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Usability, Accessibility and Ambient Assisted Living

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Alexandra Queirós • Nelson Pacheco da Rocha
Editors

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Editors
Alexandra Queirós
Health Sciences School
University of Aveiro
Aveiro, Portugal

Institute of Electronics and Telematics
Engineering of Aveiro (IEETA)
University of Aveiro
Aveiro, Portugal

Nelson Pacheco da Rocha
Medical Sciences Department
University of Aveiro
Aveiro, Portugal

Institute of Electronics and Telematics
Engineering of Aveiro (IEETA)
University of Aveiro
Aveiro, Portugal

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Chapter 1
Ambient Assisted Living: Introduction and Overview

Ana Isabel Martins, Alexandra Queirós, and Nelson Pacheco da Rocha

1.1 Ambient Assisted Living Joint Programme

Older people experience a decrease in functional capacity as they grow older, however, it is consensual that the adoption of new technologies is fundamental to optimise support services and promote active ageing (World Health Organization 2002). Therefore, in June 2007, the European Commission proposed the Action Plan Ageing Well in the Information Society with the aim of promoting and coordinating the development of information and communication technologies (ICTs) associated with services for older people in the European Union, enabling them to prolong their working life, stay socially active and age well at home. As a direct response to this action plan, 14 European members states founded the Ambient Assisted Living

A. I. Martins (✉)
Department of Electronics, Telecommunications and Informatics (DETI), University of Aveiro, Aveiro, Portugal

Institute of Electronics and Telematics Engineering of Aveiro (IEETA), University of Aveiro, Aveiro, Portugal
e-mail: anaisabelmartins@ua.pt

A. Queirós
Health Sciences School, University of Aveiro, Aveiro, Portugal

Institute of Electronics and Telematics Engineering of Aveiro (IEETA), University of Aveiro, Aveiro, Portugal
e-mail: alexandra@ua.pt

N. P. da Rocha
Medical Sciences Department, University of Aveiro, Aveiro, Portugal

Institute of Electronics and Telematics Engineering of Aveiro (IEETA), University of Aveiro, Aveiro, Portugal
e-mail: npr@ua.pt

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Joint Programme (AAL JP) at the end of 2007. The programme responded to the continuing challenge of ageing population by translating it to an opportunity to innovate (Gaßner and Conrad 2010). This programme was established to help create a better quality of life for older people and to strengthen the industrial opportunities in Europe through the use of ICTs. It carries out its mandate through funding of multinational projects with the participation of small and medium enterprises (SME), research organisations and end-users. The aim of AAL JP is to foster the emergence of ICT-based products, services and systems for ageing well at home, in the community and at work in order to increase the quality of life, autonomy, participation in society, and skills and employability of older adults and reduce the costs of health and social care (Gaßner and Conrad 2010).

The AAL JP aims to combine social, technological and business aspects to deliver (Farla and Varlai 2016):

- New models of service delivery and care that contribute to greater self-reliance for older adults and greater support for informal carers;
- Adapted living spaces that can improve the quality of older adults' everyday lives;
- New ways for older people to remain active, including contributing as volunteers or providing mutual support;
- New ways of mobilising active and trusted networks, both formal and informal, and to provide all types of support.

The first phase of the AAL JP covered the period 2007 to 2013, but it has been extended to run until 2020 to continue applied and close-to-market research for ageing well with ICT (the name of the programme having changed into Active and Assisted Living for the 2014–2020 period). During its extension, the programme seeks to support industry, particularly SMEs, to bring digital innovative products, services and solutions for ageing well to the European market (Farla and Varlai 2016).

Currently 22 countries constitute the AAL JP. These countries provide an annual contribution of approximately €35 million to fund projects in the AAL domain. The AAL JP also leverages additional public and private investment (Farla and Varlai 2016).

1.2 AAL Characteristics

In the context of technological developments in recent years, Ambient Assisted Living (AAL) has become increasingly important (Broek et al. 2009). It is a new paradigm that seeks to take advantage of ubiquitous computing devices and new forms of interaction with the aim of promoting the autonomy and independence of the older adults (Sánchez-Pi and Molina 2009; Wichert and Eberhardt 2011).

AAL solutions are related to digital environments with ubiquitous and nonobstructive intelligence (Moumtzi and Wills 2009) to support societal services (Storf et al. 2009) and are identified as a combination of products and/or services that are bundled in order to deliver a real solution to enhance the quality of life of older people. AAL components can be combined with other existing products and ser-

vices to deliver innovative AAL solutions. A component can be any discrete device or software module of a system that can be used, reused and adapted to the specific requirements of multiple AAL solutions. Moreover, AAL solutions and components may have a range of functions, for example, they can cover reliability/security, flexibility, personalisation, interoperability and accessibility (Farla and Varlai 2016).

AAL solutions can also contribute to the safety of older adults (e.g. alarm devices) and consequently to monitor their everyday situations (Ochoa 2008). Also in terms of empowerment of the older adults, these products and services can contribute to disease prevention and health promotion and provide mechanisms to overcome problematic situations, such as those resulting from chronic diseases (Wichert and Eberhardt 2011; Ochoa 2008). Indeed, AAL solutions have a huge potential not only to enhance the independence and quality of life of elderly population and patients but also to greatly reduce the costs associated with healthcare services (AAL Joint Programme 2010; Quigley and Knapp 2010).

Table 1.1 illustrates examples of innovation types that are produced as part of the AAL JP-funded projects and provides an indication of some of the relevant functions. The AAL projects place specific importance on personalisation and seek, amongst other, to contribute to the following outcomes:

- Products, systems and services that can be tailored to the needs and desires of each user;
- Products, systems and services that can be customised to meet the varying social preferences and regulatory aspects across and beyond Europe.

Table 1.1 Examples of innovations of the AAL solution or component in terms of functions from the AAL JP-funded projects (Farla and Varlai 2016)

Functions	Examples
Reliability/ security	Collection of patients' data
	Algorithms
	Storing of personal information, e.g. of social networking platforms
Flexibility	Integration of sensors and other hardware technologies already available on the market allowing a flexible answer to the users' needs
Personalisation	Assistance in products for online courses
	Tools to interact with digital services
	End-user-oriented algorithms
	Diet and activity monitoring solutions
	Medicine intake
	Service personalisation
	Sensor thresholds
	Social networking platforms
Interoperability	Gateway for transmitting any health data from/to various providers
	Remote services for different access channels
	Digital cable TV platforms
Accessibility	Social innovation concept in local communities
	Mobile phones/smart TVs
	Social networking platforms

AAL represents a new generation of products and services that must meet the following requirements (Aviles-Lopez et al. 2009):

- Invisibility – soaked in clothing, appliances or furniture;
- Mobility – ability to be transported by the user;
- Spontaneity – ability to communicate dynamically between various points;
- Heterogeneity – integration of different technologies;
- Context sensitivity – ability to interpret user actions;
- Proactivity – ability to infer behaviours according to the users' activities;
- Natural communication – interaction based on voice or gestures;
- Adaptability – ability to react to unexpected situations that may occur.

The automation of the devices is done according to the perception of the surrounding and aims to contribute to specific objectives or to anticipate certain situations (Cook and Das 2007; Costa et al. 2009). Therefore, sensing, communicating and acting are crucial issues within the AAL paradigm (Broek et al. 2009; Costa 2009; Camarinha-Matos and Vieira 1999), without neglecting the requirements for ubiquity, user transparency, reliability or scalability.

AAL solutions combine a wide range of sensors, including comfort sensors (e.g. sensors to measure temperature, humidity, carbon dioxide or atmospheric pressure), technical safety sensors (e.g. sensors for detecting water floods or fire principles), sensors that can help provide information about the environment (e.g. intrusion detectors or video surveillance systems), human activity sensors (e.g. detection of the presence of people) or sensors related to health and well-being (e.g. medical alarms for the older adults embedded in personal objects such as watches or charms, glucose metres or blood pressure metres).

The environmental data captured by the sensors are transmitted through communication networks. Based on the perception of the environment, AAL solutions use actuators to change it (e.g. a smart room where the person lies in bed and the blinds close automatically).

To translate available sensory information into beneficial actions for different users, AAL solutions must have high-level thinking and decision-making processes to assess situations and advise or assist users (Cook and Das 2007).

Although sensors have some processing capabilities, they do not have the computational power to act as comprehensive intelligent systems (De Paola et al. 2009). In addition, there are unresolved issues related to the relationship between autonomy and sensor acquisition performance (Figueiredo et al. 2010). New discoveries of nanometre-scale materials may satisfy some of the requirements that are essential for sensors. Low-energy, high-density memory sensors with high computational capacity and designed for efficient short- and long-range communication depend on the success of the next generation of emerging nanomaterials (Islam and Logeeswaran 2010).

In the scope of robotics, several contributions can be predicted in terms of AAL applications (Information Society Technologies Advisory Group 2009). Ubiquitous robotic systems, equipped with communication mechanisms for data transmission and capable of performing physical actions (e.g. movement or force), can pave the way for innovative products. In this respect, one of the main challenges of robotics

is that robots should be part of an intelligent environment capable of natural interactions (e.g. through speech), in order to perform functions as interface between users and technological services (Koch et al. 2008) (e.g. butler functions (De Carolis and Cozzolongo 2007)).

Thus, it is intended that AAL solutions have mechanisms to properly distinguish people, identify their needs and preferences and recognise their surroundings. Such is the purpose of context awareness systems, which include technologies for identifying patterns in order to prevent or detect dangerous spatial/temporal configurations (Cacciagrano et al. 2010; Almeida et al. 2009), to locate people (Fortier et al. 2010), to detect specific situations (Hartmann et al. 2010; Siciliano et al. 2009), to infer activities (Bicocchi et al. 2010; Mirarmandehi and Rabiee 2010) or to detect human behaviours and emotions (Abbasi 2010). Evidence suggests positive effects of emotional information on the ability of intelligent agents to create better models of user actions (Leon et al. 2010).

Based on the knowledge of users and their contexts, the AAL technology infrastructure, while not neglecting user safety and privacy, can decide which services to provide. Thus, AAL solutions must provide mechanisms of natural interaction, context sensitivity, security and privacy (Hoareau and Satoh 2009) supported by appropriate technological architectures (Queirós et al. 2013).

The AAL solutions described in the literature are intended for indoor or outdoor use in any environment or at home (Stelios et al. 2008; Chang and Wang 2010; Paterno et al. 2010). Some of them aim to support the older adults in a broad spectrum of activities (Quigley and Knapp 2010) such as self-care, eating (e.g. weekly menu planning or nutritional advising (Lázaro et al. 2010)), home management (Boll et al. 2010), ambulation (Krieg-Brückner et al. 2010) or shopping (Keegan et al. 2008).

In terms of prevention, AAL systems can be considered for different situations, such as falls, physical immobility, monitoring of activities of daily living, occupying spaces at home, behaviour analysis and other possibilities (Anmin Jin et al. 2009; Lopes et al. 2013; Torkestani et al. 2012).

Figure 1.1 shows the main topics related to AAL home care and their utilities, as well as technologies and techniques that can be implemented to achieve the objectives of the AAL (MAmI Research 2018).

AAL solutions have great potential in terms of reorienting health systems (Botella et al. 2009), currently organised around episodes of acute illness, by allowing the development of a wide range of services such as prevention care (Valera et al. 2009), telemedicine services (Broek et al. 2009), promotion of care or support for home care (Corchado et al. 2008), either by health professionals or by any formal or informal caregiver (Alcañiz et al. 2009), such as distance learning (Plischke and Kohls 2009), or providing accurate and up-to-date information to the caregiver (Dadlani et al. 2010) so that the right care can be provided at the right time (e.g. monitoring and controlling biological signs) (Fayn and Rubel 2010; Fanucci et al. 2009).

All these services may require the use of infrastructures composed of sensors, mobile phones and computers, amongst others, at home or abroad, connected through different communication networks (fixed or wireless) (Segarra and André

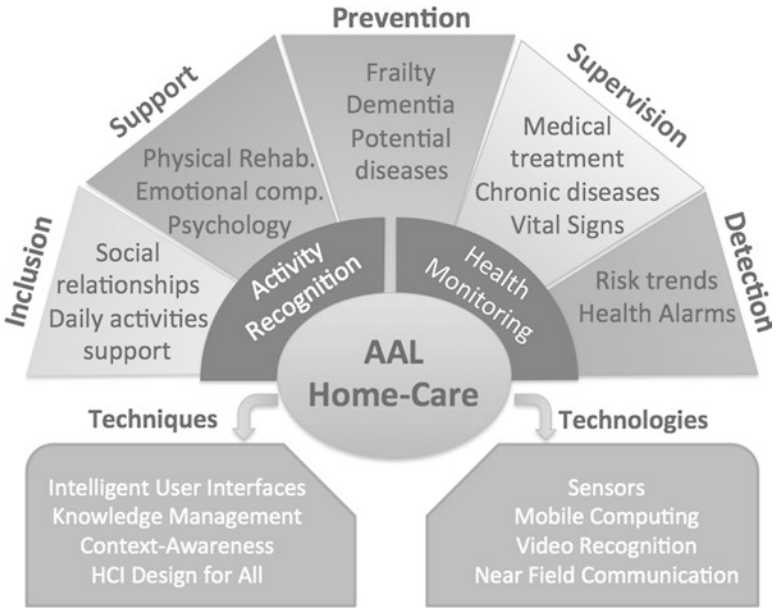

Fig. 1.1 AAL home care overview (MAmI Research 2018)

2009). This requires integrating existing technologies and ensuring their interoperability (Broek et al. 2009). This concept refers to the ability of two or more technological components to cooperate despite differences in terms of underlying technologies, interfaces or execution platforms. It is a scalable way to reuse resources, for example, for access to a server by clients whose access mechanisms are different or incompatible (Wegner 1996).

The AAL paradigm is a result of a wide range of trends associated with various technological developments, notably (Broek et al. 2009) increased capacity of communication infrastructures, vulgarisation of wireless communications, availability of the Internet, in particular the Internet of Things that may be present in an unlimited number of devices and that will provide communication capabilities embedded in the surroundings, multimedia integration, multimodality and mobility, increased computing power, availability of portable devices that combine multiple functions, alternate forms of interaction, appearance of interaction mechanisms based on virtual reality and the rise of robotics (Queirós et al. 2013).

1.3 The AAL Market

Although relatively recent, the market for the development of AAL solutions for the older adults has been growing, and it is expected to continue to grow in the upcoming decades, due to the demographic panorama.

The AAL Programme financing comes from the contribution of the 22 member countries (approximately €35 million) and additional public and private investment. This public funding consists of contribution by the European Commission and the AAL partner countries. The programme participants (SMEs, larger enterprises, end-user organisations, universities and research organisations) should at least contribute to the remaining 50% of the overall budget. The biggest contributors in terms of budget are Germany, France, Spain, Austria, Finland, Hungary and Italy (Farla and Varlai 2016).

The new programme, Active and Assisted Living, is being undertaken jointly by EU member states and countries associated with Horizon 2020 and co-funded by the European Union with an estimated overall budget of €700 million (AAL Programme 2014) and is set to bring new ICT-based products, solutions and service concepts onto the market within 2–3 years of the end of the funding period. The programme has been brought fully in line with the European Innovation Partnership on Active and Healthy Ageing (EIP AHA). It is thought that this alignment could further boost the deployment of AAL solutions at the European level. For the new AAL JP, this means that while the focus is still on 'ageing well', there will be more specific attention for industry support, especially aiming at SMEs, and innovative products. This increases the need for a monitoring system that also focuses on the innovation impacts (Farla and Varlai 2016).

A recent report summarised the socio-economic impact of the AAL JP-funded projects, by conducting a survey to project participants between November 2015 and February 2016, and 91 responses were collected about 50 AAL JP-funded projects out of the targeted 63 projects (Farla and Varlai 2016).

The funded projects meet the following requirements (Farla and Varlai 2016):

- Produce concrete solutions for independent living or 'ageing well' of older people using ICT;
- Solution reached the market within 2–3 years after the project ends;
- Conducted realistic trial set-ups at the end of the project;
- Clearly defined focus on a specific market segment;
- Involved at least three EU countries participating in the programme;
- Was in compliance with national criteria (different for each participating country).

The aim of the first post-project impact assessment report of AAL JP-funded projects was to measure the direct outcomes for project participants as well as broader socio-economic impacts of the funded projects and the overall programme (Farla and Varlai 2016).

Impact was assessed regarding a set of key impact indicators: collaboration with end-users and with enterprise and research organisations, partnerships in value chains, commercialisation of AAL solutions and components, provision of AAL solutions and components to end-users, follow-on investment for innovation activities, revenue generated from new AAL solutions or components, protection of intellectual property and the creation of spin-offs and start-ups. Table 1.2 summarises the most important results for each key impact indicator (Farla and Varlai 2016).

Table 1.2 Summary of socio-economic impact of the AAL JP-funded projects (Farla and Varlai 2016)

Collaboration with end-users	75% indicated sustained collaboration with primary (final users), secondary (informal carers, neighbours or social organisations) and/or tertiary (public or private entities that are related with the development and maintenance) end-users while developing an AAL solution or component.
Collaboration with enterprises and research organisations	68% continued to collaborate with enterprises and research and development organisations after the end of the project, indicating that strong and sustainable partnerships were formed during the funded period
Partnerships in value chains	One third of participants are part of a value chain to further develop, commercialise or deploy AAL solutions or components
Commercialisation of solutions and components	Over 40% of participants either commercially launched an AAL solution or component or plan to launch an AAL solution in the next 2 years
Users of new AAL solutions	29% of participants indicated that they provide their AAL solutions to over 6000 end-users across over 20 EU member states
Follow-on investment	More than one third of participants received financial investment mostly from public but some from private third parties for follow-on innovation activities. The total value of financial investment received is estimated to be in the range €3 m–€5.5 m
Revenue generated	41% of participants generated revenue from AAL solutions and components funded by the programme and/or expect revenue growth. Those that have already generated revenues expect to continue to generate revenue next year. The average revenue from AAL solutions and components was €112,000 with expected revenue the next year at €191,000
Intellectual property protection	Only 17% of participants indicated that they took actions to legally protect the AAL JP-funded projects' results, with mostly copyrights
Creation of new company	Only 12% of participants indicated that they created a spin-off as a result of the AAL JP-funded project

According to a study by Gaßner and Conrad (Gaßner and Conrad 2010), in 2009, in the 27 member states which at the time constituted the EU, a total of 676 organisations were involved in the development and research of technological solutions to promote and autonomous and independent life of older adults. This interest, and its investment, was more evident in the private sector, although there were service providers and research partners from the public sector (Gaßner and Conrad 2010).

Although the development of the AAL market is very relevant, the innovation on this area is also important to define new trends. In the next chapters will be described what exist in the literature, through a systematic review of literature on AAL and will be explored future trends in AAL.

1.4 Book Structure

This book is divided in two parts: the first deals with different aspects of current AAL research, and the second discusses its future trends.

