State of the art on ethical, legal, and social issues linked to audio- and video-based AAL solutions



Social responsibility: Ethical, legal, social, data protection and privacy issues

December 2021





This publication is based upon work from COST Action GoodBrother – Network on Privacy-Aware Audioand Video-Based Applications for Active and Assisted Living, supported by COST (European Cooperation in Science and Technology).

COST (European Cooperation in Science and Technology) is a funding agency for research and innovation networks. Our Actions help connect research initiatives across Europe and enable scientists to grow their ideas by sharing them with their peers. This boosts their research, career and innovation.

#### www.cost.eu





# **Details about this white paper**

#### **Abstract**

Ambient assisted living (AAL) technologies are increasingly presented and sold as essential smart additions to daily life and home environments that will radically transform the healthcare and wellness markets of the future. An ethical approach and a thorough understanding of all ethics in surveillance/monitoring architectures are therefore pressing. AAL poses many ethical challenges raising questions that will affect immediate acceptance and long-term usage. Furthermore, ethical issues emerge from social inequalities and their potential exacerbation by AAL, accentuating the existing access gap between high-income countries (HIC) and low and middle-income countries (LMIC). Legal aspects mainly refer to the adherence to existing legal frameworks and cover issues related to product safety, data protection, cybersecurity, intellectual property, and access to data by public, private, and government bodies. Successful privacy-friendly AAL applications are needed, as the pressure to bring Internet of Things (IoT) devices and ones equipped with artificial intelligence (AI) quickly to market cannot overlook the fact that the environments in which AAL will operate are mostly private (e.g., the home). The social issues focus on the impact of AAL technologies before and after their adoption. Future AAL technologies need to consider all aspects of equality such as gender, race, age and social disadvantages and avoid increasing loneliness and isolation among, e.g. older and frail people. Finally, the current power asymmetries between the target and general populations should not be underestimated nor should the discrepant needs and motivations of the target group and those developing and deploying AAL systems. Whilst AAL technologies provide promising solutions for the health and social care challenges, they are not exempt from ethical, legal and social issues (ELSI). A set of ELSI guidelines is needed to integrate these factors at the research and development stage.

#### **Keywords**

Ethical principles, Privacy, Assistive Living Technologies, Privacy by Design, General Data Protection Regulation.

#### Disclaimer and acknowledgements

This report was created within the Working Group 1 on Social Responsibility of the COST Action 19121 Good Brother funded by the COST Action.

This report's contents are the authors' sole responsibility and do not necessarily reflect the views of the COST Action nor the European Commission. The opinions expressed here are those of the authors only and do not necessarily reflect the authors' organizations.

Contents of this publication may be quoted or reproduced, provided that the source of information is acknowledged.

The authors would like to thank the COST Action for the provided support.

#### **Author details**

The CA 19121 WG 1 White Paper has been written in collaboration with members of the CA 19121 WG1 who have various backgrounds ranging from law, ethics, philosophy, psychology, sociology, science and technology studies, and engineering.

The following authors (here listed alphabetically) contributed to the White Paper State of the Art on ethical, legal, and social issues linked to audio- and video-based AAL solutions.

- 1. Alin Ake-Kob, Nord University (NO)
- 2. Aurelija Blazeviciene, Lithuanian University of Health Sciences (LT)
- 3. Liane Colonna, The Swedish Law and Informatics Research Institute (IRI), Stockholm University (SE)
- 4. Anto Čartolovni, Digital healthcare ethics laboratory (Digit-HeaL), Catholic University of Croatia, (HR)
- 5. Carina Dantas, SHINE 2Europe (PT)
- 6. Anton Fedosov, University of Zurich (CH)
- 7. Francisco Florez-Revuelta, University of Alicante (ES)
- 8. Eduard Fosch-Villaronga, eLaw Center for Law and Digital Technologies, Leiden University, (NL)
- 9. Zhicheng He, The Swedish Law and Informatics Research Institute (IRI), Stockholm University (SE)
- 10. Andrzej Klimczuk, SGH Warsaw School of Economics, (PL)
- 11. Maksymilian Kuźmicz, The Swedish Law and Informatics Research Institute (IRI), Stockholm University (SE)
- 12. Adrienn Lukács, University of Szeged (HU)
- 13. Christoph Lutz, Nordic Centre for Internet and Society, BI Norwegian Business School (N)
- 14. Renata Mekovec, Faculty of organization and informatics, University of Zagreb (HR)
- 15. Cristina Miguel, Department of Applied Information Technology, University of Gothenburg
- 16. Emilio Mordini, NORIA (FR)
- 17. Zada Pajalic, Faculty of Health Studies, VID Specialized University, Oslo, Norway (N)
- 18. Barbara Krystyna Pierscionek, Faculty of Health, Education, Medicine and Social Care, Anglia Ruskin University, Chelmsford, (UK)
- 19. Maria Jose Santofimia Romero, University of Castilla-La Mancha (ES)
- 20. Albert Ali Salah, Utrecht University (NL) and Boğaziçi University (TR)
- 21. Andrzej Sobecki, Gdansk University of Technology, (PL)
- 22. Agusti Solanas, Universitat Rovira i Virgili (ES)
- 23. Aurelia Tamò-Larrieux, University of St. Gallen, (CH)

# Table of contents

D	etails about this white paper	3	
	Abstract		3
	Keywords		3
	Disclaimer and acknowledgements		3
	Author details		4
1	. Cost Action 19121 and this White paper	7	
	1.1 Cost Action 19121: GoodBrother		7
	1.2 Working Group 1 on Social Responsibility: Ethical, legal, social, data protection and privacy issues		7
	1.3 Objectives of this White Paper		8
2	. Background information	9	
	2.1. Terminology		9
	2.2. Technical underpinnings of audio- and video-based AAL solutions		10
	2.3. Monitoring capabilities		13
	2.4 Privacy and control		14
3	. Ethical aspects	17	
	3.1 Ethical principles in the context of AAL		17
	3.2 Ethical impacts of audio- and video-based technologies for AAL		18
	3.2.1 The obtrusiveness, autonomy, consent and data ownership		18
	3.2.2. Privacy for secondary use of data		19
	3.2.3. Inequalities in access to AAL technologies		19
4	. Legal aspects	21	
	4.1 Data protection and design requirements of data protection law		21
	4.2 Cyber security		22
	4.3 Medical device regulation & health laws		24
	4.4 General product safety regulation		25
	4.5 Consumer protection		26
	4.6 Intellectual property		27
	4.7 Al Regulation		27
5	. Societal challenges to video- and audio based monitoring	29	
	5.1 Socio-political context in relation to the adoption of video- and audio based AAL		29
	5.2 Age in a life course approach: later-life, end-of-life, and dementia.		30
	5.3 Isolation		32
	5.4 Gender and vulnerability		33

References		42	
Conclusions		40	
	5.6.2 Socially driven innovations for an aged population		37
	5.6.1 Participatory design		36
	5.6 Participatory design and socially driven innovation as opportunities		36
	5.5 Social inequalities and spatial considerations		35

# 1. Cost Action 19121 and this White paper

#### 1.1 Cost Action 19121: GoodBrother

The European Cooperation in Science and Technology (COST) is a funding organisation for the creation of research networks, called <u>COST Actions</u> (CA). These networks offer an open space for collaboration among scientists across Europe (and beyond) and thereby give impetus to research advancements and innovation. Many institutions around Europe participate actively in the <u>CA19121 - Network on Privacy-Aware Audio- and Video-Based Applications for Active and Assisted Living</u>, also called GoodBrother.

Europe faces crucial challenges regarding health and social care due to the demographic change and current economic context. Active Assisted Living (AAL) technologies are a possible solution to support tackling them. AAL technologies aim at improving the health, quality of life, and wellbeing of older, impaired, and frail people. AAL systems use different sensors to monitor the environment and its dwellers. Cameras and microphones are being more frequently used for AAL. They monitor an environment and gather information, being the most straightforward and natural way of describing events, persons, objects, actions, and interactions. Recent advances have given these devices the ability to 'see' and 'hear.' However, their use can be seen as intrusive by some end-users such as assisted persons and professional and informal caregivers.

GoodBrother aims to increase the awareness of the ethical, legal, and privacy issues associated with audio- and video-based monitoring and to propose privacy-aware working solutions for assisted living by creating an interdisciplinary community of researchers and industrial partners from different fields (computing, engineering, healthcare, law, sociology) and other stakeholders (users, policymakers, public services), stimulating new research and innovation. GoodBrother will offset the "Big Brother" sense of continuous monitoring by increasing user acceptance, exploiting these new solutions, and improving market reach.

# 1.2 Working Group 1 on Social Responsibility: Ethical, legal, social, data protection and privacy issues

Experts from diverse disciplines are analysing the ethical, legal, data protection and privacy issues associated with the use of cameras and microphones in private spaces, and how to manage multi-party privacy preferences. They also study the differences according to gender and cultural/societal background in the perception of these issues. This WG aims to establish the core requirements that AAL solutions must fulfil to consider ethico-legal issues and to integrate privacy by design and by default. Those requirements will set up the guidelines for the technical WGs (WG2, WG3 and WG4).

#### The Workgroup goals are:

Review the current European and international legislation and the ethical issues that underpin
this on the use of audio- and video-based monitoring in private environments.

- Study the differences in the perception of privacy depending on the culture, society, gender and age of the users, and analyse the situations and conditions in later life, i.e. occurrence of a fall, which may affect that perception.
- Investigate the potential benefits and barriers of AAL technology adoption for people in need of care.
- Support the development of privacy-aware monitoring systems by a continuous exchange of knowledge with technological participants in the Action.
- Promote the consideration of ethical, legal, privacy and gender matters in the design of AAL solutions. Inform other WPs on the ethico-legal requirements in the design and development of AAL solutions.

#### 1.3 Objectives of this White Paper

The objectives of this white paper are to:

- Define the relevant ethical aspects relating to AAL and distinguish these from the legal issues
  which are concerned with data protection and privacy as associated with the use of surveillance
  technology: cameras and microphones in private spaces, and how to manage multi-party privacy
  preferences.
- Review the current European and international legislation and examine the ethical issues that underpin these on the use of audio- and video-based monitoring in private environments.
- Study the differences in the perception of privacy depending on cultural understandings, social practices, gender, age, and health condition of the users, and analyse the situations through life, i.e. occurrence of a fall, which may affect that perception.
- Investigate the potential benefits and barriers of AAL technology adoption for people in need of care.

# 2. Background information

#### 2.1. Terminology

The concept of "Active and Assisted Living" (AAL) emerged in the early 2000s, by evolving the concept of assistive technologies to address the societal challenges of health, demographic change and wellbeing. Several definitions of AAL have appeared so far in the literature (Florez-Revuelta & Chaaraoui, 2016; Marques, 2019). The term AAL can be broadly referred to the use of innovative and advanced Information and Communication Technologies (ICT) to create supportive and inclusive applications and environments that may enable older, impaired or frail people to live independently and stay active longer in society (AGE, 2016a). AAL has capitalized on the growing pervasiveness and effectiveness of ICT applications to supply the persons in need with smart assistance, by responding to their necessities of autonomy, independence, comfort, security and safety. From an initial version, mainly related to indoor environments, AAL concept has broadened to include outdoor and on-the-move facilities, to ensure the continuum of support and care, thus increasing autonomy and independence of the assisted individuals.

This has resulted in a plethora of AAL solutions that respond to core needs by:

- supporting and ensuring sustained wellbeing, quality of life, and safety of people with any kind of impairment
- alleviating the burden of chronic diseases, also by ensuring continuous and remote monitoring and contrasting the shortage of health personnel
- contributing towards more sustainable health, care, and social services, by reducing the pressure on formal health and care infrastructures thanks to remote monitoring and tele-assistance preventing ageing and impaired community from social isolation
- supporting and relieving the burden of formal and informal caregivers
- promoting better and healthier lifestyles for the individuals at risk
- enacting disease prevention strategies based on personalised risk assessment and continuous monitoring.

With respect to the last issue, in the middle 2010s, the so-called Quantified Self movement emerged thanks to the upsurge of consumer-friendly wearable sensors (e.g., smart watches, smart bracelets, or wristbands). The idea behind this movement is to promote the self-tracking and self-monitoring of a person's health information to increase the self-awareness of her or his health status. Quantified Self and AAL technologies strongly overlap, especially when considering lifelogging and vital signs monitoring application scenarios. Similarly, AAL can make extensive use of mobile-Health (mHealth) applications as

well as of the so-called Internet of Healthy Things (IoHT) to monitor and track health-related information (Rodrigues et al., 2018).

The monitoring of personal and vital parameters in order to improve one's health is also being studied in the Internet of Things (IoT) field. 'Health-related Internet of things' (H-IoT) or the 'Internet of Medical Things' (IoMT) technologies increasingly play a key role in health management, for purposes including disease prevention, real-time telemonitoring of patient's functions, testing of treatments, fitness, and well-being monitoring, medication dispensation, and health research data collection. H-IoT and IoMT are combined with context-aware environments, which have the capability of sensing and analysing their surroundings, to foster the concept of smart healthcare (s-health) defined as the provision of healthcare in context-aware environments such as smart cities, smart hospitals, or smart homes (Solanas et al., 2014).

Despite aiming at diverse goals, AAL systems should share some common characteristics (Blackman et al., 2016). AAL systems are designed to provide support in daily life in an invisible, unobtrusive and user-friendly manner. Moreover, they are conceived to be intelligent, to be able to learn and adapt to the requirements and requests of the assisted people, and to synchronise with their specific needs. In this respect, the field of AAL technologies overlaps, from the technological viewpoint, with many other fields, such as those of Assistive and Supportive Technologies, Ambient Intelligence, Pervasive Computing, Personal Informatics, e-textiles, Internet of Healthy Things, and Robotics. Depending on the embodiment, AAL can include a wide range of robots, especially physically or socially assistive robotics that help users perform certain tasks (Fosch-Villaronga & Drukarch, 2021). From our viewpoint, AAL is an umbrella term that comprises the whole range of adaptive and intelligent ICT solutions that fit into the daily living and working environments, to offer unobtrusive, effective and ubiquitous support to ageing, impaired or frail people. For that reason, the term AAL will be used hereafter.

#### 2.2. Technical underpinnings of audio- and video-based AAL solutions

The application scenarios that AAL is conceived to address are complex, due to the inherent heterogeneity of the end-user population, their living arrangements, and their physical conditions and or impairment (Rashidi & Mihailidis, 2012). Some of the most common and effective functionalities include:

- improving safety at home by preventing accidents and incidents that might occur in an assisted environment via, for instance, fall detection systems (see **Figure 1**), alarms and warnings
- maintaining under control chronic diseases or medication compliance, with connected devices for vital data measuring as well as medication reminders
- maintaining physical and mental abilities, with the support of intelligent mobility aids, coaching systems and brain-training activities

- maintaining interaction with other people with dedicated apps and online community platforms
- improving quality of life for caregivers with technology for information sharing, and better coordination
- early detecting risks in care homes, thus reducing the number of accidents and improving communication between caregivers and their patients.

