants with dementia for other motives than direct benefit for their participants, which contravenes Art. 4 and Art. 7 of the UDBHR. The participation of PwDs in such research would mean their increased special vulnerability due to possible exploitation, which falls below the standard set in Art. 8 of the UDBHR. Further complications with the vulnerability of PwDs may arise during likely scenarios such as that of a PwD finding it increasingly difficult to withdraw from a research study due to her progressively worsening condition. Despite the fact that the UDBHR ensures the possibility of withdrawal from research without the provision of any reasons in Art. 6 and Art. 7, PwDs may find it difficult to refuse to participate in a study. One has to consider that many circumstances may prevent the PwD from expressing her preference for withdrawal from a study: the involvement of many researchers; lack of attention to the individual needs of PwDs during research; the natural authority ascribed to scientists by the PwDs; the preference to avoid conflicts with the people involved; respect for the invested work of researchers; fear from social isolation that may occur after study withdrawal; or just the often-experienced conciliatoriness of the elderly. These all constitute various levels of vulnerability of PwDs, which can be experienced during research activities, in relation to researchers, based on either fear, exploitation, or both.

As noted by Hurst (2008), researchers have a duty to avoid the worsening of previously identified harms, if possible. Researchers have a duty to actively minimise these harms, as required by Art. 4 of the UDBHR. Researchers should also not create additional pathogenic vulnerabilities[17] for PwDs (e. g. dependence on incompetent or abusive caregiver; psychological harms due to institutionalisation, isolation, or unfamiliar surrounding; etc.; Lange et al. 2013). The UDBHR furthermore requires that researchers

17 Lange et al. (2013) define pathogenic vulnerabilities as vulnerabilities originating from dysfunctional social or personal relationships. Vulnerabilities based on prejudice, abuse, neglect, disrespect, etc., both on small (inter-personal) and large (political, social) scale belong here (Lange et al. 2013).

promote and empower the autonomy of PwDs, not only for its instrumental value but because this requirement is embedded in the highest standard set in Art. 3 of the UDBHR.

The authority of researchers may pose an additional level of vulnerability to the PwDs. Paternalistic traits expressed by researchers during the investigation may render the PwDs vulnerable without the participant herself noticing, as mentioned by Kottow (2003) and Lange et al. (2013). The natural authority of researchers originating in their expertise may increase the vulnerability of PwDs as research participants when undue influence is placed upon the participants.

Careful attention should be paid towards the direct and indirect effects of the research trial on participants' daily lives (Lange et al. 2013). The development of AAL technologies often occurs in the private home environment of PwDs, where additional and unforeseeable consequences may arise, which were not recognised from initial trials conducted in labs and/or nursing homes.

5.3.1.2 *Vulnerabilities of PwDs from Close Relatives and Proxies*

When PwDs consider participating in research studies, it is likely that they are seldom alone, and are surrounded by family or other proxies where the AAL technology may be deployed. Especially if the research focuses on AAL technologies deployed within home environments, a necessary number of relatives and/or proxies need to be briefed, contacted, and consented.

Furthermore, just as it is with researchers, the PwDs may experience undue influence from their families or partners when decisions are required. In order to alleviate or circumvent some of these issues, Horn proposes the introduction of independent mediators, which may be beneficial (Horn 2007). The role of mediators should be the protection of the the rights and interests of PwDs, in communication with family members and/or investigators of a research study in which the PwD is considering participating.

5.3.1.3 *Vulnerabilities from Developing AAL Technologies*

PwDs may also be rendered especially vulnerable in relation to the development of AAL technologies. This special vulnerability emerges due to the invasive nature of the technology in the private home environments of PwDs. This invasiveness is further multiplied by the intrusive nature of the technology, its expected partial or full autonomy and agency. Developing AAL technologies may appear to be 'less invasive research' but on closer inspection, it is apparent that the invasiveness is present in a different way to that of invasive research studies that affect the body of a participant. Researchers should be repeatedly reminded, that AAL technologies operate on the basis of continuous collection of personal and medical data in the private dwellings of PwDs. These

data must not cause concern in the PwD herself or her family members, or even third parties unrelated to the research study.

Hence, during the R&D of AAL technologies involving PwDs, it is not only possible but also necessary to provide special protections. These should include the crucial involvement of PwDs into the R&D procedure. The design of AAL technologies that disrespect the special needs of PwDs is unethical and may not be sensible. Furthermore, necessary support needs to be provided during the deployment of prototypes. Personal and medical data of PwDs and proxies recorded by AAL technologies should also be protected.

At the end of the study, the removal of AAL technologies is a source of another type of vulnerability for PwDs. Research projects developing AAL technologies typically last from 1 to 3 years, during which time, the PwDs may get accustomed to the presence of this technology, or even develop a dependency on them. This needs to be considered along with the likelihood that the PwDs' severity of dementia will progress. The removal of a device that the PwD is used to or depends on may cause anxiety, which opposes the effective management of dementia.

On a policy and wider societal level, it has to be noted that populations in developing countries currently benefit very little from the development of AAL technologies. AAL technologies are currently being developed in mostly Western, developed countries, for deployment into the homes of the developed world. As it is apparent from section 1.3, other parts of the world will also suffer from growing numbers of cases of dementia. However, by being excluded from research studies of AAL technologies, PwDs in developing countries are withheld the opportunity of having their needs understood, assessed, and met. As such, their exclusion from the R&D processes of AAL technologies may be considered discriminatory, and liable for accusations of double standards or negligence. Such negligence may add to the vulnerability of the already ageing populations in the developing world. This may ultimately result in a situation, whereby the resources (incorrectly) invested into the R&D of AAL technologies in the developed world are wasted because the results of the design of the research was one-sided, and the conclusions inapplicable in other communities.

5.3.1.4 *Respect for Personal Integrity in Research with PwDs*

The requirement of Art. 8 for the respect for the PwDs' personal integrity implies that protection against excessive objectification of the body during research must be provided. A PwD participating in a research study does not cease to look for meaningful relationships, or even partnerships, with researchers. PwDs do not provide their impairment(s) as an object for research purposes only. They do not cease to exist as human beings and persons (no matter how impaired). The researchers, thus, as required by

Art. 8 of the UDBHR, should look to build meaningful relationships with their research participants, and involve them proactively in the R&D process.

The requirement of respect for a PwD's personal integrity means considering her as a person with all her needs, frailties, and values. It also means considering their impaired condition, and even the relevance and appropriateness of research goals of the study. Respecting the PwD's personal integrity may save researchers from inducing additional vulnerabilities through inadvertent exploitation, paternalism, or double standards. Respecting the personal integrity of PwDs during the development of AAL technologies requires, first, that the PwDs are not considered as secondary to the technology and its functionings during research. Secondly, the respect for personal integrity should also include that the researchers do not regard PwDs as only sources of data and other information, no matter how relevant they are for the research study. The respect towards the PwDs' human dignity should be paramount, as it is one of the cornerstones and most highly defended standards of the UDBHR.

5.3.2 *Clinical Practice*

Compared with clinical research, both the universal/average vulnerability and the special vulnerability/susceptibility of PwDs are more apparent in the context of clinical practice. Human beings manifest by their individual preferences, wishes, personal characteristics, and other traits noticeable differences. Indeed, differences like these generic human conditions—which render all of us somewhat vulnerable—should be ascribed to average vulnerability. However, higher than average risk of possible future harms, due to various pathological conditions, should be categorised as special vulnerabilities, or susceptibilities. For cases of mild dementia, respect for average vulnerability should be applicable. This respect towards average vulnerability should lead to the provision of necessary support for recognised impairments and disturbances of PwDs. Moderate or severe dementia should trigger not only adequate support, as required by respecting average vulnerability. In addition, it should also trigger a dedicated effort of healthcare professionals for active risk-minimisation and proactive avoidance of possible future harms, in effect, respect for special vulnerability.

The vulnerabilities of PwDs during clinical practice with AAL technologies are affected on the following three levels, which serve as the main rationale for their categorisation: a) interpersonal level; b) societal level; c) technological level.

5.3.2.1 *Respect for Vulnerability on Interpersonal Level*

Interpersonal communication and socialisation of PwDs is one of the crucial goals of the management of the dementia and avoidance of social isolation and/or stigmatisation. For this reason, AAL technologies try to provide more means and opportunities for

socialisation. In everyday treatment and care for PwDs, the respect for their vulnerability, requires the practice of certain important habits (or virtues). These are, for example, tolerance, helpfulness, support for the coping with impairments. Education plays a very important part in developing these habits. Due to the ever increasing numbers of PwDs, the prevention of the development of individual indifference and neglect will be crucial for the fulfilment of the requirements of respect for their vulnerabilities. It is almost certain that relying exclusively on healthcare systems to cope with these issues will not be sufficient and individual virtues will need to be developed for everyday functioning with PwDs on a general level.

There is also an additional level of vulnerability, which has not yet been mentioned in regard to PwDs. This additional vulnerability is their exposure to fraud and confidence tricks, which can result in costly mistakes. This vulnerability is not only limited to the clinical practice but to every domain of their daily lives, including the management of AAL technologies, or basic instrumental activities of daily living (iADLs) (shopping, managing money, etc.)

5.3.2.2 *Respect for Vulnerability on Societal Level*

The respect for the vulnerability of PwDs on the societal level should manifest in the support for the empowerment of PwDs by compensating for their impairments. Leaders and members of societies should actively engage in preventing future discriminations and disrespect towards PwDs. Moreover, individuals who discriminate and show disrespect to PwDs should be legally accountable, with standards being clearly defined.

Respect for vulnerabilities in the clinical setting should furthermore avoid the overly aggressive treatment of PwDs, which causes unnecessary escalation of vulnerabilities, distress, and anxiety in the persons living with dementia. The lack of an effective cure for dementia along with the argument of scarce resources should not be used as an excuse to provide suboptimal treatment for PwDs. This will also increase the vulnerabilities of PwDs during clinical practice. Proportional and well-balanced treatment should be defined in order to provide PwDs with appropriate care.

Finally, just as in research, regulatory authorities should ensure that effective measures are applied to protect against the exploitation of the vulnerabilities of PwDs. These vulnerabilities include financial vulnerabilities, vulnerabilities related to managing healthcare services and healthcare insurances, which may be moreover be open to various forms of fraud. Furthermore, certain vulnerabilities are generated by the general introduction of AAL technologies into private homes, including vulnerabilities related to data safety and active data protection, which typically cannot be managed by the PwDs or their family members.

5.3.2.3 *Respect for Vulnerability on Technological Level*

The introduction of AAL technologies into private homes and into the healthcare process of vulnerable PwDs offer another source of additional vulnerability. The intrusiveness of AAL technologies during clinical application may cause harm to PwDs by its faulty operation, ability to manipulate or coerce its user, aggressive or inappropriate nudging that causes anxiety for the PwDs. The surveillance abilities of lifelogs may serve as beneficial reminders for their users with memory impairments but may also cause harm by their seemingly infinite memories resulting in undesired reminders of hurtful memories. The source of these and similar harmful events is the incorrect design and application of AAL technologies, which ignore the personal preferences of their users, resulting in increased vulnerabilities of PwDs.

The vulnerabilities caused by incorrect design and application of AAL technologies may also occur die to premature application. As noted in Chapter 3, lax testing standards may be identified as one source of vulnerability. Another is the adoption of relatively uncritical approach towards ICT devices overall, as they are already ubiquitous in everyday use. However, very low or even lack of satisfactory testing standards and optimisations of AAL technologies may introduce more harms and anxieties to the lives of PwDs than advantages.

It is believed that AAL technologies will offer additional empowerment and support for the everyday activities of PwDs, thus diminishing their special vulnerabilities. Nevertheless, the belief in a 'quick fix' for certain issues related to PwDs may also mislead healthcare professionals, who may gain an impression that they provided the best care for the PwDs. This impression may be harmful within the care of PwDs because certain activities cannot be replaced by services provided by AAL technologies. Amongst these are, for example, human care, which is an important source of socialisation for PwDs, eliminating some of their special vulnerabilities.

Although AAL technologies may provide PwDs and their caregivers with medical benefits (e. g. better and more effective dementia care management, etc.) and/or financial benefits (e. g. cheaper cost of management), they may also increase the PwDs's vulnerabilities in these areas. Implementing AAL technologies that are not or only partially covered by health insurance companies may increase the financial gap between the affluent and less affluent social groups of a population. The financial burden of AAL technologies plays a key role in the affordability of assistance, due to the fact that the growing numbers of PwDs are no longer the financially active part of the society. Moreover, the ever increasing pressure from the governments for the externalisation of elderly care (including dementia care), may often be based solely on fiscal considerations. These fiscal reasons should be strictly separated from the personal preferences of elderly individuals to stay living in their homes for longer, even with the assistance of AAL technologies.

On the societal level, Art. 8 ensures that such understandable and natural preferences of PwDs should not be used to generate further vulnerabilities, or otherwise be abused.

Finally, PwDs may find themselves vulnerable under the social pressure or pressure of healthcare professionals, or healthcare insurance systems to introduce AAL technologies into their private homes, in order to avoid 'missing out' or having the request made at a later date declined. It should be emphasised that refusal of using assistive technologies should not be punished in the future, and unfair pressure for their acceptance on the societal level exploits the vulnerability of PwDs.

5.3.2.4 *Respect for Personal Integrity in Treatment of PwDs*

Similar to the research activities, the respect for personal integrity of PwDs during clinical practice should reflect a new approach towards the human body and its disease. Although a person is biologically inseparable from the body, her treatment should not focus exclusively on it as an object but should entail her subjective and personal perspective. Also, Art. 8 encourages the development of new approach to disease, which should accommodate more subjective approaches, especially if there is no effective treatment. There is no cure yet for dementia. Therefore, the relationship of physicians and other healthcare professionals with PwDs should be based more on partnership, cooperation, and symmetrical relationships.

5.4 BALANCING OF PRINCIPLES

This section examines whether the principle of respect for vulnerability and personal integrity, after specification in the case of PwDs and AAL technologies, contradicts any other principles delineated in the UDBHR. In case of such a contradiction, Gert's two-step justification procedure will be applied for balancing purposes, as described in section 1.2.

5.4.1 *Principles Conflicting with Article 8*

Three principles of the UDBHR may conflict with Art. 8 on the respect for vulnerability and personal integrity. These are Art. 11 on the principle of non-discrimination and non-stigmatisation, Art. 4 on the principle of maximising direct and indirect benefit while minimising harm, and Art. 10 on the principle of equality, justice and equity. These conflicts are presented below in greater detail.

5.4.1.1 *Conflict with Article 11*

The conflict of the principle of respecting vulnerability and personal integrity (Art. 8) and the principle of non-discrimination and non-stigmatisation (Art. 10) can be expressed by the criticism formulated by Levine et al. (2004b). This criticism, as noted earlier in this chapter, focuses on the tendency of interpreting vulnerability as a form of or excuse for stereotyping research participants. All this stereotyping may occur even if the prospective participant of a research study does not consider herself, nor the researchers or RECs consider her to be, vulnerable. However, she may belong to one of the strictly defined (e. g. by law, or other binding guideline) vulnerable groups.

Similar concerns led the bioethical community to review their position on the inclusion of vulnerable groups (e. g. pregnant women, children, prisoners, etc.) into research. The driving force behind this shift in the approach towards vulnerable populations was that these groups became progressively underrepresented in research studies. As noted earlier, the reasons why this occurred were various: either the tedious extra work that was required in order to include vulnerable participants into research, or the overly protective approach of ethical codes (e. g. *Belmont Report* 1978). The shift towards a more active re-inclusion of vulnerable groups into research studies occurred in the 1990s (S. A. M. McLean 2014; Mastroianni and Kahn 2001).

Similarly, PwDs may suffer from both overly easy inclusion into research irrespective of their vulnerable position, and unnecessary exclusion from research due to their vulnerable position. The former scenario follows Art. 8 of the UDBHR, focusing on the unquestionably vulnerable condition of PwDs. The latter scenario may demonstrate the reference to special vulnerability as discriminatory, and hence, violate Art. 11 of the UDBHR.

The following sections, applying Gert's two-step justification procedure will estimate the possible consequences of actions in accordance with either of the two conflicting principles. This will be then followed by the analysis of how strong the justifications for the conflicting consequences are, attempting to balance the conflicting UDBHR principles for cases involving PwDs and for the application of AAL technologies.

CONSEQUENCES OF VIOLATING ARTICLE 8

The aim of referring to a principle of respect for vulnerability (and personal integrity) since the *Belmont Report* (1978) is the provision of necessary protection for vulnerable groups. Violating this principle leaves these populations either unprotected, or insufficiently protected. The former category of universal vulnerability remains irrespective of the special vulnerabilities, as in the case of PwDs: memory impairments, physical frailty, issues with recognition, comprehension and judgement, issues with organising and planning, changes in mood and behaviour.

The consequences of violating the principle of vulnerability and personal integrity can be estimated on either individual-level or group-level.

Individual-Level

Disrespecting individual vulnerability and personal integrity could mean that either physical or psychological harm is being done to the PwD. Such activity would, not only counteract Art. 4 of the UDBHR but also, violate the basic ethical codes, which have existed in medical settings since the time of Hippocrates, particularly that of non-maleficence.

Disrespecting the individual vulnerability of PwDs by not providing extra protection during participation in research may also mean treating PwDs as any other ordinary research participant. Considering their conditions of MCI, memory impairment, issues with comprehension and judgement, such an approach would translate into failing to provide extra support, for example, during the request for informed consent. Failure to provide necessary support for obtaining consent, and hence the expression of personal autonomy and self-determination, would violate the very basic standards of modern bioethics.

Ad absurdum, ignoring the extra needs of PwDs in the research of highly personalised AAL technologies would at the same time mean a clear contradiction in terms. This approach would be inhumane, while at the same time it would violate the basic standard of conducting research, the principle of research integrity.

Group-Level

On a group-level, the violation of the principle of vulnerability and personal integrity might result in increased freedom for researchers in research involving PwDs. This freedom may be manifested in an easier or more lax approach towards recruiting PwDs as research participants. This would mean, for example, that research with PwDs as participants would be much more 'affordable' and accessible for the researchers. Moreover, as rightly noted by Kottow (2003), such an approach carries a greater danger of double standards, exploitation, and paternalism.

Also, from historical experiences, it is evident that a careless approach has never been beneficial. One may refer to the Nuremberg trials, which also included cases of people participating in research studies against their wills. Such a 'utilisation' of PwDs would mean, despite the relative freedom for researchers, an actual lack of freedom for the PwDs.

The particular disrespect towards PwDs personal integrity would not only violate their human rights (e. g. *UDHR* 1948, Art. 22) but would also thus infringe their human dignity. Within the weak hierarchy of the UDBHR, any *prima facie* principle that contradicts Art. 3 cannot be considered as an ethical action guide.

CONSEQUENCES OF VIOLATING ARTICLE 11

The violation of the principle of non-discrimination and non-stigmatisation of Art. 11 in the UDBHR would mean that a certain level of discrimination and stigmatisation towards PwDs is allowed. Its consequences, as noted by Levine et al. (2004b), could be the stereotyping of the research participants, or—in extreme cases—the violation of their human rights and human dignity.

The danger of stereotyping lies in exclusion of PwDs from research based either on the fact that they belong to a vulnerable subpopulation, or on the consideration of them as a homogenous group, having the same severity of dementia. Both of these claims are invalid in the case of PwDs because they are a very heterogenous group. Not only the severity but also the external signs and symptoms of dementia may vary considerably between individuals with dementia. It is especially so in the early stages of the disease, that is, in the groups of people who are most often involved in research studies.

However, it has to be emphasised that—using legal terminology—the possibility to participate in research is not a right but a privilege. Participants must fulfil the conditions of eligibility in terms of the inclusion and exclusion criteria. The number of participants is often limited. An individual cannot claim a right to be a participant in a research study, against the decision of the researcher, even if she fulfils the eligibility criteria. Therefore, the notions of discrimination and stigmatisation should not be blurred together with the refusal or non-eligibility to participate in a research study.

This statement remains valid even in situations when a rejected research participant expresses her claim to the supposed direct or indirect benefits of the research. Not allowing somebody to participate would mean withdrawing the possibility of gaining any benefits resulting from participating in a study. However, in the world of scarce resources, not allowing somebody to participate can occur but not because the researchers want to withhold the possible benefits of participation. The study design may also restrict the number of participants based on the selection criteria. Research studies have to produce meaningful, reproducible, and statistically significant results, which are well-founded and valid, in order to provide relevant conclusions that contribute to the greater benefit of the wider population. Moreover, participating in a research study does not only carry the prospect of benefits but also harms. Research participation is also risky; containing risks that have to be evaluated, not solely by the prospective participant but also by the researchers.

Therefore, one can conclude that refusing a PwD's wish and preference for participation does not necessarily mean an act of discrimination or stigmatisation against the prospective participant. Such a refusal, as required by Art. 11 of the UDBHR, does not mean a violation of the PwD's human dignity, or human rights; just as it does not mean the violation of the PwD's fundamental freedoms.

BALANCING OF ARTICLE 8 AND ARTICLE 11

Applying Gert's second step from his two-step procedure, by balancing, one has to answer the question of whether the conflicting principles of Art. 8 and Art. 11, and their violations by one another presented above, can be permissible if they were made public. If such permission can be granted, every reasonable and impartial human being will be allowed to violate the principle. If permission cannot be granted in every situation, this means that the violation is only weakly justified and may be penalised. If permission can never be granted, the violation is not justified at all and should be prevented.

This is clearly highlighted in one particular conflict between Art. 8 and Art. 11. It is the situation when the protection of the especially vulnerable PwDs in research is interpreted as negative discrimination against any PwDs' preference or wish to become a research participant. The purpose of both articles is the protection of human dignity and the fundamental rights of the individual; in this case, those of a PwD being recruited into a research study.

Suspension of the requirements formulated in Art. 8, i. e. of respecting the PwD's special vulnerability, because of the special characteristics of the PwDs as research participants, cannot be publicly allowed. PwDs are people with memory problems, who have issues with recognition, comprehension and judgement, and who are unable to organise and plan their everyday life. Moreover, they experience significant changes in mood and behaviour. Even if one has only a few of these issues, others may appear during the course of time, and/or may continue to progress to a more severe stage. These progressive impairments have a significant effect on the personality of the PwD, and are irreversible. Therefore, it would be imprudent and unethical to knowingly ignore these factors and be surprised when these issues appear during a research study.

Referring to the principle of protecting the vulnerability of PwDs as a form of negative discrimination against their participation in research thus seems to be a rather extreme claim. Firstly, both articles are defined to protect the person's human dignity, their contradiction should be evaluated on the grounds whether the consequences violate the human dignity of the individual or not. Since being disrespectful towards the vulnerability of a PwD may almost certainly cause more harm than apparently discriminating against a PwD by not allowing her to participate in a research study, one must cede that the principle of respecting the vulnerability of the PwD should be favoured. The imbalance between the claims of Art. 8 and Art. 11 is even greater if one considers the fact that participation in a research study is subject to many other conditions (inclusion criteria, minimal necessary number of participants to obtain statistically significant results, scarcity of resources of the research-team, etc.). Participation in research is not a basic right of an individual but rather, a privilege. A statement of an incapacitated PwD about willingness to participate in research in her advance directive should be considered as just a wish and not an action guide for researchers. In countries where advance

directives are considered as legally binding (e. g. Austria, Switzerland, for more detail on this topic see Chapter 6 on p. 205), the words 'wish' and 'willingness' should indicate to researchers that the statements should be regarded only as an individual preference of the PwD. Thus, the interpretation of Art. 11 as discriminatory against the respect for vulnerability is rather distorted and poorly supported.

5.4.1.2 *Conflict with Article 4*

Another possible conflict of principles may exist be between Art. 8, respect for vulnerability and personal integrity, and Art. 4, the principle of applying and advancing scientific knowledge for the direct and indirect benefit to the patients and research participants; benefits which should be maximised, while harms are minimised. The maximisation of benefits of treatments and research cannot occur, if the patient or research participant is excluded from research studies or treatment provision in clinical practice. Such exclusion may occur, as noted earlier in this chapter, based on an incorrect understanding of the special vulnerabilities of PwDs.

The conflict between Art. 8 and Art. 4 contrasts against the overly broad inclusion of individuals into the especially vulnerable group, as noted by Lange et al. (2013). In this case, PwDs' fair opportunities of research participation or receiving treatment are hindered. Additionally, no active steps are taken to abate their vulnerabilities, due to misconceptions that their *status quo* is somewhat natural and unavoidable. Such practice indirectly increases the vulnerabilities of PwDs. Of greater concern is the fact that these vulnerabilities remain unaddressed.

As a reaction to this practice, a shift in inclusion of vulnerable populations into research has been promoted, since the 1990s, which focuses on the provision of potential direct and indirect benefits of research, rather than on the possible harms. This counters the exclusion of vulnerable groups based on supported with the false justifications of protection (Mastroianni and Kahn 2001).

CONSEQUENCES OF VIOLATING ARTICLE 4

The possible benefits and harms of AAL technologies, and the participation of PwDs in research of AAL technologies are presented in depth in Chapter 4.

One may easily recognise that this conflict of principles is similar to the previous conflict discussed, between Art. 8 and Art. 11, namely, that the conflict of Art. 8 and Art. 4 is a consequence of the conflict between Art. 8 and Art. 11. Art. 11 was used to argue that the 'right' of PwDs to participate in a research can be violated by protecting one's vulnerability and personal integrity. Analogously, Art. 4 may be utilised for arguing that by such 'discrimination,' one is bereaved of the potential direct and indirect benefits of participation in a research.

BALANCING OF ARTICLE 8 AND ARTICLE 4

The question based on Gert's two-step procedure may be stated as follows: can the suspension of the requirements of Art. 8 for the prospective direct and indirect benefits for the PwD to participate in a research study be publicly allowed? The answer may again be negative, given the fact that participation in research is a wish and not an automatic basic right of individuals. Furthermore, the negative claim may be supported by the possibility of dubious results from a research study. By the nature of and reasons for conducting a research study, it is not guaranteed that a participant will benefit from the participation. The serious and progressively manifesting impairments of PwDs provide strong support for a high level of caution during recruitment for research participation. This high level of caution is further supported by the formulation of Art. 4 itself, namely, the requirement to minimise the harms for research participants (and patients in clinical practice).

Therefore, suspending the requirement to protect vulnerability and personal integrity in favour of potential (and possibly questionable) research benefits cannot be publicly allowed. At the same time, remaining passive and maintaining the *status quo* of PwDs may amplify their special vulnerabilities, without the hope of any resolution. By violating Art. 4, the goals of Art. 8 are also being violated in the case of PwDs.

In contrast, a more proactive approach towards the identification to direct and indirect benefits that reduce of vulnerabilities is more promising, so long as any negative consequences, harms, and risks are eliminated or minimised. A more proactive approach would result in of greater social inclusion of PwDs into R&D processes, higher self-esteem and possibly lower levels of depressions, which would help address conditions often experienced with PwDs.

Thus, the balancing of the conflict of Art. 8 and Art. 4 promotes the proactive involvement of PwDs into research activities instead of their exclusion. However, in clinical practice, this balance favours more a cautionary approach, due to the lack of any curative treatment of dementia. Only management options that have direct or indirect benefits on PwDs would be justified sufficiently for clinical practice, especially with regard to AAL technologies. Otherwise such options may induce even more vulnerabilities for PwDs, which directly violates Art. 8 of the UDBHR.

5.4.1.3 *Conflict with Article 10*

In light of the previous conflicts, an additional conflict may be possible between Art. 8, protection of vulnerability and personal integrity, and Art. 10, respect for the fundamental equality in dignity and rights, together with just and equitable treatment. This conflict may occur if the group of especially vulnerable people, which can include PwDs, is defined too widely and generally. The effect of such a wide interpretation of especially

people may lead to their exclusion from research studies. More importantly, certain rights, which they never ceased to hold, may also be also violated, resulting in the possible infringement of their basic human rights, human dignity, and right to just and equitable treatment.

CONSEQUENCES OF VIOLATING ARTICLE 10

Just as with the conflict between Art. 8 Art. 4 described above, this conflict can be identified as similar to the conflict between Art. 8 and Art. 11. The same type of argument can apply. Disrespect of the prospective benefits provided by participation in a research may, in an extreme case, be interpreted as discrimination, and hence as a violation of the standards requiring equity and justice.

BALANCING OF ARTICLE 8 AND ARTICLE 10

This conflict of principles is the weakest conflict because all the arguments listed for the resolution of the conflicts of Art. 8 and Art. 11, and Art. 8 and Art. 4 are applicable in the case of the conflict between Art. 8 and Art. 10.

As required by Gert's second step of the two-step justification, the suspension of the requirements defined in Art. 8 for the research involvement of PwDs cannot be publicly allowed. The distinctive argument in this case is that by fulfilling the requirements of Art. 8, one is at the same time also fulfilling the requirements of Art. 10. By protecting the vulnerable during research (and therapy), one respects and protects the dignity and fundamental rights of PwDs, and thus, ensures they are also treated justly. Since participation in research is not a basic human right but a privilege, not allowing a PwD to participate in a research study due to her vulnerability (or other exclusion criteria) cannot be understood as an unjust or unrighteous act.

5.5 SUMMARY

As a result of the specification and balancing of Art. 8, applied to PwDs and the R&D and deployment AAL technologies for their care, the following recommendations can be formulated.

5.5.1 *Vulnerability of PwDs Based on UDBHR*

- The concept of vulnerability is a descriptive notion. Nevertheless, it is not a value-neutral concept. Vulnerability, having prescriptive meaning for human conduct, by describing genuine human identity also reveals considerations for every human

activity. This prescriptive meaning of vulnerability should also be translated into the development and application of AAL technologies.

- Two types of vulnerabilities can be distinguished according to Art. 8 of the UDBHR: universal vulnerability and special vulnerability. The former is applicable to every human being without exception, and is based on the general human condition of average vulnerability that a person is subjected in any medical care. The latter type of special or exceptional vulnerability is present when a person is insufficiently protected due to her condition, and, therefore, she requires specific ethical response.

- Vulnerability does not indicate a greater actual harm that already happened to the PwD but it highlights a higher likelihood of harm when problems occur.

- The special vulnerability of PwDs translates into vulnerability in relation to meeting the other ethical requirements of the UDBHR, such as Consent (Art. 6), Persons without the capacity to consent (Art. 7), Human dignity and human rights (Art. 3).

- The most common forms of violation of the respect for vulnerability in research are issues of double standards, exploitation, coercion, undue influence, or paternalism.

- PwDs should not be deprived of a chance to participate in research due to their especially vulnerable condition. Their progressively worsening condition should be regularly reviewed and necessary measures for the protection of their vulnerability and personal integrity should be established.

- Careful attention should be paid to the evaluation of juridic and deferential vulnerabilities of PwDs (undue influence from proxies, caregivers, etc.). The dangers of deferential vulnerability caused by ICT should also be considered during R&D.

- PwDs should not be stigmatised and discriminated against due to their especially vulnerable condition in research, or clinical practice.

- Removal of AAL technologies after the end of the research study may render PwDs more vulnerable. The consequences of inflicting this type of harm on PwDs should be considered during the design of the research study, and should be effectively addressed in accordance with Art. 4 of the UDBHR (e. g. minimising harm).

- PwDs, most of whom are elderly, are prone to allocational vulnerability. Therefore, the economic and societal effects of AAL technologies in relation to the vulnerabilities of PwDs should be considered, and solutions that are ethically sound provided.

- Researchers during their consideration of vulnerabilities of PwDs should avoid its overly broad or overly narrow and reductionist interpretation. Researchers should also avoid the stereotyping of research participants who live with dementia.
- Contemporary methods of assessing vulnerability may prove to be useful for considering special vulnerabilities for PwDs during research and therapy with AAL technologies. These may include special scrutiny for considering vulnerability (Levine et al. 2004b), layered vulnerability (Luna 2009), vulnerability as a special protection (Hurst 2008), and special taxonomy for considering vulnerability (Lange et al. 2013).
- Researchers conducting research with PwDs, as a part of their duties, should not exacerbate or create additional vulnerabilities.
- Research with PwDs does not provide sufficient justification for alleviating the protection of special vulnerability and personal integrity of the participants. The UDBHR does not allow any moratorium on favouring research with vulnerable PwDs in the light of prospective benefit of research activities. Nor is the disregard of the special vulnerability of PwDs allowed, despite the wish of PwDs to participate in a research study.