The first part has five chapters. The first chapter introduces and defines AAL relevant concepts. Chapter 2 comprises a systematic review of the literature aiming to present an overview of the AAL solutions. This systematic review allowed the understanding of what are the main components of AAL, which were classified, not only considering the technology being used or the target population but also the respective aims (e.g. social participation or mobility). The next two chapters, Chaps. 3 and 4, discuss fundamental aspects of AAL: Chap. 3 presents AAL systems and classify them considering the International Classification of Functioning Disability and Health (ICF), and Chap. 4 discusses the assessment methods being used to evaluate AAL solutions. Since the acceptance of AAL solutions is closely related to the usability and user interaction, Chap. 5 details a multi-method approach that promotes an accurate evaluation of the interaction mechanisms.

The second part of this book discusses future trends related to AAL. Chapter 6 considers the evolution of AAL as medical devices, namely, the need to guarantee the validity, reliability and clinical usefulness of its solutions. For that, it is necessary to implement strict assessment processes according to existing regulatory frameworks, which requires observational and interventional studies involving users and care providers. The last chapter highlights the possible application of AAL solution in rehabilitation processes.

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Chapter 2
Ambient Assisted Living: Systematic Review

Alexandra Queirós and Nelson Pacheco da Rocha

2.1 Introduction

The active ageing paradigm aims to contribute to the expectation of a healthy, autonomous and independent life with quality (World Health Organization 2002). The technological solutions might have a key role in the promotion of human functioning and in the mitigation of disabilities, particularly those resulting from the natural ageing process. This perspective is evident in the development of Ambient Assisted Living (AAL) solutions (Martins et al. 2017).

AAL, like AmI, uses the integration of computational devices in the persons' natural environments (e.g. clothes or furniture). These computational devices allow the adaptation of the physical environment to the needs of the users (Queirós et al. 2013a; Bell and Dourish 2007), through the capture of data representing the state of the surrounding environments. AAL solutions must be able to process available sensory information, which will serve as a basis for decision-making processes to anticipate reactions to possible events or to act on the environments to modify their state (Cook and Das 2007).

The acceptance of AAL solutions is closely related to the quality of the available solutions, namely, in terms of intelligent functions for the users' interaction.

A. Queirós (✉)
Health Sciences School, University of Aveiro, Aveiro, Portugal

Institute of Electronics and Telematics Engineering of Aveiro (IEETA), University of Aveiro, Aveiro, Portugal
e-mail: alexandra@ua.pt

N. P. da Rocha
Medical Sciences Department, University of Aveiro, Aveiro, Portugal

Institute of Electronics and Telematics Engineering of Aveiro (IEETA), University of Aveiro, Aveiro, Portugal
e-mail: npr@ua.pt

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Therefore, the development of AAL solutions must consider the needs of the users in order to assist them in their daily activities, making their lives more comfortable and helping them to participate in all areas of life, as well as to be accepted and included (Queirós et al. 2013a).

In this context, it is relevant to know the recent developments in AAL and to discuss its future trends and challenges. Therefore, the authors systematically review and classify the AAL literature to establish the current position regarding the AAL services being developed, users' involvement and evaluation methods.

2.2 Methods

The systematic review and classification of the AAL literature was informed by the following research questions:

- RQ1: What AAL solutions and respective application domain are being developed?
- RQ2: How are AAL solutions being evaluated?

This systematic review followed the guidelines of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) (Moher et al. 2009).

2.2.1 Data Sources and Searches

Studies were sought using general databases (i.e. Scopus, Web of Science and Academic Search Complete), a healthcare database (i.e. PubMed) and computer, information science and electrical engineering databases (i.e. IEEE Xplore).

The database queries were prepared to include all the articles where any of the keywords mentioned in Table 2.1 were presented in the title or abstract, according

Table 2.1 Search terms used for database queries

	Search terms	Type
1	"Technology-based" OR "information technology" OR "information and communication" OR "internet-based" OR "web-based" OR "online" OR "smartphones" OR "mobile apps" OR "mobile phone" OR "monitoring devices"	General terms
2	AAL OR "ambient assisted living" OR "ambient assisted technology" OR "ambient assistive technology" OR "ambient intelligence" OR AmI OR "smart home" OR "intelligent home"	General terms
3	"Independent living" OR "assisted living facilities" OR "assisted living facility"	MeSH terms
4	Aged OR aging OR elderly OR senior OR old	General terms
5	Aged OR aging	MeSH terms

to the following Boolean combination 1 AND (2 OR 3) AND (4 OR 5). Whenever the databases allowed, MeSH terms were used.

The search was performed on February of 2018 and included all references published since January 1, 2007 till December 31, 2017. The starting date was established as 2007, because it was in this year that the European Commission launched the Ambient Assisted Living Joint Programme (European Union 2007).

2.2.2 Inclusion and Exclusion Criteria

In terms of inclusion criteria, the included articles should report AAL solutions that might be used to support older adults.

Moreover, the exclusion criteria were (1) articles not published in English, (2) articles reporting editorials or prefaces, (3) articles reporting systematic reviews, (4) articles reporting surveys and (5) articles that are not relevant for the objectives of the study reported in this chapter.

2.2.3 Review Selection

After the removal of duplicates and articles not published in English, the authors independently reviewed all titles for relevance and assessed the abstracts of the retrieved articles against the inclusion and exclusion criteria. Any disagreement between the authors was discussed and resolved by consensus.

2.2.4 Data Extraction and Analysis

For every one of the included articles, the following information was registered in a data sheet prepared by the authors:

- Scope of the article – aim of the AAL solutions;
- Context – specific context where AAL solutions are planned to be used (e.g. residential environment, institutional environment or outdoor);
- Type of user – identification of the preferable type of users (e.g. older adults, patients or caregivers);
- Type of technology – description of the main technological characteristic of the AAL solutions (e.g. hardware component, software component or architecture);
- Type of services – practical AAL systems applied in a specified context and with a well-defined aim (e.g. monitoring systems, falls detection systems or medication management);

- Evaluation methods – description of the assessment of the AAL solutions (e.g. conceptual validation, prototype or pilot).

Afterwards, the collected data was analysed to answer the previous referred research questions.

2.3 Results

Figure 2.1 presents the PRISMA flowchart of the systematic review reported in the present chapter.

A total of 1342 articles were retrieved from the initial searches on Scopus (525), Web of Science (171 articles), Search Academic Complete (334 articles), PubMed (155 articles) and IEEE Explorer (157 articles). The initial screening yielded 642 articles by removing the duplicates (648 articles) or the articles without abstracts (53 articles). A total of 374 articles were excluded based on the review of the titles and abstract. From these, 11 articles reported editorials or prefaces, 26 were systematic reviews, 81 were surveys and 256 were out of scope. Consequently, 267 articles were included in this systematic review.

The evolution through the reviewed 10 years period is presented in Fig. 2.2. It is clear that in the increasing number of AAL solution over the years, although between 2015 and 2017, there was a slight decrease.

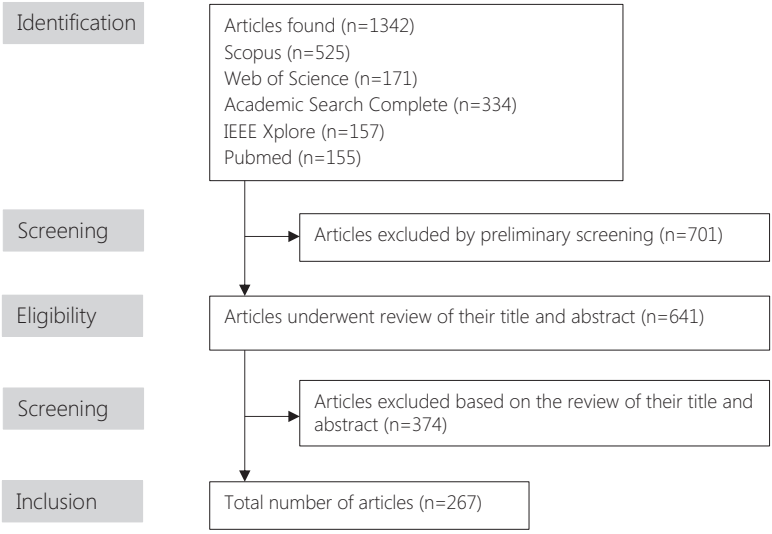

Fig. 2.1 PRISMA flowchart

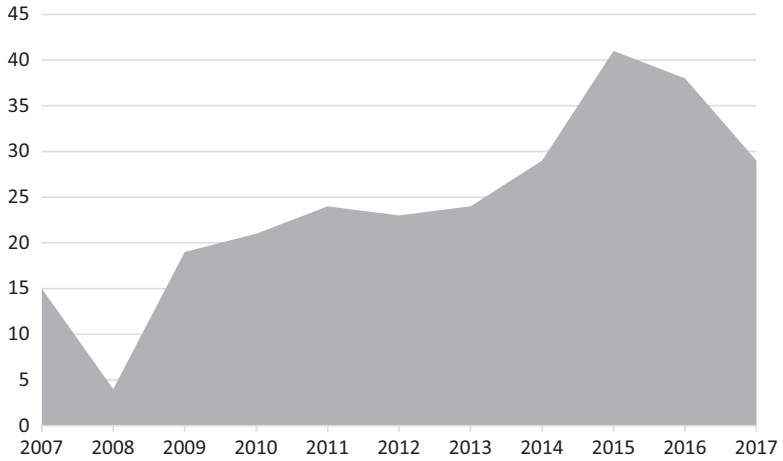

Fig. 2.2 Evolution of the number of articles per year between 2007 and 2017

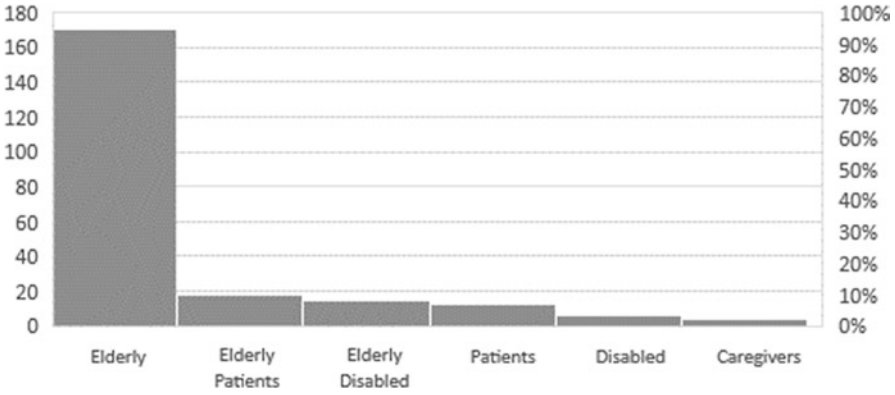

Fig. 2.3 Users of AAL solutions

In what concerns the target users (Fig. 2.3), most of the retrieved articles had older adults as target users (76%), considering that the articles referred not only older adults (170) but also older adults and patients (18) or disabled citizens (15). Only four articles reported caregivers or general citizens as target users. Finally, 19 articles developed AAL solutions for patients or disabled citizens, and 41 did not specify the preferable type of users.

The context where AAL solutions are planned to be applied is presented in Fig. 2.4. A significant percentage (i.e. 66%) referred residential environment as the context of use, just 1% of the articles indicated institutional or outdoor context of use, and 33% of the articles did not refer where the AAL solution are planned to be used, since most of them were related to the development of specific components of hardware or software which could be integrated in other AAL solutions.

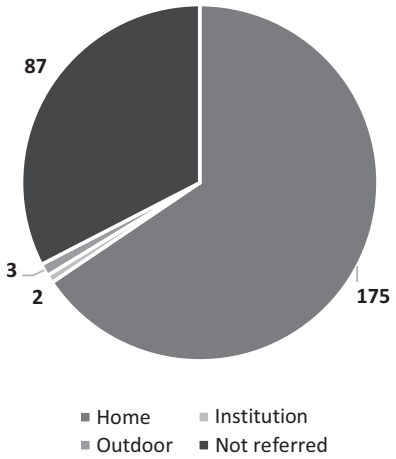

Fig. 2.4 Types of contexts where AAL solutions are planned to be used

From the analysis of the retrieved articles, they were classified as technology or systems. Technology articles refer to the description of an architecture or a component, such as a specific algorithm. A system is a practical AAL system applied in a specified context and with a well-defined aim. Near 60% of the articles were classified as technology (Ahmad et al. 2016a, b; Alemán et al. 2015a, 2016; Alexander et al. 2011; Amala Rani et al. 2015; Anastasiou 2012; Andò et al. 2014; Anguita et al. 2012; Anido et al. 2013; Arcelus et al. 2007; Armstrong et al. 2010; Atayero et al. 2016; Bae and Kim 2011; Baldewijns et al. 2016; Bamidis et al. 2010; Batool et al. 2014; Bisio et al. 2015; Blasco et al. 2014; Boers 2009; Bonino et al. 2012; Boucha et al. 2017; Bravo et al. 2012; Brestovac et al. 2014; Brulin et al. 2012; Burns et al. 2012; Carneiro et al. 2010; Chang et al. 2014; Chen 2007; Chiang and Liang 2015; Cleland et al. 2014; Conejar et al. 2016; Costa et al. 2017; 2010; Culmone et al. 2014; Cunha 2015; Davis et al. 2016; Dayangac and Hirtz 2014; de Backere et al. 2017; De Ruyter and Pelgrim 2007; De Santis et al. 2015; Demiris and Thompson 2011; Dengler et al. 2007; Dersingh 2014; Doukas and Maglogiannis 2011; Eichelberg et al. 2010; Evchina and Martinez Lastra 2016; Fan et al. 2015; Fergus et al. 2011; Fernández et al. 2009; Fernandez-Carmona and Bellotto 2016; Fleury et al. 2010; Fong et al. 2012; Freitas et al. 2014; Gappa et al. 2012; García et al. 2009; García-Rodríguez et al. 2015; Gatton and Lee 2010; Gil et al. 2007; Gjoreski et al. 2014; Havlík et al. 2012; He and Zeadally 2015; He 2016; Hegarty et al. 2009; 2010; Hein et al. 2010; Hong and Nugent 2009; Hui-Kyung and In-Cheol 2011; Islam 2011; Islam et al. 2009; Istepanian et al. 2011; Ivanov et al. 2015; Jara et al. 2009; Jenko et al. 2007a, b; Kaenampornpan et al. 2011; Kantawong 2016; Katzouris et al. 2013; Kelly et al. 2017; Kelly et al. 2009; Kentta et al. 2007; Kieffer et al. 2009; Kim et al. 2010; Konstantinidis et al. 2015; Koshmak et al. 2013; Kunnappilly et al. 2016; 2017; Lampoltshammer et al. 2014; Lankri et al. 2009; Lenca et al. 2016; Leone et al. 2011; Locatelli et al. 2017; Lopez Mejia et al. 2016; Luca et al. 2013; Madias 2016; Magherini et al. 2013; Maglogiannis et al. 2016; Marschollek et al. 2007; Miranda et al. 2016; Mitabe and Shinomiya 2017; Moraru

et al. 2017; Moreno et al. 2013; Morgavi et al. 2007; Moumtzi et al. 2009; Nef et al. 2014; Nilas 2011; Nisar et al. 2016; Nuovo et al. 2014; Oberzaucher et al. 2009; Otoom and Alzubaidi 2017; Ou et al. 2013; Ouedrago et al. 2017; Palumbo et al. 2014; Pardo et al. 2015; Persson et al. 2013; Pioggia et al. 2009; Pistorio et al. 2017; Pontes et al. 2017; Porambage et al. 2015; Qadeer et al. 2009; Quer and Danieletto 2015; Quero et al. 2007; Quintas et al. 2013; Ramlee et al. 2012; Reis et al. 2016; Ribeiro et al. 2015; Saidinejad et al. 2015; Saives and Faraut 2014; Salatino et al. 2016; Schlebusch 2011; Schneider et al. 2017; Shamsi et al. 2011; Sheahen and Skubic 2015; Sili et al. 2013; Sili et al. 2014; Sommaruga et al. 2011; Sorvala et al. 2012; Spanoudakis et al. 2010; Su 2015; Su and Chiang 2013; Su and Shih 2011; Sucerquia et al. 2017; Symonds et al. 2007; Tan et al. 2013; Terroso et al. 2013; Tran 2015; Alam 2017; Unluturk and Kurtel 2012; Vacher et al. 2014; Valero et al. 2013; Vanus et al. 2017; Venkatesh et al. 2011; Viet et al. 2012; 2013; Vineeth et al. 2017; Vinjumur et al. 2010; Xiao 2013; Yamazaki 2012; Yang et al. 2016; Yao et al. 2016a; b; Yu et al. 2012; Yuan and Bureau 2016; Yuchae 2017; Zarri 2013; Zeng 2008; Zhou 2010; Zolfaghari et al. 2016; Zou et al. 2008).