An AAL system (see Figure 1) incorporates sensor technologies that enable the acquisition of useful data about the ambient settings and the environment as well as the psychophysical conditions and the activities of the assisted individuals. The sensor technologies constitute the sensing or perception layer of the system. Dedicated algorithms process the data acquired by the sensors with the goal to understand, detect or measure the conditions of interest, for instance to recognise the activities of the assisted person to identify a risky situation (e.g., a fall) or to assist her in performing a task (e.g., dressing up). These algorithms compose the data-processing or understanding layer of an AAL system. The data can be stored locally and the algorithms can be embedded in the living environment or in mobile devices (this situation is currently referred to as computing or processing at the edge or edge processing/computing) or the processing layer can be located on distant servers on the cloud. Currently, the data processing layer is often a mixture of algorithms at the edge and on the cloud. In accordance with the information inferred by interpreting the sensed data, the AAL system can provide the end-users with feedback, for instance on suggestions on what to do next when performing a task, alarms or alerts when a risky situation is detected, or engaging them in a game. This happens through the actuator/application or interaction layer. This layer comprises the user interfaces and may require additional computing facilities to support the interactions, such as planning and controlling (Becker, 2008). The sensor layer can be composed of simple smart and connected devices (i.e., the so-called Internet-of-Things) or it can correspond to a more complex sensor network composed by environmental sensors, intelligent devices, video cameras, or audio-based home assistants (Cicirelli et al., 2021).

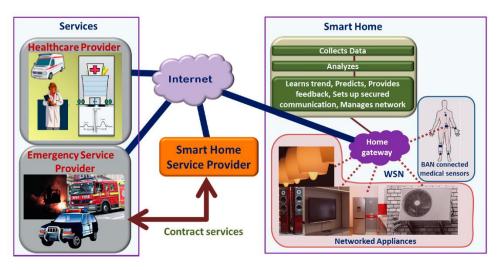


Figure 1.Diagram of a smart home showing the network among different stakeholders (retrieved from Majumder et al., 2016).

Environmental and appliance sensors can acquire information about temperature, humidity, air quality as well as the status and usage of the appliance. Moreover, non-invasive sensors, such as cameras or infrared sensors, can be mounted in several places and integrated in various devices (i.e., the so-called smart objects) and appliances (e.g., mirrors, TVs, rings, bracelets, watches), to monitor individuals in a non-obtrusive and easily acceptable manner, without affecting their normal activities. Accelerometers, gyroscopes, infrared or radar sensors can be embedded into smartphones or wearable devices, such as smart watches, fitness bands, clothing and fabrics to continuously monitor people in both indoor and outdoor applications. Other medical devices (e.g., pulse oximeters, blood pressure monitors) can be connected to the network, thus allowing for the automatic transfer of vital parameters. Among the various typologies introduced above, the video and audio sensors are some of the most powerful ones in terms of the information they convey. For instance, a single camera placed in a room can record most of the activities performed in the room, thus replacing many other non-visual sensors. As the costs of cameras dropped a lot in the last decades, a plethora of works have used cameras and Computer Vision techniques to address most of the AAL applications scenarios, boosting notably the field. Currently, video-based applications are able to recognise and monitor the activities, the movements, and the overall conditions of the assisted individuals as well as to assess their vital parameters (e.g., heart rate, respiratory rate) (Cicirelli et al., 2021). Similarly, audio sensors have shown a big potential to become one of the most important modalities for interaction with AAL systems, as they can have a large range of sensing, do not require physical presence at a particular location and are physically intangible. Moreover, using voice is a more natural way of interaction than tactile interfaces (Portet et al, 2019).

The AAL application scenarios that have been successfully addressed by taking advantage of video and audio data include:

- activity and behaviour recognition
- fall detection and prevention
- gesture recognition
- mobility assessment and frailty recognition
- cognitive and motor rehabilitation
- activity and personal assistance
- lifelogging and self-monitoring
- remote monitoring of vital signs
- emotional state recognition
- food intake monitoring.

Overall, audio and video-based sensors appear as the less obtrusive sensors with respect to the hindrance that other wearable sensors can cause to one's activities because they are usually not in direct contact with the person's body. Nevertheless, they are often perceived as the most intrusive technologies from the viewpoint of the privacy of the monitored individuals. This is in part due exactly from the richness of the information these technologies convey and the intimate setting where these are inserted.

#### 2.3. Monitoring capabilities

The Cost Action GoodBrother aims to increase the awareness of the ethical, legal, and privacy issues associated with audio- and video-based monitoring for AAL, which largely deals with personal data. The need to consider the ethical and legal issues that link to audio- and video-based monitoring for AAL is not new (Lhotska, Havlik, & Panyrek, 2011; Rashidi & Mihailidis, 2012; Belloto et al., 2017). Research in the past has shown the tension between the privacy of users and the need to closely monitor them to improve their safety (lenca & Fosch-Villaronga, 2019). Monitoring is surveillance, even though the word 'monitoring' has tended to be used in relatively benign contexts – including those relating to interpersonal care. 'Monitoring', after all, is what we do (as a matter of love, duty or felt obligation) within our families and communities – in order to respond with empathy or practical support when it is needed. Monitoring is, furthermore, embedded in the worlds of practice for those who work within statutory or private bodies whose primary role (as nurses, care and ancillary workers) is to care for or support those who are in need and, for whom, the use of technological tools (from social alarm and telecare services to tele- and video-consultations) have increasingly become part of the daily use.

New technologies carry the capacity by which we, as individuals (perhaps with the implied consent that we give when deciding to walk in the town centre) have not just our movements (where and who we meet, our conversations, what we do and our purchase of potatoes in the grocer's shop) but also our health, and our emotions identified, analysed (according to unknown, and potentially unknowable, criteria) and shared. These technologies are always sold as a convenient, smart addition to our environment, but if they are deployed without guaranteeing a privacy-by-design (PbD) approach, they create a potential surveillance architecture that might be misused having an impact, not just on us but on the future generations as well. Audio- and video-based AAL solutions are designed to operate in both private and public environments. AAL devices with communication capabilities can be seen as a particular case of IoMT or H-IoT and can be carried by the user or embedded in environments, such as the home, residential care, workplace or public spaces. In each case, as Mittelstadt (2017, p. 160) pointed out "a window into people's private life is created, thus, enabling the collection of data about the user's health and behaviours and the analysis by third parties". In addition, if the collected data are not securely stored and managed, they might be leaked and those very sensitive data could be released without authorisation, creating irreparable damage. The main issue with this technology, as observed by Mittelstadt (2017, p. 160) is that "the lives of users can be digitised, recorded, and analysed by third parties, creating opportunities for data sharing, mining, and social categorisation". Therefore, these basic functions may help to improve healthcare and safety through monitoring and personalised

interventions (Pasluosta et al. 2015), but at the same time, they create opportunities for violating informational privacy. The nature of technology use (including that which employs video- and audio-based monitoring) and the increasing use of 'black box' artificial intelligence tools to analyse data that people may or may not know to have been harvested, may have introduced a growing level of public mistrust since they consider this data gathering as privacy invasion. However, if properly used Artificial Intelligence could help us protect privacy and reduce cybersecurity risks (Kroll et al. 2021). Although there are plenty of technical solutions that enable the private and secure collection, storage, and analysis of data, namely homomorphic encryption, zero-trust architectures (Bertino, 2021), secure multiparty computation, statistical disclosure control; they are not always put in place, and people are left with their right privacy at risk.

There are various technologies that protect personal data but all of them have the same goals (Hype Cycle for Privacy by Gartner, 2021):

- Enable or improve control over the usage of personal data (for example, discovery and data classification).
- Create a transparent environment and demonstrate compliance (for example, privacy management tools).
- Reduce the possibility of data misuse (for example, zero-knowledge proofs and homomorphic encryption). Reduce the likelihood of unwanted outcomes (for example, format-preserving encryption).
- Assist with risk-reduction procedural decision-making (for example, privacy by design).
- Customer service should be improved (for example, influence engineering).

#### 2.4 Privacy and control

When interpreting the concept of privacy, different authors look at privacy from different aspects, so some talk about the physical aspects of privacy, while others focus on personal data. Solove (2008) proposed six main categories that can all be used when referring to privacy: (1) the right to be left alone, (2) limited access to self, (3) secrecy, (4) control over personal information, (5) personhood – protection of identity and dignity, and (6) intimacy. Privacy can be conceptualised as a process of border control in which an individual actually determines and controls with whom and how he will communicate (Pedersen, 1999). Privacy can be also viewed from three basic aspects (Lanier and Saini, 2008): (1) information privacy, (2) accessibility privacy, (3) expressive privacy. Information privacy refers to the control over individual data; accessibility privacy seeks to protect the individual from traditional types of privacy breaches such as eavesdropping on communications, surveillance, and unauthorized access

to private space; while the privacy of expression refers to the ability of an individual to freely decide, express himself and communicate with his environment. As observed by Miguel (2013), several authors (e.g., Fried,1968; Reiman, 1976; Innes, 1992) point out that privacy works through control over our personal information. In recent years, information(al) privacy has emerged as the key type across disciplines because of the growing importance of ICTs and legal frameworks that situate privacy predominantly as a data protection issue (Smith et al., 2011). This informational understanding is implicit in the widely used definition by Westin (1967, p. 7) of privacy as "the claim of individuals, groups, or institutions to determine for themselves when, how, and to what extent information about them is communicated to others".

However, a broader perspective is needed that goes beyond informational privacy. Burgoon's (1982) differentiation of informational, social, psychological and physical privacy proves useful (Lutz et al., 2019) to address the affordances of smart technologies, such as AAL, smart speakers and social robots, offering a holistic perspective. *Physical privacy* is understood as "the degree to which one is physically inaccessible to others" (Burgoon, 1982, p. 211). It includes spatial considerations, for example where a specific technology is implemented and used. *Social privacy* describes the communicational dynamics of privacy and has a relational component tied to interpersonal boundary management, including aspects such as intimacy and protection. When technologies are interactive and serve social needs, such as social presence, this type of privacy becomes especially important. *Psychological privacy* is about cognitive and affective inputs and their control. Thus, this form of privacy falls within the "freedom to" types of privacy, rather than the "freedom from" (Koops et al., 2016), stressing its agentic role for personal growth. Finally, *informational privacy* describes the extent to which a person's information is protected. Thus, privacy has to be understood in a physical, social, psychological and informational sense.

What some groups and cultures perceive as highly privacy-invasive constitutes a normal routine for others. Thus, it helps to situate privacy in a specific cultural, historic, and social context. Nissenbaum (2004, 2010) developed the theory of privacy as contextual integrity to systematically account for the context-specificity of privacy. The theory relates privacy to context-specific information norms, where privacy is intact as long as the context-specific information norms are respected (e.g., the use of health data for targeted advertising might be seen as a privacy violation as opposed to the use of the same health data for medical research). The framework of contextual integrity encompasses two fundamental elements: (1) social context and (2) context-relative informational norms. Context means structured social settings characterized by roles, activities, norms/rules, relationships, power structures and values. Context-relative informational norms prescribe the flow of personal information in a given context, therefore information flows within a context that does not abide by existing norms are perceived as privacy violations. Several researchers have applied the theory of contextual integrity in the context of AI/ IoT (e.g., Kökciyan & Yolum, 2020; Kurtan & Yolum, 2021; Lutz & Newlands, 2021).

As these technologies become more widely utilized, there is rising worry about what sensitive data are collected and how they are used. Audio- and video-based technologies for AAL devices generate a large

volume and variety of data describing the personal health and behaviours of users. Much of these data can be used for medical research and consumer analytics. The design of protocols to enable user and third party access to these datasets also raises ethical concerns. Since health data are usually considered as particularly sensitive information, Mittelstadt (2017, p. 163) highlights that "informational privacy is a central concern for the design and deployment of audio- and video-based technologies for AAL devices insofar as it contributes to gain control over the spread of information about the user's health status and history". Only by combining privacy management, privacy control, and security capabilities, mature privacy management can be attained.

# 3. Ethical aspects

#### 3.1 Ethical principles in the context of AAL

H-IoT, IoMT and context-aware environments promise many benefits for health and healthcare if their security and privacy are properly guaranteed (Machin et al., 2021). However, they also open the door to a variety of ethical issues stemming from the inherent risks of Internet-enabled devices, the sensitivity of health-related data, and their impact on the delivery of healthcare' (Mittelstadt, 2017). Mittelstadt (2017) analyses the ethics of H-IoT at a device, data, and practice level. In the particular arena of healthcare, there is (threatened or promised) the prospect of what were services based on care becoming simply transactions in relation to diagnoses, assessments and decisions about us based on digital information from our digitised bodies. Clinical diagnosis requires a medical expert to assume legal responsibility and subsequently relies on detailed procedures, such as those described in the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) for mental healthcare. Such a formalism will contain, for each condition, the diagnostic classification, the diagnostic criteria sets, and a descriptive text. Albased systems can become useful tools for the experts, providing quantification of indicators and facilitating diagnosis. Even then, increased mediation by automated systems in healthcare generates many ethical, legal, and societal challenges. It is necessary to point to some of the reasons why our mission in this Cost Action 19121 carries an imperative to adequately address the potential for the notion of surveillance that these technological tools might bring.

The basic ethical principles that underpin the use of audio- and video-based technologies for AAL and its incorporation into a wide range of applications, most notably healthcare-related ones, have been well defined (Beauchamp and Childress, 2019).

- Beneficence: the doing of good deeds with no specified limitation
- Non-maleficence: the avoidance of harm and requiring a risk/benefit analysis
- Respect for autonomy: the recognition that an individual can make their own choices and understand the consequence of these choices
- Confidentiality: the maintenance and protection of personal details and information that may reveal personal details

In addition, there are the tenets of justice and fair apportionment of resources, protection of the vulnerable and ensuring that information given is complete, accurate and sufficient to allow for informed consent.

In essence, all technology needs to be assessed for at least these main aspects:

- i. **its 'goodness'** i.e., what good will this novel device do, for whom, for how long and are there better alternatives? This will require a very thorough analysis to determine who will be the beneficiary. An AAL technology that allows an older person to live in their own home and have routine surveillance by an adult or carer may bring benefits to the latter, but may not necessarily be the best option for the older individual for whom it is purported to bring benefit, if or example, this person needs frequent human contact and feels that independent living equates to loneliness.
- ii. a risk/benefit analysis to determine all risks involved, current and future and to appraise these against the benefits. Ethics by design is an attempt to do this, but it is not always successful. A full and frank evaluation should always involve the full range of prospective users and requires regular re-evaluations and updates by a multi-disciplinary team.
- iii. **respect for autonomy** requires an understanding of the responsibility that is conferred on an autonomous adult and appreciation of the fact that this does not apply to all persons as enshrined in law e.g., minors and adults with impaired mental capacity are not considered autonomous and require another person to make decisions for them. An autonomous adult should be permitted to decide what technologies (s)he wishes to use or not and to have that decision respected. This also requires that all relevant information is the property and impartially conveyed to such a person so that decisions made are fully informed.
- iv. maintenance of confidential information and data that may reveal confidential information. Iln some instances, technology risks disclosure of confidential information because a complete assessment of all possible scenarios in which data can be leaked, disclosed without authorisation or misused, have not been considered. This ethical principle has a legal counterpart in data protection regulations and hence the two are often confused. Ethics ensures the consideration of the individual and respect of their confidentiality not because the law dictates that data should be protected, but because the individual is worthy of such respect, which includes the respect for intimacy, as a significant element of personal dignity and physical privacy.