5.5.2 *Personal Integrity of PwDs Involved in Research or Therapy*

- Due to the deteriorating condition of PwDs, the most relevant of the three most common variations of the definition of personal integrity appears to be the one based on the negative right of non-interference. The right of non-interference by others in the private sphere of the PwD also forms an integral part of basic human rights.
- The UDBHR also represents the broader sense of personal integrity, which means the prioritisation of the needs of groups identified as especially vulnerable. PwDs may be considered one of these groups, based on their gradual impairments (without any current cure) as especially vulnerable, both for research activities and in clinical practice.
- The concept of personal integrity assists in the interpretation of the condition of PwDs, reorienting the initial focus from the human body to the more subjective perspectives of the individual, whose body is inseparable from the whole person. Personal integrity also shifts the interest from the sole scientific description of the disease to the whole person, who lives and experiences that disease.

- Personal integrity provides a foundation for other principles (e. g. autonomy, informed consent), opening up the possibilities for a meaningful relationship between the PwD and her researcher. These relationships may take various forms: new methods of communication, a more focused approach towards the PwD, proactive involvement of the PwD in research, development of less invasive therapies, a respectful approach towards the PwD, etc.
- Persons experiencing harm, due to their special vulnerability, have impaired capabilities in retaining their personal integrity.

6

INFORMED CONSENT OF PEOPLE WITH DEMENTIA

This chapter provides a normative analysis of the ethical issue of obtaining informed consent from Persons with Dementia (PwDs). For the normative analysis a more focused view of the ethical literature is required on the issue of informed consent. Therefore, an interpretative section of the articles on informed consent present in the Universal Declaration on Bioethics and Human Rights (UDBHR) will precede the normative analysis of these articles. This chapter provides answers for the following four questions:

1. What does the literature interpreting Art. 6 and Art. 7 of the UDBHR say about the principle of informed consent, and how should the requirement of informed consent be fulfilled?
2. How is the principle of informed consent interpreted in policy documents and academic literature?
3. How should Art. 6 and Art. 7 of the UDBHR be understood in its application to the circumstances of PwDs and the context of Ambient Assisted Living (AAL) technologies?
4. Which principles of the UDBHR need to be balanced with the principle of informed consent?

The answer to the first question of the chapter is provided by overviewing the available handbooks and reports that directly interpret the UDBHR principles, with their dedicated sections referring to the principles of informed consent. This literature is mostly *The UNESCO Universal Declaration on Bioethics and Human Rights: Background, Principles and Application* (ten Have, Jean, and Kirby 2009), *Handbook of Global Bioethics* (ten Have and Gordijn 2014), *Explanatory Memorandum on UDBHR* (2005), and *Report of the International Bioethics Committee of UNESCO (IBC) On Consent* (IBC 2008).

The second question of the chapter overviews the most influential international and policy documents, followed by the overview of the academic literature relevant for the interpretation of the issue of informed consent in general, or with the use of Information

and Communication Technology (ICT) (there has been very little deployment of AAL technologies yet).

In the normative part of this chapter, first, the previously interpreted informed consent principles of the UDBHR are specified to the specific context of PwDs and AAL technologies. The specification will focus both on clinical research, and clinical practice of PwDs. Secondly, any possible conflicts between Art. 6 or Art. 7 and other UDBHR principles are identified, examined, and balanced, utilising the balancing process described in section 1.2.

Finally, at the end of the chapter a summary of the specification and balancing process is provided. This summary will aim to provide a concise overview of the normative analysis of informed consent in the light of the UDBHR principles presented in this chapter.

6.1 INTERPRETATION OF PRINCIPLES

6.1.1 *Principles of the UDBHR*

Two articles of the UDBHR list the principles that relate to informed consent. These are Art. 6–7. Art. 6 deals with the general requirements related to consent in preventive, diagnostic, therapeutic, and research activities. Art. 7 provides a general rule for cases where consent is being sought from people unable to provide consent.

6.1.1.1 *Informed Consent*

Article 6

1. Any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free and informed consent of the person concerned, based on adequate information. The consent should, where appropriate, be express and may be withdrawn by the person concerned at any time and for any reason without disadvantage or prejudice.
2. Scientific research should only be carried out with the prior, free, express and informed consent of the person concerned. The information should be adequate, provided in a comprehensible form and should include modalities for withdrawal of consent. Consent may be withdrawn by the person concerned at any time and for any reason without any disadvantage or prejudice. Exceptions to this principle should be made only in accordance with ethical and legal standards adopted by States, consistent with the principles and pro-

visions set out in this Declaration, in particular in Article 27, and international human rights law.

3. In appropriate cases of research carried out on a group of persons or a community, additional agreement of the legal representatives of the group or community concerned may be sought. In no case should a collective community agreement or the consent of a community leader or other authority substitute for an individual's informed consent.

ARTICLES 6.1 AND 6.2

Definition of Informed Consent Based on UDBHR

This section specifies three areas of the principles of informed consent: a) how the articles of the UDBHR manage the requirement for informed consent for prevention, diagnosis, therapy, and research; b) what the requirements are for valid informed consent; and finally c) how informed consent is influenced by the context of a given situation.

The principle of informed consent of the UDBHR in Art. 6 distinguishes between the practices of prevention, diagnosis, and therapy on one hand, and research activity on the other hand. Art. 6.1 and Art. 6.2 refer to these scenarios separately. In both of these principles, however, the requirements of valid informed consent are identical. The person concerned should be requested to consent prior to the treatment or research activity, which means that the request has to be, in an ideal situation, submitted beforehand (Kollek 2009; IBC 2008). The term 'free' means voluntary consent without any inducement (*Explanatory Memorandum on UDBHR* 2005). This requires a relationship between the person concerned and the healthcare professional that enjoys mutual confidence, respect, and confidentiality (IBC 2008).

The provision of adequate information stands for the requirement that the information provided has to be relevant to the case at stake.[1] Moreover, the information has to be comprehensible for the receiver. In cases of doubt regarding whether the person concerned has understood the provided information about the objectives, risks, benefits, etc., of the intervention, a mediator can be called upon. For these purposes, the notion of the *reasonable person standard* has been developed (IBC 2008).[2] The information has to be cor-

1 The 'informed' attribute adjacent to the word consent first appeared in 1957, in the *Martin Salgo v. Leland Stanford Jr. University Board of Trustees, Stanford University* judgement. The ambiguous sentence in the judgement is "in discussing the element of risk a certain amount of discretion must be employed consistent with the full disclosure of facts necessary to an informed consent" (J. Bray 1957). The distinction between the requirements of discretion and of informed consent is the basis of the majority of issues in clinical practice and research up to now (Stanton-Jean et al. 2014).

2 In Canada, researchers identified five levels of understanding health-related information (Stanton-Jean et al. 2014):

1. *Health promotion* – read food labels, purchase food, plan and exercise regimen.
2. *Health protection* – read articles in newspapers, decide among product options.

rectly structured. For the purposes of prevention, diagnosis, and therapy, this means that the information about the diagnosis and possible prognosis, the nature and process of intervention, expected benefits, and undesirable side effects (risks) has to be shared. This involves, in certain cases, the evaluation of experiences and capabilities of the healthcare professionals involved in their treatment, and their possible financial benefits in cases of conflict of interests. Lastly but not least, in seeking consent for preventive, diagnostic, or therapeutic interventions, the possibility of withdrawal has to be offered to the person concerned. A withdrawal from treatment should in no case have an effect on care provision or discriminate against the person concerned. As the emergence of certain essential circumstances may alter the initial willingness of the person to undergo treatment, similarly they also may change their willingness to continue with treatment (IBC 2008). The information presented to a research participant of a clinical study must include the aim, methodology, duration of the study, followed by the expected benefits, risks involved, and the possibility of withdrawal. Adequate information should further incorporate individually tailored, understandable information, which helps the person concerned to make an informed decision. Seeking informed consent with adequate information is a condition *sine qua non* in medical and research practice, where it is always the duty of the professional to seek consent for treatment (IBC 2008).

Express consent in the UDBHR means that the decision made about the treatment by the person concerned should leave no doubt about her will. Consent may be recorded in various forms: written, oral, or if there are no other means, as a gesture (IBC 2008). Seeking consent should never be solely procedural compliance with the administrative requirements and minimal legal obligations (IBC 2008).

The Context of Requesting Informed Consent

The context plays an important role in the interpretation and application of the principle of informed consent. It is required in the two main types of consent: that requested for prevention, treatment, or diagnosis; and that which is sought for clinical research.

3. *Disease prevention* – understand information related to test results, determine the risks involved in screening results.
4. *Healthcare maintenance* – understand health history forms, calculate timing for medicine, follow directions for medicine labels.
5. *System navigation* – understand application forms, statements, informed consent forms.

The last level of this list is rather bureaucratic and therefore poses the highest challenge for an individual due to its complexity (Stanton-Jean et al. 2014). Stanton-Jean et al. (2014) note that health literacy is at the core of every valid informed consent. It is especially so when physicians worldwide are often not prepared to explain at sufficient length the procedures to follow for treatments. Rather, consents requested for research are often too technical, containing too much information for the participant, for the sake of protection of the researchers and their sponsors. Disadvantaged countries are more vulnerable to exploit this way. To overcome these issues the use of graphics, drawings, cartoons, pictograms, or videos are highly encouraged during obtaining consent. Obtaining written consent does not automatically mean that the consent is informed (Stanton-Jean et al. 2014). Moreover, the level of health literacy may further regress by the introduction of ICT devices in the care, due to the digital divide often present in the elderly cohort.

While consent for clinical treatment is usually considered to be less critical, consent for conducting research is considered to be more crucial (Kollek 2009). In most cases of prevention, diagnosis, and treatment, implicit consent is sufficient (Kollek 2009). For example, when a patient seeks the help of a physician to diagnose an ear infection, it is implicitly assumed that the physician will examine the ear of the patient, and measure the temperature, etc. Such an agreement is sometimes called a *tacit agreement*, i. e. where no objection is raised against the decision of the healthcare professional (IBC 2008). It is, however, not assumed that a physician will request that the patient undergoes a gynaecological examination, which appears to be wholly unconnected to the presupposed ear infection (IBC 2008). The characteristics of obtaining informed consent depend on a multitude of circumstances related to the intervention: its duration, quality, invasive character, potential benefits and side effects, impact on third parties (i. e. family, relatives), and economic consequences (IBC 2008).[3]

Seeking consent is a process, rather than a one-time event. Where possible, the healthcare professional is usually obliged to provide enough time for the person concerned to think over the effects of the treatment. The general rule is that the more invasive the treatment, and the more serious the physical, psychological, and socio-economic consequences for the person concerned, the more express and formalised the consent should be (IBC 2008).

Consent for conducting research is more crucial compared with the consent for treatment. Different types of research require different types of consent: whether it is an epidemiological, biobank study (involving genetic data), involving human tissues, or health policy research, examining public health provision (Kollek 2009). Epidemiological research involves certain data collections, which might require the protection of the interest of third parties. In such cases, whenever the data obtained needs to be re-used, extra consent should be sought from the research participants (IBC 2008). This is because the participant can still be identified through the information that is reused (Stanton-Jean et al. 2014). Requesting and obtaining overall prior consent (blank consent) for the reuse of data in any future research is ethically unacceptable (IBC 2008).

The Right Not to Be Informed

For certain research including genetic data, concerns have been raised about the right not to be informed (e. g. the results of a genetic test for a late onset disease; *Explanatory Memorandum on UDBHR* 2005). Newly emerging technological developments in the fields of genetics, genomics, and nanotechnologies challenge the individualist foundations (and with this, autonomy, confidentiality, individual decision-making) of informed

3 Stanton-Jean et al. (2014) note that if the healthcare system is not funded from public funds the persons concerned may be more willing to refuse the expensive treatments, despite the benefits of such a treatment. And in contrast, research participants may be more willing to participate in a research with higher risks because of receiving free drugs and treatments during the period of the research (Stanton-Jean et al. 2014).

consent. Although adequate information is one of the core requirements of informed consent, the complexity of genetic information irreconcilably challenges this requirement. Moreover, disclosed genetic information can have a strong psychological effect on its recipient. According to present standards, it is unjustifiable to disclose information to a person who does not want to know, particularly when doing so removes the hope from that person. However, the right not to know is not an absolute right. Therefore, before the start of the research study, it is advisable to reach an agreement with the potential participants about the options and potential scenarios within the study, and to define a plan on how to cope with the information during the research. This is particularly challenging, as it is almost impossible to forecast all of the potential outcomes of the research. As a consequence, planning for the disclosure of information is limited in the research. Moreover, there is a lack of guidance in this regard. Finally, certain cases show that the right not to know is subjected to further limitations (e. g. in cases when sexually transmitted diseases are found, etc.). Despite these limitations, the policy of right not to know has made its way to international documents[4] and it has been recognised by some organisations (Stanton-Jean et al. 2014). The UDBHR, however, does not mention the right not to know. The reason for it not being adopted into the list of the principles of the Declaration can be found in the character of the principles. The principles of the UDBHR are general rules, instead of specific ones that include very detailed description of specific cases (*Explanatory Memorandum on UDBHR* 2005).

Conflicting Values in Research

Research with human beings often encompasses conflicting values, which are present in the UDBHR itself. On one hand, individualism, upheld in this case by informed consent, protects the individual rights, interests, and freedoms of individuals by emphasising these values. On the other hand, communitarianism, by referring to commonly shared values like reciprocity, mutuality, solidarity, citizenry, or universality, puts the needs of the community before the interests of the individuals (Knoppers and Chadwick 2005). Within the UDBHR, this conflict can be, in specific cases, observed between Art. 6, which relates to informed consent, and Art. 14 (in relation with Art. 13 and Art. 15), which relates to the social responsibility of promoting health and social development. While the former, amongst others, ensures the right to not participate in research, the latter defines the highest attainable standard of health as a fundamental right of every human being. A progressive standard of quality healthcare is difficult to achieve without responsible people taking part in research activities for the greater good of the community. Kollek (2009) notes that, in recent years, this conflict has lead to newly developed frameworks

4 For example, the *Universal Declaration on the Human Genome and Human Rights* (1997) has already recognised such a right.

that also extend to the question of informed consent (e. g. Knoppers and Chadwick 2005).

According to the IBC (2008), various practical decisive circumstances surround the issue of consent for research. These usually take the form of answers to the questions like, whether research is conducted on healthy volunteers or not, and if not, whether the participants enjoy direct or indirect benefit from the research, whether the participants are able to judge and thus, consent to the procedure, etc. PwDs do not belong to healthy volunteers for research; therefore, the focus of these circumstances shifts to the problem of benefit. The IBC (2008), interpreting the principles of consent discussed in Art. 6–7 of UDBHR, states that research that does not provide any direct health benefits for participants who require special protections, must be conducted with utmost restraint and ensure minimal risks and burdens for the participants. This research must also provide benefits for other patients in the same category as the participants. If an adverse event occurs, it should be treated, and the possibility of future recurrence minimised. The participant should also be compensated for the adverse event. Similarly, in research, when benefit for the participant is expected, the risks, in relation to the severity of the participant's condition, should be minimised as much as possible. Although the IBC (2008) remarks that desperate situations allow riskier procedures, it lacks a deeper explanation of what constitutes a desperate-enough situation, and how much riskier procedures would be justified in such cases. Nevertheless, Art. 7 of the UDBHR recommends that if there is a possibility to conduct the study with competent instead of incompetent ones, then it should be done. In exceptional cases, when research may bring direct health benefit to the participants, and at the same time, no comparably effective study can be undertaken with competent participants, the research may be allowed with persons unable to provide consent. Obviously, the same conditions apply to any other type of vulnerable participants, while the possibility of withdrawing at any time should be regularly communicated. None of the participants should be pressurised to participate in a research study, and researchers should refrain from enrolling prisoners, military personnel, or other participants, who may be in a dependent situation (IBC 2008).

Informed Consent – A Culturally Bound Concept

The context of informed consent is a culturally bound one.[5] By culture, Kollek (2009) means the capacity of human beings to classify, codify, and communicate people's experiences in a symbolic manner. In this light, the definition of informed consent is very much shaped by ideas of Western liberal individualism. These ideas identify person-

5 For further details see Mathooko and Kipkemboi (2014), B. Darwish (2014), Rendtorff (2014), Lolas (2014), and Kalousova and Vries (2014), reflecting African, Arab, European, Latin American, and North American perspectives, with multiple reference to the issue of informed consent. In addition the perspectives of individual countries on the issue of informed consent is covered in ten Have and Gordijn (2014, section VII).

hood as the *locus* where one's autonomous decisional capacity expresses itself and occurs (Kollek 2009). Thus, there may be issues in the universal applicability of the requirements of informed consent.[6] Kollek (2009) concludes that different strategies for the application of the principle of informed consent are needed. These strategies regarding consent, according to Stanton-Jean et al. (2014), may vary again in clinical practice and research. Consent in clinical practice can be challenged and retrospectively analysed after reporting of an official complaint (e. g. by court, etc.). Consent in research, however, can also be reviewed and discussed during the project (Stanton-Jean et al. 2014). Any consent strategy should generally be, firstly, ethically sound, and secondly, culturally sensitive. Cultural sensitivity means a considered involvement of the communities concerned into the procedure of seeking consent. However, modern medical treatments and research are dominated more by the globally defined professional culture of the physicians and researchers than the regional culture of the communities involved (Kollek 2009). The requirement for more cultural sensitivity and community involvement may also be applicable to groups related to dementia care, or to involving to a greater extent the dementia care receivers themselves.

Origins of the Requirement for Informed Consent

At the historical roots of the development of informed consent doctrine Kollek (2009) notes a thorough change in the physician-patient relationship. Firstly, the relationship between the healthcare professional and the care receiver changed dramatically in the 20th century, from a paternalistic relationship (Kollek 2009) to a more collaborative one (IBC 2008). This change, which occurred between 1960–1970s, was promoted in the new definition of patient-physician relationship, based on the notion of autonomy and individualism. Secondly, the development of the requirement for informed consent during treatment relied on a secular interpretation of medicine. Illness was no longer considered as a punishment inflicted by a Supreme Being. A third reason for the development of the informed consent requirement was the need to protect the patient or research participant during the application of an empirical approach to medicine. Modern medicine employs an empirical approach. Even in antiquity, it was recognised that there was a

6 The IBC (2008) classifies the various hurdles in obtaining informed consent into economic, educational, and socio-cultural circumstances. The classification of economic circumstances includes poor training of the healthcare professionals in developing countries, lack of time for the patients, scarcity of resources, or a lack of social provision of healthcare resources. One of the issues related to low levels of education is difficulty in accessing information. This can happen because of illiteracy of the care receiver, or because of language barriers. Sometimes, issues in documenting consent can also occur, due either to illiteracy, or to cultural reasons (e. g. certain cultures prefer oral communication, and may consider written text to be a source of suspicion, distrust, or even, insult). Another socio-cultural issue encountered in obtaining consent is the tradition of communal consent, where the decision-making process is delegated to an elder of the family, or to the community leader. Another issue might be a certain amount of fatalism, which is present in some religions and can reinforce paternalistic attitudes held by the person concerned. Finally, a socio-cultural barrier to valid informed consent may be raised by the hierarchical structures of a society, when consent may be compromised by the socio-economic status of the person concerned (IBC 2008).

requirement to protect patients of empirical medicine (e. g. Hippocratic Oath; Kollek 2009). The IBC (2008) lists other possible reasons for the increased appreciation of the role of informed consent in the modern day healthcare. Among these are the increasingly prominent patients' rights movement, and the novel ethical issues engendered by emerging biomedical technologies (IBC 2008).

In addition, there are reasons, which supported the rise of the importance of informed consent, that are exclusively related to research activities. The first of these reasons is the public and political response to the research studies involving participants who were injured by non-therapeutic interventions during the 19th century (Kollek 2009, Vollmann and Winau 1996). As a result, the requirement for requesting informed consent from research participants was issued as a ministerial directive in Germany in 1900 (Kollek 2009). The second reason for the rising importance of informed consent was the revelation of the Nazi human experimentations, which ultimately led to the development of "The Nuremberg Code (1947)" (Kollek 2009; IBC 2008). The third important rationale for the informed consent standard was the formulation of what is known today as the *Ethical Principles for Medical Research involving Human Subjects* ("Declaration of Helsinki" 2013), which was in 1964 adopted by the World Medical Association (WMA) (Kollek 2009), and is better known as the "Declaration of Helsinki" (1964).

Informed Consent as a Legal Requirement and its Justification

As the above-mentioned origins of informed consent may presage, the foundations of informed consent in the 20th century were initially described by mostly legal concepts. These concepts are embraced within the fundamental human rights theory: as the right to integrity and self-determination. However, informed consent also has truly ethical foundations. Among these are respect for persons, human dignity, and the Kantian idea of not using a human being as mere means to an end but as an end in herself. Other foundations are anthropological (bodily integrity), cultural, and social (setting limits to states governing the individual) concepts (Kollek 2009).

The legal requirement for informed consent emerged as a consequence of the abuse of patients and research participants, largely during World War II. Informed consent offered a solution for avoiding the recurrence of such abuses. This justification is ultimately based on the protection of each person's right to integrity and self-determination. These rights may further be supported by the more general requirements of common decency toward others, and minimal respect to a person. Thereby, informed consent protects the most basic rights of the individual. Furthermore, the protection provided by informed consent does not only extend to the patient or research participant but to the physician or researcher as well (Kollek 2009). Informed consent ensures that the patient's or research participant's approval is granted, and the physician or researcher cannot be indicted/accused of enforcing an unwanted action upon the patient/participant.

Informed Consent Doctrine

As a result of the historical development of informed consent described above, Kollek (2009) recognises the emergence of an informed consent doctrine in bioethics. The informed consent doctrine is built upon the indispensability of this standard within medical care. The doctrine of informed consent is an unavoidable prerequisite of any medical intervention or biomedical research. Although the foundations of the doctrine rest initially on court decisions, it is also based on a wide variety of genuinely ethical notions (*Explanatory Memorandum on UDBHR* 2005). The doctrine of informed consent may thus be defined as an expression of respect for autonomy, self-determination, human rights and human dignity, notions that form the core values of any democratic society (Kollek 2009; IBC 2008). As such, this doctrine now constitutes the foundation of many international agreements (cf. section 6.2). However, it should be borne in mind that the doctrine of informed consent is a culturally bound doctrine (Kollek 2009).

Requirements for Application of Informed Consent

According to Kollek (2009), a considerable lack of clarity persists regarding the application of informed consent in practice. The most well known procedure of application is that described by Beauchamp and Childress (2009, pp. 120–121):[7]

I. Threshold elements (preconditions)
    1. Competence
    2. Voluntariness

II. Information elements
    3. Disclosure
    4. Recommendation (not part of research study)
    5. Understanding

III. Consent elements
    6. Decision (Voluntariness in Kollek 2009)
    7. Authorisation (Formal consent in Kollek 2009)

7 Beauchamp and Childress (2009) in the 6th edition of *Principles of Biomedical Ethics* categorise the former attempts to categorise the requirements of informed consent as: a) definitions of informed consent dividing them into consent-component (voluntary decision, authorisation to proceed) and information-component (disclosure of information); b) definitions provided in most legal, regulatory, philosophical, medical, and psychological literature list five distinctive components of informed consent, namely, competence, disclosure, understanding, voluntariness, and consent; c) finally, some legal and medical definitions have only one-element definitions focusing on the disclosure of information (Beauchamp and Childress 2009). The last description relates to the narrow and reductionist legal definition of informed consent.

Competence and voluntariness of consent, due to the special conditions of PwDs, are discussed in section 6.1.1.2 interpreting Art. 7. One might question whether listing competence and voluntariness as preconditions rather than essential conditions of informed consent adds any value, especially in relation to PwDs. Therefore, for the interpretation of Art. 6 in this section, the focus of Kollek (2009) on the essential conditions of valid consent (the elements of information and consent, as denoted by Beauchamp and Childress 2009) is described. Firstly, the disclosure of relevant information depends considerably on the content of the information itself, the method in which it is being presented, and the timing and setting of the disclosure. The amount of information disclosed also plays a crucial role. Research participants often find protocols too complicated and extensive. The information may also be too complex for the participants to interpret correctly because they are unfamiliar with the basic concepts of the research study being presented to them. The lengthy and detailed descriptions of the uncertainties of the research, an essential part of any scientific study, may be misperceived by participants, whose trust may then be undermined. The differing viewpoints of the participant and researchers must be emphasised. Both parties enter the research activity with different interests (Kollek 2009).[8]

To overcome these issues, it is highly advisable for the researchers to repeat the information several times, and, if appropriate, in smaller, more digestible portions. This means providing the participants with information repeatedly, in various forms, and at different times (IBC 2008). The disclosure of information is a particularly interactive process. The condition for repeated provision of information has been also proposed during the drafting process of the articles of UDBHR that concern informed consent. The rationale behind this reiterative step is the general recognition that informed consent, by focusing on the fulfilment of its essential elements, is a procedural concept (Kollek 2009). Aspects of this interpretation of informed consent are noticeable also in one of the first drafts of Art. 6 of UDBHR, where the committee interpreted informed consent as an "ongoing participation" (*Explanatory Memorandum on UDBHR* 2005, p. 9). Ongoing participation in research necessitates a more active role on the part of the participants, where the disclosure of information is no longer a one-step uni-directional requirement but rather a continuous and mutual effort to communicate and understand the informa-

8 In certain deontological codes, the practice of *therapeutic privilege* by the healthcare professional has emerged. Therapeutic privilege is a practice, whereby a healthcare professional withholds information because disclosure would very likely result in a gravely negative impact on the person concerned. The disclosure of information is now an absolutely necessary systematic condition that healthcare professionals must comply with. Therefore, therapeutic privilege cannot be supported (IBC 2008). A similar practice called *therapeutic exception* exists. Therapeutic exception is a practice whereby, under exceptional circumstances, a provisional limitation or delay of the information disclosure is required. Although therapeutic exception is permissible, the general rule is that the information should be disclosed to the person concerned as soon as it is available (IBC 2008). Therapeutic exceptions are only applicable in situations where minimal or no major risks are posed to the person concerned, and where the participant is informed as soon as possible, providing her with the earliest opportunity to refuse consent (Stanton-Jean et al. 2014).

tion throughout the whole duration of participation in the research study (*Explanatory Memorandum on UDBHR* 2005).

Secondly, the understanding of the information provided depends on the capacity of the receiver of that information. The issue here, according to Kollek (2009), may be the very specific one-dimensional focus of medical information. The presentation of the medical information solely, without additional context of the immediate and far-reaching implications, might distort the overall understanding of the receiver, making the resulting decision improperly or insufficiently informed. Importance should also be given to the values held by the research participant. Individual participants may differ in terms of how they behave and react to disclosed information and which particular values they uphold. These reactions, which are difficult to predict and which may need to be managed, pose a challenge to the healthcare professional. A further challenge to the professional is the overall difficulty in ascertaining whether a research participant has understood the information provided, and if so, to what extent (Kollek 2009).

Thirdly, the assessment of the voluntariness of the participant in making her decision has to ensure that her decision was not made under undue influence or intimidation. The freedom to withdraw at any point from the research has to be communicated always to the participant (Kollek 2009). Stanton-Jean et al. (2014) remark that often a refusal against one particular treatment does not automatically mean a refusal against all treatments. Reasonable alternatives should be always communicated and explained in detail (Stanton-Jean et al. 2014). The participant must also be reassured that withdrawal would not result in any prejudice or disadvantage being incurred (Kollek 2009).[9]

Finally, for research purposes, the consent for participation must be explicit. Formal consent may be provided either by the participant, or by proxy. First-person consent is usually provided as a form, which has to be completed, and signed by the participant. Sometimes, an oral statement given in the presence of witness(es) may also be accepted as formal consent for participation in a research study (Kollek 2009). It must be noted that follow-ups of chronic diseases, or longstanding therapeutic relationships do not necessitate repeated formal consents, so long as the essential conditions (e. g. newly discovered drugs, surgical possibilities, or appearance of other new methods) do not change the nature of the treatment or research (IBC 2008). Proxy consent usually occurs when the person concerned is incapacitated, and therefore, a social or community leader, marital partner, or other senior family member(s) decides upon her behalf. However, one should endeavour to identify and resolve any doubts regarding the consent provided or withheld by a proxy that may be counter to the wishes of the incapacitated person (Kollek 2009).

9 Healthcare professionals should also be aware of some key factors that affect people's willingness to participate in research usually include social status, asymmetric (hierarchical) relationships, social expectations towards the participant (usually from relatives, the community, etc.), and (economic) benefits (e. g. incentives; Kollek 2009).

Types of Informed Consent

The circumstances (e. g. reasons, purposes of actions, possibility) may call for different approaches of fulfilling the necessary requirements of obtaining valid consent. Informed consent contexts and procedures can be region-specific and involve proprietary socio-cultural elements (as noted by Art. 6.3). Additionally, international and national laws and agreements may further regulate the practice of obtaining informed consent (IBC 2008). The context of obtaining consent may be further influenced by the type of research, as noted by Stanton-Jean et al. (2014). Research with the use of placebo can place the participants into a vulnerable position. Therefore, participants must be specifically informed about the possible dangers of such studies (Stanton-Jean et al. 2014).

Another factor that might affect how consent is obtained involves whether the research is conducted as part of a multi-centre and/or international study. In international, multi-centre studies various adverse issues[10] have been documented that have been addressed by different good governance models, which have provided coherence and reliability. Art. 21 of the UDBHR requires ethical reviews of the research study in both the host and the funder states. These reviews should be consistent with the principles of UDBHR, and based on ethical and (inter)national legal standards (Stanton-Jean et al. 2014).

The IBC (2008) leaves open the possibility of obtaining valid informed consent in different ways that is appropriate to the circumstances of specific situations. In this regard, the classification of the *Explanatory Memorandum on UDBHR* (2005) of various types of consents may be helpful (*Explanatory Memorandum on UDBHR* 2005, p. 9):

- *Explicit* – given directly by the patient.
- *Substituted* – in the case of terminally ill persons.
- *Presumed* – in emergency situations.

As the last two types of consents suggest, there are cases when it is impossible to obtain consent directly from the person concerned. In such cases, either substituted or presumed consent is formed, aggregating the important information from family proxies or friends.

10 Researchers in multi-centre and international studies are often burdened by the need to obtain a number of the ethical review approvals from multiple countries, which have country-specific legislative requirements. Researchers are also often frustrated by delays and by the bureaucratic processes that these reviews usually entail. Another issue may be the lack of understanding of other researchers' decision-making processes. Studies may also suffer because of a lack of sufficient scientific expertise. The aforementioned issues might be exacerbated by institutional accountability problems regarding the lack of clarity about which transnational and multi-centre study partner is responsible for various aspects of the study. This issue of accountability might be a consequence of various inherent deficiencies and hurdles encountered by the monitoring process as the study progresses (Stanton-Jean et al. 2014).

Consent and Data-Ownership, Data-Handling

The issues of consent related to biobanks introduce another issue, also relevant to AAL technologies. This issue regards the question of data ownership. It is commonly accepted that the owners of the genetic data gathered from participants are the institutions that host databanks. These institutions are accountable for the proper management of these data. However, the results of the research are the property of individual researchers, unless it is specified otherwise in the consent forms (Stanton-Jean et al. 2014). Similar questions regarding data ownership and management also arise during the research & development (R&D) of AAL technologies, when vast amounts of private, often confidential, medical data are collected. The R&D process may involve not only many researchers, but also different research institutions, often in multiple countries with different legislations. These conditions all increase the complexity of the data-ownership and -handling, both of which are scrutinised when obtaining consent from a research participant.

Reuse of Previously Collected Data from Research

It has been reported that obtaining specified consent for human tissue research is less functional because of the reuse of the samples in later research studies (IBC 2008). New technologies offer a great opportunity for re-using samples and data in new research. The logical requirement of recontacting previous participants for informed consent is an issue that is still not completely resolved (Stanton-Jean et al. 2014). A similar issue may be encountered with the data gathered during the use of AAL technologies from PwDs, after they have been anonymised. With the case of genetic data in databanks, a specific authorisation model has been developed by Caulfield et al. (2003), which enables participants to preserve a certain amount of control over their data for future analysis (Stanton-Jean et al. 2014). Furthermore, in research related to health policies, the request for consent has been deemed useless (IBC 2008). These research studies, according to the IBC (2008), may be subject to Art. 27 of the UDBHR, whereby the application of the principles of the UDBHR may be limited by law, including laws in the interest of public safety. For example, for the sake of public health, where an individual's actions or inactions may pose a threat to the public safety, medical interventions without the express consent of the person concerned may be justified. Restrictions of individual rights and freedoms may be imposed in order to protect other individuals or the general public (i. e. the rights and freedoms of others). Such actions are usually strictly regulated, and made legitimate by *ex officio* measures (IBC 2008).