Moreover, 40% were classified as systems (Alexander et al. 2011; Bamidis et al. 2010; Chiang and Liang 2015; Freitas et al. 2014; Kentta et al. 2007; Koshmak et al. 2013; Ribeiro et al. 2015; Sili et al. 2014; Terroso et al. 2013; Agoulmine et al. 2011; Ahanathapillai et al. 2015; Alam et al. 2016; Alemán et al. 2015b; Ando et al. 2015; Angelo et al. 2010; Austin et al. 2016; Backere et al. 2017; Barham et al. 2015; Basili et al. 2016; Boulos et al. 2011; Cao et al. 2012; Carús et al. 2014; Chang et al. 2016; Ciampolini et al. 2016; Coronato et al. 2010; Costa et al. 2014; Damaševičius et al. 2016; Danilovich et al. 2017; De Maso-Gentile et al. 2015; Deen 2015; Dohr et al. 2010; Doyle and Walsh 2015; Eichelberg et al. 2014; Ejupi et al. 2015; Fahim et al. 2012; Ferreira and Ambrósio 2012; Figueiredo et al. 2016; Fiorini et al. 2017; Foroughi et al. 2008; Fratu et al. 2015; Göllner et al. 2011; Govercin et al. 2016; Gschwind et al. 2015a; b; Helmy and Helmy 2015; Hervas et al. 2013; Hidalgo et al. 2011; Hill et al. 2015; Hine et al. 2012; Holthe and Walderhaug 2010; Iglesias et al. 2009a; b; Jeon et al. 2017; Juang and Wu 2015; Junnila et al. 2010; Kaluza et al. 2010; Kaye et al. 2008; Kiselev et al. 2015; Krishnan and Cook 2014; Kue et al. 2015; Kuhn et al. 2009; Lee et al. 2011; 2013; 2015; Li et al. 2009; 2015; Losardo et al. 2011; 2014; Lotfi et al. 2017; Magar et al. 2017; Maglogiannis 2014; Martin et al. 2013; McCrindle et al. 2011; Miori and Russo 2017; Mitseva et al. 2009; Mokhtari and Feki 2007; Nakagawa et al. 2016; Niemela et al. 2007; Norgall and Wichert 2013; Núñez-Naveira et al. 2016; Ogonowski et al. 2016; Passas et al. 2012; Payyanadan et al. 2017; Pensas et al. 2013; Pierleoni et al. 2015; Prescher et al. 2012; Preuss and Legal 2017; Rakhman et al. 2014; Richter et al. 2015; Rosas et al. 2014; Schaad et al. 2016; Schenk et al. 2011; Seewald et al. 2010; Shen et al. 2013; Siegel et al. 2014; Silveira et al. 2013; Spinsante 2017; Stucki and Urwyler 2014; Sun et al. 2009; Suryadevara and Mukhopadhyay 2014; 2015; Ueda et al. 2015; Ullah et al. 2012; Wolfgang Inninger and Nicole Wagner 2012; Zambanini et al. 2010; Žele et al. 2017; Zhou et al. 2016) (Fig. 2.5). Nine articles referring to different types of developments were classified both as technology and systems, considering that they reported a technological

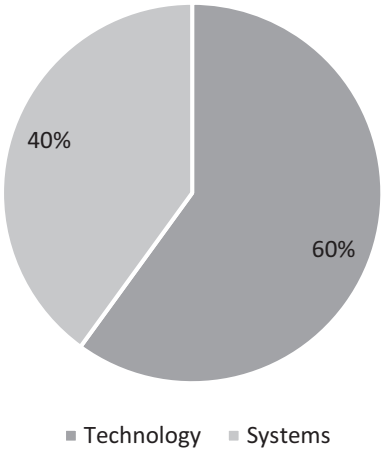

Fig. 2.5 Distribution of articles classified as technology and systems

component, as well as the system integrating that component. For example, Zhou et al. (2010) developed a personal diabetes monitoring system which integrates wearable sensors and 3G mobile phones.Several articles refer to the development of architectures (i.e. the rationale for the integration of different component and services). An example is the study of Quero et al. (2007) that presents the MIMOSA architecture and the respective development platform to create applications, or the article of J. Yuchae (2017) that proposes a hybrid inspection service middleware for monitoring older adults. Examples of specific components are a RFID prototype (Symonds et al. 2007) or a low-cost wireless sensor network (Nilas 2011). Other articles considered the development of specific algorithms to process information (e.g. ontologies to support the management of networks of sensors (Culmone et al. 2014), methods to capture and process data streams (Maglogiannis et al. 2016) or signal processing and machine learning algorithms to detect physiological symptoms and infer macro-level activities (Alam 2017)). There were also articles that reported more complex developments (e.g. Chang et al. (2014) reported a motion-sensing carpet for tele-monitoring mobility level, indoor locations and fall events and presented multiple interactive applications based on this motion-sensing carpet, or Vacher et al. (2014) that developed a voice command integrated in a smart home).

Some articles refer developments related to the interaction with AAL solutions. For instance, Férnandez et al. (2009) presented a method and an implementation of an interface with smart homes, based on natural language, or Hegarty et al. (2010) presented a cooperative interface communication coupled with context awareness to facilitate the optimisation and customisation of displays. Few of the reported solutions are based on Internet Protocol TV (IPTV). Moreover, the concerns with the interoperability of different components are scarce.

The different types of AAL systems found in this review are presented in Fig. 2.6. A description of the objective of the articles classified as systems can be found in Annex I.

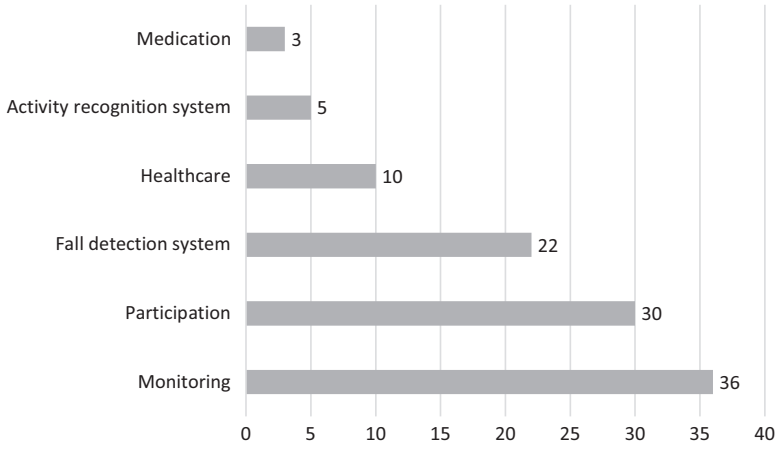

Fig. 2.6 Distribution of articles considering the type of systems

Only three articles (Fiorini et al. 2017; Lee et al. 2011; Spinsante 2017) were related to medication management. Lee et al. (2011) developed a system that integrates RFID-based medication management. Other example is the work of Fiorini et al. (2017) that presents a hybrid robot cloud approach to develop a service model for personalized medical support.

According to our analysis, the reported solutions to perform activity recognition (Damaševičius et al. 2016; Krishnan and Cook 2014; Nakagawa et al. 2016; Ueda et al. 2015; Zhou et al. 2016) (i.e. systems able to detect different activities) were classified as systems. For instance, finger-worn devices (Zhou et al. 2016), wearable devices (Nakagawa et al. 2016) or power metres attached to appliances or positioning sensor (Ueda et al. 2015) are able to recognize different daily living activities, without compromising the privacy of the users.

As expected, most of articles (i.e. 36 articles) classified as systems are related to home monitoring of different physiological parameters or activities of older adults, using different methods (Alexander et al. 2011; Zhou 2010; Agoulmine et al. 2011; Alam et al. 2016; Alemán et al. 2015b; Angelo et al. 2010; Austin et al. 2016; Boulos et al. 2011; Chang et al. 2016; Ciampolini et al. 2016; Coronato et al. 2010; Deen 2015; Dohr et al. 2010; Fahim et al. 2012; Ferreira and Ambrósio 2012; Fratu et al. 2015; Hine et al. 2012; Kaluza et al. 2010; Kaye et al. 2008; Li et al. 2015; Losardo et al. 2011; Losardo et al. 2014; Lotfi et al. 2017; Niemela et al. 2007; Richter et al. 2015; Stucki and Urwyler 2014; Suryadevara and Mukhopadhyay 2014; Suryadevara and Mukhopadhyay 2015; Žele et al. 2017). For example, Kaluza et al. (2010) proposed a system that is composed of seven groups of agents providing flexible monitoring of older adults in their environments, reconstructing positions and postures aiming to create physical awareness of the older adults, to react to critical situations, to call for help in the case of an emergency and to issue warnings if unusual behaviours are detected.

Home monitoring of health conditions together with the possibility of interaction with healthcare providers are functions presented in the AAL systems being reported. For instance, the eCAALYX (Boulos et al. 2011) android smartphone application receives inputs from a patient-wearable smart garment with wireless health sensors and from a global positioning system (GPS) location sensor in the smartphone and communicates over the Internet with a remote server accessible by healthcare providers. Also, Ciampolini et al. (2016) argued about a strategy for indirect monitoring of health conditions, requiring less participating effort of older adults. They propose the deployment of a highly heterogeneous sensing network in the older adults living environments, including clinical devices (e.g. measuring blood pressure, body weight, blood sugar or oxygen concentrations), environmental devices (e.g. room presence, bed/chair occupancy, toilet usage, fridge or pantry access) and wearable devices (e.g. accounting for physical activity evaluation, fall detection or carrying identification information).

Losardo et al. (2014) evaluate, for several months in a real context, a system that includes three sensors of presence located in the bathroom, the hallway and the kitchen: a bed-occupancy sensor, a sofa-occupancy sensor and a door sensor on the main door. All sensors were wirelessly connected with ZigBee technology, and the network activity was logged in a database. The system aims at helping relatives and caregivers to identify suggestive alterations in health status of older adults as early as possible. Also, Suryadevara and Mukhopadhyay (2015) monitor important daily activities through the observation of everyday object usages to inform caregivers about the activities of the patients.

In what concern to systems to improve the communication between the patients and caregivers, ten articles were identified (Ribeiro et al. 2015; Figueiredo et al. 2016; Govercin et al. 2016; Hervas et al. 2013; Hidalgo et al. 2011; Hill et al. 2015; Iglesias et al. 2009b; Norgall and Wichert 2013; Rosas et al. 2014; Shen et al. 2013). Some of the articles referred systems that enable caregivers to monitor patients at home (Iglesias et al. 2009b). For instance, Hervas et al. (2013) propose a system to manage cardiovascular disease through an end-to-end software application for patients and physicians and a rule-based reasoning engine that combines the monitoring of the blood pressure by means of mobile devices with other clinical parameters.

Fall detection systems were reported by 22 articles (Freitas et al. 2014; Koshmak et al. 2013; Terroso et al. 2013; Ando et al. 2015; Backere et al. 2017; Basili et al. 2016; Cao et al. 2012; De Maso-Gentile et al. 2015; Ejupi et al. 2015; Foroughi et al. 2008; Gschwind et al. 2015a; b; Helmy and Helmy 2015; Jeon et al. 2017; Juang and Wu 2015; Kiselev et al. 2015; Lee et al. 2013; Maglogiannis 2014; Ogonowski et al. 2016; Pierleoni et al. 2015; Rakhman et al. 2014; Zambanini et al. 2010). For instance, Foroughi et al. (2008) proposed a method to detect various posture-based events in a typical older adult monitoring application in a home surveillance scenario; an ambient-based fall detection system based on a pressure-sensing triboelectric nanogenerator array was proposed by Jeon et al. (2017), for appropriate filtering and distinguishing between falls and daily activities; and the use of sensors and smart devices were also reported by Backere et al. (2017). Moreover, the iStoppFalls (Gschwind et al. 2015a) project (i.e. a randomized controlled trial to assess the feasibility of the intervention programme to deliver unsu-

pervised exercises to older peoples in their residential environments) aims to prevent common fall risk factors.

AAL solutions can modify external factors (e.g. environmental factors) to improve the participation of older adults (World Health Organization 2001). In this respect, 30 articles (Bamidis et al. 2010; Barham et al. 2015; Carús et al. 2014; Danilovich et al. 2017; Doyle and Walsh 2015; Eichelberg et al. 2014; Göllner et al. 2011; Holthe and Walderhaug 2010; Iglesias et al. 2009a; Kue et al. 2015; Kuhn et al. 2009; Li et al. 2009; Magar et al. 2017; Martin et al. 2013; McCrindle et al. 2011; Mitseva et al. 2009; Mokhtari and Feki 2007; Núñez-Naveira et al. 2016; Passas et al. 2012; Payyanadan et al. 2017; Pensas et al. 2013; Preuss and Legal 2017; Schaad et al. 2016; Schenk et al. 2011; Seewald et al. 2010; Siegel et al. 2014; Silveira et al. 2013; Sun et al. 2009; Ullah et al. 2012; Wolfgang Inninger and Nicole Wagner 2012) were identified reporting AAL solutions aiming to improve the participation of older adults. In particular, some articles aim to decrease social isolation by promoting interactions with other people. Mitseva et al. (2009) developed a system to guarantee safety at home, to support basic daily activities and to promote daily interaction with relatives, friends and caregivers, giving older adults the feeling of safety and preventing their social isolation. Also, Pensas et al. (2013) presented the AMCOSOP system that might enable older adults to stay connected to their families, friends and safety networks, even if they are living by themselves.

Easy management of the social agenda to improve participation of older adults was another type of AAL system found in this systematic review. For instance, Iglesias et al. (Iglesias et al. 2009a) described a digital agenda application, which was tested by a group of older adults. This customized personal agenda allows older adults to create agenda entries and to view calendar entries and select a particular telephone number without typing any letter or number.

Also, systems to improve mobility were reported. For instance, the project 'immer Mobil – be always Mobile' enables senior citizens to use up-to-date and enhanced mobility offers in rural areas in a convenient and easy way (Wolfgang Inninger and Nicole Wagner 2012).

Finally, the control of home appliances in a home automation scenario was proposed by Magar et al. (2017) using GSM to remotely control home appliances connected by a low-cost wireless network.

Concerning the methods used to evaluate AAL solutions, in this study, the approach of Martins et al. was used (Queirós et al. 2013b) that defines three reference phases. The first phase is the conceptual validation, followed by the prototype test and, finally, the pilot test.

Figure 2.7 presents the distribution of articles by the type of evaluation: 150 articles (i.e. approximately 56%) did not refer to any information about evaluation of AAL solution proposed, 56 articles (i.e. approximately 21%) referred to a conceptual validation of AAL solutions, 31 referred to prototype evaluations (i.e. approximately 12%) in controlled environments, and 20 (i.e. approximately 7%) referred to pilot experiences.

The conceptual validation aims to verify if the idea of the AAL solution is sustainable and deserves to be explored. It can be the whole solution or just a technological component. For instance, signal processing and machine learning algorithms

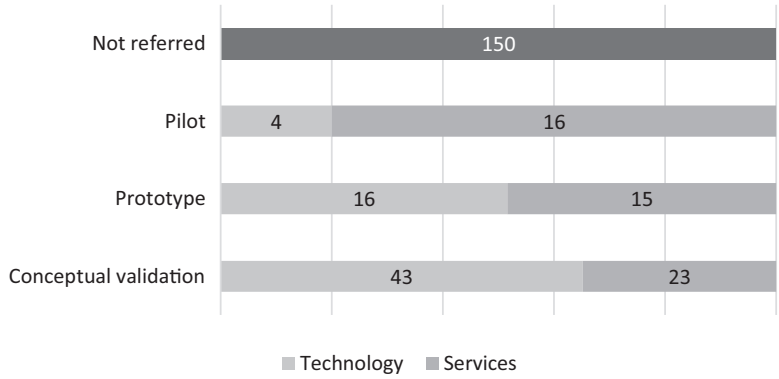

Fig. 2.7 Distribution of articles by type of evaluation

to detect physiological symptoms and infer macro-level activities of the inhabitants was evaluated by comparing the results obtained with this component and real-time data collected in a continuing care retirement community centre (Alam 2017). Also, Vanus et al. (2017) and Pardo et al. (2015) did the same type of evaluation. The first, based on the monitoring of operational and technical functions (unregulated, uncontrolled) in an experimental smart home, trained a neuronal network through the data picked up by the sensors of CO2, T and rH with the aim to indirectly predict CO_2 leading to the elimination of CO_2 sensors from the measurement process. The second study validates an algorithm through a simulation study that uses a Bayesian baseline model to compare with a database of a real application aiming to determine the performance and accuracy.

The prototype test aims to collect information regarding usability and user satisfaction. At this stage there may be a physical implementation of the prototype of the AAL solutions, to be tested by the users. The prototype test is performed in a controlled environment. Oberzaucher et al. (2009), during 14 days, tested a touch screen to interface a video telephone system to evaluate if and to what extent the older adults would benefit from using such a modern multimodal way of communication. Four prototype systems were installed in four private homes and were tested successfully by six persons. It was found that the older adults benefited from the touchscreen control, the proportionally large-scale graphical user interfaces and the video-telephone functions. Also, Fiorini et al. (2017) evaluate the technical feasibility and user acceptability level of a service model for personalized medical support service. The service was tested with 23 older adults (65–86 years) in the DomoCasa Lab (Italy), confirming the ability to utilize these innovative technologies for active and healthy ageing. Usability is often tested in prototype stage. For instance, Kiselev et al. (2015) planned a prototype study to measure usability, user acceptance and effect on physical abilities and quality of life.

Finally, the pilot test aims to evaluate, besides usability, the degree of users' satisfaction and the meaning that a given system or service may have in their lives. The period of tests has a long duration and involves users in their natural context.

The AAL solution developed by Austin et al. (2016) was evaluated for 8 months. This system to measure loneliness by assessing in-home behaviour was tested in a longitudinal study involving 16 older adults who agreed to have the sensor platform installed in their own homes. Also, Holthe and Walderhaug (2010) tested for 1 year the AAL solution they propose. Seven older people and their family carers participated in the pilot trial, which aimed to evaluate the services provided through an individual internet-based digital plan displayed as a calendar page. The video game technology proposed by Gschwind et al. (2015a) to prevent falls was tested with a 148 community-dwelling people, aged 65+ years, and assessment measures included overall physiological fall risk, muscle strength, finger-press reaction time, proprioception, vision, balance and executive functioning. The interventions were delivered as unsupervised exercise programmes in participants' homes for 16 weeks.

2.4 Discussion

AAL emerged as an initiative of the European Union to solve the increasing needs of the older adults, which is one of the major current concerns in terms of sustainability of the modern society (Sánchez-Pi and Molina 2009).

The systematic review demonstrates that the number of articles related to AAL solutions increased during the period 2007–2017, despite the slight decrease in 2017. This can be explained by the fact that the search was performed in the beginning of 2018, and probably there were articles from 2017 still not indexed. The positive development can be related to population ageing and with technological development that facilitates the integration of different components of AAL solutions (World Health Organization 2015).

AAL intends to improve human functioning, autonomy and quality of life of older adults in their natural environments. Therefore, a wide range of solutions is being considered (i.e. the first research question).

Despite that AAL solutions are supported by sensors, which are more reliable in an indoor environment than in an outdoor environment, environment context may be indoor or outdoor, once people have their daily activities inside the house or in the surrounding environments, such as public spaces. Of the retrieved articles, most of them were for indoor environment, namely, solutions for a residential context. Most of the systems were related to indoor activities, as monitoring, fall detection or activity recognition systems, for example, the development of "WhizCarpet," a motion-sensing carpet for tele-monitoring indoor movements and locations, and fall events, with multiple interactive applications, in an unobtrusive way for older adults in the home environment (Chang et al. 2014). This is also related with the number of technological component developments more directed for this indoor context (transform home into a smart home).

Comparing the number of technology and systems with a previous review of 2013 (Queirós et al. 2015), the paradigm has changed: although the number of technological component is bigger than integral solutions, proportionally, the

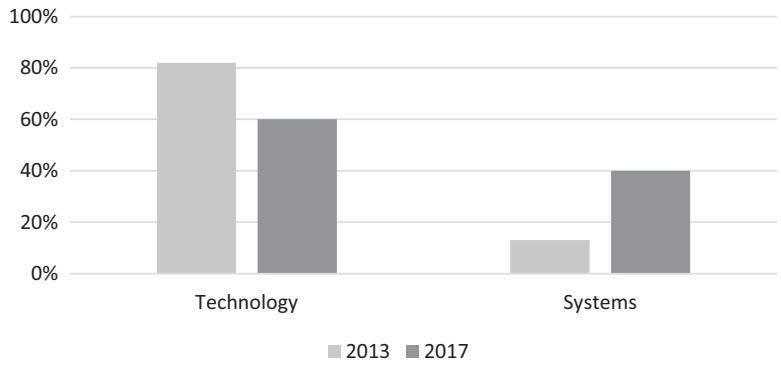

Fig. 2.8 Proportion of number of technological components and systems

number of integral solutions has increased (Fig. 2.8). The development of technological components has decreased compared with the development of systems that can be used by real users. This is in line with objectives of AAL: only systems can be in used in a real context, with real users, and only these AAL solutions can contribute to improve human functioning and guarantee autonomy and quality of life of older adults.