#### 3.2 Ethical impacts of audio- and video-based technologies for AAL

#### 3.2.1 The obtrusiveness, autonomy, consent and data ownership

The obtrusiveness of AAL technologies represents one of the significant impacts on users' life affecting users' acceptance and long term use (Mittelstadt, 2017). Different attempts to define obtrusiveness have been provided, primarily focusing on distinguishing between physical and mental obtrusiveness (Hensel et al., 2006). Another issue that emerges from obtrusiveness related to the visibility of clinical devices is stigma due to association with a disease or health condition. Stigma could impact the sense of identity and behaviours. Older users may experience feelings of frailty when devices and sensors are publicly visible as they indicate illness or a need for monitoring (Courtney et al., 2008, Mittelstadt, 2017). The sense of obtrusiveness may be distorting for a person, such as walking around the pressure sensors

or disabling them which may be embedded in-home or care environment, or on the contrary, if they "fade into the background", they can make users more comfortable (Courtney et al., 2007, Mittlestadt, 2017). One of the issues in this "fading into the background" is the validity of consent if a person forgets monitoring is occurring. The consent in these contexts need to be free and independent (Mittelstadt, 2017), and the sense of freedom and independence may be impeded due to the presence of sensors or transmission of data generated by audio- and video-based AAL devices (Mittelstadt, 2017). However, consent also implies the value of the collected data and sharing, having two important concerns. The first one is whether the collected minimal amount and types of data are necessary to deliver the promised service, according to the "minimization principle", and second to what extent users are informed of the potential value and third party uses of the data they generate (Mittelstadt, 2017). Certainly, to these concerns belongs also the most debatable one data 'ownership rights' which are rather vaguely shared by data subject and controllers when it comes to redistribution and modification of audio- and video-based AAL data and guaranteed by privacy and data protection law (Mittelstadt, 2017).

#### 3.2.2. Privacy for secondary use of data

There are many real-life situations in which personal data are stored: (i) Electronic commerce results in the automated collection of large amounts of consumer data. These data, which are gathered by many companies, are shared with subsidiaries and partners. (ii) Health care is a very sensitive sector with strict regulations. (iii) Cell phones and IoT devices have become ubiquitous and services related to the current position of the user are growing fast. If the queries that a user submits to a location-based server are not securely managed, it could be possible to infer the consumer habits of the user. (iv) The massive deployment of video cameras is a reality. On the one hand, this technology will increase security, but on the other hand, it could be seen as a privacy problem.

In some situations, information must be stored as it is and no modification is allowed (e.g. information on the taxes that a given individual should pay cannot be modified, especially when authority must control whether the individual is really paying). In this case, data encryption and access policies seem to be the only way to protect data from being stolen. On the contrary, there exist situations in which data can be slightly altered in order to protect the privacy of data owners (e.g. medical data can be modified prior to their release so that researchers are able to study the data without jeopardising the privacy of patients). In the latter case, the problem is how to modify data to minimise information loss whilst guaranteeing the privacy of the respondents.

#### 3.2.3. Inequalities in access to AAL technologies

Although AAL technologies have been presented as a solution for the global ageing population (AAL Forum, 2021) that may address existing issues in long term care (LTC), such as lack of caring personnel, lack of available places at nursing homes, by empowering individuals with greater autonomy and independence to stay at their own home (Schülke, Plischke, & Kohls, 2010), access to such technologies would be one of the most challenging ethical problems. As perceived, the current existing gap in access to new technologies in senior care provision between individuals in the same country, due to financial

capacity, as well as between high-income countries (HIC) and low and middle-income countries (LMIC) (Giacomin, Boas, Domingues, & Wachholz, 2021) may become even more significant with the widespread use of AAL technologies. Four gaps have been recognized in older adults limited access to assistive technologies in LMIC: 1) lack of awareness among their potential beneficiaries, caregivers and healthcare providers; 2) product designs are insufficiently informed by users' and caregivers' preferences and environments, and transfer of technologies to low-resource settings is limited; 3) barriers to supply include low production quality, financial constraints and scarcity of trained personnel; and 4) the existing dearth of high-quality evidence on the effectiveness of different types of technology (Tangcharoensathien, Witthayapipopsakul, Viriyathorn, & Patcharanarumol, 2018). Such disproportionate access may reflect in AAL technologies as well by enabling access only to those who can afford it, widening the existing social inequalities and affecting the social reality creating a much more significant discrepancy between the "haves" and "have nots" (Wolbring, 2008).

The question of access relates to the Rawlsian theory of distributive justice (Doorn, 2010) and distributional fairness (Cavallo, Aquilano, & Arvati, 2015; Schülke et al., 2010), impacting already existing inequalities and inclusiveness. The issue of access relates to the expenses of these technologies' affordability and research and development costs. However, the costs are with the integration capability, which depends on the technological aspects of integrating into a functional and error-free network, the two most important determinants of the market launch of AAL (Reichstein, Härting, & Häfner, 2020). Furthermore, in most countries, such technologies are not covered by the health insurance funds, and in most cases, the user will need to bear the costs.

Taking into consideration that a large majority wishes to spend most of their life in their own homes and not in nursing and care facilities, access to AAL technologies deserves much more attention already at the design stage (Duquenoy & Thimbleby, 1999).

In summary, although much is said and written about the incorporation of ethics, fundamental issues can be overlooked with respect to AAL. Some of this occurs because of the burgeoning of ethical experts and confounding of principles, some because technology advances so rapidly that ethics and indeed legal aspects can lag behind. The specific ethical challenges that AAL solutions face imply the need for robust methods, including not only compliance with legal regulations but also the search for excellence in ethics. To this aim, broader stakeholder involvement in all phases of ideation, development and market placement of an AAL solution, namely through the implementation of an ethical dialogue methodology, may prevent, mitigate or solve ethical challenges that can be harmful to the users or simply hinder user adoption (AAL Programme, 2020).

# 4. Legal aspects

#### 4.1 Data protection and design requirements of data protection law

In Europe, all the technologies that process personal data are governed by the General Data Protection Regulation (GDPR). According to the GDPR, the processing of personal data must adhere to fundamental processing principles such as lawfulness, transparency, fairness, data minimization, and purpose limitation (Article 5). Aside from adhering to the fundamental principles and ensuring an appropriate legal ground for the processing of personal data (Art. 6), data controllers (i.e., the entity in charge of determining the means and purposes of the processing) are subject to many information and documentation duties under the law, including requirements of assessing the impact of high-risk data processing practices, and ensuring the adequacy of data transfers, especially when data is being processed in countries with a less strict data protection regime than in the EU.

Data protection by design (DPbD), as enshrined as a legal norm in Article 25 of the GDPR, requires that audio-and video-based technologies for AAL are conceived with the fundamental principles set out in the GDPR in mind. Broadly speaking, DPbD aims to implement all of the principles of data protection law through technical and organizational measures that are embedded ex-ante and throughout the lifecycle of the system (Tamò-Larrieux, 2018; Bygrave, 2020). Article 25 of the GDPR states that data controllers must implement "appropriate technical and organisational measures, such as pseudonymisation, which are designed to implement data-protection principles, such as data minimisation, in an effective manner and to integrate the necessary safeguards into the processing in order to meet the requirements of this Regulation and protect the rights of data subjects." Moreover, the principle of data protection by default (DPbDf) (para. 2) requires that these measures ensure that "only personal data which are necessary for each specific purpose of the processing are processed."

While a seductive concept, DPbD has proven difficult to implement in practice (Schartum, 2016; Garcia et al., 2021; Rubinstein & Good, 2020), but specific research developing methodological approaches to DPbD in the context of AAL technologies is beginning to emerge (Colonna and Mihailidis, 2020). While Article 25 GDPR targets data controllers mainly (they are responsible for implementing measures by design and by default), this interpretation does not consider that a third party often designs technical infrastructures, but it imposes the duty to comply with the norm on the data controller as soon as the controller determines the means and purposes of processing (Bygrave, 2020). The failure to extend the requirements of DPbD to other entities along the supply chain has been criticized in the literature, as it undermines "the goal of ensuring the privacy interests are fully integrated into information system architectures" (Bygrave, 2020, p. 578). Another reason why operalizing DPbD has proven to be difficult is because the implementation of the principles of data protection law are highly context-dependent. The appropriateness of the implemented design measures depends on the circumstances of the data processing, the risk associated with the data processing, the costs of implementation of such technologies, and the current state of the art. This so-called balancing approach combined with the principles that DPbD targets create substantial leeway and discretion with respect to how design

measures should be implemented. Yet, despite these difficulties design solutions (see part 5.6.1) have been proposed in the literature that enable DPbD to be operalized. These solutions focus on implementing the principles of the regulation (lawfulness, transparency, fairness, data minimization, purpose limitation, storage limitation, accuracy, and security) via privacy-enhancing technologies and organizational measures (e.g., training, procedures).

#### 4.2 Cyber security

AAL environments (or the smart home concept on which it is based) are extremely complex environments when it comes to guaranteeing the security of their IT systems (encompassing hardware, software services and information). This is primarily due to the heterogeneity of the devices and services deployed in these environments, as well as their limited capabilities (microcontrollers with scarce resources in terms of memory and computation). For many years, IoT efforts have only been focused on achieving real interoperability (although this issue is still a work in progress), neglecting security aspects. A major turning point towards recognizing the importance of information security in the IoT was reached when the Mirai malware (Zhang et al., 2020) enabled one of the largest distributed denial of service (DDoS) attacks against a major DNS server, resulting in service disruption for providers such as Twitter, Spotify or GitHub. In 2017, the European Union Agency for Cybersecurity (ENISA) published a report about cybersecurity and related terminology (ENISA, 2017), setting forth a definition for cybersecurity. In this report, ENISA further explains that network and information security are considered subsets of cybersecurity (see further ENISA Regulation 526/2013). Further details can be found in the RFC 2828 (Shirey, 2000) about the risks and threats to asset availability, authenticity, integrity and confidentiality. Here asset is employed to refer to information, network, systems, hardware, etc.

Based on these definitions, IoT and AAL technologies share common concerns, in terms of cybersecurity. IoT objects are inherently interconnected, meaning they are exposed to the open world and, therefore, attention should be paid at preventing malicious or careless actions leading to security breaches. AAL is mainly enabled by the advances in IoT or the possibility of having interconnected devices and services gathering and processing data, in real-time, that eventually inform and support intelligent processes in decision making.

At the European level, the Directive 2016/1148<sup>1</sup> concerning measures for a high common level of security of network and information systems across the Union is intended to ensure the security of the network and information systems of operators of essential services. The Health Sector is considered one of the operators of essential services. However, the scope of this sector is broader than the services considered under the AAL domain. On the other hand, the Regulation 2019/881 on ENISA (the European Union Agency for Cybersecurity) and on information and communications technology cybersecurity

<sup>&</sup>lt;sup>1</sup> https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32016L1148 (last accessed: 07/12/2021)

certification and repealing Regulation (EU) No 526/2013 (Cybersecurity Act, also known as CSA)<sup>2</sup> aims to achieve a high level of cybersecurity, cyber resilience and trust for ICT products, services and processes. One of the main objectives of this regulation is, in fact, to lay down a framework for establishing a cybersecurity certification scheme, intended to ensure an adequate level of cybersecurity for ICT products, ICT services and ICT processes.

In accordance with this mandate, ENISA is working on the cybersecurity certification EUCC (a candidate cybersecurity certification scheme to serve as a successor to the existing SOG-IS) (ENISA, 2020). This scheme resorts to a selection of components of the catalogue of Security Functional Requirements and Security Assurance Requirements to cover the security objectives stated by the CSA in its Article 51.

The ETSI, which is a European Standards Organization, published the ETSI EN 303645 which is the European Standard that states the baseline requirements for Cybersecurity for Consumer Internet of Things (ETSI, 2020a). This standard provides a set of good practices for devising secure IoT devices and services. This standard, in compliance with the UK (UK Department for Digital, Culture, 2018), Australian (Australian Government. Department of Home Affairs, 2020) and U.S (U.S government, 2018) directives, proposes 60 provisions grouped in 13 best practices (ETSI, 2020b) that we can summarise as follows:

- No universal passwords since preloaded, shared password (e.g. unique default password implanted in the manufacturing process) of the IoT products is a security weak point.
- Implement the means to manage reports of vulnerabilities to make it easy for final users to report any failure detected in the product.
- Keep software updated to avoid IoT devices with security leaks by already reported and fixed security vulnerabilities (e.g. with security patches and/or new versions)
- Securely store sensitive security parameters (e.g. using ciphering mechanisms)
- Communicate securely (e.g. identification of parties involved, authentication, encryption, etc.)
- Minimize exposed attack interfaces including hardware interfaces and software services/interfaces (e.g. ports)
- Ensure software integrity by verifying the software (e.g. using a secure boot mechanism) and detecting unauthorized changes.

https://eur-lex.europa.eu/eli/reg/2019/881/oj (last accessed: 07/12/2021)

- Ensure that personal data are securely stored and managed using best practice cryptography mechanisms.
- Make systems resilient to outages of power and network connectivity ensuring a clean recovery in both scenarios.
- Examine system telemetry data to detect security anomalies (e.g login attempt failures)
- Make it easy for users to view and delete user data
- Make installation and maintenance of devices easy including set up, software update, etc. informing about the correctness of each procedure.
- Validate input data to detect/prevent security issues.

The objectives listed in the CSA (Article 51), the catalogue of Security Functional Requirements and Security Assurance Requirements of the Common Criteria and the EN 303645 provides an appropriate framework for ensuring the provision of secure, reliable and trusted services for AHA.

#### 4.3 Medical device regulation & health laws

The US, the EU, Canada and Australia have all enacted medical device regulations. A crucial question is whether a specific AAL technology meets the statutory definition of a "medical device" under these laws (Durkin, 2018). In general, the intended use of the technology, demonstrated through such things as labelling claims and advertising materials, is the decisive factor for whether an AAL technology can be classified as a medical device (Colonna, 2019). If an AAL device is intended to be used for medical purposes rather than to promote general health or wellness then it will likely be regulated, unless it presents very low risk (Roth, 2013). Medical purposes include things like diagnosing a disease or treating or preventing a disease whereas wellness purposes include things like promoting a healthy lifestyle (Ell, 2017).

Classifying software raises particular challenges in each jurisdiction mainly because it lacks a concrete, physical form and can have many different functionalities (Colonna, 2019). Here, it must be emphasized that the classification of particular software as a "medical device" or as a simple software has a huge impact: if the latter is the case then the more general requirements for information society services/products will apply and not the much more stringent requirements for medical devices (Mantovani & Bocos, 2017). If an AAL technology is classified as a medical device then it will be given a risk class, at least in the EU and the US. The higher the risk class, the more rigorous the scrutiny of the technology and hence, the more expensive and the more delayed it will be entering the market. Sometimes an AAL technology can be classified as higher risk in one jurisdiction than another because of the difference in the laws, which creates compliance concerns. This can happen due to the different classification rules that exist in various jurisdictions (Colonna, 2019).