The topics of data-ownership, data-collection, and data-handling (or data-reuse) are extensive areas in their own right. The literature review in Chapter 3 corroborates this fact.[11] Therefore, this topic is not elaborated further in this thesis. Instead, the focus is

11 These topics are regularly mentioned in the academic literature, e. g. Allen et al. (2008); Conley et al. (2008); Cook et al. (2009); A. Darwish and Hassanien (2011); Fairclough (2009); Kang et al. (2010); Jeffrey Kaye

on topics that are relatively new and/or received little attention in relation to informed consent of PwDs and AAL technologies.

ARTICLE 6.3

Art. 6.3 is considered to be an innovation of the informed consent doctrine (Kollek 2009). This addition to the informed consent doctrine describes situations, where, in certain cultures, legal representatives of the community may be needed to provide agreement in addition to the informed consent required from the individuals concerned. For certain genetic population studies, the heritage of a group should not be at the disposal of any single individual. Such a requirement is in accordance with the requirement of engaging in a common social responsibility (Art. 13).

In accordance with the principles described in Art. 6.3, Kollek (2009) demands the application of a more culturally sensitive informed consent strategy in general, which would involve local communities more into the decision-making process (Kollek 2009).

However, Art. 6.3 also stipulates certain limitations to this part of the informed consent principle. Firstly, no matter how much the family or wider society is involved in the consent decision, no action should be taken until it is explicitly approved by the person concerned. Secondly, communal approval of informed consent may raise questions about inappropriate paternalism. Such a practice may neglect the right of the individual to make her own choices (Kollek 2009).

6.1.1.2 *Persons without the Capacity to Consent*

Article 7

In accordance with domestic law, special protection is to be given to persons who do not have the capacity to consent:

(a) authorization for research and medical practice should be obtained in accordance with the best interest of the person concerned and in accordance with domestic law. However, the person concerned should be involved to the greatest extent possible in the decision-making process of consent, as well as that of withdrawing consent;

(b) research should only be carried out for his or her direct health benefit, subject to the authorization and the protective conditions prescribed by law, and if there is no research alternative of comparable effectiveness with research participants able to consent. Research which does not have potential direct health benefit should only be

(2010); Noury et al. (2011); Romdhane et al. (2012); A. Sharkey and N. Sharkey (2012); Viswanathan et al. (2012); Wherton and Monk (2008); etc.

> undertaken by way of exception, with the utmost restraint, exposing the person only to a minimal risk and minimal burden and if the research is expected to contribute to the health benefit of other persons in the same category, subject to the conditions prescribed by law and compatible with the protection of the individual's human rights. Refusal of such persons to take part in research should be respected.

ARTICLE 7

Legitimacy of Research with Incompetent Persons

The legitimacy of research with incompetent persons relies upon the identification of the right balance between the purposes of the research and the protection of the rights and dignity of the incompetent persons. According to Gefenas and Tuzaite (2014), research with incompetent persons may involve having to "bypass" the basic research ethics requirements, including informed consent (Gefenas and Tuzaite 2014, p. 98). This is not without precedent; the limitation of personal rights has been justified to safeguard public health (J. F. Martin 2009). Another traditional example, where personal rights are limited within medical care, is in psychiatry (Gefenas and Tuzaite 2014).[12] As well as the right to the opportunity to participate in research, incompetent persons also should have the right to access and choose from various treatment options (Gefenas and Tuzaite 2014). Clearly, these scenarios may apply to PwDs, who may have be legally proclaimed as having lost their decision-making capacity.

However, the question of research with incompetent persons is more problematic than therapy with them. In exceptional cases, interventions may be allowed on participants (newborns, mentally ill, victims of accidents, etc.) without any direct benefit from the research. A more elaborate criteria of inclusion of incompetent research participants is provided in international documents like the *Convention on Human Rights and Biomedicine* (1997), along with national regulations (J. F. Martin 2009).

12 Gefenas and Tuzaite (2014) make an important distinction regarding this practice, between involuntary hospitalisation and involuntary treatment. Before the 1970s, the two often meant the same thing. Today, it is accepted that involuntary hospitalisation may be justified by the fact that a disorder requiring hospitalisation has been diagnosed, or that the assessment of the presence of the disorder requires hospitalisation. Involuntary hospitalisation can take two forms: formal and informal. Informal involuntary hospitalisation occurs when patients sign an admission form for voluntary hospitalisation but are then not allowed to leave the institution at their will. Informal involuntary hospitalisation exists as a result of inconsistency in legal regulations that are hard to apply in practice. In response, healthcare professionals tend to avoid compulsory hospitalisations because of the complex legal procedures and other hurdles that can be encountered (scarce personnel, bureaucracy, court hearings, financial requirements, etc.). Such an adverse practice results in a situation, when *de facto* involuntary patients are left without any safeguards. Involuntary hospitalisation however is not the same as involuntary treatment. Involuntary hospitalisation does not automatically mean involuntary medication; the involuntarily hospitalised person still retains her right to reject treatment (Gefenas and Tuzaite 2014).

The ultimate justification for permitting research with incompetent persons is based on the assumption that it would be unacceptable to abandon groups of people who lack the ability to make their own choices, by not allowing them to participate in and thereby, potentially benefit from, research. These persons cannot be stripped of the right to participate in research on their conditions, even if those conditions render them incapable of consenting. Therefore, research of, amongst others, degenerative neurological diseases is needed (J. F. Martin 2009). PwDs can be considered to constitute such a group.

Drafting Procedure of the UDBHR Principle(s) Regarding Informed Consent

During the drafting process of the principle(s) of informed consent, before the two articles were separated to become Art. 6 and Art. 7, the experts considered consent as the key article of the whole UDBHR (J. F. Martin 2009). The challenge was the formulation of exceptions to this principle. In the First Intergovernmental Meeting of Experts (April, 2005), the experts started with an explicit reference to mentally disabled people. The intergovernmental delegates, however, remarked that this part of the UDBHR concerning informed consent should be more elaborate. As a result, two separate principles concerning consent were developed for the Declaration. As previously described, Art. 6 deals with the issue of informed consent by competent persons. Art. 7, on the other hand, is devoted exclusively to incapacitated persons who are unable to provide informed consent. The separation of these two themes into different principles was later approved by all the delegates. No other restrictive conditions are provided in Art. 7. For these, one has to refer to national and international laws and regulations (e. g. *Convention on Human Rights and Biomedicine* 1997, etc.; J. F. Martin 2009).

Capacity as a Requirement of Consent, and its Assessment

The crucial notion of Art. 7 is capacity. Capacity is closely linked with competence. The notion of capacity has mostly legal foundations. Legal systems, since their earliest appearances, have dealt with groups entitled to different types of rights and prerogatives (J. F. Martin 2009). For example, in the Roman Empire, only a few people were Roman citizens, who were accorded political rights. Moreover, in Europe, the legal status of women was effectively the same as that of legal minors[13] until the early 20th century. Children, mentally ill persons, or incapacitated adults, even today, have special legal status (J. F. Martin 2009; IBC 2008). To the present day, the loss of competence in a legal sense means one's loss of legal right in a specific functional domain (Gefenas and Tuzaite 2014), for example, legally declared, by the Order of Supervision, incompetent to manage one's own finances (Bond et al. 2000). Although the bioethical notion of the

13 Legal minors should not be understood in this regard as only referring to children. Like legal minors, women needed permission to exercise certain rights (e. g. husband's permission to sell goods, even the wife's own private property; J. F. Martin 2009).

loss of competence, covers the inability to make healthcare decisions, this incompetence is much more nuanced. This interpretation is broader than the narrow legal definition. Bowman (2008) emphasises that the legal interpretation of informed consent is an "artificial binary certainty,"[14] which is too narrow an interpretation for cases involving PwDs (Bowman 2008, pp. 51–52). Instead, the bioethical interpretation recognises that capacity is not an 'all or nothing' concept but rather, a fluctuating one. Thus, capacity is a continuum, which depends greatly on external variables. These variables have the power to diminish, alter or enhance the PwD's capacity to consent (Bowman 2008).[15] Moreover, the broader interpretation of the loss of competence may also apply to cases when the person still legally holds the right to decide about her healthcare (Gefenas and Tuzaite 2014). According to Bowman (2008), although the assessment of capacity rarely happens without clinical assistance, it still remains a legal rather than a medical concept. At least this is the case in the United Kingdom, where the definition of the term originates from the British common law (Bowman 2008, p. 52).

Capacity may be described as an ability in the following two areas (J. F. Martin 2009):

- *Cognitive dimension* – the ability to *understand* the given situation, and the issues involved in that situation.
- *Volitive dimension* – the ability to make *rational choices*, and evaluate their consequences and the ability to act effectively towards the implementing of the decisions made by the person.

Incapacitated persons are, therefore, often unable to form an opinion on the situation, and thus may be unable to possess a set of values and goals. Incapacitated persons may also be unable to process and communicate the information. Finally, incapacitated persons may be unable to reason and deliberate about their choices (Gefenas and Tuzaite 2014).

Another important distinction refers to circumstances during which the capacity to exercise one's autonomy is limited. A commonly shared experience is that there are people who simply lack the capacity to provide informed consent. The legal limitations

14 A similar concern is expressed in Fountoulakis and Despos (2008), when they state: "The most important elements many professionals are unaware of, is that capacity is not an all-or-nothing 'on-off' switch." (Fountoulakis and Despos 2008, p. 72).

15 Bowman (2008) proposes a strong call for 'virtuous' practice by the professionals involved in the care for PwDs. He does so by elaborating on the meaning of a rather old-fashioned term, 'conscience.' Although this term is very limiting within medical ethics, Bowman (2008) asks how the 'conscience' of medical professionals should be held to account. Her inquiry extends to the question of what will be demanded from healthcare professionals to stay receptive towards the PwDs decision-making. The common goal of the healthcare professional(s) should be to facilitate, rather than impede the capacity of PwDs. The positivist "quasi-fetishistic preoccupation" with the narrow interpretation of autonomy (Bowman 2008, p. 52) should be, according to her, transposed by a more relational understanding of the ethics of care, with a more communitarian moral framework, focusing on respect, care, person-centred, and contextual decision-making (Bowman 2008, pp. 52–57).

to the inability of making valid autonomous decisions are usually correlated to a fixed age (e. g. needing to be at least 18 years old to be deemed legally mature). Such an incapacity is also called *de iure* incapacity. Another type of incapacity is more medico-ethical, and is called *de facto* incapacity. Today, it is assumed that medical decisions about treatment options, etc., should be based on the *de facto* capacity of an individual. According to this approach, the chronological age of an individual is not decisive in ultimately determining one's valid ability to make decisions (J. F. Martin 2009).

The assessment of a person's capacity is therefore essential. Healthcare professionals during the process of capacity assessment of persons under guardianship focus primarily on the capacity to judgement (*capacité de discernment*; J. F. Martin 2009), which is the assessment of the volitive dimensions of the person concerned. Capacity is automatically assumed in any adult person. It is incapacity, which needs to be proven. The assessment of the capacity of an individual is therefore performed as a matter of appreciation based on the professional experience of the caregiver (Gefenas and Tuzaite 2014). This appreciation has, however, its limits. Inevitably, the assessment is usually based on personal, potentially subjective, perspectives. Naturally, one may also object that an appreciation of one's capacity by a professional cannot be detached from the actual culture and customs of the assessor's background. These limits invoke certain risks. Firstly, sometimes, it becomes difficult to recognise individuals that prefer to take greater risks in their lives compared with others. Similarly, it can be very hard to identify those healthcare professionals that are overly cautious towards their patients or research participants. The second risk of assessment by appreciation lies in the fact that the decision of the assessed individual must be related to reasonable outcomes of the situation, based on the assessor's opinion. If the assessed person's concerned decision is not considered reasonable enough by the healthcare professional, it is often automatically disregarded. The result is that the person is stripped of her decision-making capacity (IBC 2008). Similarly, an even more serious complaint is that healthcare professionals often request the opinions of relatives or legal guardians by default, without first including the person concerned, irrespective of her *de facto* decision-making capacity (J. F. Martin 2009, citing Cassiers 2001, pp. 511–12). In such cases, the appreciation of one's capacity by a healthcare provider does not occur at all. This negligence may extend to many vulnerable individuals incapable of consent, including PwDs.

J. F. Martin (2009) proposes the extension of the assessment of the capacity of judgement (volitive dimensions) in persons under guardianship by conducting additional comparable evaluation. This comparable evaluation should reflect upon the specific conditions of the incapacitated person involved and the severity of circumstances, as well as the decisions related to them. A general rule in these cases is: the more important the decision, the higher the requirement for competency (J. F. Martin 2009). One has to bear in mind, however, that none of the tests provide exact measurements of one's capacity of

judgement (IBC 2008). The decision-making capacity of mature children should not be, for example, hindered and undermined by setting the assessment criteria too high (J. F. Martin 2009). If such a remark is valid for children (i. e. persons with limited decision-making ability), it follows that a similar requirement should be applicable to PwDs. As children may show signs of more developed decision-making capacity (compared with competent adults), PwDs may similarly show signs of their remaining decision-making capacity, which they used to fully possess. The assessment of the decision-making capacity of PwDs, together with the additional comparable evaluation, promotes the *de facto* assessment of one's capacity, instead of the narrow binary interpretation of *de iure* decision-making capacity.

J. F. Martin (2009) distinguishes between two types of incapacities:

- Long-term, or permanent incapacity.
- Short-term, temporary incapacity.

Long-term incapacity includes conditions that severely alter the intellectual abilities of individuals, for example, Alzheimer's Disease (AD) (J. F. Martin 2009). Usually, with long-term incapacitated persons, physicians/medical teams tend not to have to solely take on non-clinical decisions. More often, the decisions are made by close relatives, or are based on the formerly expressed living wills of the persons concerned (J. F. Martin 2009).

Short-term incapacity occurs during temporary coma, or confused states, where there is a prognosis of likely recovery to full capacity to consent. In such emergency cases, healthcare professionals who require consent often refer to the tool called presumed consent. According to J. F. Martin (2009), presumed consent is a type of consent, which is constructed from the information available that has been gathered about the person. It is a consent decision that a person would most likely make, if she were able to do so. Often this decision is made by the healthcare professional, due to time-pressure, after consultation with relatives and other professionals (J. F. Martin 2009).

STRATEGIES FOR CASES OF LACK OF CONSENTING CAPACITY

Paternalism

In the case of lack of consenting capacity, various strategies are available for both the person concerned, and the clinician. One of the strategies is outlined by the term paternalism. Paternalism is usually defined as acting for (the benefit of) others (J. F. Martin 2009), or best interest judgement (IBC 2008). Paternalism can be further categorised into authoritarian paternalism and benevolent paternalism. Authoritarian paternalism is an adverse form of paternalism within the physician-patient relationship, which, in the long-term, undermines trust of the patient in the physician, as well as the empathy of

the physician towards the patient. Benevolent paternalism, however, does not necessarily infringe upon the correct physician-patient relationship. This form of paternalism is guided by a fiduciary effort to find the appropriate treatment, which aims to protect the person concerned (J. F. Martin 2009).

Advance Directives

Another available strategy in coping with the lack of capacity for self-determination of an individual is the advance directive. Advance directives were formerly also known as living wills (expressing the decisions about what kinds of treatments in particular situations are and are not acceptable for a patient; IBC 2008); or previously expressed wishes (Gefenas and Tuzaite 2014). Both of these notions belong now to a wider notion of advance directives, also called care planning (Stanton-Jean et al. 2014), or advance decision (*Consent to treatment – Capacity* 2014). Advance directives are a type of a representation and substitute decision-making (J. F. Martin 2009). Advance directives should be made by adult persons when they are competent, and expressed prior to the moment the persons become incompetent. Directives should not be subjected to any influence or constraints from the family or environment. Advance directives should be valid for a defined period of time (usually 3–5 years), and periodically renewed (IBC 2008). The healthcare professionals sometimes face a problem when the advance directive of a person is outdated. In these cases, the wish of the person might have changed. Another common issue of advance directives is that they may contain hypothetical wishes related to outcomes that were considered unacceptable at the time of formulation but that then become acceptable when the situation arises and the person is no longer considered competent to change the advance directive (IBC 2008).

Most of the advance directives may be categorised into two groups. One type of advance directive contains instructions about a well-defined situation. These instructions usually concern emergency situations, end of life decisions, and/or research activities. The purpose of advance directives that specify the course of action in emergency situations is defined by the need to rapidly save the patient's life. In cases when the treatment needs to be administered to counteract an acute medical emergency, the person concerned may be unconscious, too confused, or simply unable to validly consent to any treatment. In such cases, a general approach is accepted: namely, that professional conviction should not override the expressed directive, which has been validly made prior the emergency situation (e. g. a physician should not resuscitate a patient with a valid DNR statement). Advance directives can be made that define a person's willingness to participate in research activities. Research with people, who are not conscious, with no available advance directive or statement from her relatives and closest friends, is highly controversial among the researchers (IBC 2008).

The other type of advance directive provides instructions about proxy decision makers (IBC 2008). This form of advance directive is associated with the term, *therapeutic representative* (J. F. Martin 2009), or continuing power of attorney (Gefenas and Tuzaite 2014). An advance directive about a proxy, who is delegated as a therapeutic representative of a person in situations of incapacity or unconsciousness, has to be authorised by a competent adult. The therapeutic representative is entrusted to make decisions, in favour (and the best interest) of the incapacitated person. Individuals often use this option to extend their autonomy beyond the conditions of incurable long-term, debilitating diseases (e. g. AD, etc.). Designating a therapeutic representative is considered to be one of the simplest forms of advance directive (J. F. Martin 2009), and its aim is to provide a personal voice regarding the person's preferences (Gefenas and Tuzaite 2014).

Formal Requirements for Advance Directives

The forms of advance directives, being a relatively new instrument in the hands of individuals, are not strictly subject yet to specific formal conditions. They usually have to include the will(s) of the person concerned (J. F. Martin 2009), namely, the expressed instructions about the rejection or acceptance of medical and non-medical interventions (IBC 2008), or designating a therapeutic representative authorised to make decisions on behalf of the person. In exceptional cases, advance directives can be also made orally (J. F. Martin 2009). If no advance directive is available, the professional has a duty to obtain the opinions of the relatives. This procedure is also represented by the notion of substitute decision. Substitute decisions are made based on inquiries directed at the legal representative regarding what the person concerned would have chosen if she would be competent. It is important to note that healthcare professionals should consider the possibility that a person's interests may conflict with the decision represented by her relatives. In such cases, if the timeframe allows, a legal recourse may be available. Certain legal systems provide or require that parties concerned opt for a decision adjudicated by a court or civil judiciary authority (IBC 2008). Moreover, some legal systems have developed guidelines aimed at minimising the occurrence of these (distressing) situations. The guidelines in Québec require, upon admission to a nursing home, a comprehensive overview of the health status of every new resident, which is followed by a discussion about the orientation of care with the individual and her family, aimed towards the development of a personalised plan of intervention (Stanton-Jean et al. 2014).

Gefenas and Tuzaite (2014) discuss the difficulties related to the implementation of advance directives. The institution of advance directive is not fully implemented in all national jurisdictions. In the US, where the custom of using advance directives is the most widespread, they are used by only 22 % of all the patients. Living wills remain the most frequently used type of advance directive (Gefenas and Tuzaite 2014).

The potential conflict between the interests of the person and the decision made by her relatives also raises a question about which decision should be followed. Therefore, the binding character of advance directives needs to be established. Some countries prefer the strong binding character of advance directives (e. g. Switzerland,[16] Austria[17]), while others do not, thus allowing healthcare professionals to follow their conscience. Healthcare professionals in some cases have expressed their reluctance towards a strong binding character of advance directives because it may contravene their professional deontological duties (J. F. Martin 2009). Until recently, healthcare professionals considered advanced directives as a helpful tool but they did not follow them strictly. Today, the binding force of advance directives is more commonly accepted, and their violation requires stringent and more imperative justification (IBC 2008). The *Convention on Human Rights and Biomedicine* (1997), signed by the member States of the Council of Europe, the other States and the European Union Member States, specifies in Art. 9 that "wishes shall be taken into account" (*Convention on Human Rights and Biomedicine* 1997). However, this phrasing is insufficient for providing legally binding status to advance directives for those states which signed and ratified the Convention. Due to this fact, the integration of legally binding advance directives by European Member States is slow (Gefenas and Tuzaite 2014).[18]

Analogous Ethical Issues During Incapability to Consent In Other Populational Subgroups

Various subpopulations exist within a healthcare setting, who have limited or no capability to consent. The following paragraphs list specific details about these subpopulations, in relation to their limited ability or disability to provide informed consent; circumstances which may be analogous with those of PwDs.

Stanton-Jean et al. (2014) pick two major subpopulations: children and seniors. Neonates and children do not satisfy fully the criteria of capacity to consent. In these instances, family members may be delegated the responsibility of deciding for the person concerned. Unfortunately, some family members are not motivated to act in the best interests of the person under their guardianship. In these cases, within certain legal sys-

16 J. F. Martin (2009)

17 In Austria, it is obligatory to take advance directives into account, after fulfilling certain criteria. These are as follows (Gefenas and Tuzaite 2014):

1. Consultation with the physician has been provided.
2. The formulation of advance directive has been supervised by a lawyer.
3. The treatments refused have been described in detail within the advance directive.
4. The document is signed by a person concerned not more than 5 years ago.

18 "[...] taking previously expressed wishes into account does not mean that they should necessarily be followed" (*Explanatory Report to the Convention on Human Rights and Biomedicine* 1997, p. 15, § 62).

tems, the state is able to intervene, by making the child a ward of the court.[19] Such an intervention engenders very negative consequences affecting the relationship between the relatives (e. g. guardians) and the physicians. Therefore, such a step towards the protection of the person concerned should only be taken as a last resort (IBC 2008). A similar institution of being designated as a ward of the court is also employed in relation with PwDs without the competency to consent, where the guardians may not necessarily act in the best interest of the incompetent person (Alzheimer Society of Ireland 2004). Just as with children, the designation of ward of court should be used as a last resort, due to its detrimental effects on the relationships between the (formal and informal) caregivers.

Since the famous Gillick-case,[20] additional maturity tests[21] have to be provided to children by the healthcare professionals. Analogous to the competence tests administered to PwDs, this poses an additional burden for the healthcare professionals. Maturity tests for children should not be overly demanding, making them impossible to pass (IBC 2008). These requirements are, again, similar to the requirements for competence testing of PwDs. Just as children should not be excluded from the consenting process, the same applies to PwDs. In the case of legally incompetent persons (children, etc.), the institution of *assent* is widely applied. While giving consent refers to an "agreement *to* a proposal," assent indicates only "agreement *with* a proposal" (Ashcroft et al. 2007, p. 313). The former is a normatively-transformative act (in a sense of action), the latter is a state of mind or attitude (in a form of feelings or thoughts; Ashcroft et al. 2007). Assent is different from consent because it addresses the limitations in understanding of a person. The process of requiring assent considers the mental capacities, levels of ma-

19 In UK healthcare professionals may refer such cases for ruling to the Court of Protection, which ensures that the conditions and requirements described in *Mental Capacity Act 2005* (2005) are fulfilled (*Consent to treatment – Capacity* 2014).

20 The Gillick-case in UK was an appeal to the House of Lords in 1985. The case was initiated by Mrs Victoria Gillick, who sued her local health authority (West Norfolk and Wisbech Area Health Authority) and the Department of Health and Social Security in 1982. Mrs Gillick objected to the practice of prescribing contraception for children (mature minors) aged 16 years and younger. Her argument was that physicians do not have the right to prescribe contraceptives for children because they are unable to consent. Moreover, she argued, that the physicians may abuse their power in relation to the legal minor. The case was initially rejected, but this decision was reversed upon appeal in 1984. The was then referred to the House of Lords and Law Lords. The ruling in 1985 went against Mrs Gillick's claim. The House of Lords considered this case to be one fundamentally about the ability of a legal minor to provide consent, rather than about parental rights. The judgement became legally binding in 1985 in England, Wales, and later on in Canada, Australia, and New Zealand (*Gillick v West Norfolk and Wisbech Area Health Authority* 1985; Ashcroft et al. 2007; NSPCC 2015).

21 These tests are know as 'Gillick competency' or 'Fraser guidelines.' Gillick competence is described by the ruling of the Law Lords, Lord Scarman, Lord Fraser and Lord Bridge, "[. . .] whether or not a child is capable of giving the necessary consent will depend on the child's maturity and understanding and the nature of the consent required. The child must be capable of making a reasonable assessment of the advantages and disadvantages of the treatment proposed, so the consent, if given, can be properly and fairly described as true consent" (Willmott 2010, p. 126). Lord Fraser provided specific guidelines for physicians on contraceptive advice to children under the age of 16. For the Fraser guidelines, see Willmott (2010, pp. 126–127). The definition of competency in Gillick competence is used today and accepted in all areas of medical treatment. The use of the Fraser guidelines also expanded to other areas of reproductive health, including abortion (Willmott 2010).

turity, and overall development of the person concerned. Assent is also accepted by the "Declaration of Helsinki" (2013) as a valid way of including a person into the consenting process (Stanton-Jean et al. 2014). The fact that full competency has not been acquired yet (children), or has been lost (dementia), seems to be morally irrelevant for the process of assenting.

The second group of seniors can include clinically confused persons (including people with (late-onset) AD; IBC 2008). They once enjoyed decision-making capacity, which has since been lost. According to the IBC (2008), it is unethical to consider these incompetent persons less seriously than any other fully competent person. The reason is that in cases of clinically confused persons, the healthcare professionals usually have much more information available (e. g. values, preferences, life stories, wishes remembered by others, etc.) about the person concerned than in cases with neonates (IBC 2008). Moreover, the vulnerability of such persons should not necessarily mean their exclusion from the consent-giving process for their participation in research or therapy. For this reason, in Canada, the healthcare professional is required to include questions assessing the feelings of the participant about her inclusion into studies (Stanton-Jean et al. 2014). When the confused person's consent is impossible to obtain, instead of exclusively relying on the proxy consent, the professionals should also engage in complementarily building the whole life-picture of the incapacitated person. As mentioned earlier, it is more likely that the answer to the decision can be found in such a substituted judgement than the exclusive reliance on proxy consent (IBC 2008).

IBC (2008) lists additional subpopulations: people with learning difficulties, mentally ill patients, and unconscious patients (IBC 2008). Learning difficulties usually arise from some intellectual disability or mental illness. PwDs may also exhibit intellectual disability as a result of their mild cognitive impairment (MCI) (cf. Chapter 2). No simple capacity to consent can be assumed from people with learning difficulties due to their intellectual disability or mental illness. However, IBC (2008) emphasises that only in extremely rare and serious cases are such persons unable to make a decision. Consequently, just as in the case of confused persons, the duty of the healthcare professional is to collect as much information as possible about the person with learning difficulty, which will provide the necessary data for a substituted judgement. When the impairment extends to such a scale that the would-be wishes of the person concerned are impossible to ascertain the decision-making process has to fall back onto the best interest standard (IBC 2008). Due to dementia being an irreversible gradually progressing disease, it seems acceptable that the course of action for consenting must follow the steps of:

1. Obtaining consent from the person if possible; and

2. If not possible, trying to to develop a substitute or hypothetical judgement together with family members and friends about the possible consent; and
3. If this is not achievable, to finally, decide based on the best interest of the person concerned.

Concluding Remarks/Rules For Research with Incapable Persons

As a conclusion to the interpretation of Art. 7 in this section, it is useful to refer to J. F. Martin (2009), where he reiterates the cardinal rules linked with this principle. These rules concern essentially two areas: dignity of the vulnerable research participant (Art. 7b), and the involvement of the person in the consenting process (Art. 7a).

Firstly, the paramount rule within research with incapable persons is that, for fulfilling the requirement of respecting their human dignity as well as special vulnerability, the research should involve either direct benefit to the participants, or at least a chance of significant improvement of their conditions, while all the risks related to the research activities are minimised as much as possible (J. F. Martin 2009). If none of the aforementioned goals is achievable, then the research conducted must provide a significant improvement in the scientific understanding of the condition, disease, or disorder of the person concerned, or other persons within the same category of condition. This latter type of activity should also not expose the person to excessive risk or burdens (Gefenas and Tuzaite 2014). If the same research can be conducted with persons able to consent, this research design should be preferred (J. F. Martin 2009). Research with incompetent persons should be conducted only if there is no alternative, and only as an exception. Research with incompetent persons requires specific authorisation for research activity from the person concerned, in written form (Gefenas and Tuzaite 2014).

Secondly, the participant's involvement into research also extend to cases when she is freely expressing her view of not participating in the research anymore. The withdrawal of consent should be guaranteed at all times, if it does not result in an undesirable outcome for the person concerned (J. F. Martin 2009). However, this places the healthcare professionals into difficult situations because children often express their aversion towards treatments administered with syringes, e. g. vaccinations, or local anaesthesia. The refusal of participation and treatment is another paramount rule requiring respect. Even an incapable person may validly refuse participation in a research study. The requirements for intellectual capacity, including judgement, in cases of refusal are generally less strict than those required for providing consent to participate in research. However, small signs of opposition (e. g. gesture, weeping, fear from hospitals, etc.) should not immediately be considered as refusals. As a guiding rule, it should be borne in mind that the more adverse the effect of withdrawing from a study, the stricter the requirements should be toward the capacity of judgement of the withdrawing individual. Any failure to respect autonomy, however limited, should be minimised, while the consideration of

the person's whole situation (history, circumstances, previous care) should determine the best way of preserving the participant's integrity, health, and dignity (J. F. Martin 2009).

6.2 POLICY DOCUMENTS AND ACADEMIC LITERATURE

The global recognition of the requirement for informed consent is a result of the adoption of certain international documents. A few of them have now become legally binding. These documents, without exception, confirm the *sine qua non* condition of informed consent in medical therapy and research (Kollek 2009).

6.2.1 *Policy Documents*

Before providing the overview of the fundamental policy documents regarding informed consent, it should be noted that the policy of obtaining consent in the Republic of Ireland is regulated by *National Consent Policy* (2013). This defines consent as "the giving of permission or agreement for an intervention, receipt or use of a service or participation in research following a process of communication about the proposed intervention" (*National Consent Policy* 2013, p. 20). The following sections provide a closer look at the documents that lead to the birth of policy documents such as the *National Consent Policy* (2013).

6.2.1.1 *The Nuremberg Code (1947)*

The first appearance of the requirement of informed consent in a legally binding document was in Germany, between 1891–1900. In 1891, the Prussian Minister of Interior Affairs issued a directive to all prisons, in which he specified that tuberculosis treatment must not be administered against the will of the patient. After the Neisser case,[22] in the year 1900, the Prussian Minister for Religious, Educational, and Medical Affairs issued another directive to all hospitals and clinics in the country. This excluded all minor or otherwise non-competent persons from participation in non-therapeutic clinical studies, and necessitated that those involved must have provided "unambiguous consent" after the proper disclosure about the negative consequences of the study (Vollmann and Winau 1996, p. 1446).

22 Albert Neisser (1855–1916) was a Prussian professor of dermatology and venerology at the University of Breslau, who conducted studies on the treatment of syphilis. For the development of an effective vaccination he injected a cell free serum into patients, who were mostly prostitutes, admitted with other medical conditions. The vaccination, after a public outcry on cca. 600 cases collected by a psychiatrist Albert Moll, was deemed as 'unsuccessful.' In 1898 the Royal Disciplinary Court condemned the activities of Neisser. The main argument was not the questionable scientific background of the studies but the lack of consent from the patients (Vollmann and Winau 1996).

The first international appearance of the requirement for informed consent was in "The Nuremberg Code (1947)" (1996),[23] which was a reaction to the controversial and criminal research activities conducted during the Third Reich. After the end of World War II, the tribunal at Nuremberg defined in the first paragraph of the code the absolutely essential nature of the voluntary consent from a human participant in any type of medical experiment. The tribunal stressed that "any element of force, fraud, deceit, duress, overreaching," "constraint" or "coercion" should not be part of valid consent ("The Nuremberg Code (1947)" 1996, § 1). Also, the participant "should have sufficient knowledge and comprehension about the elements" of the study (nature, duration, purpose, method, and meaning of the experiment) involved ("The Nuremberg Code (1947)" 1996, § 1). This includes the knowledge of any inconveniences, hazards, and effects, which should be expected. The duty and responsibility for ascertaining that the consent is valid rests upon the "individual who initiates, directs or engages in the experiment" and it cannot be delegated to anybody else ("The Nuremberg Code (1947)" 1996, § 1).

The requirement for valid informed consent decision has, since 1947, been incorporated into every important ethical guideline and legal instrument. However, its stringency caused considerable issues. "The Nuremberg Code (1947)" (1996) delegitimised research with human beings incapable of providing consent. This requirement had to be later liberalised, to provide opportunities to find effective treatments for incompetent persons. As noted by Gefenas and Tuzaite (2014), the most important consecutive professional and legal guidelines (e. g. *UDBHR* (2005) in Art. 7b, *Convention on Human Rights and Biomedicine* (1997) in Art. 17, and CIOMS (2002) in Guideline 9) includes an alternative algorithm for 'bypassing' the strict rule phrased by "The Nuremberg Code (1947)" (1996). Their development occurred by implementing two novelties: the two steps of liberalisation of the requirement for informed consent, and the specification of the low-risk standard of the balancing approach (Gefenas and Tuzaite 2014).