In the previous review (Queirós et al. 2015), less than 5% of the included articles were related to participation of older adults. In this study, this number increased for more than 10%. This is a relevant result considering the main objectives of AAL and turns evident that developers are beginning to be concerned on how technology can be used in the AAL context, instead of looking at specific needs of the users and proposing ways to solve them, for example, falls detection. Despite this result, some articles suggest that even real users prefer solutions to solve health needs (e.g. home monitoring) than social activities that decrease isolation. An example of this are the results of SmartSeniors@home, where the services for general assistance and health, such as audio/video communication, blood pressure monitoring and communication with a health professional, were rated as very attractive compare with services to promote social interaction (Govercin et al. 2016).

Internet protocol television (IPTV) allows interactive and personalized systems and a broad range of interactive possibilities. Older adults know how to use television, and the IPTV protocol could be a way to solve the problem of digital literacy among this population. However, technological advances in terms of interactive services and platforms usually are accompanied complex interfaces as well as their usage, resulting in poor usability. The complexity of IPTV services and content presentations therefore demands novel solutions for IPTV systems to present contents and to allow a more natural and efficient interaction with the users (Ribeiro et al. 2015; Rojc et al. 2017). The results of this review are in line with this concern, since only five of the included articles were related to IPTV solutions.

The integration of AAL is very complex, and there is a need to guarantee interoperability between components to decrease the costs of the implementations and increase efficiency. The interoperability is still a problem (Camarinha-Matos and Afsarmanesh

2011; van den Broek et al. 2010). The results demonstrated that few articles referred concerns about interoperability, which is in line with the study of Dias et al. (2018) where only 2% studies of 2781 referred or explicitly mentioned the issue of interoperability. Common AAL platforms must be based on selected standards to allow interoperability of applications and services (van den Broek et al. 2010).

Considering the second research question (i.e. how are AAL solutions being evaluated?), most of the included article did not refer evaluation processes, which might indicate that the developers still do not give the necessary relevance to this issue. This is in line with the results of Queirós et al. (2015) that report the lack of involvement of real users in all phases of development, and many AAL solutions were only tested in laboratory.

There are many articles referring the use of conceptual validation, especially in technological components or small parts of systems that are tested for the validation of an idea. There is still a high number of this type of evaluation related to systems which may demonstrate that developers are still more concerned to the development and implementation rather than to the evaluation and efficacy of the system developed.

AAL solutions should maintain and increase human functionality through the integration of technology in the natural environment of the older person. The focus should be the person, not the technology, so it is necessary to develop AAL systems that can support users' needs. Considering the relevance of AAL systems to the main objective of AAL, the characterization of AAL systems, found in this systematic review, will be presented in the next chapter.

Annex I: Objective of the Articles Classified as Systems

Authors	Year	Objective	Type of system
Kentta et al. (2007)	2007	To evaluate technology-based service scenarios to support independent living	Safety
Niemela et al. (2007)	2007	To present three scenarios describing how independent living of older adults can be supported with mobile-centric ambient intelligence services	Monitoring
Mokhtari and Feki (2007)	2007	To provide service continuity within the living environment, both indoor and outdoor, by combining technological aids and mobile technologies to facilitate independent living for all in the home or in temporary living environments	Participation
Kaye et al. (2008)	2008	To design and implement a system for application to a community-based clinical trial of the efficacy of a basic sensor net (i.e. motion and contact sensors, RF location systems and personal home computer interaction)	Monitoring

Authors	Year	Objective	Type of system
Foroughi et al. (2008)	2008	To propose a method to detect various posture-based events in a typical monitoring application for a scenario of home surveillance of older adults	Fall detection system
Kuhn et al. (2009)	2009	To promote daily information management for older adults with decreased visual abilities, as well as with limited experience in human computer interfaces	Participation
Iglesias et al. (2009a)	2009	To develop and evaluate a digital agenda application that allows older adults to create agenda entries, to view calendar entries and to access a particular telephone without typing any letter or number	Participation
Iglesias et al. (2009b)	2009	To present a health monitoring system where users can identify themselves by a simple touch device and health information can be wirelessly collected and associated with an identified user	Healthcare
Li et al. (2009)	2009	To introduce an intelligent oven for healthier food choice that is woven inside smart home environments	Participation
Mitseva et al. (2009)	2009	To develop intelligent custom services aiming at improving the quality of life of older adults with pre- and mild dementia living in their own homes and also the quality of life of their caregivers	Participation
Sun et al. (2009)	2009	To build mutual assistance for communities not only allowing efficient utilization of the social resources in maintaining the independent living of older adults but also helping these people maintain their connections to the society and bring them entertainment	Participation
Kaluza (2010)	2010	To present a multi-agent system for the care of older adults living at home on their own, aiming to prolong their independence	Monitoring
Dohr et al. (2010)	2010	To use smart objects and technologies to facilitate home monitoring processes	Monitoring
Coronato et al. (2010)	2010	To present a software infrastructure that enables the rapid prototyping of smart applications for monitoring patients in environments such as homes or hospitals	Monitoring
Zhou (2010)	2010	To propose a personal monitoring system which integrates wearable sensors, 3G mobile phones, smart home technologies and Google Health to facilitate the management of the diabetes disease	Monitoring
Holthe and Walderhaug (2010)	2010	To develop a technical middleware platform with reusable components that enables rapid development of domain-specific applications that can be personalized for individual use	Participation

Authors	Year	Objective	Type of system
Seewald et al. (2010)	2010	To develop applications fostering the social inclusion and well-being of older adults	Participation
Bamidis et al. (2010)	2010	To present an environment offering a flexible combination of personalized care services for general citizens according to their preference or available technologies, as well as a service aiming cognitive and physical training for older adults inside an independent living setting	Participation
Angelo et al. (2010)	2010	To present an internet-based, automated home care ECG upload and prioritization	Monitoring
Junnila et al. (2010)	2010	To present a general-purpose sensor network and a monitoring platform to support applications ranging from older adults monitoring to early homecoming after a hospitalization period	Monitoring
Hidalgo et al. (2011)	2011	To propose a smart process management, based on artificial intelligence planning and scheduling, able to design timed sequences of activities that solve problems in a given environment	Healthcare
Schenk et al. (2011)	2011	To present a system that uses off-the-shelf sensors and telecommunication technologies to measure continuously individual life space and activity	Participation
Alexander et al. (2011)	2011	To present the evolution of an early illness warning system used by an interdisciplinary team composed by clinicians and engineers in an independent living facility.	Monitoring
Boulos et al. (2011)	2011	To present the development of a smartphone application for remote monitoring and management of older patients with multiple chronic conditions	Monitoring
Lee et al. (2011)	2011	To present the development and testing of a home solution for older adults' medication management and communication	Medication
Göllner et al. (2011)	2011	To introduce two design concepts based on mobile technology to help older adults carrying out daily tasks and managing meetings	Participation
Agoulmine et al. (2011)	2011	To present a smart home to help older adults to continue to live an independent life in their own home while being monitored and assisted	Monitoring
McCrindle et al. (2011)	2011	To develop a wearable device that can be used to support older people in their daily activities, to monitor their health status, to detect potential problems, to provide activity reminders and to offer communication and alarm services	Participation

Authors	Year	Objective	Type of system
Losardo et al. (2011)	2011	To identify affordable technologies suitable for contrasting (older adults) depopulation of rural and mountain areas and at fostering their exploitation within the existing framework of social and health services	Monitoring
Hine et al. (2012)	2012	To develop a domestic well-being indicator system to present information to stakeholders and a model-instrumented house to promote understanding among stakeholders regarding home care technology	Monitoring
Fahim et al. (2012)	2012	To develop an android smartphone application to assists older adults for independent living in their own homes	Monitoring
Cao et al. (2012)	2012	To present a fall detection system derived from motion sensors via an android-based smartphone utilizing adaptive threshold algorithms	Fall detection system
Wolfgang Inninger and Nicole Wagner (2012)	2012	To improve the mobility of older adults by matching transportation needs and transportation services	Participation
Passas et al. (2012)	2012	To design and implement a flexible peer-to-peer platform to allow older adults to build virtual communities dynamically based on interests and needs they share	Participation
Ullah et al. (2012)	2012	To present a touch-based smart home controlling system, which augments the older adults' experiences	Participation
Ferreira and Ambrósio (2012)	2012	To present an interoperable health-assistive platform designed to meet the requirements related to caring, monitoring and motivating the older adults in their own environments	Monitoring
Prescher et al. (2012)	2012	To present a home monitoring system aimed at supporting older adults suffering with co-morbidity	Monitoring
Koshmak et al. (2013)	2013	To propose a framework which uses mobile phone technologies together with physiological data monitoring to detect falls	Fall detection system
Pensas et al. (2013)	2013	To design and implement a system that enables the older adults to stay connected with their families, friends and safety network even though they are living by themselves	Participation
Shen et al. (2013)	2013	To propose a videophone system for the care of older adults	Healthcare
Lee et al. (2013)	2013	To design and implement an android-based smartphone with 3-axial accelerometer to support telehealth and detect falls	Fall detection system
Terroso et al. (2013)	2013	To present a system consisting of a wearable sensor unit, a smartphone and a website to detect falls and to notify the family members or stakeholders	Fall detection system

Authors	Year	Objective	Type of system
Silveira et al. (2013)	2013	To propose a system to support active and healthy ageing by providing a proactive training application, running on a tablet, to improve the balance and strength of older adults	Participation
Hervas et al. (2013)	2013	To present a system to estimate the risk of cardiovascular diseases in AAL environments, through reasoning techniques and context awareness	Healthcare
Martin et al. (2013)	2013	To present a system to support daily living activities	Participation
Norgall and Wichert (2013)	2013	To present a universal platform for both AAL and personal health applications	Healthcare
Losardo et al. (2014)	2014	To report an AAL utilization in a real-world context by describing the case of a 92-year-old woman with mild physical and cognitive age-related impairments that was supported by a system to promote her safety and confidence when staying alone at home	Monitoring
Rakhman et al. (2014)	2014	To present a prototype of ubiquitous fall detection and alert system using smartphones	Fall detection system
Siegel et al. (2014)	2014	To study the effects of AAL on quality of life, health and technology acceptance of people at advanced age living in assisted living homes	Participation
Maglogiannis (2014)	2014	To present an application that utilizes a low-cost smart watch together with an android smartphone to allow the transmission, storage and processing of motion data	Fall detection system
Carús et al. (2014)	2014	To present a self-care solution for older adults, based on self-check of health conditions and self-fitness at home	Participation
Rosas et al. (2014)	2014	To create an ecosystem for AAL aiming to facilitate partnership creation between service providers as a strategy to improve care provision and leverage its capacity	Healthcare
Eichelberg et al. (2014)	2014	To present an overview of the architecture and core functions of a technical platform to integrate various assistive systems	Participation
Krishnan and Cook (2014)	2014	To propose and evaluate a sliding window-based approach to perform activity recognition in an online or streaming fashion	Activity recognition system
Suryadevara and Mukhopadhyay (2014)	2014	To present the application of computing technology to determine the wellness of older adults living independently in their home	Monitoring
Stucki and Urwyler (2014)	2014	To propose a passive, web-based, nonintrusive, assistive technology system to recognize and classify activities of daily living	Monitoring
Costa et al. (2014)	2014	To use AAL environments to promote physical activity among older adults	Monitoring

Authors	Year	Objective	Type of system
Freitas et al. (2014)	2014	To present a fall detection system	Fall detection system
Ejupi et al. (2015)	2015	To examine the feasibility of a low-cost and portable Kinect-based system to discriminate between fallers and non-fallers and to investigate whether this system can be used for supervised clinical and supervised and unsupervised in-home fall risk assessments	Fall detection system
Helmy and Helmy (2015)	2015	To present a mobile application for continuous detection of seizures and falls to support people with epilepsy and fall risk	Fall detection system
Ando et al. (2015)	2015	To develop a smartphone-based detector of activities of daily living, able to discriminate between different kinds of falls	Fall detection system
He and Zeadally (2015)	2015	To propose an authentication protocol for AAL systems and to describe how it meets various security requirements	Security
De Maso-Gentile et al. (2015)	2015	To present a low-power free-scale board with a three-axis capacitive accelerometer and a Bluetooth connection to be used in connection with a smartphone for fall detection in AAL applications	Fall detection system
Doyle and Walsh (2015)	2015	To combine different types of technologies to predict changes in well-being and to deliver feedback and interventions to support personal wellness management	Participation
Alemán et al. (2015a)	2015	To present an AmI system that fusions geo-localization sensors data embedded in smartphone devices for the monitoring of older adults	Monitoring
Kiselev et al. (2015)	2015	To evaluate the usability of a motivational interactive training system for fall prevention and stroke rehabilitation	Fall detection system
Richter et al. (2015)	2015	To present an AAL concept related to the care of people suffering from dementia	Monitoring
(Ueda et al. 2015)	2015	To propose a living activity recognition method based on power metres attached to appliances and a positioning sensor attached to the resident	Activity recognition system
Juang and Wu (2015)	2015	To propose an algorithm using the triangular pattern rule to detect fall-down movements of humanoid by the installation of a robot with camera vision at home that will be able to judge the fall-down movements of older adults in real time	Fall detection system
Deen (2015)	2015	To introduce several low-cost, noninvasive, user-friendly sensing and actuating systems	Monitoring
Suryadevara and Mukhopadhyay (2015)	2015	To present the application of computing technology to determine the wellness of the older adults living independently in their home	Monitoring

Authors	Year	Objective	Type of system
Kue et al. (2015)	2015	To present the implementation of a mobile platform that utilizes smartphone hardware such as the accelerometer and voice recording to monitor and react to older adults physical activity and inactivity	Participation
Hill et al. (2015)	2015	To evaluate the feasibility of an attention training application for community-dwelling older adults using mobile technology	Healthcare
Fratu et al. (2015)	2015	To present how a monitoring system fits the Romanian healthcare regulations and procedures requirements for chronic obstructive pulmonary disease and mild dementia patients	Monitoring
Barham et al. (2015)	2015	To present a smartphone application to help older adults to travel independently using public transport	Participation
(Pierleoni et al. 2015)	2015	To propose a method based on the support vector machine technique and implemented on low-cost android smartphones to detect falls of older adults	Fall detection system
Porambage et al. (2015)	2015	To propose a proxy-based authentication and key establishment protocol to safeguard sensitive data generated by resource-constrained devices in IoT-enabled AAL systems	Security
Lee et al. (2015)	2015	To propose a home occupant tracking system that uses smartphones and off-the-shelf smart watches	Monitoring
Chiang and Liang (2015)	2015	To study motion-sensing interaction between patients and systems in various living spaces	Monitoring
Ahanathapillai et al. (2015)	2015	To present assistive technology able to perform activity monitoring, particularly a wrist wearable unit	Monitoring
Ribeiro et al. (2015)	2015	To present the usability evaluation of an application running in a commercial service of internet protocol TV to support home care of older adults	Healthcare
Li et al. (2015)	2015	To investigate the use of emerging sensor technology in a smart home setting to intelligently monitor lifestyle and to detect potential progressive decline in physical and cognitive abilities	Monitoring
Gschwind et al. (2015b)	2015	To compare feasibility and efficacy of two exergame interventions	Fall detection system
Gschwind et al. (2015a)	2015	To assess the feasibility (i.e. exercise adherence, acceptability and safety) of a system able to deliver unsupervised exercise programme in older adults' homes	Fall detection system

Authors	Year	Objective	Type of system
Ogonowski et al. (2016)	2016	To use participative design and persuasive health approaches to allow for seamless integration of a fall prevention system into an older adults' everyday life	Fall detection system
Nakagawa et al. (2016)	2016	To propose a method that uses the acceleration data from wearable devices for classifying activities or events	Activity recognition system
Figueiredo et al. (2016)	2016	To present an emergency application for smartphones, enabling users to simply hit their devices in order to send an alarm signal to an emergency service	Safety
Austin et al. (2016)	2016	To present a system to measure loneliness by assessing in-home behaviour using wireless motion and contact sensors, phone monitors and algorithms developed to assess key behaviours of interest	Monitoring
Chang et al. (2016)	2016	To propose a smart home care system for older adults	Monitoring
Basili et al. (2016)	2016	To propose a fall detection system based on a smartphone and a board with three-axis accelerometer	Fall detection system
Núñez-Naveira et al. (2016)	2016	To evaluate the impact of an e-learning platform on the psychological status of informal caregivers	Participation
Alam et al. (2016)	2016	To present a system able to collect patients' psychiatric symptoms through lightweight biosensors and web-based psychiatric screening scales in a smart home environment and to analyse them through machine learning algorithms to detect psychiatric emergencies	Monitoring
Govercin et al. (2016)	2016	To examine the acceptance of a healthcare system by older adults.	Healthcare
Ciampolini et al. (2016)	2016	To present a strategy for indirect monitoring of health conditions, requiring less participating effort to the older adults	Monitoring
Schaad et al. (2016)	2016	To present a prototype of an intelligent wardrobe	Participation
Damaševičius et al. (2016)	2016	To propose a method for activity recognition and subject identification based on random projections from high-dimensional feature space to low-dimensional projection space, where the classes are separated using the Jaccard distance between probability density functions of projected data	Activity recognition system
Zhou et al. (2016)	2016	To present a system of learning living status by detecting daily activities using finger-worn devices and sharing information to supporters' smartphones	Activity recognition system
Lotfi et al. (2017)	2017	To develop an AAL platform to support both older adults and their carers to overcome the challenges of the care	Monitoring

Authors	Year	Objective	Type of system
Preuss and Legal (2017)	2017	To investigate the introduction of pet robots into domestic settings.	Participation
(Žele et al. 2017)	2017	To design a prototype of a mobile application allowing informal caregivers to monitor daily activities of older adults.	Monitoring
Backere et al. (2017)	2017	To present a risk detection system able to analyse incidents occurring in the home of older adults by using several sensors and smart devices	Fall detection system
Fiorini et al. (2017)	2017	To propose a service model for personalized medical support to provide adequate healthcare service by means of a hybrid robot-cloud approach	Medication
Danilovich et al. (2017)	2017	To present a community-engaged approach to develop a mobile application exercise intervention through focus groups and interviews	Participation
Payyanadan et al. (2017)	2017	To analyse the driving challenges faced by older drivers and guide the development of a customized web-based trip-planning tool	Participation
Jeon et al. (2017)	2017	To propose a cost-effective, fall detection system based on a pressure sensing triboelectric nanogenerator array	Fall detection system
Magar et al. (2017)	2017	To propose home appliances control using GSM	Participation
Spinsante (2017)	2017	To address two case studies in which a smartphone, when equipped with a proper software application, may operate as an inactivity monitor and a drug management assistant	Medication
Miori and Russo (2017)	2017	To develop and create a reference platform by applying technological solutions to simplify the daily activities of older adults and studying how they access dedicated services	Monitoring

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Chapter 3
Ambient Assisted Living: Systems Characterization

Alexandra Queirós, Milton Santos, Ana Dias, and Nelson Pacheco da Rocha

3.1 Introduction

Ambient assisted living (AAL) can be described as concepts, products and services that, through the integration of technology, aims to promote independence and quality of life of older adults.