Some of the legal issues mentioned above have been reflected in recent legislative developments about medical devices. In May 2017, the EU adopted a new regulation on medical devices (hereinafter the "MDR"), replacing the old legal framework, i.e., the EU medical device directive (hereinafter the "MDD"). After a transition period, the new rules of the MDR have become applicable since 26 May 2021. A particularly relevant change in the new MDR is the expansion of the definition of medical device. According to the MDD, a medical device is a device intended to be used for certain medical purposes listed in the MDD (Directive 93/42). The MDR expanded the list of medical purposes by including, among other things, the "prediction" and "prognosis" of disease (Regulation 2017/745). This may be relevant for AAL tools. If such tools are used for purposes of disease prediction and prognosis, they are more likely to be caught by the new definition of medical device under the MDR. This change is also relevant for standalone software if such software is intended for the prediction or prognosis of disease. In addition, software developers should also be aware of the more stringent classification rules introduced by the MDR. Under these rules, a stand-alone software may be classified independently from any hardware (Regulation 2017/745). Software intended to monitor physiological processes (which is especially relevant for some AAL tools) may be given a higher risk class under the MDR and thus subject to more complex conformality assessment rules before they can be placed on the EU market (Regulation 2017/745).

Developers and manufacturers of AAL devices should also be aware of laws that protect patients' rights in the health care context. If a device constitutes a medical device and is involved in clinical investigations to test if it is safe to use, patients' rights that are specific to clinical investigations must be guaranteed (Purtova et al., 2015). These rights are mainly derived from the Helsinki Declaration establishing Ethical Principles for Medical Research Involving Human Subjects and include requirements such as the documentation of risks and benefits, informed consent, measures of compensation, ethical approval before trial and so on (Helsinki Declaration).

It is also worth noting that many countries have laws concerning electronic health records, generally understood to be computer records that originate with and are controlled by doctors (such as Directive 2011/24). A question that arises is whether a given AAL technology constitutes a health record within the scope of such laws. Since a health record is conceived of as something created and used by a healthcare provider, not by an individual through a commercial AAL tool, they are likely to remain outside the realm of legal protection specific to electronic health records.

#### 4.4 General product safety regulation

One of the very first questions concerning AAL is whether we can classify it as a product, or as a service. This classification is vital as different legal norms apply to products than to services. Legislation is more developed and detailed in the case of products than services. In the EU, for example, the Product Liability Directive which lays down common rules governing liability for defective products in the EU, only applies to products (Council Directive 85/374/EEC, article 2). There are no clear criteria allowing to draw a sharp border between products and services. Usually, the most often used ones are: tangibility (products are

tangible, services not), possibility to be storage (products can be stored, services cannot), factor determining quality (production in case of products, interaction in case of services).

There are a number of legal norms applicable to the general product safety of technologies. This means that even if a product does not fall into the special category of medical devices, an individual may nevertheless be able to bring a claim for injury caused by product defects associated with things such as manufacture, design or inadequate warning. Such claims may be based on direct legislation like the EU Product Liability Directive or indirect legislation such as on a common-law action of negligence (fault-based liability) or strict product liability (no-fault liability) (Andoulsi and Wilson, 167).

There is a lack of clarity surrounding the extent to which pure software applications (i.e. those not materialized or a part of a product in any way) fall within the scope of general product safety laws. For example, it is unclear whether the EU General Product Safety Directive, which imposes a general safety requirement for any product put on the market for consumers, protects users against lifelogging software that lacks tangibility (Directive 2001/95/EC, art 2(a)). Even if AAL technologies can be considered 'products' for the purposes of the law, there are additional questions about when these 'products' may be considered 'defective'. Almost all software has errors or bugs, and as such, a question is raised concerning the level of safety that the public can legitimately expect (Emanuilov, 3). As one commentator explains: 'It is often literally impossible or commercially unreasonable to guarantee that software of any complexity contains no errors that might cause unexpected behaviour or intermittent malfunctions, so-called "bugs".'(UCITA, s 403 comment 3(a)).

Furthermore, it is challenging to clearly identify the faulty 'product,' where AAL technologies generally involve the use of a number of software packages and hardware devices and involve a variety of actors operating within a complex system (Andouls and Wilson, 171). Here, the European Commission has explained that it is difficult to identify the root cause of product failure in this context and then to allocate liability between the different actors (European Commission 2016, 21). Extending notions of strict product liability to all entities involved along the chain of distribution of an AAL technology raises concern because many suppliers of software components may have little to no idea how their software will be used deep along the supply chain (Paez and Mike La Marca, 2016).

#### 4.5 Consumer protection

Another major legal framework that applies to lifelogging technologies is consumer protection law, which generally seeks to protect buyers of goods and services from unfair or deceptive business practices. In the EU, Article 38 of the EU Charter of Fundamental Rights deals with consumer protection. It states that 'Union policies shall ensure a high level of consumer protection'. Consumer protection at the EU level is also provided by the Consumer Rights Directive, Ecommerce Directive and Unfair Commercial Practices Directive, among others. These laws seek to ensure that AAL technologies do not make false claims that a product can cure a particular illness or mislead consumers in other ways (Colonna, 2019). The scope of these laws, however, is unclear (Colonna, 2019). For example, while the

Consumer Rights Directive does not apply to healthcare services, it does apply to eHealth service providers who are not medical professionals (Purtova, Kosta and Koops, 2015, 70).

#### 4.6 Intellectual property

Recognizing and securing intellectual property rights in an AAL technology is critical for a developer (Colonna, 2019). Relevant intellectual property rights include copyrights, trademarks and patents (see e.g. Directive 2001/29 on copyright in the information society). Unlike a copyright, a patent would protect the functionality of the AAL technology and not just the underlying computer code (TRIPS Agreement). That said, in the EU it is difficult to get a patent for a software-based tool (Axhamn, 2021). When it comes to trademarks and copyrights, functionality is often a major barrier to achieving protection since these protections do not apply to useful or functional features. However, it may be possible to obtain copyright protection in features like product instructions, product packaging, and data delivered or created by the device (Berman, 2015).

AAL tools that cannot be protected by patent, copyright or trademark regimes may be otherwise protected as trade secrets (e.g., Directive 2016/943). An advantage of the trade secrets regime is that trade secrets normally do not need to be applied and filed to relevant agencies. This means that AAL tools that meet the legal requirements of relevant trade secret regimes may be offered automatic protection. However, the protection offered by trade secrets mechanisms is generally not as strong as patents and cannot prevent others from developing similar tools independently.

Just as it is important to provide the intellectual property rights of the developer, it is equally important to protect the owner of proprietary rights that may be captured by an AAL device (Colonna, 2019). For example, captured images or sounds may be protected under copyright or trademark law. As such, an AAL device would be prohibited from sharing the content with third parties.

Finally, the user of the AAL technology may be able to raise intellectual property arguments concerning the data collected by AAL devices. Here, it is unlikely that copyright will protect the data collected by the AAL technology since it is not "created" in the traditional sense as there is no artistic or literary work in the data (Kauffman & Soares, 2018). However, copyright possibility lies in database rights, "where legal protection is given based upon how the data is structured, rather than in the data itself." (Kauffman & Soares, 2018)

#### 4.7 AI Regulation

For many years now, there have been intense discussions about whether AI needs specific regulation and, if so, what this regulation should look like. For example, some have argued that existing legal frameworks and soft law are sufficient to safeguard individuals from potential adverse effects of AI systems while others have contended that specific regulation is necessary. In April 2021, the European Commission set forward a proposal to regulate AI, basically making it the first regime to declare – ethical principles are not enough – the EU needs to create binding rules which can be legally enforced (AI

Regulation, 2021). In the proposal, the Commission sets forward a risk-based approach to AI, which broadly groups AI practices into four groups: unacceptable, high risk, limited risk, and minimal risk. Where an AI system is deemed to be high-risk, then providers will have an extensive range of obligations which are set forward Chapter II and include measures like data governance, technical documentation, record-keeping, transparency, human oversight and accuracy of outputs and security. Regulators will be able to fine non-compliant actors up to €30m, or 6% of their worldwide turnover.

Biometric identification, a technique which is ostensibly applied in many visual-based AAL technologies, is a central concern of the proposed AI regulation. Currently, the proposal only expressly prohibits the use of "real-time" remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement. Outside of being used for law enforcement purposes in publicly accessible spaces, Recital 33 and Annex III(1)(a) explain that "real-time" and "post" remote biometric identification systems should be classified as high-risk. There are also specific transparency requirements for emotion-recognition systems which may be deployed in certain AAL technologies.

# 5. Societal challenges to video- and audio based monitoring

#### 5.1 Socio-political context in relation to the adoption of video- and audio based AAL

Technological artefacts are a social product, that is to say, they are thought and developed collectively, in particular spaces at particular historical moments to address socio-historical needs (Sørensen and Williams, 2002; Bijker, 2015). Devices that at first might seem outrageous later become a natural part of everyday life (Pollock & Williams, 2009), to later not be needed anymore, as the historical and social conditions that saw them emerge change (Lie & Sørensen, 1996).

The use of cameras and microphones to monitor people in need of care answers then, to a specific moment in the history of Europe when demographic imbalance (Ellingsen, 2006) makes it not possible to provide one-to-one physical care for all the people who need it. However, technological artefacts when implemented in real life, are embedded not only with other technical infrastructures but in human collectives.

Human collectives or social groups live through practices and symbolic representations (Ladislav and Stuchlik, 1983; Cassirer, 1945), therefore, technological artefacts are embedded also in ways of living and cultural understandings (Sørensen, 1996; Croll and Parkin, 1992). Technological development is invariably connected to use, as technology development is an iterative collective process between designers and users (Fleck, 1993). This poses challenges for audio-video based AAL development and adoption in a variety of ways.

First, human collectives may have previous understandings of the technology at hand, video- and audio based AAL can be related by users to activities such as surveillance practices (Lyon, 2001; Lyon, 1998). Cameras and microphones as technical affordances of these devices (Hutchby, 2001) may be understood by users as devices for security practices rather than healthcare provision. Video- and audio based AAL indeed may be used for surveillance rather than healthcare supervision unless appropriate guidelines for use are developed in adopting healthcare institutions or systems. The guidelines of use should frame a justifiable use. Guidelines of justifiable use are in addition to the considerations of the risks related to data use which were already addressed in the legal section of this document.

Another challenge for adoption at an institutional level is its incorporation and coupling with working routines. These devices are currently being implemented in care institutions around Europe, where healthcare workers are identified as primary users of the devices, and vulnerable people because of age or other types of illness are identified as end-users. Even when healthcare workers may have a positive attitude towards the use of these devices (Vuononvirta et al., 2009), their incorporation should facilitate the workflow, rather than becoming one more device whose maintenance takes away time and attention from people in need of care. Technology design and implementation that is not sensitive to the working and institutional settings and infrastructures takes away healthcare workers' time and attention from patient care to technology maintenance (Weiner and Biondich, 2006). While some

studies report that the use of Information and Communication Technologies in healthcare institutions have had a positive impact, it cannot be taken for granted that its sole implementation will reduce the total cost of the service provision because of the human resources needed to install and maintain these infrastructures (Thorpe et al., 2015).

Finally, because technologies are developed to be embedded in socio-cultural contexts, political systems and the status of power relations could also pose a challenge for adoption (Winner, 1993). Technological artefacts can be used to settle political disputes (Sørensen, 1996; Jasanoff and Kim, 2015), for example, by indirectly implementing the privatization of care services which in turn may lead to enhance social inequalities where the people who can afford it will have physical care and the ones who cannot will receive mediated or machine-based supervision (Tøndel and Seibt, 2019). Political disputes over immigration policy could also be settled through technological projects as well, as working migration for healthcare may be disregarded or not acknowledged (Cozza et al., 2019). It should be avoided statements such as "technologies are doing to society", the question is how technologies and technology policies can be used by political actors to subtly settle political disputes (Winner, 1980) in some contexts.

#### 5.2 Age in a life course approach: later-life, end-of-life, and dementia.

Sociology has a long-standing concern with prejudices and stereotypes that social groups develop towards different kinds of age groups, this practice is called ageism (Palmore, 2005). It is recognized that social institutions and policies are developed and addressed towards age cohorts also known as generations (Palmore, 1999). However studies emphasize that in order for these policies to be effective they should avoid negative ageism, that is to say, assuming characteristics for a specific age cohort based on stereotypes. In order to avoid this it is recommended to understand the process of advancing on age as a biological process lived in a social and historical context. This would mean to understand that each individual ages in a particular fashion and those generations will age in a different way because they have lived through different social experiences, for example, some having experienced wars (Riley, 1987).

In this respect, for the purpose of technology development and use, it is relevant to disentangle the age with an assumed need for technology. Video- audio-based AAL technologies are used by different age cohorts in Europe and technology developers should be aware that the utility of these devices has no direct relation with any specific age group, in principle. This would entail developing technology free of ageism, with a real exploration and understanding of the users, and not on the basis of age stereotypes. Medical and sociological literature have agreed upon to understand a life course by cycles. Until now, a life cycle has been understood as three thirds in which later-life is regarded to be the third part of that cycle, or the third age (Maddox, 1979, p. 113; Phillipson, 1998, p. 116), but there is no inherent relation between frailty and later-life (Butler, 1980; Palmore, 1999). In this respect, video-audio-based AAL development needs to consider frailty as a condition, a circumstance in the course of a life that may appear at any point of a life cycle and that may prompt the need to use these devices. In short, for the Privacy by design video-audio based AAL, it would be important to consider that frailty is a situation in

life that can be experienced regardless of age, therefore the users may have different lifestyles (Mølholt, 2021).

There is another conceptual discussion in which medical literature, sociology and anthropology have agreed upon. A life cycle ends with death, from an anthropological point of view is precisely this fact why humans create and perform cultural practices aiming to relieve the anxiety produced by the uncertain character of the end-of-life (Bauman, 1992). In other words, while later-life is identified with a third cycle in a life course, the end-of-life, while can be typically related to an extreme age over 90 (Palmore, 1999, p. 5), there are other situations that can bring a human into the end-of-life at any age, while they are young or in mid-life, terminal illness, for example.

In this respect, different philosophical schools have had differing approaches to the concepts of ethics and morality, whereas some branches of philosophy make equivalent the terms ethics and moral, others differentiate them being morality a question of ultimate ends, aiming to ultimate principles or universal laws that answer "ought to" questions (Kant, 1785/1998). In practice, the application of law cannot be separated from moral reasoning (Kerr, 1999, p. 118). Therefore, the development of video-audio-based AAL and its use has also a moral dimension, as it has been stated by scholars, the implementation and use "in a morally acceptable manner" (Hofmann, 2013, p. 389).

Cultural understandings of human collectives involve moral judgments; these are ineluctable of social life (Habermas, 1990, pp. 53-54). That is to say, social groups where video-audio-based AAL devices are to be used may question what type of end-users patients would be valid to use. Moral judgments on what is right and what is wrong are part of human groups (Habermas, 1988; Habermas, 1990) When it comes to healthcare professional environments this take relevance, as they are contexts where human lives are at stake in the everyday professional practice, meaning that death is always a possibility. Caregivers in a general European context might find it troublesome to mediate care with video- and audio AAL for patients approaching the end-of-life, as they may find it not morally acceptable to let them die alone. Caring as a practice (Ray & Turkel, 2014) is a relational activity, the activities to perform care are highly dependent on the needs of each patient. Moral judgements can be a challenge for adoption if these technologies are used for terminally ill people or people with dementia, situations where the advancement of the illness is highly unpredictable and emotional needs are not possible to meet by mediated supervision (Kochovska et al. 2020; Livingston et al., 2012).