The strict rule of the Nuremberg Code obstructed the development of therapeutic processes and medications, and hampered research of novel approaches for people affected by some of the most serious conditions. The first step in liberalisation was established by the "Declaration of Helsinki" (1964). The authors of this declaration, the WMA representing physicians, proposed a distinction between therapeutic and non-therapeutic research. While the latter remained prohibited in the "Declaration of Helsinki" (1964), therapeutic research with people who are not competent to provide consent became possible. Despite the introduction of this distinction, early phase research, i. e. where the direct benefits to the participant remain questionable, was still problematic. Therefore, further liberalisation of the Nuremberg Code's rule for consent was needed. In the 1990s, with strict safeguards, the possibility of research without direct benefit to the par-

23 Also called the Doctors' Trial or the 'Medical Case' (Human and Fluss 2001).

ticipant was gradually accepted. These safeguards usually extend to circumstances that such research must significantly contribute to better understanding of either the individual's condition, or to the overall knowledge about that disease or disorder. Furthermore, research without direct benefit must pose only minimal risk and minimal burden to the research participant. Finally, the research participant must provide a valid consent for participating in such study (Gefenas and Tuzaite 2014).

The second attempt to alleviate the stringent rules of obtaining consent from incapacitated people occurred through balancing the principles of informed consent and the risk-benefit ratio. The difficulty of obtaining informed consent in certain cases was addressed by focusing on other ethical principles and values during the decision-making process. As a result of these attempts, a so-called 'low-risk' standard was developed. The low-risk standard ensured that, during research with persons of limited capability to consent, the research should not exceed the risks that are likely to be experienced during routine examinations (CIOMS 2002).[24] The low-risk standard is one of the most important complex developments within the field of bioethics related to incapable persons (Gefenas and Tuzaite 2014).

6.2.1.2 *Documents of International Biomedical Communities*

Two documents from international biomedical communities became very influential in the second half of the 20th century. One of them was the "Declaration of Helsinki" (1964), a legally not binding document originally issued by the WMA, which has undergone seven revisions ("Declaration of Helsinki" 2013).[25] Paragraphs 25–32 deal with the requirement of informed consent. The Declaration stipulates the following:

> "In medical research involving human subjects capable of giving informed consent, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, post-study provisions and any other relevant aspects of the study."[26] ("Declaration of Helsinki" 2013, § 26)

Paragraph 26 requires compliance with all the standards of valid consent for conducting research on participants (adequate information, aims, methods of the study, sources of

24 The *Convention on Human Rights and Biomedicine* (1997) uses in this regard the term "minimal risk" (*Convention on Human Rights and Biomedicine* 1997, Art. 17), which is further exemplified in the *Explanatory Report to the Convention on Human Rights and Biomedicine* (1997) as taking blood sample, making X-ray and ultrasonic scans, etc. (*Explanatory Report to the Convention on Human Rights and Biomedicine* 1997, § 111–113).

25 An informative summary of the historical development of the "Declaration of Helsinki" between 1964–2013 can be found in Human and Fluss (2001, pp. 4–6).

26 The phrase "capable of giving consent" was introduced in "Declaration of Helsinki" (2013) instead of the phrase "competent human subjects" in the earlier version *Declaration of Helsinki* (2008). This statement is valid also to other sections of the "Declaration of Helsinki" (2013) respectively.

funding, etc.). Paragraph 29 introduces the standard of seeking assent from incapacitated participants in addition to the consent provided by the legal representative of the person concerned. Paragraph 30 further defines the standard of research involving people incapable of providing consent. According to this paragraph, such research may be conducted only if the lack-of-competence condition is a necessary characteristic of the research group. In this case, the researcher is obliged to seek consent from the legally authorised representative. Interestingly, if no authorisation from the representative of the incapacitated person is available, the "Declaration of Helsinki" (2013) allows the researchers to proceed with the study. The only condition for such a practice is approval from the Research Ethics Committee (REC), with the inability to provide consent explicitly stated in the research protocol. The researcher must obtain consent as soon as the participant is capable of consenting, or as soon as the legal representative is available ("Declaration of Helsinki" 2013).

Although one of the general provisions is the statement of the responsibility of the researcher for the protection of the participants (§ 9), the "Declaration of Helsinki" (2013) provides one of the softest and most liberal requirements for seeking consent from participants lacking capacity to consent.

The other document, the *International Ethical Guidelines For Biomedical Research Involving Human Subjects*, was issued by Council for International Organizations of Medical Sciences (CIOMS) in 2002. Guideline 8 contains recommendations regarding research with capable persons. It states that the risks and burdens of the study must be minimised, the interventions involved should be reasonable and proportionate to the knowledge gained. Guideline 9 defines the 'low-risk' standard of research interventions as ones that should not incur risks that are greater than the risks linked with routine medical or psychological interventions. However, the guideline has a more liberal approach towards overcoming this recommendation. Slight or minor increase above the 'low risk' standard is permissible, if there is a strong enough scientific or medical rationale, or if there is approval from the local REC. Guideline 4 deals with individual informed consent. Guidelines 13 and 15 provide recommendations and commentaries for conducting research with vulnerable persons, and persons incapable of providing valid consent (CIOMS 2002).

6.2.1.3 *Documents of the European Union and the Council of Europe*

The documents agreed by the Member States of the Council of Europe (and legally binding to the Member States of the European Union who have already ratified them) include two documents. The first of them is the *Convention on Human Rights and Biomedicine* (1997), also called the Oviedo Convention. The Convention comes with an *Explanatory Report to the Convention on Human Rights and Biomedicine* (1997) which helps to interpret the provisions of the Convention. Since then an *Additional Protocol to the Convention*

on Human Rights and Biomedicine (2005) has been published, further specifying research interventions on human beings that are carried out following the provisions of the Convention.

The second document presented in this section is the *EU Charter of Fundamental Rights (2000/C 364/01)* (2000), since then updated to *EU Charter of Fundamental Rights (2012/C 326/02)* (2007).

CONVENTION ON HUMAN RIGHTS AND BIOMEDICINE (1997)

The *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine*, also known as the EC's *Convention on Human Rights and Biomedicine* (1997), presents the first international legally binding document for the Member States of the European Union on the topics of biomedicine and research. The entire Chapter II is dedicated to tackling the issues of informed consent, and Art. 6–9 especially delineate protection of persons unable to provide consent (*Convention on Human Rights and Biomedicine* 1997).

According to Gefenas and Tuzaite (2014), the Convention provides a comprehensive framework regarding incapable persons. Firstly, if needed, it encourages the European Member States to introduce the substituted decision-making process during the provision of care. The standard of transferring the decision-making authority to a representative includes the requirement for the provision of the same amount of information to the legal representative, as it would have been provided to the patient herself (Art. 6.4; Gefenas and Tuzaite 2014).

Secondly, it requires that the healthcare professionals involve the person lacking the capacity to consent in the decision-making procedure as much as possible (Art. 6.3). This includes involvement through previously expressed wishes, life goals, values, or other relevant information disclosed by the incapacitated person (Art. 9; Gefenas and Tuzaite 2014).

Thirdly, the risk-benefit ratio should be considered in the competency assessment for medical therapy and research, which is also called the 'sliding scale' of competence evaluation. This holds that the higher the benefit ratio for the person (e. g. life-prolonging intervention), the more stringent the assessment of competency for refusal should be of the person, whose capacity is questioned (Gefenas and Tuzaite 2014).

In emergency situations, any medically necessary interventions can be carried out, if it provides an immediate benefit to the person who is unable to consent (Art. 8). In the case of capable persons, the Convention allows for a higher level of risk (Art. 16.ii) than in the case of persons incapable to consent (Art. 17.2). This is called 'acceptable risk' in non-therapeutic research on capable persons. With persons unable to provide consent, only research with the potential of real and direct benefit to their health is allowed (Art. 17.1.ii, while fulfilling special conditions in accordance with Art. 17.2), which means that only

research with lower levels of risk are acceptable. The *Additional Protocol to the Convention on Human Rights and Biomedicine* (2005) defines the concept of minimal risk as "very slight and temporary negative impact on the health of the person concerned" (*Additional Protocol to the Convention on Human Rights and Biomedicine* 2005, Art. 17.1). This includes procedures such as taking saliva or small amount of tissue samples, taking blood, one X-ray exposure, or undergoing MRI without contrast medium (Gefenas and Tuzaite 2014).

CHARTER OF FUNDAMENTAL RIGHTS OF THE EUROPEAN UNION (2000)

Along with the Oviedo Convention, other documents of the European Union play important role in interpreting informed consent. One of these is the *EU Charter of Fundamental Rights (2000/C 364/01)*, which stipulates, in Art. 3.1, the right to respect for one's physical and mental integrity. Art. 3.2 acknowledges, amongst others, "the free and informed consent of the person concerned" in the fields of medicine and biology (*EU Charter of Fundamental Rights (2000/C 364/01)* 2000). Additionally, the *EU Clinical Trials Directive (2001/20/EC)* (2004) explicitly mentions in Art. 5 all the requirements regarding informed consent for clinical trials on incapacitated adults (*EU Clinical Trials Directive (2001/20/EC)* 2004). These regulations are mandatory and extend to all the European Member States.

6.2.1.4 *UNESCO documents*

Before the *UDBHR* (2005), United Nations Educational, Scientific and Cultural Organization (UNESCO) issued two influential documents, which refer to the standard of informed consent: *Universal Declaration on the Human Genome and Human Rights* (1997), and *International Declaration on Human Genetic Data* (2003).

UNIVERSAL DECLARATION ON THE HUMAN GENOME AND HUMAN RIGHTS (1997)

The *Universal Declaration on the Human Genome and Human Rights* (1997) defines in Art. 5b the requirements of informed consent (prior, free, informed, or consent from legal representative). Art. 5c ensures the right not to be informed. Art. 9 lists the conditions that allow limitations of the requirement to obtain consent. These limitations can only be applied, if they are prescribed by law, for compelling reasons, within the limits of public international law and the law of human rights (*Universal Declaration on the Human Genome and Human Rights* 1997).

INTERNATIONAL DECLARATION ON HUMAN GENETIC DATA (2003)

The other document of UNESCO is the *International Declaration on Human Genetic Data* (2003). Art. 8 of this Declaration defines the necessary requirements for obtaining informed consent, and the limitations of this requirement (by domestic law, consistent

with international law and human rights). Art. 9 defines the conditions under which consent may be withdrawn. Finally, Art. 10 reiterates the right to decide not to be informed about research results by an individual (*International Declaration on Human Genetic Data* 2003).

6.2.2 *Academic Literature*

The central role of informed consent is evident in the academic literature regarding informed consent, which is extensive. However, there are certain ethical issues, which refer very specifically to the particular conditions of PwDs that cannot be described sufficiently even with the detailed interpretation of the UDBHR principles. Moreover, many of these ethical issues are still open, and hence constitute current academic disputes.

This section focuses on essential ethical issues that are particular to PwDs regarding informed consent. Particular aspects of these ethical issues were not mentioned during the interpretation of Art. 6 or Art. 7. However, they received specific attention in the scholarly debate, while these may be also relevant in relation with informed consent of PwDs. These ethical issues are categorised in the following larger groups: the issue of informed consent in relation to research with placebo or placebo-effect; advance directives of PwDs; research with PwDs; informed consent and the involvement of ICT; and ethical issues related to therapy with PwDs.

Other topics often discussed in the academic literature focused on issues, such as PwDs' decision-making competence in driving a motor vehicle (Johansson and Lundberg 2008), holding firearms (Pinholt et al. 2014; Johansson and Lundberg 2008), financial affairs (Fountoulakis and Despos 2008) or voting in elections (Appelbaum, Bonnie, et al. 2005; Regan et al. 2011; Fukuyama 2003) will be omitted in this section.

6.2.2.1 *Informed Consent and the Use of Placebos*

The topic of informed consent is closely related to the issue of using placebos during research studies. Placebos are defined as inert substances or treatments, used both in treatment and clinical research (Louhiala and Puustinen 2008).[27] The term placebo-effect is the result of all verbal, non-verbal, and rituals of therapy, which efficacy cannot be derived from pharmacological or physiological interventions (Miller and Colloca 2011). Art. 6 does not explicitly specify the role of informed consent in the delivery or use of

27 The use of the term of placebo in the academic literature manifests remarkable variations. In its narrow meaning, the term placebo represents a deliberate deception (both in research and therapy) of a person by claiming the effectivity of a treatment, despite all the available evidence against any effect. Similarly, placebo is called also when a treatment lacks any evidence of being beneficial for the given condition but it had been prescribed in good faith. The information about the prescription of an inert substance or treatment disclosed to the patient is also called placebo. Finally, genuine informed consent in research settings today means that the research participant understands that, after randomisation, she may have received placebo (Louhiala and Puustinen 2008).

placebo during treatment or research. However, studies involving AAL technologies and other ICT devices may have outcomes, which can be identified with a placebo-effect.

If one considers an analogy of a child and her 'security-blanket,' the child derives comfort and feelings of security from the presence of a blanket, which is inert. Similarly, the simple presence of non-functional robots or companion toys (Broekens et al. 2009) may be found comforting enough for the person to enhance one's subjective feelings of security, akin to the effect of (active) care-robots. The best example of the latter may be the well-publicised robotic harp seal PARO (comPAnion RObot), which interactively responds and expresses emotions to a patient, just as a real animal during an animal-assisted therapy (Burton 2013). These therapies have demonstrated noticeable reduction of emotional, behavioural, and psychological symptoms by lowering agitation levels and improving the mood of PwDs (Burton 2013). However, the validity of these treatments may be still questioned because they are assumed to have placebo-effects or novelty-effects, demand characteristics, experimenter expectancy effects, or informant bias (Burton 2013).[28]

Alongside the question of validity, the consideration of such carebots (and other analogous AAL technologies) functioning as placebos, may trigger ethical issues of deception, whereby the PwDs are deceived into believing that the carebots are providing real care based on love and respect. A further ethical issue in this situation is whether a positive risk-benefit assessment may overrule the requirement and responsibilities of researchers or physicians for proper information disclosure about a research study or treatment. Since the ethical assessment of the use of placebos in research and therapy is still open often with conflicting standpoints (Broekens et al. 2009), at this point of the interpretation it must suffice that AAL technologies are not bare from this ethical issue.

6.2.2.2 *Advance Directives of PwDs*

Ethicists reflected in particular on various novel methods of obtaining informed consent from incapacitated persons. One of the method is the advance directive, which has recently been discussed extensively in the academic literature.

A study by Fazel et al. (1999) suggested that only 20 % of PwDs were competent enough to complete their advance directives, compared with a group of relatively healthy elderly volunteers, whose capacity rate was around 78 %. They concluded that only a relatively small proportion of PwDs diagnosed with dementia are competent enough to complete advance directives (those with higher premorbid intelligence). Moreover, they found that competence was affected by aspects of higher intellectual func-

28 The positive effect of companion robots in therapy of PwDs may support the claim of Louhiala and Puustinen (2008), which says that within the clinical therapy the use of the term 'placebo' should be exchanged with 'care effect.' The positive effect of these devices on the PwDs cannot be fully explained, nevertheless their beneficial effect on care is very real (Louhiala and Puustinen 2008).

tioning, which are not fully assessed by the Mini-Mental State Examinations (MMSE) test (Fazel et al. 1999).

It is important to remark that not long ago, physicians believed that a diagnosis of dementia automatically rendered PwDs incompetent in expressing their advance directives (about 72 % in an US survey (Fazel et al. 1999). As noted earlier, the competence of PwDs is not a binary, all-or-nothing switch (Fountoulakis and Despos 2008). The findings of Fazel et al. (1999) shed light on the importance of determining specific dementia subtypes. Different dementia subtypes affect different areas of the brain, and therefore, different functions. Knowing which functions can be affected helps healthcare professionals and researchers identify which PwDs could be considered competent (Fountoulakis and Despos 2008).

THE PROBLEM OF 'BAD' DECISIONS OF PWDS

Fountoulakis and Despos (2008) also highlight problems encountered by healthcare professionals when faced with a persons' 'bad' decisions. The making of a 'bad' decision should not automatically mean that the person or PwD making the decision lacks any specific capacity, or competence. Both family members and healthcare professionals are supposed to avoid 'protecting' a PwD from the her 'bad' decisions, when she is found to be competent (Fountoulakis and Despos 2008, p. 72).

ACTING IN THE BEST INTEREST OF PWDS

If healthcare professionals attempt to act against the wishes or desires of the PwD, they may still interpret their actions to be in the 'best interest' of the PwD. As Holm (2001) remarks, such an option creates more problems than it solves. For the application of the 'best interest' standard, one has to establish the following pre-conditions (Holm 2001):

- An *a priori* assumption of the person's (in this case, PwD) incompetency to make a decision within the given context.
- Create a definition of 'best interest', not only for the case of incompetence of PwD but also for the cases of competent but irrational decisions.

Both of these pre-conditions are unacceptable in the debate about autonomy in bioethics and health law. It would mean that PwDs would be the only class of people for who would not be enabled to make occasionally foolish decisions (Holm 2001).

HURDLES WITH THE USE OF ADVANCE DIRECTIVES FOR PWDS

Authenticity as a Link Between the Past – Present – Future

Hughes (2008) argues for the broadest possible view of a person and her capacity regarding advance directives. The assessment of competence should be interpreted not as

a legal exercise of examining the decision-making capacity; instead, it should represent a more evaluative interpretation, which involve a person's subjective narratives (Hughes 2008).

The *Mental Capacity Act 2005* (2005), which has been in force since 2007 in England and Wales, determines that an advanced decision is invalid if a) a person has done anything that is inconsistent with the previous decision, and b) there have been essential changes in circumstances, which had been not anticipated when the refusal of treatment in the advance decision was made (Hughes 2008). Advance directives encompass serious problems, when their authors aim to achieve a continuous link between the past – present – and future. The advance directive is a decision made in the present, about the eventual refusal of a treatment in the future. The aim is to control the future, thereby attempting to expand the autonomy of a person to the time when she will not be able to express her will directly to the healthcare professional. However, present wishes can be different to wishes in the future, when the person has no capacity to change her advance directive. The healthcare professional has no means of knowing the person's actual wishes.

Therefore, Hughes (2008) proposes that for such cases, one should take into account, firstly, the authenticity[29] of the PwD's personal and narrative story, and secondly, the whole context of the person. The authenticity of a personal history means an appropriate understanding of person's life-story, so one is able to make the right decision, which would be in accordance with the person's narrative. Hughes (2008) remarks that any detail might be interpreted as relevant. Also, a decision in an advance directive represents a more elaborate story of a person's life when it is renewed regularly (e. g. on an annual basis) over a long period of time (e. g. the last twenty years), with the views represented in it discussed thoroughly with the family and close friends regularly. Such a habit of advance directive updating represents a more decisive connection between the past and the present of a person's narrative. Hence, the eventual decision of the healthcare professional based on such an advance directive can be a justifiable end to a person's story. The authenticity of advance directives does not always need to be 'reasonable' or 'rational' (Hughes 2008).

29 Gefenas and Tuzaite (2014) also mention a criticism regarding the system of protection of incapable persons, which is embraced in Art. 7 of the UDBHR. This criticism concerns the one-sided view of the minimalist-libertarian interpretation of personal autonomy. The problem with the minimalist-libertarian account of autonomy is that it provides a reductionist view on the relationship between the healthcare professional and the person concerned. This very complex relationship cannot be represented by a simple contractual relationship of two 'strangers.' The minimalist-libertarian interpretation ignores the general caring attitude of the healthcare professionals, which is essential in relationships with vulnerable persons. The account of autonomy as authenticity is mentioned as a counterpart to the libertarian interpretation of this relationship. This alternative interpretation goes beyond the minimalist-libertarian understanding of autonomy by focusing on the authenticity of the decision-making process of the person. Every single decision of the person is imprinted with their values and whole personal life-story. Personal decisions should not be made solely on rational grounds and explicit facts. Interpreting the decision-making process based on authenticity means placing importance on personal motivations of the person concerned. Additionally, external signs expressed both by the professional or the person concerned bear special significance (Gefenas and Tuzaite 2014).

Additionally, the context in which the person is embedded is also important: one's personal and narrative story is embedded in social, cultural, historical, legal, moral and spiritual realms, which aspects often overlap. The last stages of dementia are often accompanied with the lack or impossibility of rational, verbal, or emotional communication. Even in such a grave circumstances, one can express one's wishes through bodily interactions (Hughes 2008).

To be able to recognise the authenticity of the end of a person's life, one must be a) *attuned* to the person's narrative, especially to its (subjective) normative nature, b) *engaged* with the person's normative nature, and c) *respectful* to the remaining embodied agent. Only by following these requirements would it be possible to make a decision, about the end of a person's life, which would be in accordance with that person's wishes and at the same time, be a morally right decision (Hughes 2008).

Although these requirements can provide a better understanding of the wishes of the person concerned, the compliance with them may be problematic. One of the reasons of introducing AAL technologies is the empowerment of PwDs by enabling their independent living, so that the ever increasing need for healthcare professionals can be better organised. The increasing number of patients for a decreasing number of healthcare professional renders the examination and interpretation of authenticity and personal narrative story of individuals unlikely. This regrettable forecast is not likely to change by the introduction of ICT devices because a correct interpretation of one's personal life-narrative cannot be delegated to a machine-automatisation.

Rupture Between Current and Previous Desires

Holm (2001) considers the possibilities regarding the connection of the PwD's current desires and her previous desires expressed in the pre-demented state. Dementia does not only modify the connection, with its short- and long-term memory loss, between desires and the objective state of world; it also changes one's assessment of the consequences of decisions and actions (Holm 2001).

Empirical observations also suggest that the desires of PwDs fluctuate, between those of their 'old selves' and those of their 'confused selves,' which can be unconnected to their previous selves. There is considerable ambiguity in assessing their authentic desires. Holm (2001) distinguishes two possible results from such an assessment of authentic desires:

- An authentic desire *fit*s the image of the old self, but is *not connected* to the former personality of the PwD.
- An authentic desire not only *fit*s, but is also *connected* to the former personality of the PwD.

The former scenario means that the desire would be coincidentally acceptable for the caregiver to accept/approve, however it would lack the connection with the person's psychology or narrative. This would raise doubts regarding its authenticity. The latter scenario is more desirable; although there may be issues regarding the confirmation of the connection with the former personality. Moreover, it would remain unclear, which types of psychological or narrative connections should be taken seriously, and which might be overridden. Even if one is able to divine the truly authentic desire of a PwD, one will face serious practical issues in applying the account of authentic desires on concrete decisions (Holm 2001).

A rather extreme solution for addressing the aforementioned issues would be to apply the pure 'best interest' standard[30] to every case of a PwD. Such a solution would bring negative consequences like restricting one's desires only to beneficial ones, to desires that have been assessed by somebody else, or to simply inconsequential ones. PwDs would then be a class of people that would not be able to occasionally make a reckless decision. In this case, the PwD's assessment of her best interest would be valued as always less than the assessment of any other group of people. This might result in psychological or physical coercion, which is unlikely to restore one's sense of self (except in the sense of being a *powerless* self; Holm 2001). Another extreme solution would be to follow only and exclusively the advance directives of the patient. This is called the Pure Autonomy Argument (PAA; Muramoto 2011). The foundation of this argument is based on the human dignity of the person, her autonomy for making decisions. This translates into always following previously expressed decisions to the full extent. In these cases, the contemporaneous interests might often conflict with earlier wishes expressed in advance directives (Muramoto 2011).[31]

30 Muramoto (2011) calls this Pure Beneficence Argument (PBA).

31 A similar discussion took place between the political philosophers, Ronald Dworkin, Rebecca Dresser, and Seana Valentine Shiffrin. Dworkin defines two sets of interests that every mature human being formulates within her lifetime: a) *experiential interests*, which are actions that one simply likes to do, and without which life would be preposterous (e. g. playing football, cooking, eating well, etc.); b) *critical interests*, which are convictions that reflect one's ideas about good life, without which, one's life would be worse (e. g. having close relationships with one's children, etc.). When an advance directive is being drafted, these critical interests are usually emphasised, defining how one should be treated in the case of incompetence. Therefore, according to Dworkin, advance directives represent the true competent person's wishes and wills, even in situations when one is not able to exercise these faculties anymore (Dworkin 1993). This view has been challenged by Dresser (1995) and Shiffrin (2004), whose main objections are that Dworkin's view denies the person the knowledge about a treatment and the access to relevant information that might emerge since the finalisation of the advance directive. Dworkin's approach does not leave any room for changes of heart, clarification of misunderstanding, etc.; nor are the decision-makers forced to explain and defend their choices. Dworkin counts on the idea that the person before and during dementia are the same persons. As such, Dworkin opposes the personal identity theory, which interprets the appearance of major psychological changes as the emergence of a new, different person. Furthermore, Dworkin's perception does not allow for any kind of surprise ending. This fact seems to imply that a general non-treatment standard should be adopted for any mental impairment (Dresser 1995). Finally, Dworkin's approach does not provide sufficient reasons to not respect the contemporary wishes of PwDs (Shiffrin 2004). For further comments, also see Groves (2006) and Muramoto (2011). This discussion highlights that the best interest standard raises difficulties from both ethical and legal perspectives.

The opposition of these two approaches is unsolvable through purely ethical analysis because they unavoidably incorporate metaphysical interpretations of the person and her identity before and after the onset of dementia. Therefore, until these metaphysical reflections are backed by more empirical analysis, the question of exclusive guidance based on either the best interest standard or the advance directive remains ethically unresolvable. However, as mentioned in earlier sections of this chapter, this does not mean that legal guidelines are not in force (see the examples of Switzerland and Austria in footnotes 17–16).

PRINCIPLED COMPROMISE

Huxtable (2012) also recognises the complexities regarding conflict between self-determination of incompetent persons and the beneficence standard regarding their care. He describes the clash of values imposed by these ethical principles as principled conflict: on the one hand one has to respect the person's autonomy and self-determination, on the other hand the healthcare professional or family proxy is required, and often want, to act in the best interest of the person (Huxtable 2012).

Often these competing moral perspectives are based on life-experiences and commitments of the persons involved, religious views and other values gained and lived throughout one's life. Therefore, it is extremely hard to find a termination of such conflict. Huxtable (2012) proposes the framework of *principled compromise*, a form of resolution that is based on certain principles acceptable for both parties during the decisive process. Principled compromise is "achieved in relation to conflicts of principle, in a manner which is itself also principled" (Huxtable 2012, p. 126).

Huxtable (2012) differentiates between necessary preconditions of principled compromise, and fundamental rules that lead to the formulation of compromise. The former he calls driving elements of compromise, the latter governing elements of compromise (Huxtable 2012).

The necessary reasons for discussing and forming a principled compromise is founded on the following six considerations (Huxtable 2012):

- *Prudence* serves as a starting point to the quest for any compromise, especially in situations where the omission of such compromise would lead to terrible consequences. Being part of the decision-making process may lead to losing of certain important positions but it may also leave open the possibilities for gaining some new ones. The other option would be only staying away from the decision-making process, and at the end being dissatisfied with any of the decision that has been made.

- The *scarcity* of resources poses unavoidable limitations to our decision-making processes, which enforces the seeking of reasonable and necessary compromise.

- The circumstances of the situation may require the *need* for decision because not acting would result in an even worse consequence. These situations often cannot be avoided, and morally encourage the decision-making parties to seek a compromise.
- *Coexistence* in peace is a basic requirement for any society, howsoever short the interaction between the parties lasts.
- Empirical and metaphysical *uncertainty* keeps certain questions regarding knowledgeability and existence open (cf. see the discussion about whether the PwD in a more advanced stage of dementia is a 'new' person, or not). Despite the advances in medical and other scientific disciplines will provide many answers in the future, it is unlikely that the remaining metaphysical and empirical uncertainties will render the search for compromise obsolete.
- The moral and conceptual *complexity* of problematic situations should unavoidably render the decision-making parties to reflect upon and consider the arguments of the opposing party. The unavoidability of this feature is based on the empirical and metaphysical uncertainties of existence. Sincere and intelligent arguments of both parties, followed by the virtue of humility, should accomplish this.

The morality of compromise has three conditions or virtues, which governs the parties towards reaching a compromise (Huxtable 2012):

- Parties should advance *reflective* moral stands, by allowing others to rise important arguments. These arguments should reflect considered moral stands of reasonable and intelligent people, not their biases or prejudices.
- Parties should be *reliable*, basing their discussion on trustworthiness, good faith, and sincerity.
- Parties seeking compromise should also communicate *respectfully* with each other. This limitation should results in effective communication. Other terms like tolerance, mutuality, cooperation, democratic spirit, or reciprocity are all linked with respectful communication.

All these criteria ensure that during the discussions about seeking compromise the parties will recognise each other as morally autonomous agents, thus working in cooperation towards a commonly shared resolution of the moral conflict. What Huxtable (2012) further emphasises is that, within the particular practice in UK, the decisions of courts should be supported by a greater ethical engagement of ethical committees to serve as mediators during the process of seeking principled compromise (Huxtable 2012).

Applying the principled compromise framework to particular cases of PwDs may be especially helpful. Principled compromise can be applied to cases when the self-determination and autonomy of an incapacitated person is expressed in advance directives, however, this preference is questioned or precarious to apply due to welfarist (i. e. best interest) concerns. Principled compromise may be helpful for every party involved: healthcare professionals, proxies, or other legally authorised representatives.

6.2.2.3 *Research with PwDs*

In this section the following topics, present in the academic literature, related to research with PwDs will be presented: the 'conspiracy of silence' phenomenon regarding PwDs; the so-called 'grey zone' of informed consent of PwDs; motivations of PwDs for participation in research studies; the recommendations of Alzheimer Europe for conducting research with PwDs; the rolling informed consent procedure; and finally the topic of delayed consent and its possible applicability in relation with PwDs.

THE 'CONSPIRACY OF SILENCE' PHENOMENON

Groves (2006) emphasises that research conducted on PwDs, in search of pathogenic and clinical foundations of the disease, often offer no therapeutic benefit for the research participant. Phase I studies in particular involve the administration of investigational medication to participants in increasing dosages, in order to test the drug's toxicity. Although, these drugs may carry a potential for benefit (recognition for researchers, profit for drug companies, etc.), the participants receive no direct health benefit (beyond the fulfilment of their altruistic motivations). Groves (2006) warns that there might be a "conspiracy of silence" about the phenomenon where the research results favour, to some extent, the interests of the researchers rather than those of the participants (Groves 2006, p. 20). Moreover, if participants and proxies were consistently informed about the lack of therapeutic benefits in Phase I studies, there is a danger that the enrolment rates would decline. This contributes to the controversial nature of clinical research on cognitively impaired older adults (Groves 2006).

'GREY ZONE' OF PWDS' CONSENT – ASSESSMENT OF COMPETENCY TO CONSENT

A prerequisite of obtaining valid informed consent for therapy or research with PwDs is the assessment of the PwDs' competency to consent. During therapy or research, PwDs may find themselves in a 'grey zone' between competency and incompetency.[32] This 'grey zone' is specific to PwDs with early stage or mild dementia. They might have

32 Bowman (2008) uses the expression "grey hinterland" (e. g. somewhere in between capacity and incapacity), where PwDs may occasionally or, sometimes be found to have a decision-making capacity (Bowman 2008, p. 73).

decision-making competency in one moment, and lack it in the other moment. This competency might then be regained later. Thus, this very specific condition poses extraordinary requirements for obtaining valid informed consent from PwD, even within a single research project. Due to this characteristic of PwDs, i. e. fluctuating within a 'grey zone' between competency and incompetency, it is important to continuously evaluate their level of competency to provide valid consent for treatment or participation in research. Such evaluation is supposed to clarify whether the PwD is competent to provide valid consent on her own, or whether it should be sought from a legal guardian.

Vorm and Rikkert (2008) list several instruments available for clinicians to evaluate the competency of potential participants with dementia to consent (Vorm and Rikkert 2008, pp. 86–87):

- Ability to evidence a choice.
- Ability to make a reasonable outcome of a choice.
- Ability to understand information.
- Ability to manipulate with information.
- Ability to appreciate the situation and its possible consequences.