The AAL solutions, embedded in the older adults' natural environment, should improve their functioning. For that, the developers should know and understand the needs of final users and their care providers (i.e. formal and informal care providers). It is necessary to go beyond the technology possibilities to reach the activities and participation for which final users need support, since the focus must be the person and not the technology.

A. Queirós (✉) · M. Santos
Health Sciences School, University of Aveiro, Aveiro, Portugal

Institute of Electronics and Telematics Engineering of Aveiro (IEETA), University of Aveiro, Aveiro, Portugal
e-mail: alexandra@ua.pt

A. Dias
Department of Economics, Management, Industrial Engineering and Tourism (DEGEIT), University of Aveiro, Aveiro, Portugal

Governance, Competitiveness and Public Policies (GOVCOPP), University of Aveiro, Aveiro, Portugal

N. P. da Rocha
Medical Sciences Department, University of Aveiro, Aveiro, Portugal

Institute of Electronics and Telematics Engineering of Aveiro (IEETA), University of Aveiro, Aveiro, Portugal
e-mail: npr@ua.pt

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In this context, AAL solution must be adapted to users, tasks and usage context (Queirós et al. 2015), in order to:

- Be used by older adults, their relatives and their formal and informal care providers;
- Support the realization of self-care activities (e.g. home monitoring of vital signs) or increase social participation (e.g. a digital agenda);
- Be used in an indoor context or in an outdoor context (e.g. a fall detection system should be used at home or in the garden).

Moreover, AAL solutions consist in a combination of products and technology components, and their operation requires an ecosystem of service providers for planning, installation, maintenance, operation and provision of services. In addition, since AAL technology is still relatively expensive, it is essential that AAL can be extended and maintained over a long period of time, evolving and adapting to the changing needs of their users. This can only be achieved with modular solutions, where the technological components, but also complete AAL solutions, can be flexibly adapted and combined.

Therefore, interoperability requirements assume great importance. Eichelberg et al. (2014) even argue that interoperability is an essential condition for the success of AAL solutions in the market. Also Queirós et al. (2015), in a previous systematic review of AAL, referred the importance of interoperability in the AAL domain. The results also show that, nowadays, different technologies come from different research groups with little interoperability between them.

Considering the diversity of AAL solutions, there is the need for a common language to facilitate the communication between different stakeholders (e.g. technology developers, care providers and end users) and the interoperability between different solutions and components.

The fundamental concepts of the International Classification of Functioning, Disability and Health (ICF) are related to the human functioning and performance in activities and participation (World Health Organization 2001). The existence of an international classification implies the existence of concepts able to provide a standardized language to all relevant stakeholders in the development and application of AAL solutions. Therefore, it should be possible, and desired, to use the ICF for the specification and characterization of AAL services. In addition, ICF can be used as a conceptual framework to systematize information that can influence the individuals' performance, not only in terms of health conditions or physiological functions but also in terms of contextual factors (i.e. personal and environmental) and being used as a comprehensive model to characterize users, their contexts, activities and participation (Queirós et al. 2013a).

Next sections will present the type of AAL solutions developed in the past years, retrieved in the systematic review of the second chapter of this book, and will identify what type of activities and participation are supported by these systems. Afterwards, a classification of the AAL systems according to ICF concepts will be presented.

3.2 AAL Systems

Around 40% of the articles included in the systematic review of the previous chapter were classified as systems (i.e. a practical AAL solution applied in a specified context and with a well-defined aim (Sun et al. 2009a)). The aims of the AAL systems reported in the retrieved articles are:

- Personal monitoring – systems aiming to monitor vital signs of activities to provide feedback to their users, without connection to other systems (i.e. without being able to share information with other systems or with formal and informal care providers);
- Participation – systems aiming to support the involvement of the users in real-life situations;
- Fall detection – systems aiming to identify falls and call assistance;
- Healthcare – systems aiming to promote communication and health information sharing between users and their formal care givers;
- Activity recognition – systems that use technological solution to identify activities and to suggest actions for preventing acute situations;
- Medication management – systems that aim to manage and assist the medication of the users.

Figure 3.1 presents the distribution of the identified systems according to their aims. As it is possible to observe, the most frequent systems are related with personal monitoring and participation, respectively, 29% and 23%. Moreover, the fall detection systems (21%) are still a major concern in the development of AAL systems. These results are in line with results of several studies on AAL that refer to the aim to support older adults in daily activities (e.g. shopping, home management or moving around (Boll et al. 2010; Keegan et al. 2008; Kieffer et al. 2009)), personal monitoring (Jin et al. 2009; Torkestani et al. 2012) or fall detection (Lopes et al. 2013).

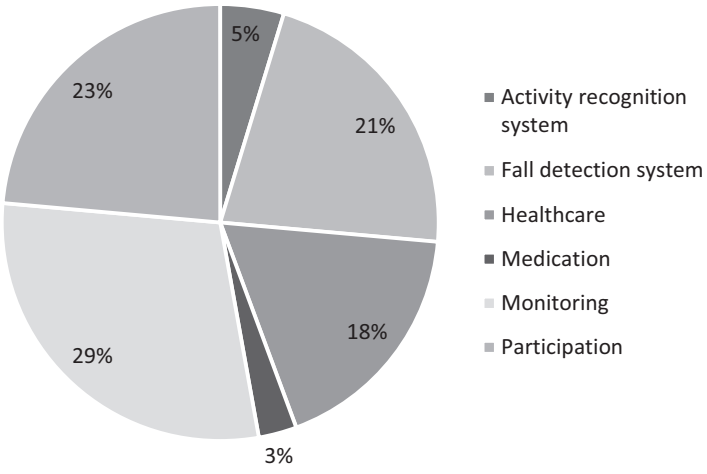

Fig. 3.1 AAL solutions classification

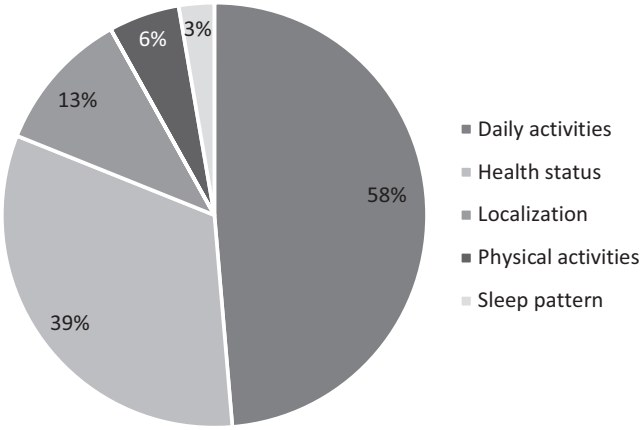

Fig. 3.2 Activities related to AAL monitoring

Although in the systematic review of Queirós et al. (2015), in 2015, participation and healthcare solutions were a major concern in the development of AAL systems, nowadays, it seems that monitoring activities to prevent acute situations and promote wellbeing and quality of life in the elderly population gained some relevance.

In what concern to the monitoring activities, Fig. 3.2 shows the distribution of the types of activities that were reported. Monitoring daily activities was a major concern, since it was referred by 58% of the retrieved articles. Then, 39% of the retrieved articles referred the monitoring of health conditions. In the opposite perspective, sleep pattern was the type of activity recognition with less references (i.e. only 3%).

The use of sensors is quite disseminated. One article (Suryadevara and Mukhopadhyay 2014) reports the use of unobtrusive sensors to monitor daily activities and to collect information related to wellness indices. Another article (Stucki and Urwyler 2014) reports the use of sensors to capture environmental variables, such as temperature, humidity, luminescence, motion or acceleration. Moreover, other article (Losardo et al. 2014) was concerned with mobility and reported the use of PIR sensors installed in the bathroom, hallway and kitchen, a bed-occupancy sensor, a sofa-occupancy sensor and a door sensor on the main door. In turn, the Helicopter project developed a sensing network that includes medical devices (e.g. devices to measure blood pressure, body weight, blood sugar and oxygen concentrations), environmental devices (e.g. room presence, bed/chair occupancy, toilet usage, fridge or pantry access) and wearable devices (e.g. devices to estimate physical activity, to detect falls or carrying identification information) (Ciampolini et al. 2016).

Daily activities comprise functional skills as self-care (e.g. dressing, eating or toileting) and mobility (Mlinac and Feng 2016). For example, one article (Niemela et al. 2007) reports the development of systems to monitor medication events or sleep apnoea and to assist older adults giving them the feeling of safety at home. The medication event monitoring uses a smart pillbox that counts the openings and closings of the cap, which is configurable according to the prescription, and the users can access the information through smartphones. The monitoring of sleep

apnoea uses a plaster integrated with sensors for detection of brain waves (ECG) and movements of the head. In what concerns to the security at home, Niemela et al. (2007) report a sensors' network to detect person and animals through infrared motion sensors, door-opening sensors and wearable accelerometers to detect falls. Also, Austin et al. (2016) defined a smart home system to assess loneliness in a continuous and nonobstructive way through sleep hours, the number of incoming or outgoing phone calls, walking speed and mobility. Finally, the SOCIALIZE project uses a network of sensors to promote social relationships (Miori and Russo 2017).

The use of smart devices (e.g. smartphones, smartwatches or smart wrists) was reported in several of the retrieved articles to monitor daily activities. One article (Chiang and Liang 2015) reports the use of simple, low-cost smartwatches and smartphones to detect falls and recognize daily activities. In turn, McCrindle et al. (2011) report the use of a smart wrist to implement an emergency button, a fall detection system and a medication reminder and also to monitor health status (i.e. blood pressure, pulse and temperature). Moreover, Fahim et al. (2012) report a system to remind older adults to perform their daily activities and, through a smartphone, to allow the caregiver to keep track on the older adults' activities.

The use of a wireless and nonintrusive network of sensors is reported by Suryadevara and Mukhopadhyay (2014) and Stucki and Urwyler (2014) to monitor several activities of daily living as sleeping, grooming, toileting, getting ready for bed, cooking, watching TV or seating. In what concern to activity recognition systems, the results indicate that are a higher concern with data processing algorithms (Damaševičius et al. 2016; Nakagawa et al. 2016), namely, machine-learning algorithms (Ueda et al. 2015).

Most of the articles classified as fall detection systems report the use of accelerometers. However, some authors (Foroughi et al. 2008) report mainly the use of video surveillance to monitor falls, and other articles present new algorithm to detect fall in a more liable and faster way (Foroughi et al. 2008; Maglogiannis et al. 2014).

Health status is related to specific health conditions. One article (Coronato et al. 2010) reports a system composed by an ECG, an accelerometer and a camera to monitor older adults with cardiac problems. Another article (Zhou et al. 2010) proposes a personal diabetes monitoring system which integrates wearable sensors, 3G mobile phone, smart home technologies and Google sheets to facilitate the management of chronic conditions (i.e. diabetes). The system uses wearable sensors and 3G cellular phone to automatically collect physiological signs (e.g. blood glucose level, blood pressure, heart rate, breathing rate or skin temperature).

The retrieved articles also report localization systems to locate older adults. Alemán et al. (2015) proposed a system that merges localization data from GPS and Wi-Fi sensors in Android OS. It also includes Google Maps in Android OS and Web environments to provide alerts for the caregivers. In turn, Chang et al. (2016) report the development of a system based on streaming video and image processing techniques to monitor older adults anytime and anywhere.

In what concern to physical activities, Deen (2015) reports the use of low-cost, compact and sensitive accelerometers and gyroscopes for a proof-of-concept walking-age pattern analysis, classification and identification system. Costa et al. (2014) was

more concerned to monitor the level of physical activity according to the objectives of active ageing.

The retrieved articles classified as participation refer systems related to social activities and mobility activities. Several articles (Passas et al. 2012; Pensas et al. 2013; Sun et al. 2009b) propose systems to promote social interaction, (Kuhn et al. 2009) propose a digital agenda to help older adults and (Barham et al. 2015; Wolfgang Inninger and Nicole Wagner 2012) propose a system to facilitate the movement of older adults using public transportation.

3.3 Classification of AAL Solutions Using ICF

In terms of healthcare delivery, there is a gradual change in the current paradigm, through the promotion of care and interventions centred on the person that contribute to autonomy, independence and quality of life. The adoption of the ICF (World Health Organization 2001) reflects this change.

The focus of the ICF is on measuring functioning in society, independently of the reason for the impairment, and, by doing so, becoming a more versatile tool than traditional classifications with focus on disability. The shift is from the cause to the impact, putting all health conditions on the same level, allowing them to be compared using a common metric, the ruler of health and disability.

The use of AAL solutions aims to improve individual performance in performing activities as well as participation, that is, involvement in life situations. In addition, different environments can have a distinct impact on people with the same health condition. An environment with or without barriers can limit or facilitate individual performance (World Health Organization 2001). In this way, the environment in which people live and lead their lives has a direct influence on functioning, and, in this sense, it can be boosted by the existence of products and services that fit the individual characteristics. Consequently, since AAL solutions aim to influence the environment that surrounds the person in a nonintrusive way, in order to improve their performance, they may be considered environmental factors in the light of the ICF.

Activities and participation (i.e. the involvement of people in life situations) justify the use of AAL systems. In the same way, the selection of the solutions that best fit the level of functioning of each person is related to their activities and participation (Queirós 2013b). Thus, the ICF can serve to structure, classify and catalogue these products and services (Queirós 2013b), in a perspective oriented to the person and not to the technology.

The ICF is a hierarchical classification based on the perspective of the body, individual and society, organized in two parts: (1) functioning and disability and (2) contextual factors. Each part is subdivided into two components; the first, functioning and disability, includes body functions and structures and activities and participation. The second, contextual factors, is divided into personal factors and environmental factors (World Health Organization 2001). In this classification, functioning indicates the positive aspects of the interaction between an individual

(with a particular health condition) and the contextual factors (environmental and personal) (World Health Organization 2001). The ICF evidences the importance of interaction between the health condition, the individual and the surrounding environment.

AAL systems can describe activities and participation that these services aim to improve. In other words, it is possible to link the tasks involved in the AAL to ICF categories. The definition of activities and participation according to ICF is:

- Activities – Activities are the individuals' recital of assignments and tasks. Difficulties with these activities are noted as activity limitations. Limitations are usually due to function depreciation of body functions but also due to environmental hindrances;
- Participation – Participation covers the individuals' involvement in daily life and society. Difficulties in participation are classified as participation restrictions.

Table 3.1 presents the classification of AAL systems retrieved from the systematic review presented in the previous chapter using ICF.

The activities and participation found in the articles of the systematic review of the previous chapter were linked to the following categories: using transportation (d470); caring for body parts (d520); toileting (d530); dressing (d540); eating (d550); drinking (d560); looking after for one health (d570); self-care, other specified (d598); and recreation and leisure (d920).

The difficulty found when classifying the articles also suggests the need for a common classification that could be used to characterize existing AAL solutions. The activities and participation described in AAL solutions are only a small part of those described in the ICF. It is necessary to rethink the future research approach on the development of AAL solutions in order to take advantage of already existent technologies and systems to improve human functioning. It is clear that the needed requirements to deliver viable, adaptative and personalized AAL systems are still not fulfilled. This is in line with previous studies of AAL (Queirós et al. 2012).

Table 3.1 ICF activities and participation described in the articles

AAL solutions		ICF
Monitoring	Daily activities – sleeping	d598
	Daily activities – cooking	d550/d560
	Daily activities – getting ready to bed	d520/d540
	Daily activities – watching TV	d920
	Daily activities – grooming	d540
	Daily activities – toileting	d530
Participation	Social activities	d920
	Mobility activities	d470
Healthcare		d598
Fall detection		d570
Activity recognition		d570

3.4 Conclusion

The activities and participation classified in AAL systems indicate a clear concern to AAL systems related to activity recognition, especially in terms of social relationship and daily activity support. There is also concern to health monitoring, although in a less number. About 60% of AAL systems articles were related to inclusion systems (Research 2018).

Considering the AAL solutions as a way to improve human functioning, it is important to guarantee that robust and liable assessment is made, which is essential for the certification of the system. The results of the systematic review indicate that do not exist a real concern with real conditions assessments. Moreover, when assessments are performed, only a short period of time is considered, most of the time, without the necessary instruments to evaluate the impact in the life of the older adults. In the next chapter, this issue will be detailed.

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Chapter 4
Ambient Assisted Living: Assessment

Anabela G. Silva

4.1 Introduction

AAL products need to be comprehensively evaluated before full-scale implementation can be advocated. This requires the stakeholders involved in AAL product development to look beyond the product itself and to include aspects such as ethics, impact on quality of care, meaningful use, economy or social impact in terms of, for example, quality of life. Østensen et al. (2014) suggest a framework to guide a comprehensive assessment of AAL systems. They chose three models from those existing in the literature and propose that these three models allow for a comprehensive evaluation of technology. The models are Reach Effectiveness Adoption Implementation Maintenance (RE-AIM), Unified Theory of Acceptance and Use of Technology (UTAUT) and the Model for Assessment of Telemedicine (MAST) applications. The RE-AIM can be used to guide the evaluation of technology implementation, but it was developed to evaluate public health interventions (Glasgow et al. 1999). It covers five areas: reach, effectiveness, adoption, implementation and maintenance (Glasgow et al. 1999). In contrast, MAST was developed as a framework for assessment of technologies based on data from workshops with users and stakeholders of telemedicine (Kidholm et al. 2012). It covers three areas: preceding considerations, multidisciplinary assessment and transferability assessment. The UTAUT aims to assist predictions regarding potential future technology use, addressing surrounding factors and user evaluations, and covers four aspects: performance expectancy, effort expectancy, social influence and facilitation factors (Venkatesh et al. 2003). In a critical analysis of each of the three models and of their

A. G. Silva (✉)
Health Sciences School, University of Aveiro, Aveiro, Portugal

Center for Health Technology and Services Research (CINTESIS), University of Aveiro, Aveiro, Portugal
e-mail: asilva@ua.pt

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complementarity, Østensen et al. (2014) suggest the inclusion of users' perspective from the very beginning of the process of developing AAL technologies to the framework encompassing the three models.

4.2 Methods

A preliminary overview of the results of the systematic literature review present in Chap. 2 revealed that a detailed characterization of studies according to the proposed framework would not be possible. Therefore, considering the included studies of the aforementioned systematic review, we provide an overview of how AAL solutions have been assessed and published and categorized into one of the following broader categories: (1) description of the system, (2) assessment of usability, (3) assessment of performance accuracy or (4) assessment of impact (e.g. on the person, family or society).