To summarize, sociology as a discipline has resisted defining the meaning of age and prefers to use the term ageing as a processual experience pertaining to each individual in which in every stage there are biological, psychological and social needs for a human to have fulfilment in life. Social needs for wellbeing are often underestimated or completely disregarded, more is to be explored in relation to how the promotion of video-audio-based AAL may facilitate the isolation of humans and in this way decrease their wellbeing, but this topic will be addressed in a more comprehensive way in the subsection on isolation in this document.

#### 5.3 Isolation

The notion of solitude comprises at least two different concepts, loneliness and isolation. Loneliness and isolation are often confused; there are important differences between being emotionally isolated (loneliness) and being socially isolated (isolation). Loneliness is the subjective perception of being deprived of a connection with other people, of being excluded from the community, of feeling alone, but not wanting to be. Loneliness is a psychological state: one can be in the midst of lots of people and yet not feel connected to them. Loneliness reflects a dissatisfaction with social relationships that the person has or does not have. Loneliness may elicit feelings of aggression and a desire for revenge (Stevens & van Tilburg, 2000), which in turn inhibit the person's ability to acquire and develop supportive relations and reconstruct his personal network. In other words, soon or later, loneliness leads also to isolation. Isolation is the objective condition of having too few and too poor social ties, of not being in any relevant social network. Isolation is the concrete condition of living alone.

Both loneliness and isolation may be perceived in a positive way (Long, Seburn, JR, & More, 2003). One may wish to be alone (either emotionally and/or socially) in order to devote oneself to the cure of something valued more than social ties (Mordini E. de Hert P., 2010), The Benedictine motto "Beata solitudo, sola beatitudo" is an example of such a positive understanding of solitude. The idea of solitude as a positive condition is also implicit in the notion of (emotional or social) independence. Such independence suggests a capacity to survive, or even to flourish when social and/or emotional ties are weak or absent.

Despite stereotypes to the contrary, older senior citizens tend to feel isolation less stressful than younger people (Rokach, 2000). Many older senior citizens do not view living alone as particularly distressful. Some deliberately seek to be alone as an expression of independence (Mordini E, et al., 2009),. Be that as it may, any prolonged solitude, emotional or social, is likely to impair people's physical and mental conditions, as countless medical and psychological studies have shown (Cacioppo & Hawkley, 2003). Researchers have demonstrated that both isolation and loneliness tend to accelerate the rate of physiological decline with age. This is particularly true of frail older senior citizens, who are already physiologically and emotionally distressed (Gibson, 2000).

New technologies address both isolation and loneliness. Trends in family structures (e.g., declining birth rates, smaller families, single-parent families, childless, rather than extended families, etc.) and trends in mobility, which increase the physical distance between generations of a family, have resulted in increasing social isolation. On the other hand, new forms of communication – from phone calls to emails, instant messaging, Web meetings, social networking, wireless personal area networks and so on – help to alleviate, if not overcome, isolation. Here, however, the digital divide is critical. Very often, older senior citizens are precluded from using new communication tools, which could help them to overcome isolation, because of their digital illiteracy, which may stem from several factors (lack of user-friendly interfaces, appropriate education, familiarity with computer jargon, financial resources, etc.), as mentioned above.

New digital technologies can also address loneliness. Sites such as Eons, Rezoom, Multiply, Maya's Mom, Boomj and Boomertown are all examples of websites aimed at senior citizens. Although it is unlikely most older senior citizens could fully exploit these new social media, the second generation of the World Wide Web (Web 2.0) may increase social networking and interaction among older seniors. In the near future, virtual friends may play an important role in the lives of senior citizens. Robotic pets for senior citizens are already a reality and they have proven to be as useful as real animals for senior citizens suffering from dementia (Sakairi, 2004). Japanese hospitals and senior citizens' homes have been experimenting with robot therapy sessions (Tamura & al., 2004). Some scientists believe robots are the answer to caring for ageing societies where the young might otherwise be overwhelmed by the surging population of senior citizens. These robots look like puppies and have built-in sensors enabling them to respond to both contact and a user's voice, with either motion or speech. At the same time, these robots can be used to monitor the safety of older senior citizens because the interaction between them and their owners can be recorded and accessed remotely. A few robot companions are already in use – such as the "dogs" AIBO and SPARKY – and many others are in development.

The new communication technologies and robot companions do, however, raise ethical issues, ranging from privacy issues (older senior citizens are less likely to be able to defend themselves from informational intrusiveness) to more substantial objections (are we giving machines and virtual contacts to people who ask for warm human contacts?). Moreover, new communication technologies may diminish the interest in going outside the home, which would only compound the reduction in face-to-face contacts. All these issues could be categorised under the common heading of threats to the notion of self-respect. Being somehow forced to consider digital media and inanimate objects as the comprehensive universe of one's own social life may become humiliating and may hurt self-respect. In other words, the issue at stake is that of emotional dignity, as Badcott proposes to call situations that could elicit profound feelings of personal humiliation (Badcott, 2003).

#### 5.4 Gender and vulnerability

Although age can be a vulnerability factor and thus older adults are often considered a vulnerable population, structural ageism is a form of discrimination. Systematic stereotyping that stems from ageist attitudes, actions or language in laws, policies, practices or culture can be encountered in the legal system, the media, health care provision and the economy, among many other areas. Therefore, ageing is not, as such and by itself, considered a vulnerability factor in ethics since it is a process that can be developed in a variety of different ways and is not always associated with particular experiences of vulnerability (AGE, 2016b).

Bracken-Roche et al. (2017, pp. 2) state that the definition of vulnerability must be "comprehensive enough to capture those in need of additional protections, without overburdening participants for whom protection beyond the norm is unnecessary". In the legal framework, a person with a vulnerability is usually described as someone who is at a higher risk of harm than others. The statutory term 'vulnerable adult' describes people over the age of eighteen, towards whom the state has specific

safeguarding responsibilities, such as: living in residential or sheltered accommodation; receiving certain types of health and social care; receiving certain types of welfare support; being detained in lawful custody (SRA, 2016).

In general, older, impaired or frail people would like to live at their own homes as long as they can. Women tend to live longer than men do and women live longer with disabling conditions (Gender statistics - Statistics Explained<sup>3</sup> (europa.eu)). Women are also carrying the bulk of informal care that men as well as women receive. Additionally, most formal caregivers in home care or long term care are women. Audio and video monitoring systems will therefore involve and affect more women than men and therefore a special focus on women needs and demands is needed. GoodBrother will include the gender issue in the guidelines and publications.

The statutory definition of vulnerability is usually very specific, but other aspects may contribute to consider that a person might be vulnerable, such as a personal characteristic, for example, having low income or a low level of literacy. These factors (Figure 2) are the main elements of one of the biggest injustices of the 21st century: unequal access to the internet and ICT's due to poverty or lack of education and skills.

CHARACTERISTICS			SITUATION		
Age	Low income	Inexperience	Threat of harm	Victim of crime or accident	
Low literacy	Learning disabilities	Cultural barriers	Bereavement	Loss of income	
Physical disabilities	Mental health issues	English as a second language	Relationship breakdown	Loss of employmen	
Health problems	Location	Being a carer	Having recently left care	Threat of deportation	
Lack of internet access	Lone parent	Living alone or in poor living conditions	Concern over access to children	Concern over child welfare	

Figure 2. Vulnerability factors (retrieved from (SRA, 2016))

https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Gender statistics (last accessed: 07/12/2021)

#### 5.5 Social inequalities and spatial considerations

From research on digital inequality and digital divides more broadly, we know that access to digital technology, digital skills, and benefits from digital technology are unevenly distributed within and between societies (Lutz, 2019; Robinson et al.,2015, 2020a, 2020b; Van Dijk, 2020). Privileged individuals who possess disproportionate economic capital (e.g., income, wealth), cultural capital (e.g., education, family background), social capital (e.g., being part of elite networks), or who are otherwise advantaged (e.g., in terms of gender, ethnicity, disability, age, or caste) tend to fare better. They have higher quality access to digital technology. For example, they often have more modern and cutting edge software and hardware at hand. Underprivileged individuals, by contrast, rely disproportionately on mobile access, which comes with substantial downsides in terms of functionality, openness and productivity (Napoli & Obar, 2014). Privileged individuals also tend to have better digital skills than disadvantaged ones, with education and age playing a particular role (Van Deursen & Van Dijk, 2011, 2015). Finally, capital-enhancing uses (i.e., digital technology uses that improve life chances) are more widespread among privileged citizens (Zillien & Hargittai, 2009). Thus, the benefits from digital technology accrue disproportionally to those who are already advantaged in society (Blank & Lutz, 2018; Lutz, 2019; Van Deursen & Helsper, 2015).

AAL technology comes with particular challenges in terms of digital inclusion as it is deployed on and with user groups that have been shown to be on the "wrong" side of the digital divide in terms of several social categories such as age, gender, and disability. Such low levels of access, skills and familiarity with digital technology more generally. Especially if the technology is employed in rural settings and or in regions of countries with low internet/digital technology penetration among the target group, meaning that there might be substantial barriers and resistance to adoption as well as misunderstandings about the technological capabilities and limitations. In addition, there are considerable divides not only between the target group and the general population but in particular between the target group and those developing and deploying AAL systems. In other words, the power asymmetries that exist between different stakeholders in the AAL ecosystem are potentially more severe and extreme than with other digital technology (e.g., smart speakers, social media). This could lead to governance challenges, ethical questions and potential misuse of the technology. Thus, sufficient safeguards need to be in place to make this a truly inclusive technology, ideally safeguards that reduce the aforementioned power asymmetries. Beyond design-related strategies (see next chapter) and legal protection (see chapter 4), strengthening digital literacy and user self-determination should thus be an important consideration. Literacy initiatives should be holistic and not only focus on technical/operational skills but also on contextual aspects that connect to the lifeworlds of the (end-)users.

In relation to the urban and rural spatial contexts, its development should consider the differences in these settings, the latter with characteristics such as bigger houses and longer distances to physically reach the people in need of care (Jordan et al., 2004; Petersson, 2011). Human groups have also other-than-human elements in life situations and ways of living, elderly or fragile people living at home may

share their spaces with other people or companion animals (Erickson, 1985; Chur-Hansen et al., 2009; Baun and McCabe, 2000), that is an additional challenge in terms of behavior prediction and development of video-audio based AAL technology.

#### 5.6 Participatory design and socially driven innovation as opportunities

#### 5.6.1 Participatory design

A small number of prior studies in computing research looked at situating design scholarship in the Privacy by Design context (PbD) and developed specific methods and taxonomies to involve various stakeholders in a privacy-inclusive design process, for example, participatory design and co-design (e.g., Wong et al., 2019). Other scholars conceptualized as well design instruments like toolkits and patterns to aid transfer knowledge between design research and design practice (e.g., Luger et al., 2015). For example, Yao et al. (2019) conducted a co-design study to explore user-centred privacy designs for smart homes. Instead of designing privacy tools only by experts, the authors engaged various groups of participants with diverse backgrounds and levels of experiences to explore how people desired to protect their privacy in the domestic context.

Privacy, with its associated concerns of continuous data collection, sharing, and misuse, has been identified as the main roadblock for adoption in smart homes. Authors such as (Jacobsson and Davidsson, 2015) have distinguished six key design factors to enhance privacy mechanisms for smart homes: (1) data transparency and control; (2) security; (3) safety; (4) usability and user experience; (5) system intelligence; and (6) system modality. However, the authors also point out that power dynamics and social relationships lead to varying privacy norms. By discussing the intricacies of privacy in the context of home, the authors posed an open-ended question for designers: "Whose privacy should be protected and who should make the decision?"

Driven by the convoluted legal rules and incumbent privacy regulations when it comes to personal data protection, Luger et al. (2015) created and field-tested a privacy-focused design toolkit to be employed at the early stages of a design process. The solution called ideation aimed to tackle hindrances in the design of interactive systems, which need to process and store personal user data, as well as to highlight emergent European data protection issues and associated. The toolkit, a collection of GDPR-inspired cards, is geared toward design practitioners and researchers to conceptualize operationalizable heuristics and development guidelines, which can be used in system design. During deployment of the toolkit with several groups of design practitioners they concluded that despite an emergent call for accountability in design, the data protection regulation is merely viewed as a compliance issue. They concluded that, while wishing to protect users, designers struggle to engage with regulations. The authors, ultimately, called for the development of translational resources to draw designers into the coproduction of meaningful privacy heuristics by implementing human-centred design approaches to regulation (Colusso et al., 2017).

## 5.6.2 Socially driven innovations for an aged population

Socially driven innovations, with its shortened name social innovations, are social and technical solutions combined to address social problems. According to Robin Murray, Julie Caulier-Grice, and Geoff Mulgan (2010), a social innovation may be characterised as novel strategies, ideas, goods, services, and organisational forms targeted at meeting unmet needs, particularly those at the periphery of different sectors of the social system. These innovations are defined by their social aims, the social methods by which they are accomplished, and the fact that they result in the formation of new social relationships and collaborative links. These innovations broaden the scope of public activity by improving social capital and promoting an ethical entrepreneurial culture.

Liangrong Zu (2013) defines social innovation as the development of new solutions to social problems that are more effective, efficient, and sustainable than previous solutions and that are created with social goals in mind rather than for the benefit of private individuals. According to Zu, social innovations are often connected with social entrepreneurship, but they may also be defined as innovation in public policy, governance, inside government, inside for-profit businesses, or within the third sector. However, social innovations are more often created at the nexus of many sectors via various hybrid and cross-sectoral collaboration types (Felix & Klimczuk, 2021).

According to Rolf G. Heinze and Gerhard Naegele (2012), social innovation is critical in ageing populations for at least seven reasons. These include the following: (1) a modification of working conditions to demographic change; (2) the need to promote the workability and employability of older employees; (3) the need to alter health care solutions and long-term care systems; (4) the need to adjust housing conditions to enhance independent living; (5) the need to develop lifelong learning systems; and (7) the need for a diversified stakeholder and policy mix. Additionally, the review by Andrzej Klimczuk and Łukasz Tomczyk (2020) identifies at least five themes in studies on social innovation for older populations: (1) critical evaluation of older people's social image; (2) innovation and quality of life; (3) innovation in the context of supporting active and healthy ageing; (4) transformation and modernisation of care services; and (5) development of crucial competencies and creativity of older people. All of these considerations point to the essential need for a more cross-sectoral and multisectoral approach to the challenges of ageing societies.

Heinze and Naegele (2012) use the idea of ambient assisted living (AAL), also known in the literature as networked living or smart living, to highlight solutions developed for older individuals as an example of social innovation. These goods and services include the use of mobile devices such as smartphones and tablets, which may run software that encourages a healthy lifestyle or enable users to easily assess the nutritional content of goods adapted to the senior diet. Another example is serious games, which may influence or mobilise individuals to modify their behaviour via the inclusion of tools for health prevention, promotion, and rehabilitation. For instance, Nintendo's "Brain Age" initial edition has sold nineteen million copies worldwide. The objective of this game is to exercise the brain with mathematics, arts and letters, and Sudoku challenges. Thus, cognitive-enhancing activities can be presented in a motivating and engaging manner (Sixsmith, 2013).