The MacArthur Competence Assessment Tool (MacCAT) is believed to be the best validation instrument at the moment (Vorm and Rikkert 2008). MacCAT is available for both research and clinical application (e. g. MacCAT-CR, where CR means clinical research; and MacCAT-T, where T stands for treatment), and shows good validity and reliability. Wide application in clinical settings is however questionable because the completion of the test requires 30-60 minutes, not including former training and familiarity with the instrument. Another issue with the MacCAT and any other assessment instrument is the inability to measure the moral capacity and/or emotional ability of the person. Both are closely related to the decision-making capacity of the participant, the results of which must be aligned with the life history of the person. Therefore, Vorm and Rikkert (2008) recommend the combination of the MacCAT questionnaire with specific questions regarding the hopes, beliefs and personal history of the participant.

Also, the proportionality principle should be applied, as a criterion of capacity to consent in research with PwDs. This means that the riskier and more burdensome the trial, the higher the standards required for consent. For example, the consent requirements for a therapeutic, low-risk study are the lowest; while on the other hand, they should be the highest for a high risk non-therapeutic research study (Vorm and Rikkert 2008).

MOTIVATIONS OF PWDS FOR PARTICIPATION IN A RESEARCH STUDY

As noted in the literature review (Chapter 3), PwDs were found to be relatively approachable regarding participation in research activities. Participants take part in the research projects for the following reasons: largely to compensate for feelings of loneliness and social isolation, some out of curiosity, and some in order to contribute to the development of AAL technologies (Grönvall and Kyng 2012; Novitzky et al. 2015).

Firstly, the reasons for concern arise due to the nature of the vulnerable position of PwDs, e. g. in their limited and changing consenting abilities, and in their easy approachability for research purposes. The convergence of these two factors may raise concerns about the ethical nature of the study itself. The promise of being a part of a research study, with daily contact with researchers to socialise with, while using neat-looking technology may distort the insight unduly influencing the participants. The distorted insight of the less pleasant and more worrying aspects of participation (e. g. blaming oneself for 'doing something wrong,' Oberzaucher et al. 2009; causing some problem, Wallace et al. 2010; etc.), may be disregarded by the PwDs.

Secondly, the previous concerns multiply in accord with the previously reported issue, namely that PwDs are prone to please (and hence also unwillingly mislead) the researchers (Novitzky et al. 2015; Oberzaucher et al. 2009; Wallace et al. 2010). PwDs were already recruited for participation because of their diagnosis with mild-dementia, meaning that they are most likely already in the process of developing MCI. This condition renders them more vulnerable to withdraw from a study, and instead, to do what they are being told to do. Such behaviour may infringe upon the validity of the results of the whole study.

Due to the aforementioned possible complications, it seems to be important to investigate and also record the motivations of the PwDs participation during the consent-seeking process. Although, it may be difficult and time-consuming to investigate the motivations of the PwDs as participants, this information may be helpful in clarifying the interests of PwDs in their less capable periods. Both of the aforementioned issues related to the PwDs' motivations to participate may not only provide true answers, whether PwDs have honest motives for their participation. Furthermore, it may also extend the autonomy of the PwDs beyond the period of their personal capability. Such practice would also ensure that some sort of record about the wishes and interests of a PwD is recorded for the later consideration of researchers.

RECOMMENDATIONS OF ALZHEIMER EUROPE AND EDCON

Recently specific recommendations from groups of specialists on dementia have been published (e. g. initiatives of Alzheimer Europe, and European Dementia Consensus Network), who tried to present some general remarks regarding how to conduct ethi-

cally acceptable research with PwDs summarised in a form of recommendations (Vorm and Rikkert 2008; EDCON and Stoppe 2008). The reason for these initiatives was mainly that despite great similarities in national and international regulation, ethical codes in practice are still highly heterogenous in dementia-related research. The assessment of the capacity to consent is only a first step of assessment for research; further assessments of mental status, hearing, speech and vision would also need to be performed. Researchers generally agree with the statement that the confirmation of a diagnosis of dementia does not reveal much about the capacity of the PwD (Vorm and Rikkert 2008). Vorm and Rikkert (2008) emphasise that there have been very few studies regarding informed consent in dementia research. In one of the few longitudinal studies on healthy ageing and dementia, 100 % of persons without dementia and 92 % of persons with mild-dementia proved capable of understanding informed consent information for a non-therapeutic study. Understanding declined with moderate stages of dementia (participant numbers were 250 PwDs, and 165 participants without dementia; Buckles et al. 2003).

Vorm and Rikkert (2008) cite the input of the organisation, Alzheimer Europe (`www.AlzheimerEurope.com`), in the ongoing discussions with the Council of Europe's *Convention on Human Rights and Biomedicine* and the Draft Additional Protocol to the Convention on Biomedical Research about the participation of PwDs in research. Alzheimer Europe adopted the following general principles (Vorm and Rikkert 2008, pp. 89–90):

- The diagnosis of dementia should not automatically mean a lack of legal capacity of the affected person.
- Capacity is not an all-or-nothing matter, PwDs should be involved in decisions concerning research even they are considered 'unable to consent.'
- PwDs have a right to participate in research, if they express such desire.
- PwDs should be encouraged to write their advance directives clarifying their stand regarding participation in research.
- The legal representative of an incompetent PwD, under certain conditions, should be allowed to consent on behalf of a PwD to participation in research.

Based on these principles, Alzheimer Europe developed the following position on the question of the participation of PwDs in research (Vorm and Rikkert 2008, p. 90):

- In the early stages of dementia, PwDs can themselves consent to participate in research (irrespective of direct personal benefit), or declare their willingness to do so, in their advance directives.

- A clinician with the relevant expertise, unrelated to the actual research, should assess the capacity of the PwD and check whether the person can make a decision regarding whether to participate, and is fully aware of the possible consequences.
- Legal representatives should be able to consent on behalf of a PwD regarding participation in research so long as the following conditions are met:
  - The potential benefit for the PwD's health outweighs the possible risks.
  - The risk of causing discomfort or distress is minimal; the research has been approved by an independent REC.
  - The same results could not be obtained with other subjects.
  - The legal representative does not benefit financially from the decision.
  - The legal representative is authorised to give consent by a court or the PwD herself.
  - Safeguards have been taken to protect the privacy and dignity of the PwD.
- In all cases, an independent adviser should be appointed to be responsible for the safety and welfare of the participants.

Alzheimer Europe also does not endorse the participation of PwDs in research that does not offer any potential benefit for the participant, unless the PwD with sufficient capacity has decided otherwise, either verbally or in the form of an advance directive (Vorm and Rikkert 2008).

Vorm and Rikkert (2008) advise that researchers should adopt a step-by-step procedure for performing clinical research with PwDs. This includes the provision of sufficient time and effort in the delivery of the information to the participants about the study. Also, a trial run should be implemented, which may help the PwDs understand the study procedures better. One has to consider that the participants are PwDs, some of whom suffer from depression. Furthermore, the quality of consent is tightly linked with the proportion between the potential risks and burdens in the study, and its benefits. On this ground, informed consent can be judged irrespective of the diagnosis of dementia (Vorm and Rikkert 2008).

According to Vorm and Rikkert (2008), PwDs, deemed incompetent most of the time, should not be included in research. This general rule can be ignored only if such an inclusion is found to be necessary for the promotion of PwD's health, whereby the research cannot be performed on a competent person instead. Furthermore, research with incompetent participants should only be permissible, if the condition that makes the participant unable to consent is the necessary characteristic under investigation in the research study (Vorm and Rikkert 2008).

Extra precautions are necessary when including PwDs in research, particularly if the PwD lacks the capacity to consent, and where there is an absence of any advance directive (Vorm and Rikkert 2008).

In the case of potential participants, who are under legal guardianship, the investigator of the research study should obtain informed consent from the legally authorised representative,[33] in accordance with the international and national legislation. In order to better facilitate this, advance directives should encompass such a scenario by default. In general, Vorm and Rikkert (2008) favour a dual consent procedure, when the investigator responsible for research acquires consent from the authorised representative, followed by the assent (or consent, if the participant is capable of providing it) from the PwD.

In 2008, a Consensus on Assessment of Competence has been reached, providing recommendations to be adopted in European countries (EDCON and Stoppe 2008). These recommendations are as follows (EDCON and Stoppe 2008, p. 11):

1. The assessment of competence should be used to enhance the welfare of people with dementia and should serve to provide help and shelter to those whose competence is reduced and autonomy to those where competence is maintained.

2. The diagnosis of dementia should not be taken to automatically imply a lack of competence.

3. Competence should be assessed with respect to specific purposes. It should not be assumed that the lack of competence to perform with regard to a particular purpose means that there is a lack of competence to perform with regards to other purposes.

4. Competence should be assessed repeatedly at intervals defined by the purpose of the assessment.

5. The assessment of competence requires special skills and should be performed by persons who can use currently available methods in an optimal manner.

Árnason et al. (2011) remark that there is no pure and abstract understanding of clinical treatments or research for a patient or research participant. For example, a research participant who used to be a former engineer will understand the disclosed information much easily if that is presented to him using the terminology of engineering, with

33 In academic literature and legal documents, this person is referred by various names: general attorney, durable power of attorney, healthcare power of attorney, guardian, healthcare proxy, medical surrogate, etc. Also the procedure of obtaining informed consent through these representatives is also referred to by various names: substituted judgement, proxy consent, surrogate consent, etc. Although there might be minor differences, the main ethical aspects are usually: a) a person consents for another person, b) this method is used to extend the participant's autonomy (Vorm and Rikkert 2008).

metaphors linking the information to the knowledge gained for his former profession. In every case, the professional's duty is to find a correlation between the shared information by and the background knowledge of the participant. The correlation has to be reached with the usage of comprehensible language; this means that the participant should be neither overloaded with information, nor under-informed (Árnason et al. 2011). These guidelines should be carefully noted in the case of PwDs living with MCI.

ROLLING INFORMED CONSENT

An alternative method of obtaining informed consent is the mechanism offered by the introduction of *rolling informed consent*. The method has been discussed earlier, in the literature review in Chapter 3.[34] The benefits of this approach lie in the ability of the PwD to reflect upon the possibility of withdrawal from research. This approach also ensures that the researcher is up-to-date on the willingness and decision of the participant to participate and continue in the research activity. Furthermore, rolling informed consent overcomes the overly legalistic interpretation of informed consent. The major disadvantage of the approach it that is time-consuming. This can make the research activity considerably slower and take longer than usual. Such objection, however, has little strength from the ethical point of view, especially if this approach ensures the rights and protection of the vulnerable participant. To fulfil the normative ethical requirement for obtaining informed consent, rolling informed consent seems to be one of the possible ways of to obtaining valid consent from PwDs. The approach of rolling informed consent is, of course, only possible in cases when a person is capable of (even limited) decision-making, and is competent in providing valid consent.

DELAYED CONSENT

As the discussion of Art. 6–7 of the UDBHR, other international documents, and the recommendations of expert groups suggest, direct consent from the individual, if possible, should always be preferred compared with any form of substituted judgement. Nevertheless, PwDs may find themselves trapped in a particular situation that is relevant for providing consent. This is when one is transiently incapacitated for a relatively short

34 To summarise, rolling informed consent involves:

a) The necessity of repeatedly providing information on an iterative basis (i. e. not only when requested), and also asking for consent during the various stages of the treatment or research;

b) Listening to the content and nuances of the speech of the PwD and continuously assessing whether her participation is voluntary and not subject to coercion, persuasion, manipulation, or simple distress, which if so subject, would be sufficient reason to end the session for the researcher, without needing the expressed request of the participant (Astell et al. 2009); while also

c) Communicating the possibility of opting-out or withdrawing from treatment or research at any given stage.

amount of time, and after that becoming lucid again, temporarily recovering from the incapacitated state. For situations like this, which can occur while research activities are ongoing, researchers have two possible options. First, they may temporarily interrupt the research and wait until the person recovers lucidity again. This might impede the continuity of the research, causing gradually increasing delays. The second option is to use a form of 'retrospective consent,' which involves seeking consent after the research activity has been performed (without prior consent), when the person recovers from the incapacitated state (e. g. Honeybul et al. 2014). Retrospective consent is already practised in medical treatment and research. It is used when a person is not competent at the time of the life-saving treatment (e. g. mature minors, Ashcroft et al. 2007; whose bone-marrow is required for donation to save the sibling's life). Consent sought after the research activity (often called also as 'delayed consent') is used in cases where the research cannot be performed with competent participants, either because of time constraints or the permanent condition of the participant (Faden et al. 2014; Potter et al. 2013).

The protocol of the *NICE-SUGAR* (2004) in ICU environment allows the possibility of a form of retrospective consent (i. e. delayed consent) where the respondents who provided delayed consent were less likely to delegate the decision-making to another person or an organisation (Potter et al. 2013). However, the *NICE-SUGAR* (2004) did not focus on PwDs. There is a dearth of academic literature providing any further insight into the possibilities of retrospective consent specifically in relation with PwDs.

6.2.2.4 *Issues Related with Consent for Research with ICT*

A considerable amount of current research is focused on the investigation of the effects of AAL technologies for PwDs. There are particular nuances, which need to be considered at the early design phases of the R&D and during the research activity of any trial in this area.

OBTAINING OF CONSENT WITH ICT DEVICES

A relatively new trend in the research with human participants is the obtaining of consent with ICT devices. The benefits of such an approach are the personalised provision of important information about the study, and the easily accessible and retrievable proofs of consent. A study conducted by Antoniou et al. (2011) provides insights into the personalisation capabilities of electronic personalised information sheets. The forms offered, by default, the necessary minimum of information about the study, with participants then having the option to interrogate that information to obtain further details on specific content of the form that they were interested in. However, the study itself

admits that a relatively high percentage (23 %) of people consented to the ICT form without even reading the necessary minimum information (Antoniou et al. 2011).

While Antoniou et al. (2011) see the benefit in electronic consent and information forms in their possible personalisation for the individual, rather different benefits are highlighted by other researchers. Purcaru et al. (2011) perceive that one of the goals of electronic informed consent forms is the simplification of the document, which benefits the participant. As they rightly remark, such a simplification should not however result in a reduction of the time made available for understanding the form. The electronic informed consent form may be valuable in supporting consent as a continuous interactive process. However, one of the desires of the authors was to achieve greater standardisation of electronic informed consent forms, which seems to contradict the aim of personalising forms by Antoniou et al. (2011).

It might be argued that obtaining consent has never been as easy as with the use of ICT services and devices. The consenting process may be divided into smaller and more focused segments. At the same time, ICTs can make the provision of the necessary information considerably shorter. The utility of ICT for seeking consent became even greater due to the ubiquity of mobile devices, where additional ways of delivering information and supporting their understanding (e. g. video, audio, graphs, etc.) can be applied.

However, even healthy volunteers are prone to succumbing to the danger of routinisation during the provision of consent made by an electronic ICT service. Studies showed that often the provision or refusal of informed consent occurs as an unreflective, habitual act performed on electronic devices (Ploug and Holm 2013; Ploug and Holm 2014; Ploug and Holm 2015). The reasons can be various: the form is too long to read, the service offered by the form has been recommended to the reader by somebody else, the text is incomprehensible, etc. PwDs may be at an advantage because the study showed that as the average age of the consenting person rises, so too does the extent of their reading the form. Also, the extent to which the information is read increases with the number of female participants. Finally, there is a negative correlation between the highest achieved education level and the extent to which the information is read (Ploug and Holm 2015).[35]

The study conducted by Ploug and Holm (2015) finds that the two common reasons for not reading consent forms are the burden of reading and the low risk related to the consequences of not reading the consent. This suggests that shortening consent forms will not be sufficient to change reading behaviour (Ploug and Holm 2015). In this regard, PwDs may be at greater risk because even if there is sufficient means for enhancing readability, their assessment of risks might be fragmentary.

35 The previous two studies showed the opposite (Ploug and Holm 2013; Ploug and Holm 2014).

DYNAMIC CONSENT

ICT provide researchers and research participants with novel opportunities in interacting, re-consenting through the framework of dynamic consent. Dynamic consent is currently developed and investigated within biobank projects, however, the researchers propose this approach or concept also to the wider application within clinical research or other fields (Jane Kaye et al. 2014).

Dynamic consent is defined as "a new approach for engaging individuals about the use of their personal information [...] [by] an interactive personalised interface that allows participants to engage as much or as little as they choose and to alter their consent choices in real time" (Jane Kaye et al. 2014, p. 2). The consent of an individual is wrapped in an encrypted information container. Employing asymmetric cryptography, the consent, together with other personal information, can be publicly shared with a trusted research centre through a trusted authority. Thus, it is also ensured that the research centre has access only to those information, for the access of which it had been previously approved (Jane Kaye et al. 2014, and the documentation of the EnCoRe Project[36]). The research centre thus gains access to the most recent consent and other necessary sensitive medical information of the participant, relevant for the study, while preserving the privacy of the participant. The flexibility and relative ease of receiving information is also beneficial for the participant. She may easily alter or withdraw her consent, follow-up on the use of her data and the results of the study, or being recontacted for data reuse (Jane Kaye et al. 2014). Eventually other personal preferences or advance directives may also be in the course of time included in this information container. The container would then serve as a logbook of these information over a life-span of the person.

However, even such a record of the preferences and long-term data on the evolution of a PwD's advance directive throughout time should not necessarily solve all the possible issues delineated above. The PwD in her less lucid state may still request something that may be contrary to her previously expressed wish in her own advance directive. A researcher and physician may find herself in a dilemma which wish to follow, and how she should justify that decision. Undoubtedly, the developing framework and concept of dynamic consent may bring more data to this interpretative process, what in certain circumstances can be beneficial to resolve a particular question, in other situations may provide even more and unresolvable complexities.

36 EnCoRe – Ensuring Consent & Revocation Project: `http://www.hpl.hp.com/breweb/encoreproject/index.html` (visited on 31/09/2015). The details of the process is described in deliverable D2.3 Third EnCoRe Technical Architecture: `http://www.hpl.hp.com/breweb/encoreproject/deliverables_material/D2_3_EnCoRe_Architecture_V1.0.pdf` (visited on 31/09/2015).

INFORMED CONSENT OF THIRD PARTIES

A further issue in research with ICT and informed consent regards the informed consent of third parties. It emerges as an ethical issue where visual or audio research of participants is in progress.[37]

The study by Wiles et al. (2008) identified the core ethical guidelines for visual research, as follows (Kelly et al. 2013, Wiles et al. 2008):

- Researchers should strive to protect the rights, privacy, dignity and well-being of those that they study.
- Research should (as far as possible) be based on voluntary informed consent.
- Personal information should be treated confidentially and participants anonymised unless they choose to be identified.
- Research participants should be informed of the extent to which anonymity and confidentiality can be assured in publication and dissemination and of the potential reuse of data.

Research with participant-created (visual) data has, until recently, been conducted by deploying cameras to participants. The cameras were supposed to created pictures of certain things at a defined time. Such an approach allowed researchers to shift from the researchers' created datasets to the participants' created datasets. The introduction of automated and wearable cameras allows researchers a more perfect collection of participant-created data. The collection of data with this technology is more automated, and more frequent, resulting in a much higher amount of data (Kelly et al. 2013).

Kelly et al. (2013) state that in order to fulfil the actual ethical standards, and to maintain respect for the autonomy of research participants, participants should be made fully aware of the fact that the audio-visual data will be aggregated, before informed consent. Due to the larger volume of aggregated data, the need to respect confidentiality and data security gains much higher importance. The possibility of causing harm by the gathered data being leaked and mistakenly becoming public is also greater. Therefore, the participants' consent about data retention, and any potential secondary analyses that might follow, should be explicit, if possible (Kelly et al. 2013).

Due to the automated nature of data capturing, the research participants' control over the data collection is also limited. Therefore, the following list of interventions has been proposed by Kelly et al. (2013) to regain the loss of control (and autonomy)

37 Four main visual research data are traditionally identified: found or existing data (e. g. photo albums originally not made for research purposes); researcher-created data; respondent (participant) created research data; and representations (e. g. photos, videos, films, drawings, and other graphical representations; Kelly et al. 2013). This list from an ethical point of inquiry might be extended to all audio recordings and other forms of representations from which individuals might be clearly identified.

over the data collection. Firstly, it is advised that a privacy button be introduced. By pushing the button on the wearable camera, the device pauses any data capture for cca. 7-minute period (useful for activities during bathrooms visits, etc.). Secondly, participants should be expressly advised that they can remove the device or turn them around, so that the camera faces inward, whenever they wish, for whatever reason. Thirdly, participants should be given the option to review and delete any unwanted recordings (online banking, trying on clothes, etc.). Finally, all these options should be provided to the participant, without the participant needing to provide an explanation for her decisions (Kelly et al. 2013). It is possible that not all three options can be ensured (esp. the second) in practice with PwDs.

Therefore, the participants should be always made aware that even with all the precautionary measures, unwanted recordings might be made. Therefore, the best standard would be to give the participants the opportunity to review and delete these recordings before the researcher gets them (Kelly et al. 2013).

Moreover, in certain cases, confidentiality is not always achievable. Especially when activities are recorded, which might be criminally liable. Participants risk incriminating themselves with their own recordings, which may be subpoenaed. Only in exceptional cases, might research data be inadmissible through subpoena (e. g. of very limited groups of: medical employees, clinical psychologists, etc.). Participants should also be informed about these possibilities in advance to a satisfactory degree (Kelly et al. 2013).

The presence of third parties poses a very particular issue because these people's presence is captured within the location where the research takes place, without their being provided an opportunity to give informed consent. A participant may meet throughout the course of their usual day many other people, who may knowingly or unknowingly be captured on a recording (audio, video). Kelly et al. (2013) categorise third parties who are likely to be thus captured as follows (Kelly et al. 2013):

- Family members, cohabitants, friends.
- Colleagues, coworkers.
- Strangers, general public.

Family Members, Cohabitants, Friends

In the first group, the existing guidelines should include protection of privacy in places where one would be recorded unknowingly. This should embrace also third parties in the homes of research participants. Kelly et al. (2013) consider it unnecessary to obtain written informed consent from family members in such cases but verbal permission prior to the recording should be sought. Researchers are obliged to provide the necessary information on the recording process, the storage of the data and the ways in which

these recordings will be disseminated. The privacy of friends and acquaintances should be also respected. If prior verbal permission is impossible or impractical to obtain, it should be sought on first contact (Kelly et al. 2013).

Colleagues, coworkers

The requirement of consent from the second group, that of colleagues and coworkers, mostly depends on the research rationale and the appropriateness of recording in workplaces. These locations should be assessed by the researchers prior to device deployment. Although in the case of PwDs, colleagues and coworkers are usually not an issue, children may be present and thus pose a similar issue. Special attention should be given to the presence of children, where parents should be informed in advance about the fact and nature of the ongoing research. Studies focusing on leisure-time physical activities or travel may not require the wearing of the recording device to work. However, research focusing on diet or sedentary behaviour might necessitate the wearing of a recording device during working hours. In these cases, participants should seek verbal permission from managers and supervisors. They should also inform their colleagues about the presence of such a recording device. Third parties may ask the research participant to remove or turn off this device, in which case, the participant should do so. Participants who work with their clients should be advised that a study with recording devices is not appropriate for them (Kelly et al. 2013).

Strangers, General Public

As the third group, strangers and general public, is usually present in public spaces, it is not necessary to obtain individual informed consent. This is so only if the recordings are not published or disseminated in a way in which the individuals are recognisable. Participants, however, should turn the devices off in those public places in which privacy or security might be expected (e. g. gym changing rooms, airport security checkpoints, etc.). Considerations should also be given to the fact that studies in certain cultural settings may not be allowed (e. g. aboriginal communities, etc.). For all of these aforementioned cases, researchers should provide clear guidance for participants when the devices are being deployed (Kelly et al. 2013).

Additional Recommendations

There might be situations when wearing of a recording device might be considered as potentially hostile and, by suspicious third parties, as intrusive. In such cases, it has been found to be effective to prepare the participants to provide basic and simple information about the nature and purpose of the study. The participants should also eventually offer the removal of the device if it burdens the third party. Participants should also inform

any third parties that by expressed request, they are allowed to delete the recordings they do not want to share with the research team (Kelly et al. 2013).

Other cases report that the wearing of a recording device may pose a security threat for the participant because of the possibility of mugging. Providing instructions for the participants to remove the device in situations in which they feel uncomfortable or threatened might reduce such risks and related potential harms (Kelly et al. 2013).

In certain cases, third parties may not be aware of the ongoing recording. Kelly et al. (2013) admit that this might pose serious ethical and legal issues. However, a distinction is often applied regarding the focus of the research, which is on the participant and not on the third parties that may incidentally be recorded. Kelly et al. (2013) note that nevertheless, the ethical standard of respect for autonomy directs that the privacy of third parties must be protected. If the study is designed to investigate the influence on the research participant by third parties (e. g. eating, drinking habits in group settings), the anonymity of these third parties should be preserved. None of the disseminated and published material should enable the identification of the research participants (Kelly et al. 2013).

Finally, participants of the research study should be made aware that the recorded data will need to be processed. This might be done by automatic algorithms or trained researchers. Therefore, participants should be informed that the recordings may also be viewed by the researchers (Kelly et al. 2013).

6.2.2.5 *Issues Related to Obtaining Consent During Therapy Involving ICT/AAL*

The aim of this section is to present few ethical issues that are likely to occur when AAL technologies will be applied in clinical therapy. These are: the issue regarding the definition of AAL technologies (their ambient nature, and partial- or full-autonomy); unrealistic expectations of PwDs regarding ICT and their abilities; the issue of information overload inherent in ICT; the problem of 'infinite memory' of the lifelogging capabilities of AAL; and finally the third-party consent.

AMBIENT AND AUTONOMOUS TECHNOLOGY, AND THE ISSUE OF REQUEST FOR CONSENT

One of the crucial attributes of AAL technologies is their ability to disappear into the background of the environment. Sensor technologies may collect the data and respond to some events or states in an automated manner. For example, a higher blood pressure or pulse rate might be related only to the fear of watching a horror movie, and not to a worsening health condition. While the former should not trigger the safety procedures of calling for help, the latter should. Cases like these naturally pose issues about consent in relation with AAL technologies. The person using ambient technologies might forget

their presence, during which time, the AAL technology may perform certain undesirable tasks.

The automated and autonomous nature of these technologies certainly pose ethical risks to the PwDs, as noted by Joost van Hoof, Kort, et al. (2007). They might expose the PwDs, due to their inability to fully comprehend the extent of data collection and transmission by ICT, to misuse, criminal activities, privacy breaches, or dehumanising treatment (Joost van Hoof, Kort, et al. 2007). Additionally, such a scenario, would strip PwDs of their freedom to make decisions, making them the only group of people without this right (Holm 2001). The reaction to an undesired activity of the AAL technology may also be detrimental from the point of view of dementia management, as it could cause higher levels of anxiety in the PwD (e. g. the issue of 'false alarms,' etc.).

Even if the ICT service would require consent from the PwD, there is still a risk that, within a shared dwelling, the consent is provided illegitimately by somebody else (e. g. carer, family member, etc.), and not by the PwD directly. Thus, an unobtrusive authentication of the PwD for consent will be needed. This might be challenging to achieve because of the possible forgetfulness of the PwDs. For these reasons, authentication by fingerprint-reading, voice- or face-recognition seem to be preferable.

Even by introducing these precautionary measures, the question of autonomous ICT and the requirement for consent remains unresolved. Therefore, further research is required for more focused and detailed insight into the extent to which needs of PwDs can be served by autonomous decisions made by ICT. The research should target the use of autonomous devices in particular contexts, i. e. when such activity is acceptable for the person compared with when it is not, for example, when it results in a greater state of disturbance for the person. Also, more research is needed to establish a valid proportion between the need for and the degree of autonomous ICT and the requirement of informed consent for certain actions of PwDs. Such research should also seek to identify how often consent should be sought from PwDs during the research and/or clinical practice.

UNREALISTIC EXPECTATIONS FROM ICT

During clinical trials and clinical application the deployment of AAL technologies into the home environments of PwDs, researchers and clinicians should not be mislead by the enthusiasm of the PwDs and caregivers about the ICT services. The initial levels of acceptance and expectations of older people regarding ICT devices are reported to be very high (Marcellini 2012). Therefore, it should be advised that, from the very early experimental stages, a realistic view of ICT should be promoted through appropriate training. Such practice would result in the promotion of acceptance of the AAL technologies (Marcellini 2012). Additionally, it might prove to be helpful for the overall as-

sessment of the need and usefulness for ICT services in the care for the PwDs, resulting in the effort being more ethically sound.

INFORMATION OVERLOAD OF PWDS

The PwDs are more vulnerable to the information overload (Duquenoy and Whitehouse 2006; Kang et al. 2010), which may occur during the acquisition of informed consent. The concerns about information overload might be addressed to some extent by the division of the information, into smaller, more digestible blocks, distributed on a wider timeline. However, despite all these efforts, the overload of information is not completely avoidable, due to the unfortunate condition of PwDs. As one of the possible consequences of information overload, the problem of routinisation, mentioned earlier, may also apply to this issue (Ploug and Holm 2015). Therefore, an appropriate, and probably personalised, balance of information will need to be tailored for every individual PwD. This means that the information should be interactively and dynamically adjusted to the actual state of the person's competence and other faculties, in order to obtain informed consent successfully and ethically.

AAL AS LIFELOGS AND THE ISSUE OF 'INFINITE MEMORY'

AAL technologies may function also as lifelogs. Lifelogs are a form of pervasive computing, which consists of unified, digital record (Jacquemard et al. 2014). Thus, lifelogs, due to their 'infinite memory' capabilities, are not only perfect for logging information about health status, physiological data, or other relevant health information, they are also useful for storing the consent and previously expressed wishes and preferences of individuals. While *prima facie*, one might consider this beneficial, especially for forgetful PwDs, this might not be necessarily so. Generally speaking, forgetting is an intrinsic form of controlling one's memory (Jacquemard et al. 2014). This control may be lost. One might prefer certain memories to be forgotten, without reminder. The opposite scenario might result in lethargy, depression, or anxiety. Analogously, if the previous consent of the PwD is always remembered and recorded, this may not be easily changed in cases of diminishing competency. Therefore, it seems important to regularly renew the consent of PwDs, although the frequency has to be carefully set. Regular requests for consent can enforce the PwD's feeling of control over the AAL technologies, the PwD's involvement in their care, and reaffirm their feeling of security. However, seeking consent too often may be considered burdensome and upsetting for the PwD. Therefore, an individually tailored approach that strikes the right balance needs to be developed for the consent-seeking process, with the emphasis on avoiding causing anxiety, routinisation, or reducing acceptability. These conditions pose a very high requirement on researchers and developers of the AAL technologies.

THIRD-PARTY CONSENT IN THERAPY

Finally, the formerly mentioned issue of third party consent is also present during clinical application. Although there are some proposals for best practices (Kelly et al. 2013) in this regard, the solutions are far from perfect and will require more specific regulation and further ethical investigations.

6.3 SPECIFICATION OF THE UDBHR PRINCIPLES

The ethical requirements for respecting one's autonomy and self-determination, and therefore requesting one's consent for treatment or research participation is one of the most elaborated topics in bioethics. Since its emergence in the early 1900s and especially since the Nuremberg trial, the informed consent doctrine is a fundamental element of any research involving human beings. Also, the informed consent doctrine may be considered one of the main driving forces for the birth of bioethics, as a new field in science.

Since its emergence, informed consent has become more well-defined and nuanced in application to the special requirements of the times. Research with persons without the capacity to provide valid consent, and the safeguarding of their benefits (maximisation of direct and indirect benefits, while minimising risks and harms) has, since the 1990s, been incorporated by degrees to international guidelines.

The informed consent of PwDs is very specific in a few particular aspects. Firstly, PwDs constitute a group whose consent may fluctuate between valid and invalid consent. Secondly, this may cause ethical issues with the interpretation of the recorded consents of advance directives, either through being supported or questioned by family or healthcare professionals. Moreover, the incapacitated PwD may also manifest contradictory wishes to previously expressed directives. Thirdly, due to the fact that no effective treatments for dementia (and its development) are available, one has to consider the research of AAL technologies for PwDs as non-therapeutic research. The implementation of AAL technologies into the care about PwDs can, thus, only be categorised as assistive.

In the following sections, the principles in Art. 6–7 of the UDBHR, on PwDs capable and incapable of providing valid and informed consent, are specified for the areas of research and clinical practice. Special attention will be paid to the possible effects of AAL technologies upon the informed consent of PwDs in these contexts.

6.3.1 *Clinical Research*

Most of Art. 6 and Art. 7 concerns research, defining standard requirements for valid informed consent (as being prior, free, express and informed), that is as a result of

adequate and comprehensible disclosure of information, which is communicated along with all the possibilities of withdrawal.

Regarding PwDs, these criteria are fulfilled either when the person is still competent enough to provide valid consent for research (i. e. having mild dementia), or through her wish to participate expressed in her advance directive, or through the authorisation of the therapeutic representative (i. e. in cases of moderate or severe dementia). In exceptional cases, PwDs may be incompetent to provide valid consent for research participation, even in mild the stages of dementia.