4.3 Characteristics of the Retrieved Studies

Of a total of 99 papers screened, 32 (32.3%) were mainly concerned with the description of the technology itself without focusing either qualitative or quantitative data on aspects of assessment. Therefore, 66 (66.7%) manuscripts were considered as assessing aspects of the technology developed. Of these, 42 (63.6%) reported mainly on the assessment of accuracy, 24 (36.4%) reported mainly on aspects of usability, and only 2 (3%) reported mainly on the impact of the technology.

4.4 Accuracy

Of the 42 that reported on accuracy, most were concerned with falls in older adults and reported results in terms of sensitivity and specificity or percentage of events correctly identified. At least 14 papers clearly stated that their concern is the fall problem in older adults and another 14 dealt with the ability of the system to recognize daily life activities. Other examples of activities tested for accuracy are the ability of the system to recognize gestures ($n = 1$), voice ($n = 1$), states of loneliness ($n = 1$) and emergency situations ($n = 2$), among others. In general, the high levels of sensibility and specificity suggest that the technology tested has a good ability to correctly detect events of interest (at least in the type of samples used in the papers included in this review). Nevertheless, the consequences of false negatives and false positives, i.e. what happens to the user when the technology is unable to correctly identify a situation, are seldom reported.

Despite the number of manuscripts clearly stating that they are concerned with falls in older adults, they assess the systems' accuracy with young adults. Furthermore, a considerable number of manuscripts describe tests that ran on laboratory settings

instead of real environments with quite small samples of users (less than ten). Nevertheless, patterns of movement are quite different between young adults and older adults. Whilst from a security and no harm perspective, this methodological option is understandable, it may compromise the ability to generalize the findings from a young population to the target population. In addition, real houses are very different from controlled environment. For example, the quantity and disposition of the furniture might occlude the systems' view of the user. The reduced number and the characteristics of subjects, which are different from the target population, used in the assessment phase might compromise the transferability of the findings during the assessment phase to the real world and, consequently, the future use and impact of the technology developed. Sucerquia et al. (Sucerquia et al. 2017) investigated the accuracy of the system when 23 young adults performed 19 activities of daily living and 15 fall types, when 14 healthy and independent participants over 62 years old performed 15 activities of daily living and when 1 participant of 60 years old performed all activities of daily living and falls. Their results showed that sensitivity varied between 93% and 99% for young adults and between 63% and 88% for older adults, suggesting that tests with older adults significantly reduced the detection performance of the system. This is an example that supports the need to test the systems with individuals that belong to the target population for which the system is intended.

Examples of technology tests are Hong and Nugent (Hong and Nugent 2009) who collected data from a three-room apartment home of a single 26-year-old man for 28 days. Sensors were installed throughout the apartment on the doors of the front door, bedroom, toilet, shower room, fridge, freezer, cup cupboard, plate cupboard, pan cupboard, groceries, microwave, dishwasher, washing machine and the toilet flush. A total of 245 activities were recorded over seven classes: leave house, use toilet, take shower, go to bed, prepare breakfast, prepare dinner and get drink, and a global accuracy of 90% was reported.

Hein et al. (Hein et al. 2010) assessed in a laboratory setting the ability of system to recognize the preparation and intake of food or beverages using six subjects aged between 25 and 40 years old and five subjects aged between 72 and 84 years old. They reported that food preparation was detected with a sensitivity of 74.7% and a specificity of 84.2% using a vision sensor.

4.5 Usability

Regarding usability, studies tend to use a sample with characteristics that are similar to intended end users of the service (older adults), and some of them also use formal and informal caregivers. Nevertheless, sample size tends to be smaller than ten participants. The methodologies of assessment for usability rely mainly on observation, indicators of performance (e.g. time to perform a specific activity) and qualitative description of how participants handled the systems or of participants' opinions on the system. Validated questionnaires on usability used isolated or combined with other strategies to access usability are seldom reported.

Commonly, participants in usability studies are given a set of tasks to perform, and their behaviour when interacting with the system, the number of interactions with the system, the time taken to perform the tasks and the number of tasks performed correctly (Iglesias et al. 2009a, b) are assessed. Other indicators considered, are the use of questionnaires to evaluate the degree of task difficulty (Iglesias et al. 2009b). Often, no mention is given regarding the type of questionnaires used, how they were built and whether they were validated (Iglesias et al. 2009b; Lee et al. 2011). In-depth interview to participants to discuss specific scenarios given or to debrief participants after their experience using the system to gather detailed feedback on system features and the user experience is also common (Lee et al. 2011). Triangulation of methods for usability assessment, for example, combining questionnaires, observation of participants during the interaction with the system and in-depth interviews, is also reported (Nuovo et al. 2014). Details on the interview guide, whether interviews were audiotaped and how interview data was analysed, are missing in some studies, and it would improve the transparency of study results and reports. Nevertheless, a few good examples (Hill et al. 2015; Ogonowski et al. 2016) were also found. The study of Hill et al. (2015) detailed that interviews were audiotaped, that a co-interviewer took field notes during the process, that the audio recordings were transcribed and that the data from interviews and field notes were used for content analysis. The authors also give details on content analysis, including the assignment of codes to data and the development of the code tree.

Another example of combining different methodologies to assess usability is the study of Ribeiro et al. (2015). This study clearly describes the structure on the usability assessment session as:

1. Introduction – the investigator applied a social and demographic questionnaire and then delivered the session script, explaining orally all information;
2. Interaction with the system – the participant performed the tasks described in the session script, and the investigator collected data on the user interaction;
3. Usability evaluation using validated instruments – the investigator assisted the participant when filling in the usability questionnaires and scales;
4. Summary – the investigator thanked the participant.

This study also combines questionnaires that give the perspective of the user on the systems' usability (the Post-Study System Usability Questionnaire – PSSUQ) and questionnaires that give the perspective of the researcher based on his/her observations of the interaction of the user with the system (the International Classification of Functioning-based Usability Scale I (ICF-US I) and the International Classification of Functioning-based Usability Scale II (ICF-US II)). Furthermore, the use of these questionnaires is complemented with objective indicators of performance (the success or failure in carrying out the task, the execution time (in seconds) and the total number of errors) and the record of critical incidents, defined as behaviours that contribute to the participants' success or failure in specific situations (e.g. easy/difficult interaction with the application or calmness/restlessness).

4.6 Impact

In terms of impact, 1 study (Gschwind et al. 2015) used 148 community-dwelling people, aged 65+ years to compare the efficacy of 2 16-week exergame interventions: step-mat-training (SMT) and Microsoft-Kinect® (KIN) exergames. A total of 29 participants received the KIN exergames, and 47 received the step-mat-training, and 72 were allocated to the control group. Both groups of participants were assessed for fall risk, muscle strength, finger-press reaction time, proprioception, vision, balance and executive functioning. Results showed that participants allocated to the intervention arms played (median time) each week 17 min (IQR 32) for KIN and 48 min (IQR 94) for SMT. Compared to the control group, SMT participants improved their fall risk score ($p = 0.036$), proprioception ($p = 0.015$), reaction time ($p = 0.003$), sit-to-stand performance ($p = 0.011$) and executive functioning ($p = 0.001$), whilst KIN participants improved their muscle strength ($p = 0.032$) and vision ($p = 0.010$) and showed a trend towards improved fall risk scores ($p = 0.057$). Study authors conclude that it is feasible for older people to conduct an unsupervised exercise programme at home using exergames and that both interventions reduced fall risk and SMT additionally improved cognitive function. The other study (Núñez-Naveira et al. 2016) tested an e-learning platform to provide support to informal caregivers of people with dementia. A total of 61 informal caregivers completed the study, taking part in the experimental ($n = 30$) or control ($n = 31$) groups. The experimental group (receiving the e-learning platform) showed a decrease in their depressive symptomatology. These findings suggest that a greater emphasis should be placed on the assessment of the impact of the technology, exploring the impact on the individual (user) at broader levels (function, quality of life, economic, social, negative effects, etc.), but also other types of impact could be assessed such as potential negative effects, the social or economic impact both at the individual and the impact at the family and the healthcare or society levels.

Interestingly, the use of the framework of assessment detailed by Østensen et al. (2014) or the instruments that constitute it is seldom reported. It has been suggested that technology contributes to increased access to health services, cost-effectiveness, enhanced educational opportunities, improved health outcomes, quality of care, quality of life and enhanced social support (Jennett et al. 2003). However, it seems that there is no convincing evidence that supports the impact of AAL. The results described in this chapter agree with the conclusions of Haux et al. (2016) on the past, present and future of AAL. The author of this chapter concludes in her analysis that there has been a clear progress on the use of technologies but that there is still much to be done.

4.7 Conclusion

Despite a high level of technological innovation and implementation, and promising early results, most of the developments aimed the design, development and evaluation of prototypes with a few number of participants. Furthermore, there is the lack of

longitudinal studies. In contrast, the researchers must be aware that new developments require assessments with statistical significance to show they are able to make a difference and are cost-effective. Collecting this kind of evidence requires robust trials. These demand considerable resources to integrate new applications in the daily living activities, to be used by thousands of users, and running over long periods of time.

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Chapter 5
Ambient Assisted Living – A Multi-method Data Collection Approach to Evaluate the Usability of AAL Solutions

Ana Isabel Martins and Margarida Cerqueira

5.1 Introduction

Ambient Assisted Living (AAL) is related to digital environments with a ubiquitous nonobstructive intelligence (Moumtzi and Wills 2009) organized to support a wide range of solutions. It is an important research and development area nowadays, foreseen as an important instrument to potentially effective solutions to answer the needs of citizens, in order to enable people with specific demands to live longer in their natural environment by alleviating disabilities and promoting human functioning.

Most systems are intended to be used by the layperson (Queirós et al. 2015), and the acceptance of the AAL paradigm is closely related to the quality of the available systems, namely in terms of intelligent functions for the user interaction. In that context, usability evaluation is an important issue of the development of solutions based on information technologies, becoming a demanding process due to its complexity. The development process usually focuses on the adherence to technical specifications. This is one of the reasons why a significant number of systems are either partially used, misused, abused, not used at all or fail to gain broad acceptance (Bevan and Bruval 2003). The introducing of user-centered methods ensures

A. I. Martins (✉)
Department of Electronics, Telecommunications and Informatics (DETI), University of Aveiro, Aveiro, Portugal

Institute of Electronics and Telematics Engineering of Aveiro (IEETA), University of Aveiro, Aveiro, Portugal
e-mail: anaisabelmartins@ua.pt

M. Cerqueira
Health Sciences School, University of Aveiro, Aveiro, Portugal

Center for Health Technology and Services Research (CINTESIS), University of Aveiro, Aveiro, Portugal

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that "real products can be used by real people to achieve their tasks in real world" (Bevan 1998). Usability evaluation must be understood holistically within particular project context and cannot be performed disaggregated from the functions that are intended to be supported. Being an important part of the overall design of user interaction mechanisms, ideally usability evaluation must be present at all development stages and must be iterative to enable a continuous evolution of the quality of results, which consists of interactive cycles of design, prototyping, and validation (Ivory and Hearst 2001).

Good usability has several benefits (Queirós et al. 2015; Bevan 1998; Bevan et al. 2005): increases efficiency and productivity; allows reducing task execution times, errors, or learning times; specifies training requirements; improves acceptance and user satisfaction. Furthermore, good usability has impact in disadvantaged costumers and users with special needs. In this respect, user-centered design provides a framework for achieving accessibility and Design for All. The Design for All philosophy emphasizes the need to provide access to information systems for the broadest possible range of users, mainly the young and elderly, and people with impaired physical and visual capabilities (European Commission 2006). Designing for All is developing for human diversity, social inclusion, and equality. It enables all people to have equal opportunities to participate in all aspects of life in society. To accomplish this, every product or service developed should be accessible and designed for everyone, regardless of their individual differences (Wegge and Zimmermann 2007; Queirós et al. 2013). Despite of all the benefits described above, there are also barriers to usability. For large organizations, successful usability design requires technical and cultural changes and strategic commitment: usability must be a system development objective of all the involved stakeholders. Given the change of paradigms associated with usability, translated by the evolution of standard ISO 9241-11 to the standard ISO 25010, a wide range of methods for a correct evaluation of the usability issues is necessary. The usability of a system is the result of a complex set of interactions of users with the system and the surrounding context, so it is impossible that a single method can address all the factors involved (Cockton 2013).

5.2 Usability Concept

Originally described as the slogan "easy to learn, easy to use," often used to refer whether a product is easy to be used (Carroll 2013), the usability concept has undergone some changes over the long last four decades (Martins et al. 2015b). The current understanding comprises a broader concept – the user experience – which includes all the users' emotions, perceptions, preferences, beliefs, physical and psychological responses, behaviors, and accomplishments that occur before, during, and after the user experience interaction (ISO 2010; Nielsen and Norman 2013). It subsumes qualities like, among several others, well-being, fun, aesthetic tension, enhanced creativity, collective efficacy, or support for human development. The users' desire and consequently their performance in the experience are influenced by aspects such as image, fun, aesthetics, language, and sophistication, whereby the product or service

should be (Gualtieri et al. 2009): (1) useful, wherein he must accomplish his goals; (2) usable, wherein he should be able to achieve the goals proposed while performing tasks with minimal effort; and (3) desirable, wherein it should appeal his emotions. These aspects will allow users' emotional involvement, focusing on their performance in the experience, that is, usability in context. Usability can not only be one of the factors to be taken into account, it is rather one of several complementary contributors to design quality (Cockton 2013). In this sense, the design of interactive systems can not only consider the features and attributes of the systems, and whether or not software is inherently usable (Cockton 2013). On the contrary, designers should focus on the interaction of user with the software in specific configurations, considering what happens or what will happen when product or systems are used, with or without success, or in a combination of both.

The standard ISO 9241-11, precursor of ISO 9241-210, distinguishes three usability factors: (1) effectiveness, related to the achievement degree of the intended objectives and increases the evaluation complexity; (2) efficiency, if user can perform the key tasks within an acceptable time interval; and (3) satisfaction, to consider whether the use may be, objectively, efficient and effective and do not cause uncomfortable experiences to user. These factors should be evaluated in a holistic manner that combines multifaceted parameters and criteria. However, in practical terms, the tendency is to evaluate, for each parameter, whether the minimum thresholds are met (Cockton 2013). The standard ISO 25010 (ISO 2011) has added two new factors to the standard ISO 9241-11: (1) absence of risk, focuses on security issues of end-user; and (2) context coverage, a broader concept which, in terms of usability, associates specific users and their goals to the context of use.

A very recent approach about usability, referred as PET design, which stands for persuasion, emotion, and trust, has its basis in a deep understanding of customers' subtle emotional triggers and employs a rigorous set of new research-based methods and techniques (Schaffer 2009). This approach is being applied in web design and is based on the assumptions that user engagement, rather than classic usability, is what sets effective web design apart. Once a customer has entered a web site, it is important to create a sense of trust. Persuasive design is more qualitative, deep, and subtle than usability, since the thinking processes that guide our commercial choices are complex and emotional, not logical and linear (Schaffer 2009).

5.3 Usability Evaluation Methods

The literature describes several methods and tools to ensure that usability issues are considered during the development process. The selection of these methods and tools usually depends on the development stage and available resources (Martin et al. 2012). The evaluation may be performed in a laboratory, but since the context of use is important, it must be performed in the real context of use whenever possible (Marques and Nunes 2012).

Based on existing literature the usability evaluation procedures can be classified into two types of methods: (1) empirical, based on actual usage of data collected

from users; (2) analytical, based on experts' examination upon an interactive system or product and/or potential interactions with it. The (1) empirical methods can be divided into (a) test methods, (b) inquiry methods, and (c) controlled experiments methods, and the (2) analytical methods can be classified as (d) inspection methods.

The (a) test methods aim to observe and measure the users while they perform predefined tasks using one system or service. In order to understand how to improve their interaction, it seeks empirical evidence mostly through quantitative data. Centered in how well the users can use it, the test methods focus mainly on their behavior (Martin et al. 2012; Afonso et al. 2013; Mitchell 2007).

The (b) inquiry methods aim to identify the strengths and weakness in terms of usability of a certain system or service, collecting qualitative data from users' opinions, attitudes, perceptions, experiences, and behaviors (Bevan and Bruval 2003; Brandt et al. 2007; Shneiderman 1992; Tomitsch et al. 2010; Wilkinson 2003). It may take a form of an interview (usually conducted by an interviewer through one-to-one mode, where errors and misunderstandings can be quickly identified and clarified), a questionnaire (usually applied in the written form and since does not require test equipment has the advantage of being a cheap method), a focus group (usually conducted by a moderator, involving informal discussion about a specific subject within a small group, often used in the idealization process of new products), or a diary study (involves data collecting by recording specific events throughout the daily users activities).

The (c) controlled experiment methods aim to obtain statistical significance through the application of the scientific method. It implies test hypotheses and the control of variables, for what it requires the use of big samples and their respective variables to control (Rubin and Chisnell 2008).

The (d) inspection methods aim to assess various aspects of the users' interaction involving the experts' participation. Some inspection methods are performed early in the usability engineering lifecycle on user interface specifications that have not been yet implemented (Martin et al. 2012; Nielsen 1995a, b). It may take a form of a task analysis (assesses what user should perform in terms of actions and cognitive processes to perform a certain task), cognitive walkthrough (the simulation of the users' cognitive behavior by answering questions regarding their cognitive model), and heuristic evaluation (the analysis of the user interaction through the utilization of recognized usability principles, the heuristics) (Bevan and Bruval 2003; Marques and Nunes 2012; Nielsen 1995a, b; Mahatody et al. 2009).

In accordance with the systematic review by Martins et al. (2015b) about usability evaluation methods that have been used during the last years, the empirical methods are the most frequently used (as mentioned in the literature), which seems to confirm the recognition of the end-users' roles as a source of knowledge for usability evaluations. Regarding the test methods, the most widely used method was the performance evaluation. The inquiry method most frequently used was the questionnaire.

However, the use of only one data collection method may not be sufficiently comprehensive and complete to acutely assess the complexity of all relevant AAL

products or services' issues (Martins et al. 2016). Each method evaluates different assessment dimensions, wherein some require data from users, while others rely on usability experts, and more general or finer instruments can be chosen in the evaluation protocol. However, the more general instruments may not be accurate in the measure of all relevant aspects and require longer application time as a whole, and the finer instruments may not be effectively filled by the sample since it may not be familiar with the issues addressed.