Social innovations are also seen as a subset of the social or solidarity economy. However, a significant portion of these solutions is developed in sectors connected to public services and as part of corporate social responsibility (CSR) or creating shared value (CSV) programmes (Felix & Klimczuk, 2021). Some researchers argue that the notion of social innovation originated in the writings of classical sociologists such as Max Weber and Emile Durkheim, as well as economists Karl Marx and Joseph A. Schumpeter (see Jenson & Harrisson, 2013). Weber, for example, tried to establish a link between social order and creativity, which may aid in changing people's negative actions. Durkheim examined the effect of technological advancement on the changing social division of labour. Marx called attention to the changing patterns of uneven power and income distribution. By contrast, Schumpeter emphasised the critical role of entrepreneurs as change agents as a driver of economic progress.

Only in the 1990s did the notion of social innovation resurface, this time in the context of seeking answers to the negative consequences of economic transformation brought about by the spread of information and communication technologies (ICTs), like the digital divide and climate change. The financial crisis of 2007–08 heightened interest in creating social innovations to resolve the fiscal deficit issue. President Barack Obama of the United States of America (US) created an Office of Social Innovation and Civic Participation in the White House in 2008 (OSICP, 2021). While the European Commission first financed research on social innovation in the 1990s, the European Commission supported the Social Innovation Europe programme in 2011 to identify and implement innovative social solutions to social challenges (European Commission, 2021). However, it is necessary to emphasise that many modern social innovations originate in the Global South and take the shape of more informal efforts and less institutionalised forms.

Social innovations are inextricably linked to the three economic systems that intend to contribute to the well-being of ageing people: the silver economy, the creative economy, and the social and solidarity economy. These economic systems may be coupled with new theories of change that emphasise incentives rather than disincentives, that prioritise encouraging rather than discouraging desirable behaviours (so-called "push-pull" models and "urban acupuncture") (Lerner, 2014; Zu, 2013). Additionally, social innovations may be seen as a source of new development due to their considerable benefit. Numerous social breakthroughs are built on the use of universal access to ICTs and information (through Creative Commons and open access policies, for example), which has never occurred in the past.

In her study, Halima Khan (2013) shows a need to investigate at least four areas of social innovation for older adults and ageing societies, resulting in systemic change when combined. The first area is product and service innovation, which encompasses new technology such as ICTs and genomics and new methods for gathering statistical data on health and social care and online consultations. The second area of innovation is market development, which encompasses novel business models, organisational structures, and new markets. We can assume that this field includes social enterprises serving older adults and segments of the silver market such as informal care, self-help groups, intergenerational assistance activities (such as do-it-yourself, shopping, and cleaning), personal health budgets, and new

public procurement tools. The third area of innovation is political leadership, which encompasses new laws, legislation, and infrastructure and coordination of health and social services and public involvement. The fourth element, dubbed cultural innovation, encompasses new social norms, behavioural change, and the potential for the emergence of social movements that advocate for systemic change, for example, under the banner of a "society for all ages" or "age-friendly cities and communities." These domains may be merged, as recommended by mixed economy theories of welfare and governance, via collaborations of diverse entities and stakeholders from diverse sectors and economic systems. In summary, in order to tackle the social challenges surrounding the development and use of video-audio based solutions, it will be necessary to create community-based projects aimed to foster age-friendly societies, that go hand in hand with privacy by design technologies.

## **Conclusions**

The global population is ageing. Given that age is the primary risk factor for many diseases and coupled with the concomitant advances in healthcare technologies and modern medicine permitting individuals to live longer with chronic conditions, the introduction of AAL is inescapable. Whilst AAL technologies offer hope in addressing economic challenges to healthcare and the prospect of prolonging independent living thereby improving life quality, the underlying ethical concerns and legal issues cannot be overlooked.

It could be argued that as all technologies need to pass certain regulatory processes, the legal aspects pertinent to AAL have been addressed. The relevant regulations such as the GDPR cover collection, use, processing and sharing of personal data. Consumer protection laws deal with the safety of components used in these technologies. Yet as technologies advance, the laws must stay abreast of such progress. A framework for which further research can be performed is presented. It concludes that AAL technologies require a legal system that both promotes their development while at the same time safeguards against risks posed by the technology. Here, it is clear that the law is failing to provide a speed of adoption commensurate with the development of the technology. Not only are there serious uncertainties in the application of existing legal frameworks to AAL technologies but there is also a lack of appropriate legal restrictions and precautions to control some of the risks posed by lifelogging technologies. It is recommended that a more holistic approach to the regulation of AAL technologies is taken, one that integrates deeper technological and international perspectives than the current legal framework represents.

The more nebulous aspects of AAL application lie with the ethics of their implementation. AAL technologies are by their nature intrusive. They can also be deemed to be overprotective which can subtly erode respect for autonomy. The benefits brought by AAL need to be carefully weighed against the risks and the risk/benefit ratio assessed on a regular basis as individuals age and applications of technology change. An ethical approach and a thorough understanding of all ethical principles relevant to surveillance/monitoring architectures are essential. AAL poses many ethical challenges, raising questions which will affect immediate acceptance and long-term usage. Furthermore, ethical issues emerge from social inequalities and their potential exacerbation by AAL, accentuating the existing access gap between high-income countries (HIC) and low and middle-income countries (LMIC). Ethics should be incorporated at the AAL design stage taking all of these aspects into account and evaluating (i) beneficence, (ii) non-maleficence i.e., a risk/benefit analysis (iii) respect for autonomy, and (iv) protection of confidential information and data that may reveal personal and sensitive attributes

The social issues focus on the impact of AAL technologies before and after their adoption. Some are rooted in the collective understandings of the technology at hand, whereby users can relate audio-video based AAL to activities such as surveillance practices. One of the prominent social and design challenges will be facilitation of the workflow and avoiding the sense of additional technological burden. Taking care of that will directly impact institutional and individual adoption of AAL. Future AAL technologies

need to consider all aspects of equality such as gender, race, age and social disadvantages and avoid increasing loneliness and isolation among, e.g. older and frail people. Finally, the current power asymmetries between the target and general populations should not be underestimated nor should the discrepant needs and motivations of the target group and those developing and deploying AAL systems. These differences could lead to governance challenges, serious ethical questions, and potential misuse of the technology.

Whilst AAL technologies provide promising solutions for the health and social care challenges, they are not exempt from ethical, legal and social issues (ELSI). A set of ELSI guidelines is needed to integrate these factors at the research and development stage.

## References

AAL Forum. (2021, July 18). The global ageing megatrend: crisis or opportunity? - AAL Forum. Retrieved from <a href="https://www.aalforum.eu/global-ageing-megatrend-crisis-opportunity/">https://www.aalforum.eu/global-ageing-megatrend-crisis-opportunity/</a> (last accessed: 07/12/2021)

AAL Programme. (2020). *AAL Guidelines for Ethics, Data Privacy and Security*. Retrieved from <a href="http://www.aal-europe.eu/wp-content/uploads/2020/08/AAL-guidelines-for-ethics-final-V2.pdf">http://www.aal-europe.eu/wp-content/uploads/2020/08/AAL-guidelines-for-ethics-final-V2.pdf</a> (last accessed: 07/12/2021)

AGE Platform Europe. (2016a) Glossary & Acronyms. (2016). *Glossary & Acronyms*. Retrieved from: <a href="https://www.age-platform.eu/glossary/active-and-assisted-living-programme-aal">https://www.age-platform.eu/glossary/active-and-assisted-living-programme-aal</a> (last accessed: 07/12/2021)

AGE Platform Europe. (2016b). *AGE Platform Europe Position on Structural Ageism*. Retrieved from: https://www.age-

platform.eu/sites/default/files/AGE IntergenerationalSolidarity Position on Structural Ageism2016. pdf (last accessed: 07/12/2021)

Akrich, M. (1992) The de-scription of technical objects. In W. Bijker & J. Law (Eds.) *Shaping Technology/Building Society: Studies in Sociotechnical Change*. Cambridge, Mass.: MIT Press.

Andoulsi, I. & Wilson, P. (2012). Understanding Liability in eHealth: Towards Greater Clarity at European Union Level. In C. George, D. Whitehouse & P. Duquenoy (Eds.) *eHealth: Legal, Ethical and Governance Challenges*. Cham: Springer.

Axhamn, J. (forthcoming, 2021). Transparency in Automated Algorithmic Decision-Making: Perspectives from the Fields of Intellectual Property and Trade Secret law, In L. Colonna & S. Greensteineds (Eds.) 2020-2021 Nordic Yearbook - Law in the Era of Artificial Intelligence. The Swedish Law and Informatics Research Institute (IRI).

Australian Government. (2020). *Code of Practice: Securing the Internet of Things for Consumers*. Technical Report. Department of Home Affairs..

Badcott, D. (2003). The basis and relevance of emotional dignity. *Medicine, Health Care and Philosophy,* 6(2), 123-131.

Barta, K., and Neff, G. (2016). Technologies for Sharing: lessons from Quantified Self about the political economy of platforms. *Information, Communication & Society*, 19(4), 518-531.

Bauman, Z. (1992). Mortality, immortality and other life strategies. Stanford: Stanford University Press.

Baun, M. M., & McCabe, B. W. (2000). The role animals play in enhancing quality of life for the elderly. In A. H. Fine (Ed.), *Handbook on animal-assisted therapy: Theoretical foundations and guidelines for practice* (pp. 237–251). Academic Press.

Beauchamp, T.L. & Childress, J.F. (2019). Principles of Biomedical Ethics. New York, NY:Oxford University Press.

Becker, F. and Becker, S. (2008) Young Adult Carers in the UK: Experiences, Needs and Services for Carers aged 16-24. London: The Princess Royal Trust for Carers.

Berman, R. (2015). *Wearable technology: Brand Implications and Strategies*. Retrieved from <a href="http://articles-jmbm.lawblogger.net/2015/07/18/thomson-reuters-wearable-technology-brand-implications-strategies/">http://articles-jmbm.lawblogger.net/2015/07/18/thomson-reuters-wearable-technology-brand-implications-strategies/</a> (last accessed: 07/12/2021)

Bertino, E. (2021). Zero Trust Architecture: Does It Help?. *IEEE Security & Privacy*, 19(5), 95-96. doi: 10.1109/MSEC.2021.3091195.

Bijker, W. (2015) Social construction of technology. *International Encyclopedia of the Social & Behavioral Sciences* (2nd edition, pp. 135-140). Amsterdam: Elsevier. 135-140.

Blank, G., & Lutz, C. (2018). Benefits and harms from Internet use: A differentiated analysis of Great Britain. *New media & society*, *20*(2), 618-640.

Bracken-Roche, D. et al., (2017). The Concept of 'Vulnerability' in Research Ethics: An In-Depth Analysis of Policies and Guidelines. *Health Res Policy Syst.* 15(1), 8.

Burgoon, J. K. (1982). Privacy and communication. *Annals of the International Communication Association*, *6*(1), 206-249.

Butler, R. N. (1980). Ageism: A foreword. Journal of social issues, 36(2), 8-11.

Bygrave, L. A. (2020). Article 25 data protection by design and by default. In C. Kuner, L. A. Bygrave, C. Docksey & L. Drechsler (Eds.) *The EU General Data Protection Regulation (GDPR)*. Oxford: Oxford University Press.

Cacioppo, J., & Hawkley, L. (2003). Social Isolation and Health, with an Emphasis on Underlying Mechanisms. *Perspectives in Biology and Medicine*, 46(3), S39-S52.

Case T-8/89 DSM NV v Commission of the European Communities EU:T:1991:76

Case 85/76 Hoffmann-La Roche EU:C:1979:36.

Cases C-503/13 and C-504/13, Boston Scientific Medizintechnik GmbH v AOK SachsenAnhalt — Die Gesundheitskasse and Betriebskrankenkasse RWE [2015] ECLI:EU:C:2015:148.

Cassirer, E. (1945), An Essay on Man. New York: Yale University Press.

Cavallo, F., Aquilano, M., & Arvati, M. (2015). An ambient assisted living approach in designing domiciliary services combined with innovative technologies for patients with Alzheimer's disease: A case study. *American Journal of Alzheimer's Disease and Other Dementias*, 30(1), 69–77.

Centrum för rättvisa v. Sweden, No. 35252/08, ECtHR (Grand Chamber), 25 May 2021

Chur-Hansen, A., Winefield, H. R. & Beckwith, M, (2009). Companion animals for elderly women: The importance of attachment. *Qualitative Research in Psychology*, 6(4), 281-293.

Cicirelli, G., Marani, R., Petitti, A., Milella, A., & D'Orazio, T. (2021). Ambient Assisted Living: A Review of Technologies, Methodologies and Future Perspectives for Healthy Aging of Population. *Sensors*, *21*(10), 3549.

Colonna, L. (2019). Legal and regulatory challenges to utilizing lifelogging technologies for the frail and sick. *International Journal of Law and Information Technology*, 27(1), 50–74.

Colonna, L. and Mihailidis, A. A (2020). Methodological Approach to Privacy by Design within the Context of Lifelogging Technologies, *Rutgers Computer & Technology Law Journal*, 16, 1-52.

Colusso, L., Bennett, C. L., Hsieh, G., & Munson, S. A. (2017, June). Translational resources: Reducing the gap between academic research and HCI practice. In Proceedings of the 2017 Conference on Designing Interactive Systems, 957-968.

Commission Proposal for a Regulation of the European Parliament and of the Council Laying Down Harmonised Rules on Artificial Intelligence (Artificial Intelligence Act) and Amending Certain Union Legislative Acts, COM (2021) 206 final (Apr. 21, 2021).

Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, OJ.

Courtney, K. L., Demiris, G., & Hensel, B. K. (2007). Obtrusiveness of information-based assistive technologies as perceived by older adults in residential care facilities: A secondary analysis. Medical Informatics and the Internet in Medicine, 32, 241–249. doi:10.1080/14639230701447735.

Courtney, K. L., Demiris, G., Rantz, M., & Skubic, M. (2008). Needing smart home technologies: The perspectives of older adults in continuing care retirement communities. Informatics in Primary Care, 16, 195–201.

Cozza, M., Crevani, L., Hallin, A., et al. (2019). Future ageing: Welfare technology practices for our future older selves. Futures, 109, 117-129.

Croll, E., & Parkin, D. (Eds.). (1992). Bush Base, Forest Farm: Culture, Environment, and Development (1st ed., pp.23-48). Routledge. https://doi.org/10.4324/9780203036129.

Crystal, S., Siegel, M.J.(2009). Population Aging and Health Care Policy in Cross-National Perspective. In the Uhlenberg P. (Ed.) International Handbook of Population Aging (pp. 607-630). Dordrecht; Springer.

Dantas, C., Hoogendoorn, P., Kryspin-Exner, I., Stuckelberger, A. & Tijink, D. (2019). AAL Guidelines for Ethics, Data Privacy and Security. Technical Report. Active and Assisted Living Programme.