However, it is important to emphasise that informed consent should never be interpreted as a legal requirement. The capacity of every human being forms rather a continuum, and the consenting abilities of PwDs fluctuates. As presented by EDCON and Stoppe (2008), and supported by authors like Fountoulakis and Despos (2008), PwDs' competence to consent is not an on-off, binary, all-or-nothing switch. Also, the diagnosis of dementia should not automatically render PwDs incompetent of making medical decisions (EDCON and Stoppe 2008), including wishes of participating in research (Vorm and Rikkert 2008). PwDs, according to the recommendations of the professional expert bodies, EDCON, and Alzheimer Europe, or academic literature, should not be automatically declared incompetent after the diagnosis of dementia. PwDs may manifest limited competencies for providing valid consent that may be sufficient for the necessary treatment or successful participation to research. Therefore, the validity of every PwD's consent should be evaluated individually and within the context of the activity the consent is being sought for.

6.3.1.1 *Consent of Competent PwDs for Research*

The question at stake with involving PwDs in research with AAL technologies is, what kind of protections should be provided for PwDs as research participants? For therapeutic research, the inclusion criteria should be less stringent, due to the likely benefits the participant may receive, which may alleviate the pain and burdens that she may be experiencing. For non-therapeutic research, however, the inclusion criteria should be rather strict because it is unlikely that the participant will enjoy any direct health benefits as its result. The research of AAL technologies can be regarded, at best, as assistive means for reducing the consequences of dementia. AAL technologies do not, and cannot address the causes of dementia. The requirement defined in Art. 7b but more importantly in Art. 4 of the UDBHR requires that maximisation of direct and indirect benefits, which, in the case of researching non-therapeutic treatments, should require strict assessment of inclusion of PwDs into research studies. The reason behind this requirement is the protection of especially vulnerable groups of possible research participants, whose capabilities to consent, and defend their well-being may be severely diminished.

Consequently, the standards for requesting consent from PwDs for research participation should be evaluated rigorously, due to the fact that such research is non-therapeutic, and does not provide participants with any direct benefit, and which is also risky.

CONSENT OF PWD AND DATA OWNERSHIP

When a PwD in the early stages of dementia, with very mild disturbances in memory and cognition, consents to participate in a research study, which involves ICT, one of the crucial points to clarify is the data ownership. The involvement of a PwD into research is justified only if the research is investigating for some specific aspects of dementia or dementia-related complications, which cannot be obtained from other fully competent and less impaired (or even healthy) research participants. These research studies often collect medical, personal, and other sensitive data, which either remain in the possession of the PwD, or their management is transferred to the research centre. In the former case, any future reuse of these data needs to be authorised again by the PwD, and only anonymised data can be published. This poses certain challenges for the researcher and the research centre because the PwD's condition may rapidly deteriorate, causing significant issues for the future study.

As a result of the consideration of such a scenario, researchers may be tempted to ask for broader consent from a PwD, which would authorise the researchers to reuse the data, while it is being stored in the research centre. However, signing such a broad consent can be ethically and/or legally questionable. It is also in the interest of the researchers to use data legally obtained from research participants, while fulfilling high standards of research ethics.

One possible solution, proposed by Jane Kaye et al. (2014), is the use of dynamic consent, which may enable the researchers in the future to maintain regular contact with the participants with dementia, informing them about the results of the research; and recontacting them easily if their data needs to be reused. Dynamic consent also appears to be the correct means for fulfilling the requirement of 'express consent' defined in Art. 6.2 because it maintains the most straightforward connection between the PwD, who offers the data, and the researchers, who require consent.

COMMUNITY INTERESTS FOR PWDS' PARTICIPATION IN RESEARCH

Art. 6.3 refers mainly to the "legal representatives of the group or community" from whom additional agreement for research authorisation may be sought. This condition in the UDBHR is helpful in recruiting research participants from different cultural and ethnic groups, where the local customs require such approval.

However, it may be questioned whether this condition of Art. 6.3 should also be extended to PwDs, requiring additional authorisation for research participation from the

mediators between the (group of) PwDs and the researchers. This question was also raised earlier in Chapter 5, in relation to special vulnerability and personal integrity, again by EDCON. The special vulnerabilities of PwDs, with the likelihood of fluctuating capabilities to provide valid consent for research, would justify the extension of this standard to this case. If the legal institution of mediators for PwDs is approved for PwDs, it would provide additional levels of security for research, and would also certainly elevate the ethical standards of research conducted with this especially vulnerable population.

REGULAR REVIEW OF CONSENT

Even though a PwD is capable of providing valid consent at the beginning of a research study, Art. 6.2 requires that the withdrawal of her consent should be allowed and granted for any reason, at any time. This requirement may cause additional issues during the progress of the research study, if a PwD becomes incapable of reaffirming or withdrawing previously granted consent. To circumvent such an adverse scenario, regular reviews of the PwD's consent should be scheduled. This may occur either in a form of rolling informed consent, or through the framework of dynamic consent (with the assistance of ICT devices). If a PwD does not satisfactorily confirm (i. e. with understanding, competence, and voluntariness) the extension of her consent for the next part of the research study, her lack of confirmation should be treated as a withdrawal of consent. It should be reminded that a PwD's condition may worsen so much that she becomes incapable of expressing any statement regarding her previous consent. The degree of change in a PwD's condition renders further inclusion of such participant in the research study ethically unjustifiable, unless otherwise explicitly specified for precisely this scenario in the design of the research study.

The regular review of a PwD's consent may function as an effective reporting tool, to report updated user needs, which, during the progression of dementia, change considerably within a relatively short period of time. Such review would enable researchers to provide necessary adjustments for the PwDs, in response to their changing conditions and needs.

6.3.1.2 *Consent of Incompetent PwDs for Research*

The phrasing at the beginning of Art. 7, referring to the requirement of "special protection" towards incapacitated persons, resembles the requirement of protection and respect for special vulnerabilities in Art. 8, described in Chapter 5.

Art. 7 of the UDBHR, on consent from persons without capacity, is divided into two sections. Section A refers to the authorisation for research and medical practice of the

person incompetent to consent. Section B defines the additional requirements for the involvement of such a person in research.

AUTHORISATION FOR RESEARCH OF INCOMPETENT PWDS

The phrasing of Art. 7a defines the condition, under which the authorisation for research participation of the incompetent person (PwD) is permitted, which is specified as in the 'best interest' of the person concerned. It appears that this phrasing disregards the internal step of developing a substitute or hypothetical judgement by relatives and/or researchers, as has been defined earlier in this chapter, allowing such practice for cases in clinical practice. The UDBHR's formulation moves directly from express consent of the PwD with capacity to consent, to the best interest standard for the authorisation of the incompetent PwD. Furthermore, it is not defined in detail who should be allowed to authorise the participation of an incompetent PwD in research. Whoever it is, she should be doing it without exception in the best interest of the incapacitated PwD.

Following up on the interpretation of competence of PwDs earlier in this chapter, the consenting capacity of PwDs may fluctuate, ranging anywhere from temporary incompetence to competence, within a relatively short interval of time. The second part of Art. 7a, however, ensures that the PwD incompetent to consent, should still be involved, to the greatest extent possible, in the authorisation. This provides sufficient basis for taking into account the limited consenting capabilities of PwDs.

However, the authorisation of participation in a research study may come from the advance directive of the PwD. An additional controversy may emerge during this scenario, namely, who should be the person that interprets the authorisation for research participance of the PwD? If it is a therapeutic representative (usually a close relative or family member), she may be in a conflict of interest due to financial or other interests. If the authorisation should be interpreted by a researcher, it may also trigger conflicts of interests. Researchers, having interests in the success and goals of the research, following their own agenda, may be succumb to the phenomenon called the 'conspiracy of silence' (Groves 2006).

There are additional issues with the best interest standard itself, as presented at length in this chapter. Due to the fluctuation of the consenting capacity of the PwD, the authorisation for research participation granted in her advance directive may conflict with wishes manifest in the changing behaviour of the PwD during a temporary non-lucid period. Furthermore, acting according to the 'best interest' standard does not necessarily mean that the interests imagined by the researcher/proxy for the PwD are really the best. Hence, the best interest standard mentioned in Art. 7a for the authorisation of research participation, in the case of incapacitated PwDs, should be referred to as a standard for not causing harm to the PwD, not violating her autonomy unnecessarily, and at the same time, preserving and actively protecting her human dignity and rights.

Fulfilling this interpretation of the 'best interest' standard may be achieved by the application of principled compromise between all the stakeholders involved in the decision-making process, including the PwD with limited competency, as defined by Huxtable (2012).

ADDITIONAL REQUIREMENTS FOR RESEARCH WITH INCOMPETENT PWDS

Art. 7b further limits the inclusion of incompetent PwDs into research studies, by specifying which conditions must apply for such inclusion. In addition to the authorisation of PwDs' participation, which should be granted in the best interest of the PwDs along with their inclusion into the decision-making process to the greatest extent possible (Art. 7a), the requirements for research with PwDs must also fulfil further protective conditions: it should be carried out for the direct health benefit of the PwD, and the research cannot be conducted with comparable effectiveness on competent participants.

Art. 7b does not categorically rule out research studies that do not have direct health benefit for PwDs. They may be conducted only by "way of exception, with the utmost restraint" (Art. 7b). This exception is further specified in the UDBHR as (Art. 7b):

- PwDs during research studies without direct health benefit should only be exposed to minimal risks and minimal burdens.
- PwDs may be participants of research studies without direct health benefit only if the research results may significantly contribute to the health benefit of other PwDs.
- Research studies where PwDs participate without any direct health benefits should comply with the legal conditions of the given country, and special protection should be given to the human rights of each individual PwD.
- PwDs participating in research studies without direct health benefit have the right to refuse participation.

The minimal risks and burdens, as noted earlier in this chapter, should not be greater than that experienced or potentially experienced by PwDs during their usual everyday activities (cf. footnote 24).

Even the aforementioned conditions presented in Art. 7 do not resolve the issues related to research authorisation. An incapacitated PwD's advance directive, the authorisation of the therapeutic representative and family proxies, the interests of the researchers, and the ostensible refusal behaviour of the incompetent PwD may all question the validity of the research participation authorisation. The problem here remains the same: which of these 'authorisations' or 'refusals' should be taken seriously, if most of these occur at the same time? One can easily imagine a situation, when the PwD in her advance

directive expressed her wish to participate in research studies, and while the therapeutic representative supports this decision the family members do not. Moreover, the incompetent PwD herself shows certain signs of disapproval, all of which make it difficult to interpret the true wishes of the PwD, including the refusal to participate. Art. 7b, with the use of the word 'refusal,' seemingly does not include consideration of such scenario. The word 'refusal' in Art. 7b suggests that this decision should have been made somehow before research participation. However, as the specific conditions of PwDs indicate, PwDs may be competent enough in their effective expression of their refusal of participation, even though they are no longer capable of providing valid informed consent. Therefore, the condition for 'refusal' of research participation by incompetent persons in the case of PwDs should be extended to the withholding previously granted consent. This extension of meaning is justified by the supportive statements on research withdrawal in Art. 6.2 and Art. 7a, and the provision of special protections defined in Art. 7. AAL technologies, moreover, should allow the monitoring of any change in the authorisation for participation, signalling to researchers if refusal is occurring regularly and under specific circumstances.

R&D of AAL technologies usually occur within a larger research project. By definition, AAL technologies involve a certain amount of monitoring, surveillance, and other data analysis. Certain tasks of larger combined research studies may focus on the pathogenic aspects of dementia and their compensation with AAL technologies, which may require incompetent PwDs as research participants. However, other parts of these larger combined research studies regarding AAL technologies may focus more on tasks that can be completed by competent PwDs. The rationale behind Art. 7b authorising research studies with incompetent persons, alongside the direct health benefit criterion, is the lack of comparable effectiveness of the research conducted with competent persons. It may be argued that Art. 7b requires that during the design of larger research projects, special consideration should be paid and additional justifications provided for the inclusion of incompetent PwDs, while strictly separating these from the tasks that may be conducted with the collaboration of competent research participants with dementia.

6.3.2 *Clinical Practice*

Upon closer inspection, only two sections of the pair of UDBHR principles related to informed consent refer to medical treatments explicitly. Art. 6.1 refers to preventive, diagnostic, and therapeutic medical treatments, and Art. 7a refers to authorisation for medical practice with incapacitated persons.

Due to the likelihood that the PwDs are seldom alone during their treatments (in a therapeutic, non-research setting), and also the fact that inherent surveillance capabilities in this respect cannot be ignored, additional consent will be needed from informal

caregivers, and/or family members. This consent will need to include a statement that by being a PwD's caregiver, who uses AAL technologies for care management information about her and the care she provides may be included in data being recorded and stored about this management. Furthermore, information about how these data are being further processed and managed, and about when the data will be irrecoverably destroyed should also be a part of consent for people who participate in the care for a PwD.

This issue highlights another related problem, which is the consent of third parties. PwDs, who enjoy a longer stay in their home dwellings, also want to continue engaging uninterrupted social lives, by being free to invite guests or other members of their wider family. These people may not be informed about the PwD's diagnosis. Eventually, it is the preferred choice of the PwD not to disclose such information to these third parties. It appears that such a preference of PwDs should be protected, given the requirements defined in Art. 4, on the autonomy of persons, further supported by protecting the PwDs special vulnerability with Art. 8, and possibly by avoiding stigmatisation of PwDs required by Art. 11. Neither Art. 6 nor Art. 7 consider the scenario where unrelated people to the treatment or research (i. e. third parties) are knowingly or unknowingly participating in some form in the activities related to PwDs. It remains a question whether such an addition to the UDBHR in relation to PwDs is necessary, and if so, how such a requirement to obtain consent from third parties, and the autonomy of PwDs opposing such requirement can be satisfactorily balanced.

The clinical practice of dementia management with AAL technologies may violate the autonomy of PwDs in other areas. The definition of AAL technologies, in particular the assistive services offered by ambient intelligence (AmI) through their intelligence, adaptability, and ubiquitousness, characteristics which may be further extended by the condition of 'disappearance into background' suggest a certain level of autonomy represented by the devices themselves. If such automation is present in the home environment of PwDs, where AAL technologies in certain scenarios may act, in effect, in an autonomous way, this would pose a threat to the requirement for PwDs' consent in therapy (Art. 6.1) but also to their respect for autonomy and self-determination (Art. 5).

Recent developments in the IT sector shed light on other related issues of consent, the level of control of ICT devices, and the security of their users. The series of recently discovered security issues (i. e. bugs, vulnerabilities)[38] forced operating system developers to encourage their users to upgrade to newer systems (e. g. from the widely popular

38 For Android devices it was Stagefright: `http://fortune.com/2015/07/28/stagefright-google-android-security/` (visited on 28/10/2015); for Windows systems it was a zero-day exploit of Internet Explorer, CVE-2014-1776: `http://www.cve.mitre.org/cgi-bin/cvename.cgi?name=CVE-2014-1776` (visited on 28/10/2015); for OS X and iOS systems it was XARA allowing unauthorised access to KeyChain: `http://arxiv.org/pdf/1505.06836.pdf` (visited on 28/11/2015); and for all of these systems, including Linux it was the FREAK attack, allowing interception of HTTPS connections: `https://freakattack.com` (visited on 28/10/2015).

Windows XP used even after the discontinuation of official support, or Android 4.2 to 4.4 or higher, etc.). However, these newer operating systems, besides the higher security protection and offered official support, also come with upgraded user-interfaces, new functionalities and different behaviours compared with their previous versions. All these changes require study and adjustments of workflows for the users. It is not hard to imagine that such requirement cannot be fulfilled by PwDs. PwDs' special vulnerability does not allow them to study and adhere to the new elements and functionalities of the user-interface. PwDs being only single users, and not corporate users, lose the official support from IT companies by not upgrading their systems. On top of this, due to their inability to upgrade the systems on their devices, they also lose control over their private and medical data that are stored in these devices, by exposing these to hackers. These issues should be included in the consent forms when offering treatment with AAL technologies.

To provide the end-users with the greatest possible security protection, companies offering operating systems offer remotely controlled automatic updates to their systems.[39] A PwD, unaware of the differences introduced by the new system into her workflow, may face extreme difficulties after such pseudo-intentional consent. Although the PwD may have 'consented' to such an upgrade (in hope of greater security), at the end she may find herself so unfamiliar with the system upgrade that it becomes unusable. This may result in raised levels of anxiety and worse management of dementia as well as a greater digital divide and the loss of the computer-using functionality in PwDs. The support behind AAL technologies, therefore, must factor in the need for long-term and system-wide support of the ICT devices deployed to the PwDs.

6.3.2.1 *Unresolvable Issue of Understanding in PwDs*

As mentioned in this chapter, informed consent for treatment purposes is usually considered as less critical (N.B. not to be confused with absent) than consent for research. However, this rather general statement has to be carefully evaluated for the clinical practice with PwDs. PwDs in early stages of dementia with only mild symptoms usually manifest all the necessary conditions for valid informed consent (e. g. competence, voluntariness, understanding). However, as dementia progresses, PwDs may temporarily or permanently reveal loss in (at least) one of these essential requirements of valid informed consent. Even if one holds the view that a limited competence and voluntariness of PwDs in non-lucid states is preserved, based on external signs exhibited by PwDs, a physician may find the sufficient level of understanding absent. Even though all the efforts have been made to receive a confirmation that the PwD understood the disclosed

39 Such automatic upgrade, with minimal need for user input, has been recently advertised: http://www.forbes.com/sites/gordonkelly/2015/10/30/windows-10-upgrades-now-automatic/ (visited on 30/10/2015).

information, such feedback cannot always be granted. Moreover, even if such signs of apparent understanding of the disclosed information for consenting purposes has been confirmed by the PwD, this does not necessarily mean that a) the PwD actually understood the information, and b) this understanding will prevail for the period of time for which the consent was requested.

One may further speculate about what 'proper' understanding means, even in the case of fully competent, and completely healthy, individuals. Although this remark reaches the limits of epistemological phenomena, it is important to note that the requirement of express consent (Art. 6.1–2, and tacitly in Art. 7a) does not fully provide physicians with definite proof about the PwD's understanding, beyond any doubt. Moreover, as it has been presented in the case of authorisation for research (section 6.3.1.2), acting based on the best interest standard may also lead to disputes about therapy/research with PwDs that result in a deadlock. Therefore, for the resolution of these issues, one of the roles of the mediators, alongside those of protecting the interests and preferences of PwDs, should be the facilitation of an environment of principled compromise, as described by Huxtable (2012).

6.3.2.2 *Obtaining Consent with ICT*

One of the greatest achievements of the introduction of ICT devices into healthcare for PwDs may be the possibility of obtaining consent in circumstances, which were previously considered impossible. ICT devices in general, and AAL technologies in particular, may facilitate a setting through which the consent of PwDs may be requested, regularly checked (rolling informed consent), and the PwD continuously informed. The provision of this information may occur in a much more piecemeal way, avoiding the issues of information overload, allowing the PwDs to digest the information over a longer period of time. Ultimately, such a mechanism may partially assuage the social isolation of PwDs, by enabling their inclusion into treatment and/or research in a much more proactive way.

The framework of dynamic consent appears to provide promising elements to this goal (Jane Kaye et al. 2014). Moreover, the independent authority, where the information about consent are stored and managed can also provide a basis for the independent mediator, whose role should be the protection of the interests and preferences of PwDs, along with the protection of their human dignity.

6.4 BALANCING OF PRINCIPLES

6.4.1 *Principles Conflicting with Article 6*

During the specification of Art. 6 of the UDBHR no other conflicting principles have been identified.

6.4.2 *Principles Conflicting with Article 7*

The specification of Art. 7 highlighted several possible conflicts with other principles. These conflicts relate to Art. 4, on the benefit and harm of patients and research participants, and Art. 5, on autonomy and individual responsibility.

The possible conflict between Art. 7 and Art. 4 may occur during the authorisation for research participation of an incompetent PwD, when the 'best interest' requirement is interpreted. There may be issues, for example, if the opinions of the therapeutic representative of the PwD, or the PwD's family members' idea of the PwD's best interest diverges from that defined in Art. 4 under maximisation of direct and indirect health benefits. Relatives may consider participation in research as providing the best care for the PwD, which apparently would be in the best interest of the PwD. Any effort to exclude the PwD from research participation might then be interpreted as contravening the maximisation of (possible) direct and indirect benefits. However, such an interpretation of best interest is too narrow because it fails to recognise that research participation comes with specific, and potentially relatively high risks.

Another possible conflict between Art. 6 on consent (including Art. 7 indirectly), and Art. 5 on respecting autonomy may emerge from the possible semi- or fully-automated functioning of AAL technologies. Overcoming the self-determination and autonomy of PwDs with the autonomy of AAL technologies would, in effect, place the decision of the AAL technologies (and their creators) above that of the current users. This would result in the disrespect of the PwD's autonomy and right to self-determination, by skipping the requirement for express consent (Art. 6). This would also impinge on the PwD's human dignity. Therefore, due to the strong links of Art. 5 to the highest ranking article, Art. 3 on human dignity, in the weak hierarchy of the UDBHR principles, further balancing is no longer required.

6.5 SUMMARY

As a result of the specification of the UDBHR principles the following synopsis can be formulated. For easier overview, they will be categorised under the following four

categories of clinical research, advance directives, requirements for caregivers, and the development and deployment of AAL technologies:

6.5.1 *Informed Consent of PwDs During Research Involving AAL Technologies*

- The assessment of a PwD's capacity to consent should always be followed by further assessments of her mental status, hearing, speech, and vision.
- Informed consent interpreted solely on the basis of legal requirements should, especially in the case of PwDs, be avoided. PwDs constitute a 'grey zone' regarding the requirement of informed consent, so strict adherence to regulations can result in harmful and unethical consequences.
- The diagnosis of dementia should not always automatically imply the lack of competence to provide informed consent.
- PwDs have the right to participate in research, should they express such a desire.
- The assessment of the capacity of a PwD to consent to participation in a research study should always be conducted by a specialist with the necessary expertise in an optimal manner, who is also independent and unrelated to the research.
- The risk-benefit ratio should always be part of the competency assessment of PwDs, irrespective of whether it is for medical therapy or research. If the research participation confers no, or very little, direct health benefits for the participant, the ethical standards for conducting research with PwDs require that the research activity should be undertaken with utmost restraint, and should provide benefits for the same category of people as participants. The research should pose minimal risks and burdens to the participants (e. g. as much as the participant would face in her normal everyday life).
- If there is a way of conducting the research with healthy volunteers instead of vulnerable populations, such as the PwDs, it should be done. Research with vulnerable populations can only be allowed if there is a prospect of direct health benefit to the participants, and if no comparable study can be undertaken.
- The prospective participant of a research study should always be informed in advance, and a meaningful discussion should be conducted between the researcher(s) and PwD about the aims, nature, and consequences of the study. All the potential benefits and harms should be clearly explained.
- A trial run of the research study with PwDs is advisable. It will also help the PwDs to better understand the study procedures.

- The use of rolling informed consent should be applied, whenever possible, throughout the research study. This approach is in accordance with the ongoing process of obtaining consent from the participant, and hence with the appropriate interpretation of the informed consent requirement of the UDBHR. Rolling informed consent also ensures that the voluntariness of participation is regularly assessed.

- Consent from PwDs should be obtained in accordance to the current ethical standards. This means that it is the responsibility of the researcher(s) to assess whether the PwD's competency has changed during the research study, and to conduct the research in compliance with the requirements delineated in the respective articles of the UDBHR (i. e. Art. 6 or Art. 7). If such scenario is not defined in the design of the study, the researcher bears the responsibility for excluding the participant from the rest of the study, or require amendment from the REC.

- If a person is not fully competent to provide valid informed consent, she should, at least, always be requested to provide assent, if possible.

- Consent should also always be obtained in a culturally sensitive manner (as required by Art. 12).

- Invasive research should trigger the need for higher consenting capacity. Invasive research should not necessarily mean only corporeal invasiveness but also the invasion of privacy (into home, etc.).

- The possibility of withdrawing from participating in a research study should be clearly and regularly communicated. The decision to stop participating in a research study does not need a reason, and the decision should not have any negative consequences on the healthcare management of the PwD.

- The assessment of the capacity of judgement in persons under guardianship requires a comparable evaluation. As this happens by a matter of appreciation, it is advisable that this be performed by more than one specialist/researcher.

- The life-story and the personal narrative of PwDs, with their documented values, preferences, wishes, remembrance by others, should be respected. This can further serve as a basis for any substituted or presumed consent, or hypothetical judgement.

- The PwDs and their proxies should be always re-contacted for permission to re-use data, obtained during research, for further scientific purposes.

- The appointment of an independent adviser, whose responsibility it is to protect the safety, welfare and interests of the PwDs during the research study, is highly advisable.

6.5.2 *Recommendations For Advance Directives*

- The PwD should be advised to formulate an advance directive, as soon as possible after the initial diagnosis of dementia. Studies suggest that the competence to formulate advance directives after the initial diagnosis decreases quickly. Therefore, having some form of an advance directive before a diagnosis of dementia would be ideal.
- The advance directive should incorporate the designation of a therapeutic representative, and the definition of the conditions under which the PwD is willing to participate in research.
- Advance directives should be updated regularly.
- When a PwD is admitted into a professional institution, if is advisable for healthcare professionals to record their advance directives, if possible.
- It is advisable to also record the motivation(s) that would lead the PwD to enrol into a research study, for later evaluation.
- A 'right not to know' should be documented in the advance directive of the PwD.
- The life-story (personal narrative) of the PwDs should, if possible *always*, be taken into account in interpreting the advance directive. This requirement should also serve as a reference point for requests for ward of the court protection, in case of conflict between the proxies and advance directives.
- The researchers must adhere to national regulations regarding the legal weight of advance directives.
- It is not advisable to conduct research with incompetent PwDs, who lack any advance directive or statement from their relatives.
- Lifelogs can prove to be helpful in recording the advance directive of a PwD but also in documenting the various elements of one's personal narrative, helping the healthcare professionals in interpreting the PwD's will in an incompetent state.

6.5.3 *Requirements For Formal and Informal Caregivers*

- Different subtypes of dementia affect different domains of the intellectual functioning. Therefore, healthcare professionals should help assess and identify the domains in which the PwD should be still considered competent.
- With the advent of ICT, express informed consent became easier to obtain. Therefore, formal and informal caregivers should encourage the development and use of ICT devices for PwDs. Such frequent use will likely result in improvements in the recording of PwDs' wishes, making them more traceable.
- Tacit agreements for research (and treatment) should be minimised in the care of PwDs with AAL technologies.
- Healthcare professionals should fall back onto the 'best interest' standard, during the care for PwDs, only as a last resort. While it is possible to obtain any form of (even partial) direct consent or assent, it should be obtained. The rationale for this requirement consists of the lack of clarity regarding the vestigial traces of a PwD's psychological narrative, some of which is essential, and which others are not important and can be overlooked.
- Healthcare professionals should make the effort to acknowledge the PwD's authenticity, by being attuned to the person's narrative, staying engaged with the person's normative values, and being respectful to the remaining traces of personality.
- Healthcare professionals should be aware of the tendency to consider the seemingly irrational desires of the PwDs as signs of incompetency. While on their own, these may be interpreted as irrational desires, seemingly disconnected from the PwDs' former personalities, together with the whole life-story of the person, the desires may be completely rational and valid.
- Researchers and healthcare professionals should adopt a step-by-step procedure for performing clinical research with PwDs.
- Researchers and healthcare professionals should avoid the approach described as a 'conspiracy of silence', which covertly places that the research above the interests of the participants.
- Research with PwDs should include the right, individually personalised, balance between information overload, and the under-informing of research participants. The information should be divided into and presented in small, digestible blocks, and distributed on a wider timescale.

- Researchers and healthcare professionals should adhere to the highest standards of transparency for conducting research. Only such an approach will secure the willingness of participants to take part in research.

6.5.4 *Recommendations For the Development and Deployment of AAL Technologies*

- Due to the ubiquitousness of ICT devices, they may prove useful in the obtaining of informed consent in situations where it was not currently possible. Therefore, a well-balanced method of repeatedly asking PwDs for consent with the support of ICT should be developed.
- Asking for consent with ICT devices is prone to routinisation, thus effective measures should be developed to prevent these.
- ICT devices should be developed to ensure that they are only used by authenticated users. For PwDs the authentication should be made unobtrusive and user-friendly. The preferred ways of validating the authorised user is by fingerprint, voice, face-recognition, or other biomarkers.
- ICT devices should be made user-friendly in order to optimise their acceptability for PwDs.
- The expectations of PwDs regarding AAL technologies are commonly very high. Therefore, their users should be warned in advance that the technology is still being tested; and a realistic view about the used ICT should be emphasised during the R&D.
- As the autonomy and privacy of PwDs must be respected, similarly the autonomy, privacy, and confidentiality of eventual third parties should be respected when deploying and using ICT technologies in research and clinical application.
- Researchers and computer engineers have to adhere to the highest standards of security and encryption during data retention and data transfer, given the fact that these data are of a private and medical nature. The researchers should ensure that the data will not be misused or abused for criminal activities, privacy breaches, or dehumanising actions.
- PwDs should be informed about precautionary measures that they can implement to prevent data recording when they do not want to be recorded. PwDs should also have the opportunity to review and delete the recorded data, before they are submitted for analysis.

- Both research participants and researchers should be made aware that the collected data may be subpoenaed. Both parties should be informed about this fact before the start of the research study.
- PwDs, or their legal representative(s), should always be allowed to retain a certain degree of control over their data, despite the state of PwDs. The sensitive nature of these data requires that the alleviation of the right to retain control, and the ultimate surrender of this right should always be clearly stated by the PwD herself or her legal representative. Such a statement should also always be recorded and documented.

7

CONCLUSION

7.1 SUMMARY

7.1.1 *Introduction*

The aim of this dissertation is to contribute to the responsible development, clinical research, and application of AAL technologies for PwDs, by providing a normative analysis of the most prominent ethical issues related to research and clinical application of AAL technologies for PwDs. The normative analysis is concluded with recommendations.

The importance of this subject is growing, and it is expected to continue doing so due to ageing populations worldwide. As the number of PwDs rises, so will the demand for care, and the burden placed upon informal and formal caregivers, including physicians, and healthcare systems (cf. Chapter 1). Therefore, in recent years, the possibility of care provision support using assistive technologies has been investigated. These technologies are aimed mainly at allowing PwDs to stay at home for longer, by compensating for their impairments, and empowering them in their everyday activities, as well as supporting caregivers, and providing data for researchers in dementia to help them better understand this currently incurable and difficult-to-diagnose condition.

The main research objectives of this dissertation are the following:

1. *Ethical Challenges and Opportunities* – The identification of the ethical challenges and opportunities associated with the development and application of AAL technologies for PwDs, and the selection of the most prominent ethical issues. These prominent ethical issues are identified from the systematic literature review presented in Chapter 3 and are as follows:
    - Values of the goals of AAL technologies.
    - Special vulnerability of PwDs.
    - Informed consent of PwDs.

2. *Interpretation of UDBHR Principles* – The interpretation of the UDBHR principles related to the most prominent ethical issues. This interpretation is based on the overview of the related essential literature and policy documents.

3. *Normative Analysis of Ethical Issues* – The normative analysis of the most prominent ethical issues in specifying the UDBHR principles to the context of PwDs and AAL technologies.

4. *Conclusions of the Ethical Analysis* – The analysis is concluded with a list of recommendations regarding how to tackle the ethical issues related to the application of AAL technologies for PwDs.

7.1.2 *Findings*

The first research objective is met by an extensive literature review in Chapter 3. This review lists a comprehensive set of ethical challenges and opportunities (cf. Table B.2), highlighting three prominent ethical issues that provide the content for the normative analysis. These prominent ethical issues are: the value of the goals of AAL technologies for PwDs, the special vulnerability of PwDs, and the requirement of informed consent in the case of PwDs.

For the normative analysis (the second research objective of this dissertation), the principles of the UDBHR are employed. The UDBHR principles are considered to be *prima facie* principles (in the sense of Ross 2002) with a weak hierarchy (where Art. 3 is the strongest, and Art. 12 the weakest principle). The interpretation of these principles employs the essential literature regarding the UDBHR articles, followed by key international and national policy documents that further contextualise the interpretation of UDBHR principles, and academic literature on recent and ongoing scholarly debates that may be generally related to the UDBHR principles.

The third research objective is met by the specification of the interpreted UDBHR principles to the specific contexts of PwDs and AAL technologies. This specification focused on two areas: clinical research, and clinical practice. Whenever the specification of a UDBHR principle yielded a conflict with another UDBHR principle, the conflict was analysed using a balancing step (described in section 1.2).