It can be also pointed that using several procedures allows to complement the users' perspective with the evaluators' perspective. This is important because users may not be familiarized to filling some instruments, occurrence that is mentioned in the literature with some regularity (Sauro and Lewis 2011). One of the most studied processes in the psychology of aging relates to reaction time, the ability to respond quickly and accurately after a stimulus, and that is related to physical health, visual and auditory acuity, and the speed and coordination of information (Belsky 2001). Although it varies from person to person, as the human being ages the central nervous system tends to have a lower capacity to process information quickly, reducing response time. Older adults tend to have larger reaction times when they are asked to perform complex tasks or perform a certain sequence of steps to which they are not accustomed under pressure. The main reason is that complex and unfamiliar tasks make us think more, and what tends to decrease with age is "time to think" and not "time to act" (Salthouse 1996). That was what happened with the older adults' sample in the study of Martins et al. (Martins et al. 2015a) whose participants needed to decide if they agreed or disagreed with a positive sentence, followed by a negative one, which may have induced mistakes as it is complex logical reasoning. However, when familiar with the tasks, older adults tend to present values similar to those of the younger ones, where the acquired experience compensates for slowness. Other aspect to be taken into consideration in the usability evaluation is the attitudes of the older adults in the test situations (Schaie and Hofer 2001). It is known that many older adults present inferior results when comparing to the younger ones because they consider, a priori, that they will not respond correctly, or many times overestimate their perception of a test to please evaluators or researchers.

Therefore, the best way to evaluate the usability of AAL solutions is through the combination of distinct methodologies, in order to obtain different standpoints. This chapter proposes the multi-method data collection developed by Queirós et al. (Queirós et al. 2015) to evaluate the usability of AAL solutions.

5.4 The Multi-method Data Collection to Evaluate the Usability of AAL Solutions

The proposed multi-method data collection comprises several test methods eyeing the (a) self-perceived usability, (b) usability evaluation based on the opinion of the evaluator on the users' performance, (c) registration of quantitative data on the

performance of the users in carrying out specific tasks, and (d) registration of critical incidents.

For the (a) self-perceived usability, that is, taking into account the users' opinion, several instruments, can be used, such as the Post-Study System Usability Questionnaire (PSSUQ) (Lewis 2002), the International Classification of Functionality, Disability and Health based Usability Scale (ICF-US) (developed by Martins et al. (2013) considering the conceptual model of the International Classification of Functionality, Disability and Health (ICF) (World Health Organization 2002)) and as the System Usability Scale (SUS) (Brooke 1996).

To evaluate the usability (b) based on the opinion of the evaluator on the users' performance, two components of the ICF-US can be used: (Martins et al. 2016): the (1) ICF-US (one general instrument) to evaluate the usability according to the evaluators' opinion about the performance of the users, and the (2) ICF-US II (one specific instrument) to identify potential barriers or facilitators of the AAL solutions, also according to the evaluators' opinion.

Concerning the (c) registration of quantitative data on the performance of the users in carrying out specific tasks, a performance evaluation grid to register the success or failure in carrying out the tasks, the runtime (in seconds), and the total number of errors can be used. Lastly, in order to perform the (d) registration of critical incidents, a critical incident grid by the observer to generate a systematic identification of the behaviors that contributed to the success or failure in specific tasks, considering details such as ease/difficulty of interaction with the application or tranquility/restlessness can be used.

As an outcome, this multi-method approach added value in relation to other usability evaluation, which normally assign a score but do not identify or classify the barriers that must be mended in order to improve the prototype. According to Martins et al. (Martins et al. 2016), a significant fact is that the collected data based on the opinion of the evaluator on the users' performance through the critical incident records is consistent with the barriers identified by the specific instrument (ICF-US II), filled by two different researchers. Another point is that services' main problems can also be identified through the performance evaluation, which showed in parallel the same tasks related to these aspects with technical hitches.

This means that global usability evaluation tools can be the most suitable, where quantitative instruments can be enriched if complemented with qualitative instruments, and as well as both in the perspective of the self-perceived usability and in the perspective of the evaluator on the users' performance, enabling a more complete and accurate evaluation. Furthermore, it allows the collection of qualitative data on positive aspects (facilitators) and negative aspects that need to be corrected (barriers).

It is clear that end-users' involvement, both in the development phase and in the validation and evaluation of the results – the whole life cycle of the development process – as well as the usability and accessibility issues, should be as complete as possible. Each of the data collection methods for usability evaluation has different capabilities and limitations and incompletely specified to be consistently applied, provides as well different information types, and their combination allows a com-

prehensive assessment of diverse features (Martins et al. 2016). The proposed multi-method data collection approach endorsed, simultaneously, the implementation of quantitative and qualitative data collection methods, which avoided burdening end-users – especially since one of the major limitations in usability evaluation is the fact that they usually are time consuming and tiring for users, since they generally imply the fulfillment of several questionnaires – and also enhanced the evaluators' perspective.

5.5 Conclusions

The environments where AAL can be used are very complex and can use either simple solutions or a combination of existing technologies. Most of the literature on systems focuses on how technology can be used in the AAL context instead of looking at the users' needs and proposing ways to solve them, focusing on the person (Queirós et al. 2015). That is why a multiple data collection method seems to be an efficient approach for usability evaluation of AAL solutions. By using a diversity of instruments to collect large amounts of subjective data from users, it considers not just the opinion of the evaluator and researcher but also the users' opinion on their own performance. Additionally, it is required that evaluation teams are composed of professionals with different backgrounds and skills such as health or social professionals and engineers (interdisciplinary teams) and that all stakeholders, including the future users, are actively involved in all stages of AAL development and evaluation processes, including the conceptualization phase (Queirós et al. 2015). This involvement of end-users will probably also facilitate field trials of AAL systems and promote their use, currently a challenge that needs to be addressed, considering the small number of studies in the literature describing systems being evaluated in field trials.

It is also suggested that the evaluation of AAL solutions for specific end-users such as elderly and disabled people should have a careful selection of the sample (Belsky 2001) and should be done as well in their natural environments rather than a test center situation (Goodman-Deane et al. 2009; Zajicek 2004) – which itself introduces additional difficulties whereat requires organizational challenges (Astell et al. 2009; Newell et al. 2011). Relating to selection of the sample, the characteristics of the participants and their daily interests must be taken into account. It is known that the less psychologically and physically active are the participants, the lower their intellectual performance tends to be, which has effects on the results of a usability evaluation. Concerning the test situation site, infrastructures such as living laboratories could have an important role, particularly when assessing the impact of the environmental factors (Alvarelhão et al. 2012) is the main objective. Successfully designing universally accessible interfaces, and therefore its evaluation, requires technical and cultural changes and strategic commitment: usability and accessibility must be an objective of system development. Therefore, it is con-

sidered that the multi-method data collection approach proposed brings an important added value to the AAL solutions research and development area.

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Chapter 6
Ambient Assisted Living as Medical Devices: A European Perspective

Bruno Gago

6.1 Introduction

The World Health Organization describes health technology as 'the application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of life' (Sixtieth World Health Assembly 2007). This definition includes generically all types of technologies used to save human lives.

Among health technologies, the sector of medical technologies has been in outright development for several years with increasing levels of innovation. Currently, we can find more than 500,000 medical technologies on the market. Due to their particularities and comprehensiveness, medical technologies provide a vast range of options for ambient assisted living (AAL) and tailors perfectly into the AAL industry.

AAL emerged in 2007 as a response to the challenges posed by the ageing population. With age, we experience a natural decrease in functional capacities, with distinct tendencies for each individual, according to social and health contexts. It is consensual that the monitoring and management of these capacities benefit from the adoption of new behaviours supported by technologies that promote active ageing (World Health Organization 2002). In this context and as evidenced in other chapters of this book, AAL has become increasingly important (Broek et al. 2009) by resorting to novel devices and interactions, aiming to promote autonomy and independence of the elderly (Sánchez-Pi and Molina 2009; Wichert and Eberhardt 2011).

AAL intends to address needs of older adults and respective major diseases, by meeting the specific individual needs, which might include the access of the

B. Gago (✉)
Medical Sciences Department, University of Aveiro, Aveiro, Portugal

Institute of Biomedicine of Aveiro (IBIMED), University of Aveiro, Aveiro, Portugal
e-mail: bmgago@ua.pt

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caregiver to up-to-date clinical information, so that the right care at the right time can be delivered (e.g. continuous home monitoring of physiological parameters). Therefore, AAL combines solutions (e.g. home monitoring), which can easily borderline with medical technologies, with implications on regulatory and legal frameworks that guarantee the safety of users. Current tendencies are highly based on eHealth tools that represent a significant portion of the medical technology innovation, including more and more AAL solutions, with prompt applicability in ageing.

At this point, AAL cannot be dissociated from medical technologies as they provide devices that can greatly foment the independence of the elderly while guaranteeing better life conditions. Moreover, by working in proximity with the populations, AAL can boost innovation in the medical devices sector, during the search for novel strategies that can further increase the quality of life of older persons. By sharing this reality, scientists, developers and project managers of AAL projects face new challenges mainly at the regulatory affairs level, being impelled not only to reach the market but also to guarantee, by legal standards, the safety of users.

This chapter aims to highlight the importance of development and integration, as soon as possible, of a regulatory strategy concerning AAL solutions that guarantees the safe and sustainable development and commercialization of products that can fall under the umbrella of medical technologies.

6.2 Translational Challenges on Medical Devices Development

Basic research is of utmost importance to predict and understand the principles and mechanisms of processes and to characterize, at the micro level, the impact of novel strategies in humans. However, many times, the findings of basic research do not become real outcomes in clinical practice, due to a lack of efforts and channels to transpose the acquired knowledge to the resolution of concrete challenges (Mensah 2018). This can be a consequence of the particular functioning and metrics of the academia, but there are also cases in which the involved institutions do not plan research adequately, at a scientific and regulatory level, or never managed to see their research firmly funded. Either way, basic research becomes inconsequent.

This is particularly evident in AAL where most of the developments aimed the design, development and evaluation of prototypes (i.e. proof of concept). In contrast, evidence-based medicine is supported on statistical and clinical significance, and new developments are required to show they are able to make a difference and are cost-effective.

The concept of translational medicine was first mentioned in the 1990s – but only gained consistency in the early 2000s – as a consequence of the urgency to optimize product development processes and transform laboratory findings in useful clinical tools. Despite the multiple available definitions, translational medicine is globally recognized as a multidisciplinary branch of biomedical research that intends to transfer the knowledge collected from basic research to clinical practice – from bench to bedside – with the aim of improving the success of prevention, diagnosis

and treatment of human diseases (Gannon 2014; Mirvis 2009). In the process, laboratory findings are integrated within clinical research, and results are applied in the discovery of novel treatment strategies, in a continuous bidirectional flow of information.

Translational medicine can be divided in four stages that fill the gaps detected in the translation process: T1, translation to humans; T2, translation to patients; T3, translation to practice; and T4, translation to population (Waldman and Terzic 2010).

According to the principles of translational medicine, basic research must be carefully planned and supported according to future perspectives. At this stage, scientists must be aware of the demands and challenges – related to technical and regulatory support, costs, good practices and logistics – inherent to the translation of their results to humans, specifically to clinical research of medicines and medical devices. Several aspects must be considered and debated: animal models, stability and mechanism of action, adequacy of design, construction and testing of medical devices and target population, among others. This will determine whether a promising medicine or device will be able to cross 'the valley of death' with sufficient and adequate conditions to be integrated in clinical research and reach market (Waldman and Terzic 2010; Hudson and Khazragui 2013; Westfall et al. 2007).

The translation process itself begins with the transfer of basic research to humans with the objective of assessing clinical effect and viability – T1 translation (Fig. 6.1). This is a critical step involving the collection of the first clinical insights of the device prototype in feasibility/pilot trials conducted in humans (healthy or with disease). The evidences of clinical effect in humans must then be confirmed in patients treated in controlled environments during pivotal clinical trials – T2 translation. At the end of this stage, researchers will have insights about the clinical application, efficacy/performance, safety and the implications of the treatment to patients. Entry in the market will happen at this stage.

Next, research will be focused on the best strategies to apply clinical research outcomes to define recommendations for routine clinical practice – T3 translation. At this point, research is no longer conducted in controlled environments but is rather implemented in 'real-world' conditions, among a variety of uncontrollable

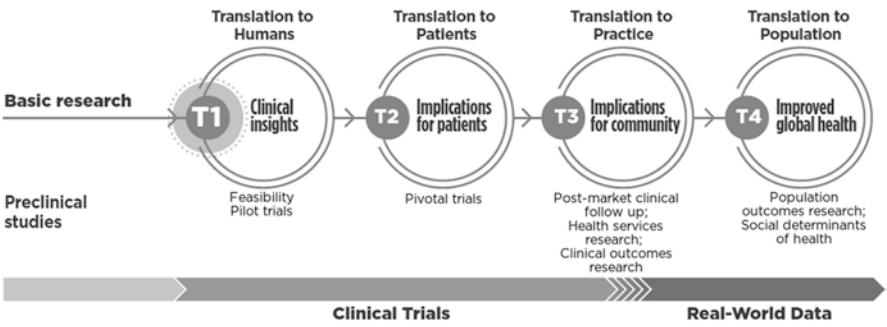

Fig. 6.1 Stages of translation medicine (T1 to T4)

and unpredictable factors. Main implications of the technology for the community will arise from this stage as a result of therapeutic use trials and health outcomes research.

But, considering the ultimate goals of translational medicine, the process cannot be closed with the translation of results to patients: a global approach regarding whole populations is mandatory (Mirvis 2009). Outcomes must be integrated in the search for factors and interventions that affect the daily life and health of a population – T4 translation. This can be achieved through cost-benefit evaluations, surveillance studies and policy analysis. The major objective of this stage, and of the whole translation process, is to improve global health through the integration of the research outcomes collected during basic research and stages T1, T2 and T3. Improvements can arise from both the generated clinical outcomes and from policy development in the sequence of the translation process.

Like in pure medical devices development, in AAL the success of the translation of knowledge – from laboratories to clinical/assistance practice, with the aim of improving the health of populations – depends on a solid and continuous communication between academic researchers and health technologies industries. Their philosophies and expectations are distinct, but cooperation is the only channel that guarantees the bidirectional flow of data that is essential for the successful process that transforms an AAL concept into a valuable therapeutic tool. Also, AAL will benefit from a process that gives preponderance to the new reality of T3 and T4 stages, since being close to the populations and learning with them are in its own genesis.

6.3 Medical Devices Qualification and Classification

Since 2017, the European Union is crossing a transition period in terms of medical technology regulation with the publication, on 5 April 2017, of two new European regulations that revoke Council Directive 93/42/EEC concerning medical devices (MDD) (European Council 1993), Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the member states relating to active implantable medical devices (European Council 1990) (both directives, as amended by Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 (European Parliament and European Council 2007)) and Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices (IVDD) (European Parliament and European Council 1998). Regulation (EU) 2017/745 of the European Parliament and of the Council, of 5 April 2017, on medical devices (MDR) (European Parliament and Council of the European Union 2017) will repeal MDD and AIMDD, as from 26 May 2020, while regulation (EU) 2017/746 of the European Parliament and of the Council, of 5 April 2017, on in vitro diagnostic medical devices (IVDR) (European Commission 2017) will repeal IVDD, as from 26 May 2022. During this transition period, both sets of legislation will apply to medical technologies in Europe. While new legislation is

ready to be followed by scientists, developers and manufacturers, guidelines for its application are still unavailable. In this context, this chapter will follow, whenever possible, the articles of the new legislation.

Besides providing a definition of medical device, MDR establishes the aims, requirements and results that must be achieved in this field and creates a new legal framework regarding medical devices entry into force in all member states on 26 May 2017 with expected date of application as from 26 May 2020.

According to Article 2(1) of MDR, a medical device is defined as '… any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes':

- New models of service delivery and care that contribute to greater self-reliance for older adults and greater support for informal carers;
- Diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease;
- Diagnosis, monitoring, treatment and alleviation of, or compensation for, an injury or disability;
- Investigation, replacement or modification of the anatomy or of a physiological or pathological process or state;
- Providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations, and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

The following products shall also be deemed to be medical devices:

- Devices for the control or support of conception;
- Products specifically intended for the cleaning, disinfection or sterilization of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point (European Parliament and Council of the European Union 2017).

To be qualified as medical device, a health technology must first comply with Article 1 of MDR, which defines the subject matter and scope of the regulation – describing which product categories are included/excluded from the scope of the regulation – and must also comply with the definition of medical device. If a health technology passes the scrutiny of Article 1, it can be qualified as medical device by resorting to a simple yes/no algorithm (Fig. 6.2). Accordingly, a health technology that has a medical purpose, as described in medical device definition, can be either a medicine or a medical device. It is important to highlight that the developer has the obligation to validate this medical purpose, with proper scientific data. It is not acceptable to identify the medical purpose based only on the assumption that the technology will be used in medical environments or applied by health professionals. At this point, if the principal mechanism of action is pharmacological, metabolic or immunological, the product will probably fall under the scope of medicines´ regulation; if this is not the case, it can be qualified as a medical device. Again, the

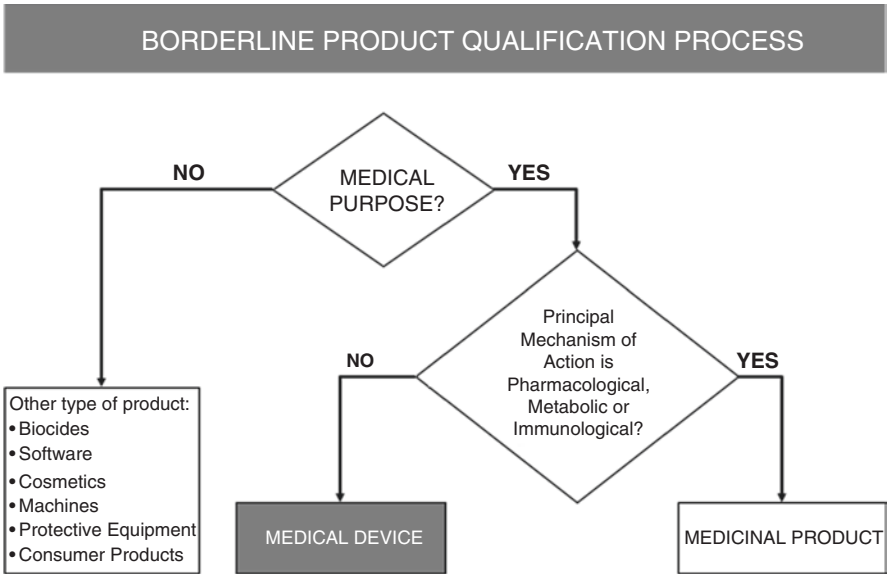

Fig. 6.2 Basic decision flowchart for qualification of a health technology as a medical device

developer must support the principal mechanism of action of the technology with adequate scientific data. Sometimes, it is not clear from the outset whether a given product is a medical device or other product with similar characteristic like biocides, protection equipment, cosmetics, software and medicines. These products – called borderline products – must be carefully analysed, case-by-case, as their classification might be difficult (Medical Devices Expert Group on Borderline and Classification 2018). This issue will be addressed below in the chapter.

The pathway for the development of a medical device, from concept to market, presents particularities that distinguish it from other health technologies (Fig. 6.3).

Three main entities can be identified in this process: manufacturers, competent authorities and notified bodies (when a third party is required).