De Maeyer, C. (2017). Can Quantified Self Be a Facilitating Technology to Help Older Adults Stay Longer in Their Home?. In H. Marston, S. Freeman, C. Musselwhite (Eds.) *Mobile e-Health* (pp. 71-93). Cham: Springer.

Directive 2011/24. European Parliament, Council of the European Union. The application of patients' rights in cross-border healthcare. OJ L88/45

Directive 2016/943. European Parliament, Council of the European Union. The protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure. OJ L 157, 15.6.2016

Directive 85/374/EEC, OJ L210/29 (Product Liability Directive).

Directive 93/42. Medical devices. Council of the European Union. OJ L 169, 12.7.1993

Directive 2001/95/EC, OJ L11/4 (General Product Safety Directive).

Directive 2001/29/EC of the European Parliament and of the Council of 22 May 2001 on the harmonisation of certain aspects of copyright and related rights in the information society, OJ L 167 (2001).

Directive 2005/29/, OJ L149/22 (Unfair Commercial Practices Directive).

Donnelly, M. and White, F. (2019). Digital Content and Consumer Protection: An Empirical Study of Supplier Compliance with Consumer Information Obligations. *The Computer Law and Security Report*, 35(6), 105343.

Doorn, N. (2010). A procedural approach to distributing responsibilities in R&D networks. *Poiesis & Praxis*, 7(3), 169–188.

Durkin, T. M. (2018). Health Data Privacy and Security in the Age of Wearable Tech: Privacy and Security Concerns for the NFLPA and WHOOP. *Journal of High Technology Law*, 19(1.5), 279–299.

Duquenoy, P. & Thimbleby, H. (1999). Justice and Design. In *Human-Computer Interaction INTERACT '99: IFIP TC13 International Conference on Human-Computer Interaction, Edinburgh, UK, 30th August-3rd September 1999* (pp. 281–286). Edinburgh.

Ell, E. (2017). *Medical Devices vs. Wellness Devices*. Retrieved from <a href="https://www.nectarpd.com/blog/medical-devices-vs-wellness-devices">https://www.nectarpd.com/blog/medical-devices-vs-wellness-devices</a> (last accessed: 07/12/2021)

Emanuilov, I. (2017, *November*). Autonomous Systems in Aviation: Between Product Liability and Innovation' (Seventh SESAR Innovation Days, Belgrade, Serbia) Retrieved from <a href="https://www.sesarju.eu/sites/default/files/documents/sid/2017/SIDs 2017 paper 29.pdf">https://www.sesarju.eu/sites/default/files/documents/sid/2017/SIDs 2017 paper 29.pdf</a> (last accessed: 07/12/2021)

ENISA (2017). *ENISA overview of cybersecurity and related terminology*. Retrieved from <a href="https://www.enisa.europa.eu/publications/enisa-position-papers-and-opinions/enisa-overview-of-cybersecurity-and-related-terminology">https://www.enisa.europa.eu/publications/enisa-position-papers-and-opinions/enisa-overview-of-cybersecurity-and-related-terminology</a> (last accessed: 07/12/2021)

ENISA (2019). *Good Practices for Security of IoT. Secure Software Development Lifecycle*. Retrieved from <a href="https://www.enisa.europa.eu/publications/good-practices-for-security-of-iot-1">https://www.enisa.europa.eu/publications/good-practices-for-security-of-iot-1</a> (last accessed: 07/12/2021)

ENISA (2020). *Cybersecurity Certification: EUCC Candidate Scheme*. Technical Report. Retrieved from <a href="https://www.enisa.europa.eu/publications/cybersecurity-certification-eucc-candidate-scheme">https://www.enisa.europa.eu/publications/cybersecurity-certification-eucc-candidate-scheme</a> (last accessed: 07/12/2021)

Erickson, R. (1985). Companion animals and the elderly. *Geriatric nursing*, 6(2), 92-96.

ETSI (2020a). *Cybersecurity Certification: EUCC Candidate Scheme*. Technical Report. European Telecommunications Standards Institute.

ETSI (2020b). ETSI EN 303645 final draft: Cyber Security for Consumer Internet of Things: Baseline requirements.

European Commission, 'Commission Staff Working Document on the existing EU legal framework applicable to lifestyle and wellbeing apps (EU Framework Working Document)' COM (2014) 219 final.

European Commission. (2016, April) *Commission Staff Working Document, Advancing the Internet of Things in Europe*. Retrieved from <a href="https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52016SC0110&from=EN">https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52016SC0110&from=EN</a> (last accessed: 07/12/2021)

European Commission. 2021. Social Innovation Europe. Retrieved from <a href="https://webgate.ec.europa.eu/socialinnovationeurope/">https://webgate.ec.europa.eu/socialinnovationeurope/</a> (last accessed: 07/12/2021)

European Parliament (2020). Resolution of 20 October 2020 with recommendations to the Commission on a civil liability regime for artificial intelligence (N. 8). Retrieved from <a href="https://www.europarl.europa.eu/doceo/document/A-9-2020-0178">https://www.europarl.europa.eu/doceo/document/A-9-2020-0178</a> EN.html (last accessed: 07/12/2021)

Felix, J., & Klimczuk, A. (2021). Social Entrepreneurship and Social Innovation in Aging. In D. Gu & M. E. Dupre (Eds.), *Encyclopedia of Gerontology and Population Aging: Living Edition* (pp. 1–8). Cham: Springer International Publishing.

Fleck, J. (1993). Configurations: Crystallizing contingency. Int. J. Hum. Factors Manuf. 3: 15-36.

Florez-Revuelta, F., & Chaaraoui, A. A. (2016). Active and Assisted Living: Technologies and Applications.

Fosch-Villaronga, E. & Hadassah Drukarch (2021) On Healthcare Robots: Concepts, definitions, and considerations for healthcare robot governance. ArXiv pre-print, 1-87, https://arxiv.org/abs/2106.03468

Fried, C. (1968). Privacy: [A moral analysis]. In: F. Schoeman (Ed.), Philosophical dimensions of privacy: *An anthology* (pp.203-222.). Cambridge: Cambridge University Press.

Gartner. (July, 2021). *Hype Cycle for Privacy*. Retrieved from <a href="https://infocert.digital/2021-gartner-hype-cycle-for-privacy/">https://infocert.digital/2021-gartner-hype-cycle-for-privacy/</a> (last accessed: 07/12/2021)

Giacomin, K. C., Boas, P. J. F. V., Domingues, M. A. R. da C., & Wachholz, P. A. (2021). Caring throughout life: peculiarities of long-term care for public policies without ageism. *Geriatrics, Gerontology and Aging*, 15, 1–3.

Habermas, J. (1988). Morality and ethical life: Does Hegel's critique of Kant apply to discourse ethics. *Nw. UL Rev.*, 83, 38.

Habermas, J. (1990). Moral consciousness and communicative action. MIT press.

Heinze, R. G., & Naegele, G. (2012). Social Innovations in Ageing Societies. In H.-W. Franz, J. Hochgerner, & J. Howaldt (Eds.), *Challenge Social Innovation* (pp. 153–167). Berlin, Heidelberg: Springer.

Helsinki Declaration. (1964). World Medical Assembly Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects adopted by the 18th World Medical Assembly in 1964, as last amended in 2013. Retrieved from <a href="https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/">https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/</a> (last accessed: 07/12/2021)

Hensel, B. K., Demiris, G., & Courtney, K. L. (2006). Defining obtrusiveness in home telehealth technologies: A conceptual framework. Journal of the American Medical Informatics Association, 13, 428–431. doi:10.1197/jamia.M2026.

Hofmann, B. (2013). Ethical challenges with welfare technology: a review of the literature. Science and engineering ethics, 19(2), 389-406.

Horder, J. (1997). Gross Negligence and Criminal Culpability. University of Toronto Law Journal, 47, 495.

Hutchby, I. (2001), Technologies, texts and affordances. Sociology, 35(2), 441-456.

Ienca, M. and Fosch-Villaronga, E. (2019) Privacy and Security Issues in Assistive Technologies for Dementia. In: Jotterand F., Ienca M., Wangmo T. and Elger B. (2019) Assistive Technologies for Dementia Care (pp. 221-239). Oxford University Press.

Gibson, H. (2000). Loneliness in later life. New York, NY: St. Martin's Press.

Inness, J.C. 1996. Privacy, Intimacy, and Isolation. Oxford: Oxford University Press.

Jacobsson, A., & Davidsson, P. (2015, December). Towards a model of privacy and security for smart homes. In 2015 IEEE 2nd World Forum on Internet of Things (WF-IoT)(pp. 727-732).

Jasanoff, S. & Kim S. H. (2015). Dreamscapes of modernity: sociotechnical imaginaries and the fabrication of power. Chicago, London: The University of Chicago Press.

Jenson, J., & Harrisson, D. (2013). Social Innovation Research in the European Union: Approaches, Findings and Future Directions: Policy Review. Luxembourg: Publications Office of the European Union.

Jordan, H., Roderick, P., Martin, D., et al. (2004). Distance, rurality and the need for care: access to health services in South West England. International Journal of Health Geographics, 3(1), 21.

Kauffman, M. E., & Soares, M. N. (2018). New technologies and data ownership: Wearables and the erosion of personality rights. Revista Direitos Sociais e Políticas Públicas (UNIFAFIBE), 6(1), 512–538. https://doi.org/10.25245/rdspp.v6i1.444

Khan, H. (2013). Five Hours a Day: Systemic Innovation for an Ageing Population. London: NESTA.

Klimczuk, A., & Tomczyk, Ł. (Eds.) (2020). *Perspectives and Theories of Social Innovation for Ageing Population*. Lausanne: Frontiers Media. Retrieved from <a href="https://doi.org/10.3389/978-2-88963-620-4">https://doi.org/10.3389/978-2-88963-620-4</a> (last accessed: 07/12/2021)

Kochovska, S., Garcia, M. V., Bunn, F., Goodman, C., Luckett, T., Parker, D., Phillips, J. L., Sampson, E. L., van der Steen, J. T., & Agar, M. R. (2020). Components of palliative care interventions addressing the needs of people with dementia living in long-term care: A systematic review. *Palliative Medicine*, *34*(4), 454–492.

Kökciyan, N., & Yolum, P. (2020). TURP: Managing Trust for Regulating Privacy in Internet of Things, IEEE Internet Computing, 24(6), 9-16. doi: 10.1109/MIC.2020.3020006.

Koops, B. J., Newell, B. C., Timan, T., Škorvánek, I., Chokrevski, T., & Galič, M. (2016). A typology of privacy. *University of Pennsylvania Journal of International Law, 38*(2), 483-575.

Kroll, J. A., Michael, J. B. and Thaw, D. B. (2021). Enhancing Cybersecurity via Artificial Intelligence: Risks, Rewards, and Frameworks, *Computer*, 54(6), 64-71. doi:10.1109/MC.2021.3055703.

Kurtan, A. C., & Yolum, P. (2021). Assisting humans in privacy management: an agent-based approach. *Autonomous Agents and Multi-Agent Systems*, *35*(1), 1-33.

Ladislav, H. & Stuchlik, M. (1983). *Actions, norms and representations : foundations of anthropological inquiry.* Cambridge: Cambridge University Press.

Lanier, C.D., & Saini, A. (2008). Understanding consumer privacy: a review and future directions, *Academy of Marketing Science Review*, 12(2), 1-31.

Lerner, J. (2014). Urban Acupuncture. Washington, DC: Island Press.

Livingston, G., Pitfield, C., Morris, J., et al. (2012). Care at the end of life for people with dementia living in a care home: a qualitative study of staff experience and attitudes. *International Journal of Geriatric Psychiatry*, 27(6), 643-650.

Long, C., Seburn, M., JR, A., & More, T. (2003). Solitude experiences: Varieties, settings, and individual differences. Personality and Social Psychology Bulletin, 29(5), 578-583.

Lhotska, L., Havlik, J., & Panyrek, P. (2011, June). System approach to AAL applications: a case study. In International Workshop on Ambient Assisted Living (pp. 151-158). Berlin, Heidelberg: Springer.

Luger, E., Urquhart, L., Rodden, T., & Golembewski, M. (2015, April). Playing the legal card: Using ideation cards to raise data protection issues within the design process. In *Proceedings of the 33rd Annual ACM conference on human factors in computing systems* (457-466).

Lupton, D. (2016). he Quantified Self: A Sociology of Self-Tracking. Cambridge: Polity.

Lutz, C., & Newlands, G. (2021). Privacy and smart speakers: A multi-dimensional approach. *The Information Society*, 37(3), 1147-162.

Lutz, C. (2019). Digital inequalities in the age of artificial intelligence and big data. *Human Behavior and Emerging Technologies*, 1(2), 141-148.

Lutz, C., Schöttler, M., & Hoffmann, C. P. (2019). The privacy implications of social robots: Scoping review and expert interviews. *Mobile Media & Communication*, 7(3), 412-434.

Lutz W., Sanderson. W., Scherbov. S. (2008). The Coming Acceleration of Global Population Ageing. *Nature*. 451, 716–719.

Lyon, D. (1998) The world wide web of surveillance: The internet and off-world power-flows. *Information, Communication & Society*, 1(1), 91-105.

Lyon, D. (2001). Surveillance society: monitoring everyday life. Buckingham: Open University Press.

Machin, J., Batista, E., Martínez-Ballesté, A. & Solanas A. (2021). Privacy and Security in Cognitive Cities: A Systematic Review. *Applied Sciences* 11(10), 4471.

MacKenzie, D. & Wajcman, J. (1999). *The social shaping of technology.* Croydon, England: Open University Press.

Maddox, G. L. (1979). Sociology of later life. *Annual review of sociology*, 5(1), 113-135.

Mahajan, A. (1999). Intellectual Property, Contracts, and Reverse Engineering after PROCD: A Proposed Compromise For Computer Software. *Fordham Law Review*, 67, 3297-3335.

Majumder, S., Aghayi, E., Noferesti, M., Memarzadeh-Tehran, H., Mondal, T., Pang, Z., & Deen, M. J. (2017). Smart homes for elderly healthcare—Recent advances and research challenges. *Sensors*, *17*(11), 2496.

Mantovani, E., & Bocos, P. C. (2017). Are mHealth Apps Safe? The Intended Purpose Rule, Its Shortcomings and the Regulatory Options Under the EU Medical Device Framework. In H. R.

Marques, G. (2019). Ambient assisted living and internet of things. Harnessing the Internet of everything (IoE) for accelerated innovation opportunities, 100-115.

Marston, S. Freeman, & C. Musselwhite (Eds.), Mobile e-Health (pp. 251–275). Cham: Springer International Publishing.

Miguel, C. (2013). The transformation of intimacy and privacy through social networking sites. In *Proceedings of the 1st SSI (Society for Socio-Informatics) International Workshop for Young Researchers, September 16, 2012,* Japan: University of Gunma.

Mittelstadt, B. (2017). Ethics of the health-related internet of things: a narrative review. *Ethics and Information Technology*, 19(3), 157-175.

Mølholt, A.-K. (2021). 'Sometimes I feel 60, sometimes I feel 13': perceptions of age among vulnerable young people in Denmark. *Journal of Youth Studies*, *24*(1), 62-76.

Mordini, E. et al. (2009). Senior citizens and the ethics of e-inclusion. *Ethics and Information Technology*, 11, 1888-1957.