The fourth research objective comprises a list of recommendations based on the findings of the first three research objectives, mainly on the normative analysis.

7.1.2.1 *Value of the Goals of AAL Technologies*

One of the main findings of the analysis of the value of the goals of AAL technologies is the assumption of the *a priori* positive impact of these goals, which was apparent in the academic literature. The aims of AAL technologies, to enable PwDs to stay at home for

longer, to empower them during their activities of daily living (ADLs), and to provide assistance, were uncritically assumed to be of value, with only occasional mention of ethical issues in the academic literature.

Inconclusiveness has been noticed regarding the differing motives of the various stakeholders during the R&D and deployment of AAL technologies for PwDs. The motivation of PwDs for accepting the assistance of AAL technologies can be significantly different (and even contradictory) to the motives of formal and informal caregivers, including physicians, who perceive AAL technologies as a way to alleviate their care burden. Researchers perceive the main role of AAL technologies as an important source of valuable data about the PwDs, a motive which may conflict with that of PwDs who seek, amongst other things, comfort. Finally, healthcare systems are interested in increasing the deployment of AAL technologies, in order to externalise the costs related to PwDs, although this may prove counter-productive in the future.

The goals (cf. Chapter 3) of AAL technologies are very ambitious. The challenge is not only that the AAL technologies have to fulfil the divergent needs of their various current users (e. g. heterogeneous group of PwDs, formal and informal caregivers, etc.) but that they also need to extend to future implementation in various parts of the world, where new, culturally diverse user needs may be encountered.

Art. 4 of the UDBHR may provide valuable guidance for the ethical development and deployment of AAL technologies, e. g. by requiring the active involvement of PwDs in the R&D process of AAL technologies. Researchers that lack expertise or familiarity with PwDs should be informed during the R&D about the special needs of their users, and about the need to avoid the malignant approaches (e. g. treachery, disempowerment, infantilisation, etc., cf. Table 4.1) towards PwDs defined by T. Kitwood (1997).

Although some doom scenarios may overstate the case, it is recognised that some of the risks linked with the use of AAL technologies cannot be completely eradicated (Coeckelbergh 2015a).

7.1.2.2 *Special Vulnerability of PwDs*

The origin of the special vulnerabilities of PwDs is not based solely on their MCI. Their special vulnerabilities come from various sources, some of which are related to their condition, while others are related to specific situations. These situations can include clinical research and application of AAL technologies for PwDs. The normative analysis describes several of these sources of vulnerability.

PwDs are especially vulnerable when their needs and demands are ignored. This can occur during research as well as clinical practice with AAL technologies. Another circumstance in which PwDs are especially vulnerable is one where undue influence is exercised by proxies or close relatives, which can occur again in both clinical research and application. Similarly, PwDs are particularly vulnerable in the presence of AAL

technologies that are invasive or record personal data because of their impairments. For example, data safety and protection must be actively managed, which cannot be performed by the PwDs themselves. Moreover, the infinite memory of lifelogs may cause distress and anxiety, thereby increasing the vulnerability of PwDs.

PwDs may also be particularly vulnerable in clinical research or practice with AAL technologies for healthcare because of a lack of regulation or less rigorous testing standards. During research, PwDs may be exposed to unnecessary risks e. g. when premature or faulty prototypes are tested. PwDs are especially vulnerable as research participants and researchers can themselves be a source of vulnerability for PwDs. PwDs may also be vulnerable as patients in clinical practice, exposed to potentially over-aggressive therapy, which can cause distress and anxiety. PwDs are often vulnerable to isolation and stigmatisation, which may be exacerbated in clinical practice where human care is replaced by AAL technologies.

PwDs are also especially vulnerable because of their MCI. Their condition makes them more vulnerable to being victims of fraud and confidence tricks. Another source of vulnerability may stem from the exclusion of PwDs from developing countries because of lack of access to research or application of AAL technologies, which raises ethical concerns about double standards and negligence.

The vulnerability of PwDs may be minimised by involving them responsibly in the R&D process, and by not ignoring their specific requirements and demands. AAL technologies can provide PwDs with opportunities to socialise and to benefit from greater empowerment, independence, and more effective management of their dementia care.

According to Art. 8 of the UDBHR, the respect for special vulnerability is closely linked with the respect for personal integrity. Researchers and caregivers therefore need to also respect the personal integrity of PwDs during research and clinical practice. This can lead to the development of meaningful relationships between researchers/caregivers and PwDs, enabling them to better consider the needs and wishes of the PwDs, and the appropriateness and relevance of research and treatment goals. Thus, PwDs should be perceived as more than mere data sources that are secondary to the AAL technologies during R&D. In clinical practice, respect for personal integrity means that treatment should not be focused on the needs of PwDs from only a biological perspective but also from the personal and subjective perspective of the PwD. The relationship of caregivers and physicians with PwDs should therefore be based on partnership, cooperation, and symmetry.

7.1.2.3 *Informed Consent*

The requirement of valid informed consent remains a challenge in relation to PwDs. The three main criteria of valid informed consent (e. g. competence, understanding, and voluntariness, cf. Árnason et al. 2011) cannot always be fulfilled by PwDs. Methods of

rolling informed consent may be used to track any changes in the informed consent of PwDs. Eventually, a principled compromise may be employed in order to resolve issues between the self-determination of incompetent persons (e. g. as expressed in advance directives) and the need for caregivers to act in their best interest.

Despite the issues encountered with informed consent of PwDs, professional bodies (e. g. Alzheimer Europe, EDCON) do not recommend the exclusion of PwDs from research activities.

ICT introduce novel opportunities for obtaining consent from PwDs, or for updating previously provided consents. The approach of dynamic consent is also promising in this regard.

An additional issue during the care of PwDs is the problem of consent from third parties, who temporarily or permanently share the location with PwDs and AAL technologies. The prospective autonomy (i. e. artificial intelligence) of AAL technologies may result in the technology questioning a decision made by PwDs (or others). This issue may escalate in the future with the advancement of AAL technologies.

The introduction of mediating persons between researchers/physicians and PwDs may be beneficial in order to protect the interests of the PwDs.

7.1.3 *Implications*

This dissertation presents that alongside the obvious issues of security and privacy, there are distinctive ethical issues related to the clinical research and clinical application of AAL technologies. These ethical issues relate to all the stakeholders involved in the care of PwDs (i. e. formal and informal caregivers, physicians, researchers, PwDs, designers, ICT engineers). Moreover, these ethical issues are relatively under-represented in published scholarly debate. This implies that there are important ethical issues that are relevant for the R&D and clinical application of AAL technologies, which have not been fully or sufficiently considered.

Firstly, the reflection about the ultimate purpose and goals of AAL technologies, and whom they are really aimed for, needs to be regularly reviewed in research projects. The lack of success of AAL technologies (reported by Joost van Hoof, Wouters, et al. 2011, referring to Nispen 2004) developed purposely for PwDs should not discourage researchers in the pursuit of research with PwDs because of the expected increase of PwDs in populations worldwide. Rebranding AAL technologies, which have been developed and tested with PwDs, for the elderly in general implies additional ethical complications, which may negatively impact, not only the justification of previous research projects, but also the prospect of much needed research for PwDs in the future.

Secondly, researchers should design their research projects in a way that would enable PwDs to receive direct benefits of AAL technologies whenever possible. The vulnerabil-

ity of PwDs makes research projects with only aspirational benefits ethically questionable, since these studies need additional justification for involving PwDs. Moreover, research projects investigating multiple technologies (e. g. video surveillance and analysis) may test many of these technologies on healthy volunteers, including elderly people in general. According to Art. 3.2, there is no excuse to use AAL technologies solely in the interests of scientific knowledge or society, especially if it overrides the interests and welfare of individuals with dementia. It has been analysed in this dissertation that respect for the vulnerability and personal integrity of PwDs should not result in their being subject to additional discrimination and stigmatisation.

Thirdly, ethical issues in obtaining valid informed consent remain an essential feature of research with PwDs. Although the introduction of ICT into this process may be beneficial in monitoring any changes in the consent, such technology also introduces additional ethical issues. Amongst these are the issues of third party consent, or the prospective autonomy (i. e. artificial intelligence) of technologies (which may ignore PwDs' decisions that they deem meaningless or 'bad'). A considerable amount of literature refers to advance directives as one of the solutions for extending the PwD's autonomy. However, as it has been argued in this thesis, even the existence of an advance directive from a PwD may not provide enough security in interpreting the actual desires of the person concerned. Therefore, the analysis of the topic of informed consent highlighted a grey area between competence and incompetence, which is yet another issue that will be exacerbated by the growing number of PwDs.

The dissertation also provides, as a result of the normative analysis, in summary, a number of recommendations. These recommendations are supposed to support researchers, healthcare professionals, and RECs in the ethical development of AAL technologies within this important field of research.

From the point of view of policy and regulation, future testing and approval procedures for AAL technologies in the healthcare setting needs to be stricter. RECs should also clearly distinguish between AAL technologies that are developed for PwDs and those developed for the elderly in general, by requiring strong justification of the inclusion of PwDs in research with AAL technologies. In their reviews, RECs should scrutinise the direct benefits of these technologies, clearly separating them from indirect and aspirational benefits. RECs should also require better disclosure of information about the potential benefits of research participation to PwDs. AAL technologies should not be considered as simply as another type of technology present in the care of PwDs. Their risks and benefits should always be deeply scrutinised by RECs. Community Advisory Boards (Horn 2007) that represent the interests of PwDs may assist in these deliberations.

7.2 OUTLOOK

As the section 1.3 concerning the relevance of research related to PwDs highlights, research and clinical practice with the assistance of AAL technologies is expected to gain greater importance in the future.

The ethical assessment of these projects needs to pay increasing attention to the validity and justification of the inclusion of PwDs into research projects of AAL technologies. As noted in the literature, researchers already perceive an increase in technology push from industry. This technology push may grow in the future, and RECs should be informed about this.

The advances in ICT in relation to artificial intelligence pose additional concerns about the 'smartness' and partial- or full-autonomy of AAL technologies in the future. This may become a greater issue in relation to the specific condition of PwDs, such as their MCI. Further research about the benefits and risks in this regard is required.

AAL technologies involve a great number of sensors for their operation. As these sensors are gradually becoming smaller, there is a chance of their implementation *in vivo*. This may pose further ethical concerns in relation to PwDs with limited ability to provide valid informed consent.

The topic of third party consent requires satisfactory resolution. It may become one of the major obstacles in the acceptance of AAL technologies by society. Furthermore, it may result in the stigmatisation of PwDs who require the help of AAL technologies, further worsening their vulnerable situation. It is one of the resulting ethical implications of this dissertation that such a scenario should be avoided.

Future research should also consider the assessment of the potential placebo effect of AAL technologies for PwDs because to date, no studies have been conducted with placebo controls. However, the consideration of placebo controlled trials of AAL technologies with PwDs is a matter for discussion in order to assess its feasibility. Data is required to ensure that the benefits observed in trials and clinical practice are due to the direct effects of AAL technologies, in order to justify their use, especially for the provision of healthcare and for PwDs.

Finally, further investigations are needed into the societal consequences of the deployment of AAL technologies for PwDs and the elderly in general. Further analysis should be conducted regarding whether governmental incentives to externalise care for PwDs would further widen the gap between the economically affluent PwDs and the economically impoverished PwDs.

APPENDICES

A

UNIVERSAL DECLARATION ON BIOETHICS AND HUMAN RIGHTS[1]

The General Conference,

Conscious of the unique capacity of human beings to reflect upon their own existence and on their environment, to perceive injustice, to avoid danger, to assume responsibility, to seek cooperation and to exhibit the moral sense that gives expression to ethical principles,

Reflecting on the rapid developments in science and technology, which increasingly affect our understanding of life and life itself, resulting in a strong demand for a global response to the ethical implications of such developments,

Recognizing that ethical issues raised by the rapid advances in science and their technological applications should be examined with due respect to the dignity of the human person and universal respect for, and observance of, human rights and fundamental freedoms,

Resolving that it is necessary and timely for the international community to state universal principles that will provide a foundation for humanity's response to the ever-increasing dilemmas and controversies that science and technology present for humankind and for the environment,

Recalling the Universal Declaration of Human Rights of 10 December 1948, the Universal Declaration on the Human Genome and Human Rights adopted by the General Conference of UNESCO on 11 November 1997 and the International Declaration on Human Genetic Data adopted by the General Conference of UNESCO on 16 October 2003,

Noting the United Nations International Covenant on Economic, Social and Cultural Rights and the International Covenant on Civil and Political Rights of 16 December 1966, the United Nations International Convention on the Elimination of All Forms of

1 This is the full text of the *UDBHR* (2005). Resolution adopted by UNESCO on the report of Commission III at the 18th plenary meeting, on 19th October 2005. Online: `http://portal.unesco.org/en/ev.php-URL_ID=31058&URL_DO=DO_TOPIC&URL_SECTION=201.html`.

Racial Discrimination of 21 December 1965, the United Nations Convention on the Elimination of All Forms of Discrimination against Women of 18 December 1979, the United Nations Convention on the Rights of the Child of 20 November 1989, the United Nations Convention on Biological Diversity of 5 June 1992, the Standard Rules on the Equalization of Opportunities for Persons with Disabilities adopted by the General Assembly of the United Nations in 1993, the UNESCO Recommendation on the Status of Scientific Researchers of 20 November 1974, the UNESCO Declaration on Race and Racial Prejudice of 27 November 1978, the UNESCO Declaration on the Responsibilities of the Present Generations Towards Future Generations of 12 November 1997, the UNESCO Universal Declaration on Cultural Diversity of 2 November 2001, the ILO Convention 169 concerning Indigenous and Tribal Peoples in Independent Countries of 27 June 1989, the International Treaty on Plant Genetic Resources for Food and Agriculture which was adopted by the FAO Conference on 3 November 2001 and entered into force on 29 June 2004, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) annexed to the Marrakech Agreement establishing the World Trade Organization, which entered into force on 1 January 1995, the Doha Declaration on the TRIPS Agreement and Public Health of 14 November 2001 and other relevant international instruments adopted by the United Nations and the specialized agencies of the United Nations system, in particular the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO),

Also noting international and regional instruments in the field of bioethics, including the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine of the Council of Europe, which was adopted in 1997 and entered into force in 1999, together with its Additional Protocols, as well as national legislation and regulations in the field of bioethics and the international and regional codes of conduct and guidelines and other texts in the field of bioethics, such as the Declaration of Helsinki of the World Medical Association on Ethical Principles for Medical Research Involving Human Subjects, adopted in 1964 and amended in 1975, 1983, 1989, 1996 and 2000 and the International Ethical Guidelines for Biomedical Research Involving Human Subjects of the Council for International Organizations of Medical Sciences, adopted in 1982 and amended in 1993 and 2002,

Recognizing that this Declaration is to be understood in a manner consistent with domestic and international law in conformity with human rights law,

Recalling the Constitution of UNESCO adopted on 16 November 1945,

Considering UNESCO's role in identifying universal principles based on shared ethical values to guide scientific and technological development and social transformation in order to identify emerging challenges in science and technology taking into account the

responsibility of the present generations towards future generations, and that questions of bioethics, which necessarily have an international dimension, should be treated as a whole, drawing on the principles already stated in the Universal Declaration on the Human Genome and Human Rights and the International Declaration on Human Genetic Data and taking account not only of the current scientific context but also of future developments,

Aware that human beings are an integral part of the biosphere, with an important role in protecting one another and other forms of life, in particular animals,

Recognizing that, based on the freedom of science and research, scientific and technological developments have been, and can be, of great benefit to humankind in increasing, inter alia, life expectancy and improving the quality of life, and emphasizing that such developments should always seek to promote the welfare of individuals, families, groups or communities and humankind as a whole in the recognition of the dignity of the human person and universal respect for, and observance of, human rights and fundamental freedoms,

Recognizing that health does not depend solely on scientific and technological research developments but also on psychosocial and cultural factors,

Also recognizing that decisions regarding ethical issues in medicine, life sciences and associated technologies may have an impact on individuals, families, groups or communities and humankind as a whole,

Bearing in mind that cultural diversity, as a source of exchange, innovation and creativity, is necessary to humankind and, in this sense, is the common heritage of humanity, but emphasizing that it may not be invoked at the expense of human rights and fundamental freedoms,

Also bearing in mind that a person's identity includes biological, psychological, social, cultural and spiritual dimensions,

Recognizing that unethical scientific and technological conduct has had a particular impact on indigenous and local communities,

Convinced that moral sensitivity and ethical reflection should be an integral part of the process of scientific and technological developments and that bioethics should play a predominant role in the choices that need to be made concerning issues arising from such developments,

Considering the desirability of developing new approaches to social responsibility to ensure that progress in science and technology contributes to justice, equity and to the interest of humanity,

Recognizing that an important way to evaluate social realities and achieve equity is to pay attention to the position of women,

Stressing the need to reinforce international cooperation in the field of bioethics, taking into account, in particular, the special needs of developing countries, indigenous communities and vulnerable populations,

Considering that all human beings, without distinction, should benefit from the same high ethical standards in medicine and life science research,

Proclaims the principles that follow and adopts the present Declaration.

GENERAL PROVISIONS

Article 1 – Scope

1. This Declaration addresses ethical issues related to medicine, life sciences and associated technologies as applied to human beings, taking into account their social, legal and environmental dimensions.
2. This Declaration is addressed to States. As appropriate and relevant, it also provides guidance to decisions or practices of individuals, groups, communities, institutions and corporations, public and private.

Article 2 – Aims

The aims of this Declaration are:

(a) to provide a universal framework of principles and procedures to guide States in the formulation of their legislation, policies or other instruments in the field of bioethics;

(b) to guide the actions of individuals, groups, communities, institutions and corporations, public and private;

(c) to promote respect for human dignity and protect human rights, by ensuring respect for the life of human beings, and fundamental freedoms, consistent with international human rights law;

(d) to recognize the importance of freedom of scientific research and the benefits derived from scientific and technological developments, while stressing the need for such research and developments to occur within the framework of ethical principles set out in this Declaration and to respect human dignity, human rights and fundamental freedoms;

(e) to foster multidisciplinary and pluralistic dialogue about bioethical issues between all stakeholders and within society as a whole;

(f) to promote equitable access to medical, scientific and technological developments as well as the greatest possible flow and the rapid sharing of knowledge concerning those developments and the sharing of benefits, with particular attention to the needs of developing countries;

(g) to safeguard and promote the interests of the present and future generations;

(h) to underline the importance of biodiversity and its conservation as a common concern of humankind.

PRINCIPLES

Within the scope of this Declaration, in decisions or practices taken or carried out by those to whom it is addressed, the following principles are to be respected.

Article 3 – Human dignity and human rights

1. Human dignity, human rights and fundamental freedoms are to be fully respected.
2. The interests and welfare of the individual should have priority over the sole interest of science or society.

Article 4 – Benefit and harm

In applying and advancing scientific knowledge, medical practice and associated technologies, direct and indirect benefits to patients, research participants and other affected individuals should be maximized and any possible harm to such individuals should be minimized.

Article 5 – Autonomy and individual responsibility

The autonomy of persons to make decisions, while taking responsibility for those decisions and respecting the autonomy of others, is to be respected. For persons who are not capable of exercising autonomy, special measures are to be taken to protect their rights and interests.

Article 6 – Consent

1. Any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free and informed consent of the person concerned, based

on adequate information. The consent should, where appropriate, be express and may be withdrawn by the person concerned at any time and for any reason without disadvantage or prejudice.

2. Scientific research should only be carried out with the prior, free, express and informed consent of the person concerned. The information should be adequate, provided in a comprehensible form and should include modalities for withdrawal of consent. Consent may be withdrawn by the person concerned at any time and for any reason without any disadvantage or prejudice. Exceptions to this principle should be made only in accordance with ethical and legal standards adopted by States, consistent with the principles and provisions set out in this Declaration, in particular in Article 27, and international human rights law.

3. In appropriate cases of research carried out on a group of persons or a community, additional agreement of the legal representatives of the group or community concerned may be sought. In no case should a collective community agreement or the consent of a community leader or other authority substitute for an individual's informed consent.

Article 7 – Persons without the capacity to consent

In accordance with domestic law, special protection is to be given to persons who do not have the capacity to consent:

(a) authorization for research and medical practice should be obtained in accordance with the best interest of the person concerned and in accordance with domestic law. However, the person concerned should be involved to the greatest extent possible in the decision-making process of consent, as well as that of withdrawing consent;

(b) research should only be carried out for his or her direct health benefit, subject to the authorization and the protective conditions prescribed by law, and if there is no research alternative of comparable effectiveness with research participants able to consent. Research which does not have potential direct health benefit should only be undertaken by way of exception, with the utmost restraint, exposing the person only to a minimal risk and minimal burden and, if the research is expected to contribute to the health benefit of other persons in the same category, subject to the conditions prescribed by law and compatible with the protection of the individual's human rights. Refusal of such persons to take part in research should be respected.

Article 8 – Respect for human vulnerability and personal integrity

In applying and advancing scientific knowledge, medical practice and associated technologies, human vulnerability should be taken into account. Individuals and groups of special vulnerability should be protected and the personal integrity of such individuals respected.

Article 9 – Privacy and confidentiality

The privacy of the persons concerned and the confidentiality of their personal information should be respected. To the greatest extent possible, such information should not be used or disclosed for purposes other than those for which it was collected or consented to, consistent with international law, in particular international human rights law.

Article 10 – Equality, justice and equity

The fundamental equality of all human beings in dignity and rights is to be respected so that they are treated justly and equitably.

Article 11 – Non-discrimination and non-stigmatization

No individual or group should be discriminated against or stigmatized on any grounds, in violation of human dignity, human rights and fundamental freedoms.

Article 12 – Respect for cultural diversity and pluralism

The importance of cultural diversity and pluralism should be given due regard. However, such considerations are not to be invoked to infringe upon human dignity, human rights and fundamental freedoms, nor upon the principles set out in this Declaration, nor to limit their scope.

Article 13 – Solidarity and cooperation

Solidarity among human beings and international cooperation towards that end are to be encouraged.

Article 14 – Social responsibility and health

1. The promotion of health and social development for their people is a central purpose of governments that all sectors of society share.

2. Taking into account that the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition, progress in science and technology should advance:

   (a) access to quality health care and essential medicines, especially for the health of women and children, because health is essential to life itself and must be considered to be a social and human good;

   (b) access to adequate nutrition and water;

   (c) improvement of living conditions and the environment;

   (d) elimination of the marginalization and the exclusion of persons on the basis of any grounds;

   (e) reduction of poverty and illiteracy.

Article 15 – Sharing of benefits

1. Benefits resulting from any scientific research and its applications should be shared with society as a whole and within the international community, in particular with developing countries. In giving effect to this principle, benefits may take any of the following forms:

   (a) special and sustainable assistance to, and acknowledgement of, the persons and groups that have taken part in the research;

   (b) access to quality health care;

   (c) provision of new diagnostic and therapeutic modalities or products stemming from research;

   (d) support for health services;

   (e) access to scientific and technological knowledge;

   (f) capacity-building facilities for research purposes;

   (g) other forms of benefit consistent with the principles set out in this Declaration.

2. Benefits should not constitute improper inducements to participate in research.

Article 16 – Protecting future generations

The impact of life sciences on future generations, including on their genetic constitution, should be given due regard.

Article 17 – Protection of the environment, the biosphere and biodiversity

Due regard is to be given to the interconnection between human beings and other forms of life, to the importance of appropriate access and utilization of biological and genetic resources, to respect for traditional knowledge and to the role of human beings in the protection of the environment, the biosphere and biodiversity.

APPLICATION OF THE PRINCIPLES

Article 18 – Decision-making and addressing bioethical issues

1. Professionalism, honesty, integrity and transparency in decision-making should be promoted, in particular declarations of all conflicts of interest and appropriate sharing of knowledge. Every endeavour should be made to use the best available scientific knowledge and methodology in addressing and periodically reviewing bioethical issues.
2. Persons and professionals concerned and society as a whole should be engaged in dialogue on a regular basis.
3. Opportunities for informed pluralistic public debate, seeking the expression of all relevant opinions, should be promoted.

Article 19 – Ethics committees

Independent, multidisciplinary and pluralist ethics committees should be established, promoted and supported at the appropriate level in order to:

(a) assess the relevant ethical, legal, scientific and social issues related to research projects involving human beings;

(b) provide advice on ethical problems in clinical settings;

(c) assess scientific and technological developments, formulate recommendations and contribute to the preparation of guidelines on issues within the scope of this Declaration;

(d) foster debate, education and public awareness of, and engagement in, bioethics.

Article 20 – Risk assessment and management

Appropriate assessment and adequate management of risk related to medicine, life sciences and associated technologies should be promoted.

Article 21 – Transnational practices

1. States, public and private institutions, and professionals associated with transnational activities should endeavour to ensure that any activity within the scope of this Declaration, undertaken, funded or otherwise pursued in whole or in part in different States, is consistent with the principles set out in this Declaration.
2. When research is undertaken or otherwise pursued in one or more States (the host State(s)) and funded by a source in another State, such research should be the object of an appropriate level of ethical review in the host State(s) and the State in which the funder is located. This review should be based on ethical and legal standards that are consistent with the principles set out in this Declaration.
3. Transnational health research should be responsive to the needs of host countries, and the importance of research contributing to the alleviation of urgent global health problems should be recognized.
4. When negotiating a research agreement, terms for collaboration and agreement on the benefits of research should be established with equal participation by those party to the negotiation.
5. States should take appropriate measures, both at the national and international levels, to combat bioterrorism and illicit traffic in organs, tissues, samples, genetic resources and genetic-related materials.

PROMOTION OF THE DECLARATION

Article 22 – Role of States

1. States should take all appropriate measures, whether of a legislative, administrative or other character, to give effect to the principles set out in this Declaration in accordance with international human rights law. Such measures should be supported by action in the spheres of education, training and public information.

2. States should encourage the establishment of independent, multidisciplinary and pluralist ethics committees, as set out in Article 19.

Article 23 – Bioethics education, training and information

1. In order to promote the principles set out in this Declaration and to achieve a better understanding of the ethical implications of scientific and technological developments, in particular for young people, States should endeavour to foster bioethics education and training at all levels as well as to encourage information and knowledge dissemination programmes about bioethics.

2. States should encourage the participation of international and regional intergovernmental organizations and international, regional and national non governmental organizations in this endeavour.

Article 24 – International cooperation

1. States should foster international dissemination of scientific information and encourage the free flow and sharing of scientific and technological knowledge.

2. Within the framework of international cooperation, States should promote cultural and scientific cooperation and enter into bilateral and multilateral agreements enabling developing countries to build up their capacity to participate in generating and sharing scientific knowledge, the related know-how and the benefits thereof.

3. States should respect and promote solidarity between and among States, as well as individuals, families, groups and communities, with special regard for those rendered vulnerable by disease or disability or other personal, societal or environmental conditions and those with the most limited resources.

Article 25 – Follow-up action by UNESCO

1. UNESCO shall promote and disseminate the principles set out in this Declaration. In doing so, UNESCO should seek the help and assistance of the Intergovernmental Bioethics Committee (IGBC) and the International Bioethics Committee (IBC).

2. UNESCO shall reaffirm its commitment to dealing with bioethics and to promoting collaboration between IGBC and IBC.

FINAL PROVISIONS

Article 26 – Interrelation and complementarity of the principles

This Declaration is to be understood as a whole and the principles are to be understood as complementary and interrelated. Each principle is to be considered in the context of the other principles, as appropriate and relevant in the circumstances.

Article 27 – Limitations on the application of the principles

If the application of the principles of this Declaration is to be limited, it should be by law, including laws in the interests of public safety, for the investigation, detection and prosecution of criminal offences, for the protection of public health or for the protection of the rights and freedoms of others. Any such law needs to be consistent with international human rights law.

Article 28 – Denial of acts contrary to human rights, fundamental freedoms and human dignity

Nothing in this Declaration may be interpreted as implying for any State, group or person any claim to engage in any activity or to perform any act contrary to human rights, fundamental freedoms and human dignity.

B

FIGURES AND TABLES

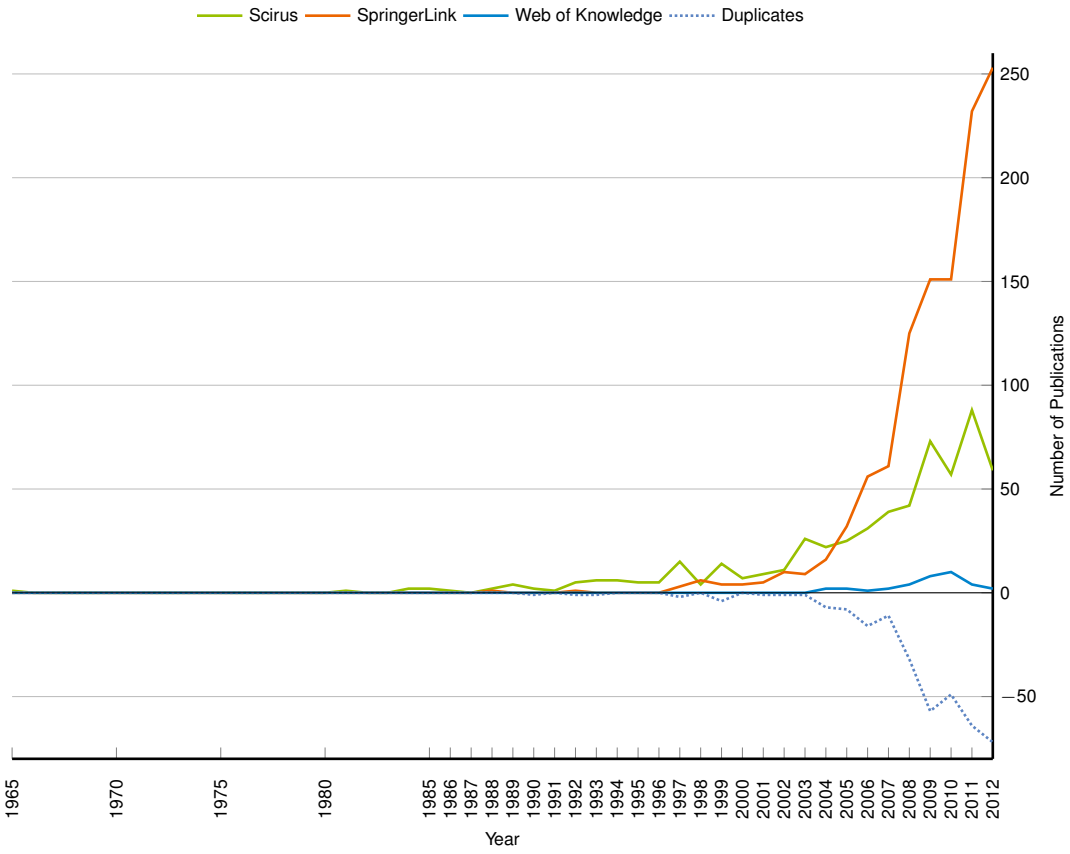

Figure B.1: Overall Timeline of the Results

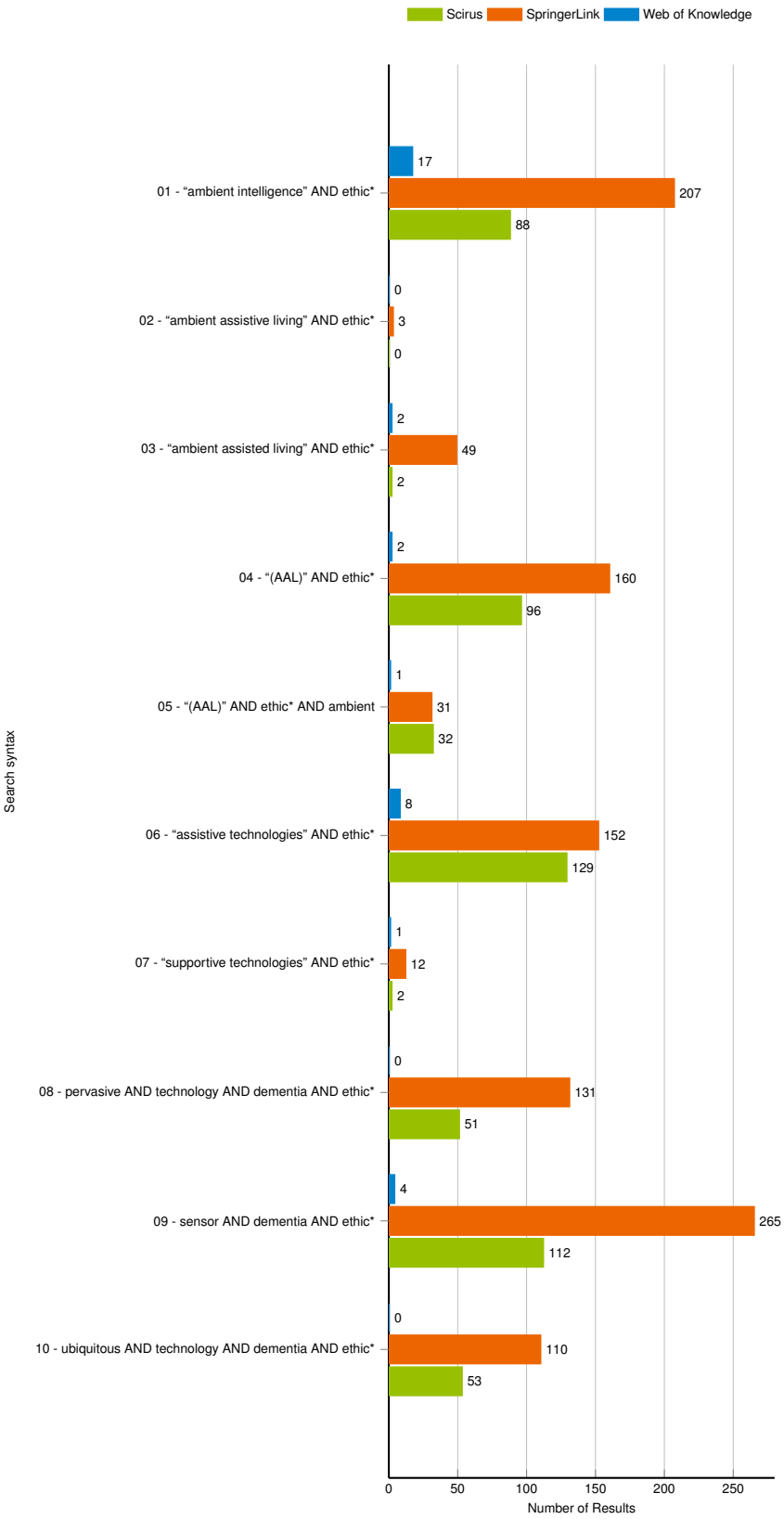

Figure B.2: Search Results in the Individual Databases

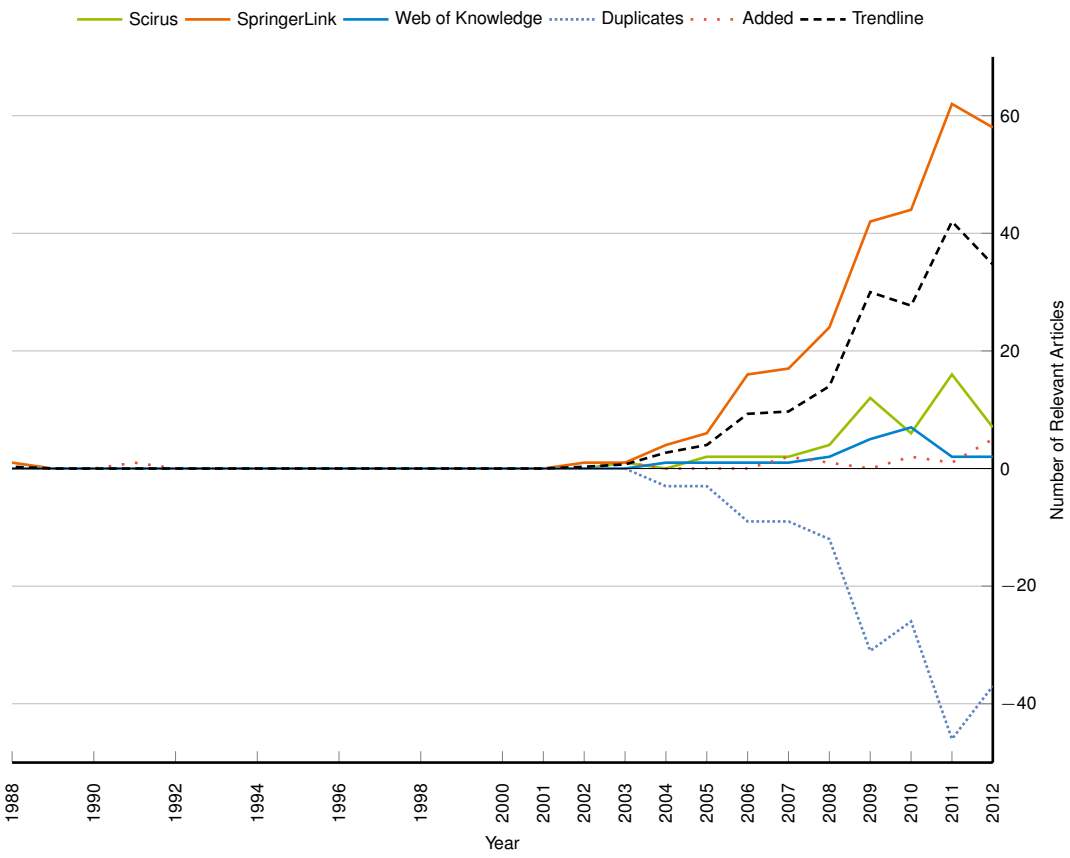

Figure B.3: Timeline of Relevant Articles

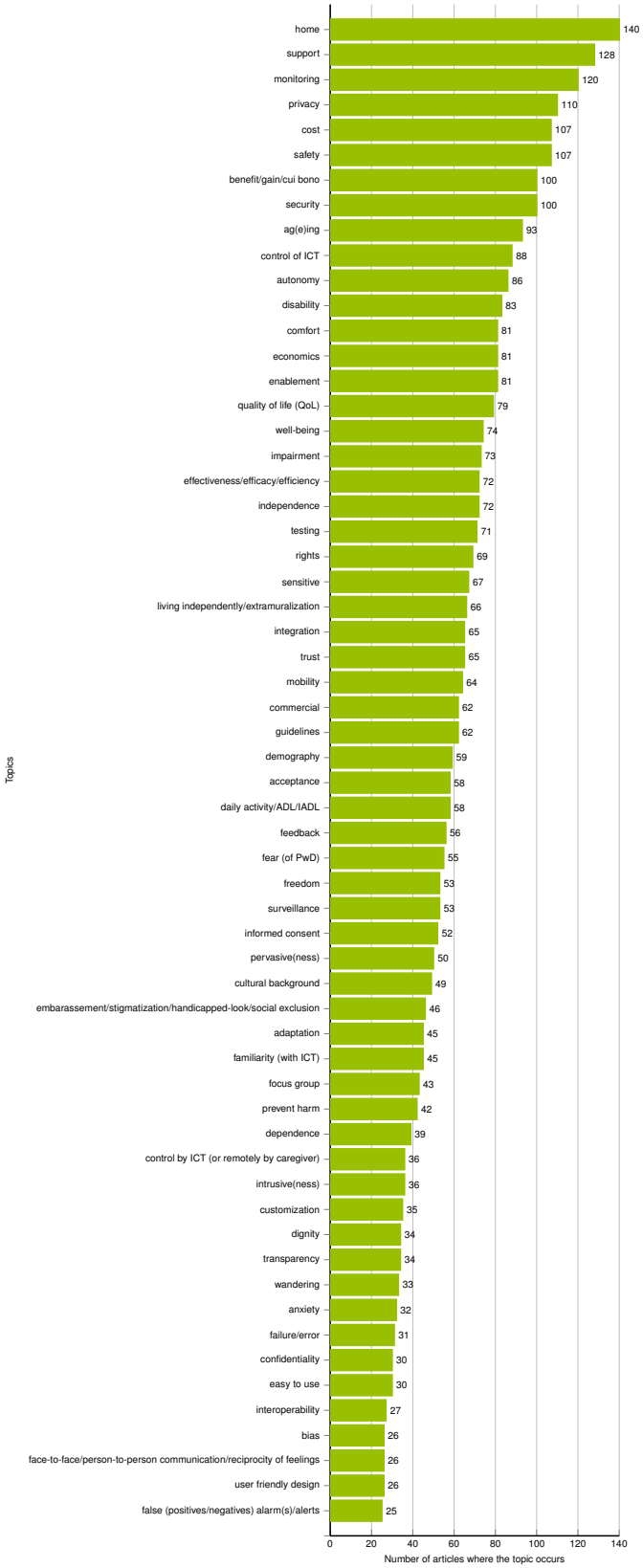

Figure B.4: Frequency of Ethical Terms

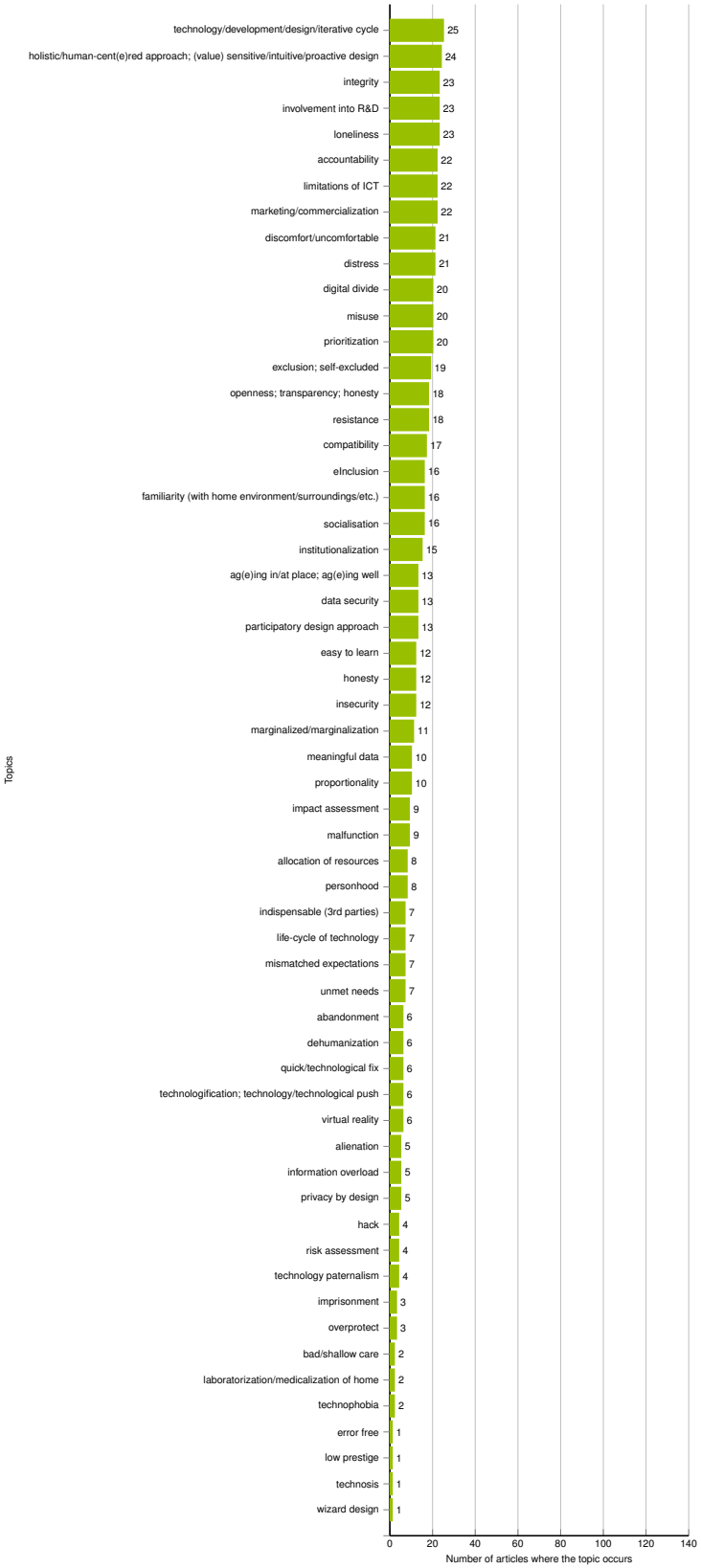

Figure B.4: Frequency of Ethical Terms (cont.)

Table B.1 – Database Search Syntax

No.	Search Syntax
	"ambient intelligence"
01	"ambient intelligence" AND ethic*
	"ambient assistive living"
02	"ambient assistive living" AND ethic*
	"ambient assisted living"
03	"ambient assisted living" AND ethic*
	"(AAL)"
04	"(AAL)" AND ethic*
05	"(AAL)" AND ethic* AND ambient
	"assistive technologies"
06	"assistive technologies" AND ethic*
	"supportive technologies"
07	"supportive technologies" AND ethic*
	pervasive AND technology
	pervasive AND technology AND ethic*
08	pervasive AND technology AND ethic* AND dementia
	sensor AND dementia
09	sensor AND dementia AND ethic*
	ubiquitous AND technology
	ubiquitous AND technology AND ethic*
10	ubiquitous AND technology AND ethic* AND dementia

Table B.1: Database Search Syntax

Table B.2 – Mepham's Ethical Matrix of Ethical Issues for AAL Technologies Used for PwDs

	Research & Development (R&D)	Clinical Trials	Clinical Application
Persons with Dementia (PwD)	Abandonment (lack of user involvement in R&D)	AmI has "life on its own"	Acceptance
	Dignity	Anxiety	Ageing at place
	Familiarity	Control	Alienation
	Feedback	Discomfort	Anxiety
	Honesty	Easy-to-learn	Autonomy
	Integrity	Easy-to-use	Comfort/discomfort
	Involvement into R&D	Enablement	Control
	Mismatched expectations	Error-free	Cultural background
	Not only informed consent but interviews (simple sentences TASC)	Failure, error	Customization
	Participatory design approach	False (positives) alarm(s)	Daily activity (ADL, IADL)
	Personhood	Fear	Dehumanization
	Privacy by design	Home	Dependence
	Risk assessment	Information overload	Digital divide
	Safety	Informed consent	Dignity
	Self-reports (Titration approach)	Insecurity	eInclusion
	Special approach	Integration	Embarrassment/stigmatization, handicapped-look, social exclusion
	Virtual reality	Intrusive(ness)	Enablement
		Laboratorization of living environment/medicalization of home	Error-free
		Mobility	Exclusion (self-excluded)
		Pervasive(ness)	Face-to-face, person-to-person communication, reciprocity of feelings
		Prevent harm (e.g. fall accidents)	Failure, error
		Privacy	False (positives) alarm(s)

Table B.2 – Continued From Previous Page

Research & Development (R&D)	Clinical Trials	Clinical Application
	Resistance	Fear
	Safety	Freedom
	Security	Home
	Socializing	Impairment
	Special approach	Imprisonment
	Support	Independence
	Technophobia	Institutionalization
	Unmet needs	Integrity
	Voice control >LCD control	Limitation
	Wandering	Living independently, extramuralization
		Loneliness
		Mobility
		Monitoring
		Pervasive(ness)
		Prevent harm
		Privacy
		Quality of life (QoL)
		Resistance
		Safety
		Security
		Socializing
		Support
		Surveillance
		Technophobia
		Trust

Table B.2 – Continued From Previous Page

	Research & Development (R&D)	Clinical Trials	Clinical Application
			Unmet needs
			Wandering
			Well-being
Formal/Informal Care-givers (nurses, proxies)	Continuous monitoring	Acceptance	Acceptance
	Feedback	Easy-to-learn	Against institutionalization (ageing at place)
	Focus groups	Easy-to-use	Bad care/shallow care
	Honesty	Familiarity	Cultural background
	Mismatched expectations	Fear	Dehumanization
	Monitoring	Interoperability	Dependence
	Privacy by design	Life-cycle of ICT	Dignity
	Social exclusion/eInclusion	Limitations of ICT	Easy-to-learn
	Who will gain?, whose benefit (*cui bono*)?	Mismatched expectations	Easy-to-use
		Misuse – whose responsibility?	Effectiveness
		Overprotection	Efficacy
		Prevent harm	Efficiency
		Reciprocal accountability	Enablement
		Resistance	Face-to-face, person-to-person communication, reciprocity of feelings
		Safety	Familiarity
		Security	Impairment
		Technophobia	Institutionalization
		Trust	Interoperability
		Unmet needs	Life-cycle of ICT
		User-friendly design	Mismatched expectations
		Well-being	Misuse – whose responsibility?

Table B.2 – Continued From Previous Page

	Research & Development (R&D)	Clinical Trials	Clinical Application
			Monitoring
			Overprotection
			Quality of life (QoL)
			Reciprocal accountability
			Resistance
			Support
			Technologification, technology push, technological push
			Technology paternalism
			Technophobia
			Trust
			Unmet needs
			User-friendly design
			Well-being
Researchers and Clinicians	Allocation of resources	Bias	Bad care/shallow care
	Continuous monitoring	Confidentiality	Bias
	Dignity	Daily activity (ADL/IADL)	Confidentiality
	Holistic approach, human-centred approach, human-centered approach, (value) sensitive design, intuitive design, proactive design	Data security	Data security
	Personhood	Dignity	Dignity
	Who will gain?, whose benefit (*cui bono*)?	Disability	Disability
		Easy-to-learn	Easy-to-learn
		Easy-to-use	Easy-to-use
		Honesty	Effectiveness
		Informed consent	Enablement

Table B.2 – Continued From Previous Page

Research & Development (R&D)	Clinical Trials	Clinical Application
	Laboratorization of living environment/medicalization of home	Honesty
	Life-cycle of ICT	Human-centred approach
	Meaningful data collection	Impairment
	Misuse – whose responsibility?	Independence
	Monitoring	Integration
	Overprotection	Interoperability
	Personhood	Is the person really in a need for AmI?
	Prevent harm (e.g. fall accidents)	Life-cycle of ICT
	Prioritization of medical data	Living independently, extramuralization
	Proportionality	Misuse – whose responsibility?
	Reduce insecurity	Mobility
	Reliability	Monitoring
	Rights	Overprotection
	Safety	Prevent harm
	Security	Prioritization of medical data
	Trust	Proportionality
	Well-being	Quality of life (QoL)
		Reliability
		Rights
		Safety
		Security
		Socializing
		Support
		Trust
		Well-being

Table B.2 – Continued From Previous Page

	Research & Development (R&D)	Clinical Trials	Clinical Application
			What is normal ADL/IADL?
Software/Hardware Engineers	Allocation of resources	Customization	Bandwidth prioritization
	Compatibility	Failure, error	Comfort/discomfort
	Cost-benefit ratio	False (positives) alarm(s)	Commercial
	Customization	Familiarity	Cost
	Data security	Home	Data security
	DoS attacks	Indispensability of 3rd parties	Easy-to-learn
	Feedback	Information overload	Error-free
	Hacks	Interoperability	Failure, error
	Impact assessment	Laboratorization of living environment/medicalization of home	False (positives) alarm(s)
	Implantable sensors overheat	Lax testing	Familiarity
	Integration	Life-cycle of ICT	Home
	Interoperability	Limitations of ICT	Imprisonment
	Involvement into R&D	Low prestige	Indispensability of 3rd parties
	Low prestige ICT development	Meaningful data	Information overload
	Mismatched expectations	What is normal ADL/IADL?	Interoperability
	Mobility	Prioritization	Life-cycle of ICT
	Participatory design approach	Privacy by design	Limitations of ICT
	Privacy by design	Proportionality	Loneliness
	QoS	Quick fix, technological fix	Marketing
	Quick fix, technological fix	Resistance	Prioritization
	Resistance	Risk assessment	Proportionality
	Risk assessment	Safety	Quick fix, technological fix
	Special approach	Security	Safety

Table B.2 – Continued From Previous Page

	Research & Development (R&D)	Clinical Trials	Clinical Application
	Technologification, technology push, technological push	Technologification, technology push, technological push	Security
	Technology paternalism	Technology paternalism	Support
	Transparency	Technophobia	Technology paternalism
	Unmet needs	Technosis	Technophobia
	User friendly design	Testing	Technosis
	Virtual reality	Tracking for safety, not with physical restrictions	Testing
	Wizard design	Transparency	Transparency
		Trust	Trust
		Unmet needs	
		Very few testing in actual homes	
Designers	Acceptance	Acceptance	Acceptance
	Alienation	Adaptation	Adaptation
	Anxiety	Anxiety	Anxiety
	Bias	Comfort	Comfort/discomfort
	Dehumanization	Control	Commercial
	Design-for-all approach	Customization	Compatibility
	Dignity	Dignity	Control
	Feedback	Discomfort (e.g. battery, etc.)	Cost
	Focus groups	Familiarity	Cultural background
	Impact assessment	Indispensability (of 3rd parties)	Customization
	Intrusive(ness)	Integration	Dependence
	Involvement into R&D (participatory design approach)	Intrusive(ness)	Digital divide
	Mismatched expectations	Laboritarization/medicalization of home	Dignity
	Privacy by design	Life-cycle of ICT	Easy-to-learn

Table B.2 – Continued From Previous Page

	Research & Development (R&D)	Clinical Trials	Clinical Application
	Proactive design	Limitations of ICT	Easy-to-use
	Risk assessment	Mismatched expectations	Efficiency
	Safety	Misuse – whose responsibility?	Embarrassment/stigmatization, handicapped-look, social exclusion
	Sensitive	Prevent harm (e.g. fall accidents)	Enablement
	Special approach	Resistance	Ergonomics
	Testing	Support	Failure, error
	Trust	Technologification, technology push, technological push	Familiarity
	Unmet needs	Technology paternalism	Indispensability (of 3rd parties)
	User friendly design	Technophobia	Integration
	Wizard design	Testing	Integrity
		Trust	Interoperability
		Unmet needs	Laboritarisation/medicalisation of home
			Life-cycle of ICT
			Limitations of ICT
			Marketing
			Misuse – whose responsibility?
			Mobility
			Prevent harm
			Resistance
			Technologification, technology push, technological push
			Technology paternalism
			Technophobia
Technicians		Home	Indispensability (of 3rd parties)

Table B.2 – Continued From Previous Page

Research & Development (R&D)	Clinical Trials	Clinical Application
	Sensitive installation of devices	Special approach during maintenance
	Trust	Support
		Trust

Table B.2: Mepham's Ethical Matrix of Ethical Issues for AAL Technologies Used for PwDs

Table B.3 – Overview of the Ethical Issues In the Resulted Literature

	Person with dementia	Formal caregivers, informal proxies	Researchers, clinicians	Software/hardware engineers	Designers	Technicians
User involvement in R&D	Francis et al. (2009), Wallace et al. (2010)			Francis et al. (2009), Gaul and Ziefle (2009)	Allen et al. (2008), Aarts et al. (2007), Borenstein and Pearson (2010), Burleson et al. (2012), Duquenoy (2004), Francis et al. (2009), M. Hersh et al. (2003), Kosta, O. Pitkänen, et al. (2008), Kosta, Olli Pitkänen, et al. (2010), Lorenzen-Huber et al. (2011), Maguire et al. (2011), Maier and Kempter (2009), Newell et al. (2011), O'Neill, Parente, et al. (2011), Picking et al. (2012), Pulli et al. (2012), Sponselee et al. (2008), Wallace et al. (2010), Wright (2011)	

Table B.3 – Continued From Previous Page

	Person with dementia	Formal caregivers, informal proxies	Researchers, clinicians	Software/hardware engineers	Designers	Technicians
Acceptance of ICT	Abascal and Azevedo (2007), Duquenoy and Whitehouse (2006), Fairclough (2009), Francis et al. (2009), Gaul and Ziefle (2009), Grönvall and Kyng (2012), Holzinger et al. (2008), S. Lauriks et al. (2007), Steve Lauriks et al. (2010), Mordini et al. (2009), O'Neill, Mason, et al. (2011), Oppenauer et al. (2007), Panek and Zagler (2008), Portet et al. (2011), Remmers (2010), Salces et al. (2006), Sponselee et al. (2008), J. van Hoof et al. (2011), Wallace et al. (2010), Zaad and Ben Allouch (2008)					
Informed consent, independence, self-determination	B. Hofmann (2012), Kosta, Olli Pitkänen, et al. (2010), Picking et al. (2012), Remmers (2010), Scanaill et al. (2006)					

Table B.3 – Continued From Previous Page

	Person with dementia	Formal caregivers, informal proxies	Researchers, clinicians	Software/hardware engineers	Designers	Technicians
Control, customisation	Decker (2012), Duquenoy and Whitehouse (2006), Kang et al. (2010), Kosta, Olli Pitkänen, et al. (2010), Portet et al. (2011), J. van Hoof et al. (2011), Wallace et al. (2010), Zaad and Ben Allouch (2008)					
Prevention of harm, medicalization of home environment	Ahonen et al. (2010b), Batchelor et al. (2012), Belbachir et al. (2010), Cavoukian et al. (2010), Chan, Estève, et al. (2008), Friedewald and Raabe (2011), B. Hofmann (2012), Kosta, Olli Pitkänen, et al. (2010), Landau and Werner (2012), Piasek et al. (2013), Sponselee et al. (2008), J. van Hoof et al. (2011)					
Ageing at home, autonomy, dependence on a system	A. Darwish and Hassanien (2011), Harrefors et al. (2012), Kosta, O. Pitkänen, et al. (2008), Kosta, Olli Pitkänen, et al. (2010), Maguire et al. (2011), Portet et al. (2011), J. van Hoof et al. (2011)					

Table B.3 – Continued From Previous Page

	Person with dementia	Formal caregivers, informal proxies	Researchers, clinicians	Software/hardware engineers	Designers	Technicians
Embarrassment, stigmatization, social isolation	Kumar and H.-J. Lee (2011), Chan, Campo, et al. (2009), Dishman and Carrillo (2007), Fairclough (2009), Francis et al. (2009), Kosta, Olli Pitkänen, et al. (2010), S. Martin et al. (2010), A. McLean (2011), O'Neill, Mason, et al. (2011), Oppenauer et al. (2007), Palm (2012), Portet et al. (2011), Louise Robinson et al. (2009), Salces et al. (2006), A. Sixsmith and J. Sixsmith (2008), Sorell and Draper (2012), Sponselee et al. (2008), Kleinberger et al. (2007), J. van Hoof et al. (2011), Wright (2011), Wright and Wadhwa (2010), Zwijsen et al. (2010)					

Table B.3 – Continued From Previous Page

	Person with dementia	Formal caregivers, informal proxies	Researchers, clinicians	Software/hardware engineers	Designers	Technicians
Monitoring, surveillance	Gaul and Ziefle (2009), Grönvall and Kyng (2012), B. Hofmann (2012), Jeffrey Kaye (2010), Kosta, O. Pitkänen, et al. (2008), Kosta, Olli Pitkänen, et al. (2010), Lynch et al. (2009), Mordini et al. (2009), Oppenauer et al. (2007), Remmers (2010), Salces et al. (2006)					
Social exclusion, digital divide, familiarity with ICT, affordability	Abascal and Nicolle (2005), Batchelor et al. (2012), Daniel et al. (2009), Francis et al. (2009), B. Hofmann (2012), Kosta, O. Pitkänen, et al. (2008), Kosta, Olli Pitkänen, et al. (2010), A. McLean (2011), Mordini et al. (2009), Niemelä et al. (2007), Oppenauer et al. (2007), Satava (2003), Walsh and Callan (2011), Wright and Wadhwa (2010), Zaad and Ben Allouch (2008), Zwijsen et al. (2010)					
Benefit		A. Darwish and Hassanien (2011), B. Hofmann (2012)				

Table B.3 – Continued From Previous Page

	Person with dementia	Formal caregivers, informal proxies	Researchers, clinicians	Software/hardware engineers	Designers	Technicians
Data collection, safety, protection		Fairclough (2009)		Abascal and Azevedo (2007), Chan, Estève, et al. (2008), Duquenoy (2004), Kosta, O. Pitkänen, et al. (2008), Kumar and H.-J. Lee (2011)		
Prevalence of technological rationality in human care		Dekkers (2009), B. Hofmann (2012), Oost and Reed (2011), R. Sparrow and L. Sparrow (2006), Sponselee et al. (2008)				
Instrumentalisation of care, the value of human care, tasks not suitable for ICT		Borenstein and Pearson (2010), Coeckelbergh (2010), B. Hofmann (2012), Oost and Reed (2011), Portet et al. (2011), A. Sharkey and N. Sharkey (2012), R. Sparrow and L. Sparrow (2006), Stip and Rialle (2005), Vallor (2011), Walsh and Callan (2011)		B. Hofmann (2012), R. Sparrow and L. Sparrow (2006)		
Overprotection, paternalism, previous working habits, rigid application of protocols		S. Martin et al. (2010), Sponselee et al. (2008), L. Robinson et al. (2007)				

Table B.3 – Continued From Previous Page

	Person with dementia	Formal caregivers, informal proxies	Researchers, clinicians	Software/hardware engineers	Designers	Technicians
Not-invented-here syndrome		Sponselee et al. (2008)				
Motives for participation in research, eagerness to please, power relationship			Grönvall and Kyng (2012), Maier and Kempter (2009), Oberzaucher et al. (2009), Wallace et al. (2010)		S. Brown et al. (2004), S. Brown et al. (2006), Francis et al. (2009), Maier and Kempter (2009), Sponselee et al. (2008), Wallace et al. (2010), Walsh and Callan (2011)	
Meaningfulness and prioritization of data			Allen et al. (2008), Conley et al. (2008), Cook et al. (2009), A. Darwish and Hassanien (2011), Kang et al. (2010), Jeffrey Kaye (2010), Noury et al. (2011), Romdhane et al. (2012), Sponselee et al. (2008), Viswanathan et al. (2012), Wherton and Monk (2008)			
Safety and security			B. Hofmann (2012), S. Lauriks et al. (2007)	Chan, Estève, et al. (2008), A. Darwish and Hassanien (2011)		
Human-centred approach			B. Hofmann (2012), Portet et al. (2011), Scanaill et al. (2006), Zaad and Ben Allouch (2008)			
Allocation of resources			Duquenoy (2004)			

Table B.3 – Continued From Previous Page

	Person with dementia	Formal caregivers, informal proxies	Researchers, clinicians	Software/hardware engineers	Designers	Technicians
ICT and diagnosis, automated machine diagnosis			Camarinha-Matos and Afsarmanesh (2011), Chan, Estève, et al. (2008), A. Darwish and Hassanien (2011), Dishman and Carrillo (2007), Friedewald and Raabe (2011), Fairclough (2009), Gaul and Ziefle (2009), B. Hofmann (2012), Kosta, O. Pitkänen, et al. (2008), Kosta, Olli Pitkänen, et al. (2010), Merilahti et al. (2012), Plaza et al. (2011), Palm (2012), Kleinberger et al. (2007)			
Technical or 'quick' fix, R&D for PwD as low prestige endeavour				B. Hofmann (2012), Mordini et al. (2009)		
Mismatched expectations				Allen et al. (2008),Duquenoy and Whitehouse (2006), Duquenoy (2004), J. van Hoof et al. (2011)		
Interoperability, compatibility of systems				Chan, Estève, et al. (2008), A. Darwish and Hassanien (2011), Román et al. (2009)		

Table B.3 – Continued From Previous Page

	Person with dementia	Formal caregivers, informal proxies	Researchers, clinicians	Software/hardware engineers	Designers	Technicians
Special status of human experimentation				Mordini et al. (2009)		
Indispensable third parties				Decker (2012), B. Hofmann (2012), Kosta, Olli Pitkänen, et al. (2010), J. van Hoof et al. (2011), Wright (2011)		J. van Hoof et al. (2011)
Testing of AAL technologies, impact assessment				B. Hofmann (2012), Portet et al. (2011)	Cahill et al. (2007), Chan, Estève, et al. (2008), Chan, Campo, et al. (2009), Steve Lauriks et al. (2010), Portet et al. (2011), Scanaill et al. (2006), Wright (2011)	
Principle of proportionality				B. Hofmann (2012)		
Easy to learn, error free ICT				Portet et al. (2011)		
Different life-cycle of technology and service, technology push				Chan, Campo, et al. (2009), Kosta, O. Pitkänen, et al. (2008), Kosta, Olli Pitkänen, et al. (2010)		
The role of AAL technologies				Rapoport (2012)		

Table B.3 – Continued From Previous Page

	Person with dementia	Formal caregivers, informal proxies	Researchers, clinicians	Software/hardware engineers	Designers	Technicians
Design-for-all approach, heteronomous group of PwD					Abascal and Azevedo (2007), A. Darwish and Hassanien (2011), Duquenoy and Whitehouse (2006), Kosta, O. Pitkänen, et al. (2008), Kosta, Olli Pitkänen, et al. (2010), Newell et al. (2011), Portet et al. (2011), Sponselee et al. (2008), Wallace et al. (2010)	
Definition of disability					Abascal and Nicolle (2005), Appleyard (2005), Darzentas and Miesenberger (2005), Lynch et al. (2009)	
Sensitive installation of devices						J. van Hoof et al. (2011)

Table B.3: Overview of the Ethical Issues In the Resulted Literature

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