Mordini, E., & de Hert, P. (2010). Ageing and Invisibility. Brussels: IOS Press.

Mulgan, G., Tucker, S., Ali, R., & Sanders, B. (2007). *Social Innovation: What It Is, Why It Matters and How It Can Be Accelerated*. Oxford: Said Business School; The Young Foundation.

Murray, R., Caulier-Grice, J., & Mulgan, G. (2010). The Open Book of Social Innovation. London: NESTA.

Napoli, P. M., & Obar, J. A. (2014). The emerging mobile Internet underclass: A critique of mobile Internet access. *The Information Society*, *30*(5), 323-334.

Nissenbaum, H. (2010). *Privacy in context: Technology, policy, and the integrity of social life*. Stanford: Stanford University Press.

Nissenbaum, H. (2004). Privacy as contextual integrity. Washington Law Review, 79, 101–139.

O'Regan, G. (2018). Legal Aspects of Computing. In G. O'Regan (Ed) *World of Computing* (pp. 267-280). Cham: Springer.

OSICP. 2021. Office of Social Innovation and Civic Participation. 2015. Retrieved from http://www.whitehouse.gov/administration/eop/sicp (last accessed: 07/12/2021)

Paez, M., & La Marca, M. (2016). The Internet of Things: Emerging Legal Issues for Businesses. *Northern Kentucky Law Review*, 43, 29-71.

Pasluosta, C.F., Gassner, H., Winkler, J., Klucken, J., & Eskofier, B. (2015). An Emerging Era in the Management of Parkinson's Disease: Wearable Technologies and the Internet of Things. *IEEE Journal of Biomedical and Health Informatics*, 19, 1873-1881.

Palmore, E. (1999). Ageism: Negative and positive. Springer.

Palmore, E. (2005). Three decades of research on ageism. *Generations*, 29(3), 87-90.

Pedersen, D.M. (1999). Model for types of privacy by privacy functions. *Journal of Environmental Psychology*, 19, 397-405.

Petersson, J. (2011). Medicine at a distance in Sweden: Spatiotemporal matters in accomplishing working telemedicine. *Science & Technology Studies*, 24(2), 43-63.

Phillipson, C. (1998). Reconstructing old age: New agendas in social theory and practice. Sage Publications Ltd.

Portet F., Caffiau S., Ringeval F., Vacher M., Bonnefond N., et al. (2019). Context-Aware Voice-based Interaction in Smart Home -VocADom@A4H Corpus Collection and Empirical Assessment of its Usefulness. PICom 2019 - 17th IEEE International Conference on Pervasive Intelligence and Computing, Aug 2019, Fukuoka, Japan. pp. 811–818.

Purtova, N., Kosta, E., & Koops, B.- J. (2015). Laws and Regulations for Digital Health. In S. A. Fricker, C. Thümmler, & A. Gavras (Eds.), *Requirements Engineering for Digital Health* (pp. 47–74). Springer International Publishing.

Ray, M. A. & Turkel, M. C. (2014). Caring as Emancipatory Nursing Praxis: The Theory of Relational Caring Complexity. *Advances in Nursing Science*, 37(2), 132-146.

Rashidi, P., & Mihailidis, A. (2012). A survey on ambient-assisted living tools for older adults. *IEEE journal of biomedical and health informatics*, 17(3), 579-590.

Reiman, J. (1976). Privacy, intimacy and personhood. *Philosophical and Public Affairs*, 6(1), 26-44.

Regulation 2017/745. Medical devices. European Parliament, Council of the European Union. OJ L 117 5.5.2017

Regulation (EC) No 139/2004, OJ L 24, 29.1.2004, p. 1–22 (Merger Regulation)

Reichstein, C., Härting, R. C., & Häfner, F. (2020). Challenges in the market launch of active assisted living solutions - Empirical results from European experts. *Procedia Computer Science*, *176*, 2000–2009. https://doi.org/10.1016/j.procs.2020.09.236

Riley, M. W. (1987). On the significance of age in sociology. *American Sociological Review*, 52(1), 1-14.

Robinson, L., Cotten, S. R., Ono, H. et al. (2015). Digital inequalities and why they matter. *Information, Communication & Society,* 18(5), 569-582.

Robinson, L., Schulz, J., Blank, G., Ragnedda, M., Ono, H. et al. (2020). Digital inequalities 2.0: Legacy inequalities in the information age. *First Monday*, 25(7). Retrieved from <a href="https://firstmonday.org/ojs/index.php/fm/article/view/10842/9561">https://firstmonday.org/ojs/index.php/fm/article/view/10842/9561</a> (last accessed: 07/12/2021)

Robinson, L., Schulz, J., Dunn, H. S., Casilli, A. A., Tubaro, P., Carvath, R., ... & Khilnani, A. (2020). Digital inequalities 3.0: Emergent inequalities in the information age. *First Monday*, 25(7). Retrieved from https://firstmonday.org/ojs/index.php/fm/article/view/10844/9562. (last accessed: 07/12/2021)

Rodriguez-Garcia, M., Sicilia, M. A., & Dodero, J. M. (2021). A privacy-preserving design for sharing demand-driven patient datasets over permissioned blockchains and P2P secure transfer. PeerJ. Computer science, 7, e568.

Rodrigues, J. J., Segundo, D. B. D. R., Junqueira, H. A., Sabino, M. H., Prince, R. M., Al-Muhtadi, J., & De Albuquerque, V. H. C. (2018). Enabling technologies for the internet of health things. Ieee Access, 6, 13129-13141.

Rokach, A. (2000). Loneliness and the life cycle. *Psychological Reports*, 86(2), 629-642.

Roth, V. J. (2013). The mHealth Conundrum: Smartphones & Mobile Medical Apps - How Much FDA Medical Device Regulation Is Required. *North Carolina Journal of Law & Technology*, 15(3), 359–424.

Rubinstein, I. & Good, N. (2020). The Trouble with Article 25 (and How to Fix It): The Future of Data Protection by Design and Default. *International Data Privacy Law*, 10(1), 37-56.

Sakairi, K. (2004). Research of robot-assisted activity for the elderly with senile dementia in a group home. *SICE 2004 Annual Conference*, *3*, 2092-2094.

Schurr, F. A. (2007). The Relevance of the European Consumer Protection Law for the Development of the European Contract Law. *Victoria University of Wellington Law Review*, 38, 131-144.

Schülke, A. M., Plischke, H., & Kohls, N. B. (2010). Ambient Assistive Technologies (AAT): Sociotechnology as a powerful tool for facing the inevitable sociodemographic challenges? *Philosophy, Ethics, and Humanities in Medicine*, *5*(1), 8.

Sciancalepore, M. E. ((2006/2007). Protecting New Technologies in Latin America: The Case for Computer Software Patents in Argentina. *The University of Miami Inter-American Law Review*, 38, 349-404.

Shirey, R. (2000). RFC 2828. Internet Security Glossary.

Sixsmith, A. (2013). Technology and the Challenge of Aging. In A. Sixsmith & G. M. Gutman (Eds.), *Technologies for Active Aging* (pp. 7–25). New York: Springer.

Smith, H. J., Dinev, T., & Xu, H. (2011). Information privacy research: an interdisciplinary review. *MIS Quarterly*, *34*(4), 989-1015.

Solanas, A., et al. (2014). Smart Health: A Context-Aware Health Paradigm within Smart Cities. *IEEE Communications Magazine*, 52(8), 74-81.

Solicitors Regulation Authority (SRA), 2016. Providing services to people who are vulnerable. Retrieved from <a href="https://www.sra.org.uk/globalassets/documents/solicitors/freedom-in-practice/vulnerable-people.pdf?version=4a1ab1">https://www.sra.org.uk/globalassets/documents/solicitors/freedom-in-practice/vulnerable-people.pdf?version=4a1ab1</a> (last accessed: 07/12/2021)

Solove, D.J. (2008). *Understanding privacy*, Harvard University Press.

Sørensen, K. H. (1996). *Learning Technology, Constructing Culture: Socio-technical Change as Social Learning*. Trondheim, Norway: Centre for Technology and Society.

Sørensen, K. H., & Williams, R. (2002). *Shaping technology, guiding policy: Concepts, spaces, and tools*. Cheltenham, UK: Elgar.

Stevens, N., & van Tilburg, T. (2000). Stimulating friendship in later life: a strategy for reducing loneliness among older women. *Educational Gerontology*, *26*(1), 15-35.

Tamura, T., Yonemitsu, S., Itoh, A., Oikawa, D., Kawakami, A., Higashi, Y., Fujimooto, T., & Nakajima, K. (2004). Is an entertainment robot useful in the care of elderly people with severe dementia? *The journals of gerontology. Series A, Biological sciences and medical sciences, 59 1,* 83-5.

Tamò-Larrieux, A. (2018) *Designing for Privacy and Its Legal Framework: Data Protection by Design and Default for the Internet of Things*. Cham: Springer.

Tang, P. (1997). The use of copyright as a measure of innovation: software applications in the digital age. *Intellectual Property Quarterly*, 1, 71-91

Tangcharoensathien, V., Witthayapipopsakul, W., Viriyathorn, S., & Patcharanarumol, W. (2018). Improving access to assistive technologies: challenges and solutions in low- and middle-income countries. *WHO South-East Asia Journal of Public Health*, 7(2), 84–89.

Terry, N. P. (2015, May). Mobile Health and Wearable Technologies: Systemic Liability. American Association for the Advancement of Science Workshop, Washington. Retrieved from <a href="https://www.aaas.org/sites/default/files/Terry%20Mobile%20Health%20and%20Wearable%20Technologies%20Systemic%20Liability.pdf">https://www.aaas.org/sites/default/files/Terry%20Mobile%20Health%20and%20Wearable%20Technologies%20Systemic%20Liability.pdf</a> (last accessed: 07/12/2021)

Thorpe, J., Barrett, D. & Goodwin, N, (2015). Examining perspectives on telecare: factors influencing adoption, implementation, and usage. *Smart homecare technology and TeleHealth* 3, 1-8.

Tøndel, G., & Seibt, D. (2019). Governing the Elderly Body: Technocare Policy and Industrial Promises of Freedom. In U. Meyer, S. Schaupp, & D. Seibt (Eds.), *Digitalization in Industry: Between Domination and Emancipation* (pp. 233-259). Springer International Publishing.

TRIPS Agreement. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994).

Uniform Computer Information Transactions Act s 403 comment 3(a)(US 2002) (UCITA).

UK Department for Digital, Culture, M., Sport (2018). *Secure by Design: Improving the cyber security of consumer Internet of Things Report*. Technical Report. UK Department for Digital, Culture, Media and Sport.

US Federal Trade Commission (2016, February). FTC Approves Final Order Prohibiting "Ultimeyes" Manufacturer from Making Deceptive Claims that the App Can Improve Users' Vision. Retrieved from <a href="https://www.ftc.gov/news-events/press-releases/2016/02/ftc-approves-final-order-prohibiting-ultimeyes-manufacturer">https://www.ftc.gov/news-events/press-releases/2016/02/ftc-approves-final-order-prohibiting-ultimeyes-manufacturer</a> (last accessed: 07/12/2021)

US Federal Trade Commission (FTC) Act, 15 USC s45(a)(1).

US Food and Drug Administration. (2015). *Policy for Device Software Functions and Mobile Medical Applications—Guidance for Industry and Food and Drug Administration Staff*. Retrieved from <a href="https://www.federalregister.gov/documents/2013/09/25/2013-23293/mobile-medical-applications-guidance-for-industry-and-food-and-drug-administration-staff">https://www.federalregister.gov/documents/2013/09/25/2013-23293/mobile-medical-applications-guidance-for-industry-and-food-and-drug-administration-staff</a> (last accessed: 07/12/2021)

US Food and Drug Administration (2015). *Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff* (9 February 2015) (FDA Mobile Medical Applications)

U.S government (2020). An act to establish minimum security standards for Internet of Things devices owned or controlled by the Federal Government, and for other purposes. Technical Report.

Van Deursen, A. J., & Helsper, E. J. (2015). The third-level digital divide: Who benefits most from being online? In *Communication and information technologies annual* (pp. 29-52). Bingley: Emerald Group Publishing Limited.

Van Deursen, A., & Van Dijk, J. (2011). Internet skills and the digital divide. *New media & society, 13*(6), 893-911.

Van Deursen, A. J., & van Dijk, J. A. (2015). Internet skill levels increase, but gaps widen: A longitudinal cross-sectional analysis (2010–2013) among the Dutch population. *Information, Communication & Society, 18*(7), 782-797.

Vermeulen, G., De Bondt, W., Ryckman, Ch. (2012). Liability of Legal Persons for Offences in the EU. Maklu, Antwerpen – Apeldoorn – Portland

Vuononvirta, T., Timonen, M., Keinänen-Kiukaanniemi, S., et al. (2009). The attitudes of multiprofessional teams to telehealth adoption in northern Finland health centres. *Journal of Telemedicine and Telecare*, 15(6), 290-296.

Wac, K. (2018). From Quantified Self to Quality of Life. In H. Rivas, & K. Wac (Eds.), *Digital Health: Scaling Healthcare to the World* (pp. 83-108). Springer. Health Informatics Series https://doi.org/10.1007/978-3-319-61446-5\_7

Weiner, M. & Biondich, P. (2006). The influence of information technology on patient-physician relationships. *Journal of general internal medicine*, 21(1-1), 35-39.

Westin, A. (1967). Privacy and Freedom. Atheneum Press.

Wiese Schartum, D. (2016). Making privacy by design operative, *International Journal of Law and Information Technology*, 24(2), 151–175.

Winner, L. (1980). Do artifacts have politics? *Daedalus*, 109(1), 121-136.

Winner, L. (1993). Upon Opening the Black Box and Finding It Empty: Social Constructivism and the Philosophy of Technology. *Science, Technology & Human Values*, 18(3), 362-378.

Wolbring, G. (2008). The politics of Ableism. *Development*, 51(2), 252–258.

Wong, R. Y., & Mulligan, D. K. (2019, May). Bringing design to the privacy table: Broadening "design" in "privacy by design" through the lens of HCI. In *Proceedings of the 2019 CHI conference on human factors in computing systems* (pp. 1-17).

Woolgar, S. (1990). Configuring the user: the case of usability trials. *The Sociological Review*, 38(1), 58-99.

Yao, Y., Basdeo, J. R., Kaushik, S., & Wang, Y. (2019, May). Defending my castle: A co-design study of privacy mechanisms for smart homes. In *Proceedings of the 2019 CHI Conference on Human Factors in Computing Systems* (pp. 1-12).

Zhang, X., Upton, O., Beebe, N. L., & Choo, K. K. R. (2020). Iot botnet forensics: A comprehensive digital forensic case study on Mirai botnet servers. *Forensic Science International: Digital Investigation*, 32, 300926.

Zillien, N., & Hargittai, E. (2009). Digital distinction: Status-specific types of internet usage. *Social Science Quarterly*, *90*(2), 274-291.

Zu, L. (2013). Social Innovation. In S. O. Idowu, N. Capaldi, L. Zu, & A. Das Gupta (Eds.), *Encyclopedia of Corporate Social Responsibility* (pp. 2213–2223). Berlin, New York: Springer.