Competent authorities adapt EU regulations to national realities, designate and supervise notified bodies (described later in the chapter) in member states and are involved in vigilance and market surveillance of medical devices.

Manufacturers develop, qualify and classify their medical devices – classification will define the course of development of the products – and must ensure that they are developed and manufactured in conformity with the general safety and performance requirements, set by Annex I of MDR (European Parliament and Council of the European Union 2017):

- General requirements (Chapter I of Annex I of MDR). Focuses on risk management associated with the design and manufacture of medical devices. As a general principle, a medical device must be designed and manufactured in such a way that guarantees that it has adequate performance during normal conditions

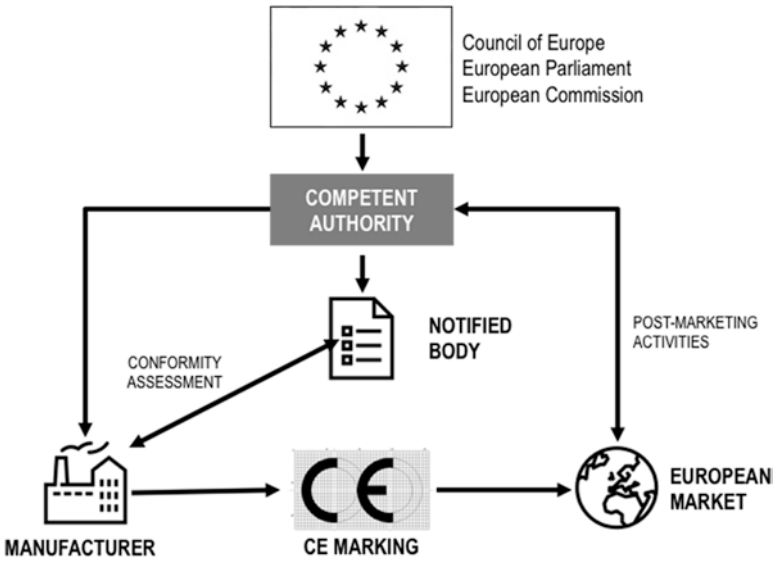

Fig. 6.3 Entities involved in the CE marking process of medical devices in Europe

of use, is suitable for the intended purpose, is safe and effective and does not compromise the clinical condition of the user. As far as possible, the risks associated to the use of the medical device should be reduced, without compromising the overall benefit-risk ratio. For this, manufacturers shall establish, implement, document and maintain a risk management system that evaluates the acceptability of the involved risks and shall inform users about any residual risk.

- Requirements regarding the design and manufacture (Chapter II of Annex I of MDR). Describes in detail specific requirements regarding design and manufacture of medical devices and is divided into the following subtopics:
  - Chemical, physical and biological properties;
  - Infection and microbial contamination;
  - Devices incorporating a substance considered to be a medicinal product and devices that are composed of substances or of combination of substances that are absorbed by or locally dispersed in the human body;
  - Devices incorporating materials of biological origin;
  - Construction of devices and interaction with their environment;
  - Devices with a diagnostic or measuring function;
  - Protection against radiation;
  - Electronic programmable systems – devices that incorporate electronic programmable systems and software that are devices in themselves;
  - Active devices and devices connected to them;
  - Particular requirements for active implantable devices;
  - Protection against mechanical and thermal risks;

  - Protection against the risks posed to the patient or user by devices supplying energy or substances;
  - Protection against the risks posed by medical devices intended, by the manufacturer for use by lay persons.

- Requirements regarding the information supplied with the device (Chapter III of Annex I of MDR). Addresses detailed information on label and instructions for use:

  - General requirements regarding the information supplied by the manufacturer;
  - Information on the label;
  - Information on the packaging which maintains the sterile condition of a device ('sterile packaging');
  - Information in the instructions for use.

The manufacturer must create and keep updated versions of all technical documentation that support the evidence of conformity with the general safety and performance requirements described above. Annex II and III of MDR describe in detail the principles of this documentation that can be grouped as follows (European Parliament and Council of the European Union 2017):

- Device description and specification, including variants and accessories;
- Information to be supplied by the manufacturer;
- Design and manufacturing information;
- General safety and performance requirements;
- Benefit-risk analysis and risk management;
- Product verification and validation;
- Preclinical and clinical data;
- Additional information required in specific cases;
- The post-market surveillance plan drawn up in accordance with Article 84;
- The PSUR [periodic safety update report] referred to in Article 86 and the post-market surveillance report referred to in Article 85.

To prepare technical documentation, manufacturers can resort to notified bodies' recommendations since these will be involved in the conformity assessment process, as described below. Currently, recommendations are only available for old directives, but revision is expected soon (Coordination of Notified Bodies Medical 2000).

The list of requirements and documentation described above clearly evidences that manufacturers are responsible for preclinical (design, engineering, laboratory, animal) and clinical evaluation, always under a risk management system. Manufactures are advised to use European harmonized standard to guarantee conformity with the set of requirements applicable to their medical devices. A compilation of the references of harmonized standard is published in the Official Journal of the European Union (European Commission 2017); the most used are EN ISO

13485:2016 (Quality management systems – requirements for regulatory purposes) (European Committee for Standardization 2016), EN ISO 14971:2012 (Application of risk management to medical devices) (European Committee for Standardization 2012), EN ISO 14155:2011 (Clinical investigation of medical devices for human subjects – good clinical practice) (European Committee for Standardization 2011) and EN ISO 10993–1:2009 (Biological evaluation of medical devices) (European Committee for Standardization 2009). Manufacturers are also responsible for CE marking of their medical devices through which they declare that the product meets legal requirements and can be freely commercialized in the European Economic Area.

Depending on the risk classification of the medical device, the process may have the intervention of a notified body selected by the manufacturer.

Notified body 'is an organisation designated by an EU country to assess the conformity of certain products before being placed on the market. These bodies carry out tasks related to conformity assessment procedures set out in the applicable legislation, when a third party is required. The European Commission publishes a list of such notified bodies' (European Commission 2018). Notified bodies evaluate if the medical device is compliant with the high safety, health and environmental protection requirements established in the legislation. As so, they must actuate under the principles of non-discrimination, transparency, neutrality, independence and impartiality assuring confidentiality throughout conformity assessment. If compliance is confirmed, the manufacturer can affix the CE marking in the medical device and proceed to marketing. The life cycle of the product follows with continuous post-marketing surveillance that generates reports to the competent authorities, manufacturer and notified body. Figure 6.4 describes the main stages of research and development process in the medical device industry.

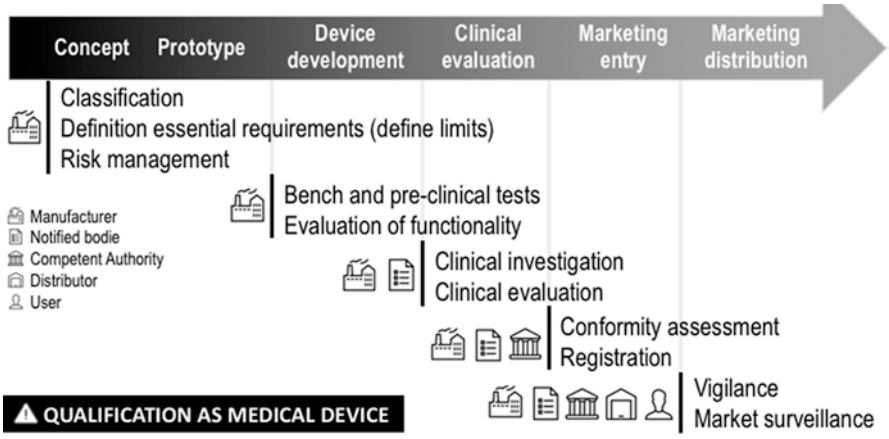

Fig. 6.4 Stakeholder involvement in the research and development process for a medical device

Due to the overwhelming developments on this field, the new MDR introduces updates in the life cycle of the product, giving more importance to the following aspects:

- Premarket procedures (with the creation of the figure of the person responsible for regulatory compliance, implementation of common specifications and deeper scrutiny of high-risk devices);
- Clinical evidence (demanding more clinical data for high-risk devices, publication of clinical and safety data, reinforced equivalence criteria and providing new rules for post-market surveillance);
- Notified bodies (with reinforced designation criteria, unannounced visits and joint audits);
- Post-market surveillance and vigilance (with the introduction of a central database, trend reports, post-market surveillance plan/reports and periodic safety update reports);
- Transparency and traceability (with the registry of devices and economic operators in EUDAMED, development of unique device identifier (UDI), implant cards and adoption of summary of safety and clinical performance);
- Governance, cooperation and oversight (with creation of a medical device coordination group expert panels and expert laboratories).

Qualifying and classifying medical devices – in the early stage of their development – are of utmost importance to distinguish different products while guaranteeing a safe and sustainable development. It is not acceptable to subject all medical devices to similar evaluation procedures, and thus a classification system based on potential hazardous is desirable, to avoid unnecessary procedures. In the scope of AAL, this aspect is fundamental as manufacturers greatly benefit from a harmonized reality that allows the effective development of novel products, with impact on the quality of life of populations.

In the European Union, the classification system for medical devices – defined in Annex VIII of MDR – guarantees harmonized rules and proper development and evaluation. Several criteria are considered in the classification system: duration of use, degree of invasiveness (non-invasive/invasive), type of effect (local/systemic), target organs, use of energy and associated risks.

When analysing AAL solutions, it is expected that several systems fall under the scope of MDR. To classify them in accordance with MDR classification rules is mandatory and a responsibility of the manufacturer. Some aspects must be taken into consideration when dealing with AAL; for example, regarding time of contact, three situations can occur that will have impact in medical devices classification (all of them possible in the scope of AAL): transient use occurs when a medical device is normally intended for continuous use for less than 60 min, short-term use when the medical device is normally intended for continuous use for between 60 min and 30 days and finally long-term use when the medical device is normally intended for continuous use for more than 30 days.

It can be envisaged that the majority of AAL solutions will fall under the category of non-invasive medical devices (Article 2(6) of MDR) – “invasive device means any device which, in whole or in part, penetrates inside the body, either

through a body orifice or through the surface of the body" – but we can easily identify solutions with some degree of invasiveness, such as a continuous glucose monitor. Also, the use of energy in medical devices will increase the risks. Article 2(4) of MDR defines active device as '… any device, the operation of which depends on a source of energy other than that generated by the human body for that purpose, or by gravity, and which acts by changing the density of or converting that energy. Devices intended to transmit energy, substances or other elements between an active device and the patient, without any significant change, shall not be deemed to be active devices. Software shall also be deemed to be an active device'. Many AAL solutions are indeed active devices and many others are software applications; as such, if the manufacturer intends to present a product with medical purpose, it must be classified according to MDR rules dedicated to active devices. Manufacturers can remove the medical purpose from the intended use of a device – stating that the product does not have a medical purpose – but this does not exclude the product from the scope of the MDR, if the definition criteria of medical device are satisfied. Manufacturers must demonstrate, by means of scientific/technical data, that such medical purpose is not achieved.

Under MDR, medical devices are divided in four risk classes:

- Class I (low risk);
- Class IIa (medium risk);
- Class IIb (elevated risk);
- Class III (high risk).

To identify the specific risk class of a medical device, the manufacturer is guided by a set of decision algorithms that enable a final classification. In Annex VIII of MDR, 22 rules of classifications are defined. MDD rules were updated; some became more stringent ('up-classification'), and five new rules of classification were created: Rule 11 (software classification), Rule 19 (devices incorporating or consisting of nanomaterials), Rule 20 (body orifice invasive devices intended to administer medicines by inhalation), Rule 21 (devices consisting of substances and introduced into the body via body orifice or skin and are absorbed by or locally dispersed) and Rule 22 (active therapeutic device with an integrated or incorporated diagnostic function). By applying to MDR rules the orientations defined in MEDDEV 2.4/1 Rev. 9 from June 2010 (Classification of medical devices) (European Commission 2010), we can envisage four major groups of rules:

- Non-invasive devices that can be classified from class I to IIb by rules 1 to 4. In the perspective of AAL, several products with these characteristics can have impact on the well-being of populations and on the effectiveness of their healthcare procedures;
- Invasive devices with risk classes from class I to III according to rules 5 to 8. As examples with interest in the context of AAL, we can point out rechargeable nonactive drug delivery systems;
- Active devices with risk classes from class I to III according to rules 9 to 13. In particular, new Rule 11 is dedicated to the classification of software as medical

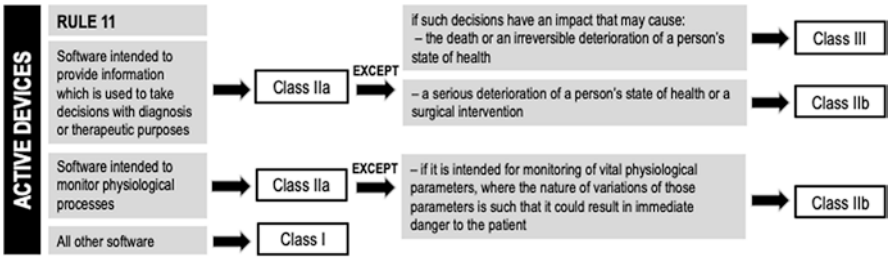

Fig. 6.5 Example of algorithm for application of Rule 11 (software) in accordance with Annex VIII of MDR

device (further described in the next section of this chapter) defining parameters that can classify a software application from class I to class III (Fig. 6.5);

- Special rules that include risk classes from class IIa to III according to rules 14 to 22. New rules 19, 20, 21 and 22 were created as a response to recent innovations within medical technologies. The advent of nanotechnology is well represented in Rule 19 (devices incorporating or consisting of nanomaterials) with possible impact in AAL when nanomaterials are used.

Manufacturers are responsible for propounding a classification for their devices; as such, research teams must be adequately trained to guarantee the adequate planning of the initial stages of development, avoiding wrong decisions that can delay the development process and increase costs and time to access market.

While qualification and classification are of major importance in the first steps of product development, in AAL, developers must be aware that if their technology is qualified as a medical device, the translation to humans needs to be supported with clinical evidence. If quality data on bench and animal tests gives the confidence to advance for research in humans, clinical data to support demonstration of clinical benefit is mandatory to be in conformity with MDR. In medical devices, clinical evaluation is defined in Article 2(44) of MDR as '… a systematic and planned process to continuously generate, collect, analyse and assess the clinical data pertaining to a device in order to verify the safety and performance, including clinical benefits, of the device when used as intended by the manufacturer' and Article 2(48) defines clinical data as '… information concerning safety or performance that is generated from the use of a device and is sourced from the following':

- Clinical investigation(s) of the device concerned;
- Clinical investigation(s) or other studies reported in scientific literature of a device for which equivalence to the device in question can be demonstrated;
- Reports published in peer-reviewed scientific literature on other clinical experience of either the device in question or a device for which equivalence to the device in question can be demonstrated;
- Clinically relevant information coming from post-market surveillance, in particular the post-market clinical follow-up.

To perform clinical evaluation of medical devices, manufacturers need to assess sufficient clinical data to verify the safety and performance, including clinical benefits, of the device in evaluation. As set in the definition of clinical data, different sources can be used to gather information for the assessment procedure. In specific cases, and when clinical, biological and technical equivalence can be demonstrated to other device, clinical evaluation can be based on scientific literature. If the technology in question is innovative, equivalence is probably not possible to demonstrate, and manufacturers must generate their own clinical data resorting to clinical investigation. It is important to emphasize that implantable devices and class III devices are always obligated to be subjected to clinical investigation except if they meet the exception identified in Article 61(4) of MDR. In the end, to be in conformity with clinical evaluation requirements, manufacturers must follow Annex XIV (Clinical evaluation and post-market clinical follow-up) and Annex XV (Clinical investigation of the MDR) (European Parliament and Council of the European Union 2017). Manufacturers can guide the clinical evaluation process of their medical devices by applying the guidelines of MEDDEV. 2.7/1 Rev.4 from June 2016 that divide the process in five stages: Stage 0, Definition of the scope of the clinical evaluation; Stage 1, Identification of pertinent data; Stage 2, Appraisal of pertinent data; Stage 3, Analysis of clinical data; and Stage 4, Clinical evaluation report.

In AAL, if a simple or complex innovative solution falls under the scope of medical technologies, its correct qualification and classification determine the regulatory roadmap to follow and the successful pathway to market.

6.4 Borderline Challenges of Medical Technologies

Medical technologies are present in our daily life – from birth to advanced ages – making healthcare more efficient and increasing autonomy and quality of life of individuals, with emphasis on elderly populations. As age advances, the number of available products increases exponentially along with the needs that individuals have for them (Fig. 6.6). A plethora of technologies are explored from medical devices, in vitro diagnosis, imaging and eHealth, among many others. This is in good agreement with the objectives of AAL, as evidenced by the large variety of products and services that are being developed to increase the quality of life of population.

Some of these products are difficult to classify due to their patterns of innovation related mainly to the combination/confounding with medical approaches. They can be considered borderline products – a concept in the scope of medical technologies that defines cases where it is difficult to state if a given product is, for example, a medical device, an *in vitro* diagnostic medical device, a software as medical device and a health and wellness software, or cases where the accepted classification rules cannot be promptly applied (Medical Devices Expert Group on Borderline and Classification 2018).

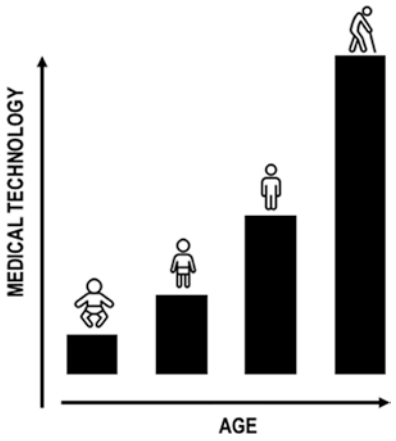

Fig. 6.6 The use of medical technology increases as age advances

Current developments in medical technologies are based on miniaturized, intelligent, low invasive and combination products. Along with this, research strategies consider the demand for personal use products and the particular needs of special populations. Thus, it is expected that borderline products continue to emerge in the scope of AAL, demanding particular attention concerning to regulatory issues, control of quality, safety and performance.

To highlight this tendency, we can focus our attention on some challenging strategies that demand particular analysis. With this problem, several fields emerged inside medical technologies; for instance, eHealth with software and mobile applications are major challenges in AAL systems.

In a time where technologic platforms such as mobile computers, smartphones and tablets are available for most people, different kinds of software are being widely used in healthcare, both with medical and nonmedical purposes. The incorporation of software in medical devices became widespread so that specific regulation was conceived for these particular cases, minimizing the risks associated to this combination. Big challenges began when software was suggested as a medical device, forcing regulators to create adequate tools for proper and convergent control of these devices. According to the International Medical Device Regulators Forum (IMDRF), software as medical device is defined when it is '… intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device' (International Medical Device Regulators Forum (IMDRF) 2013). This implies that the software guarantees a valid clinical association between its output and the clinical condition and provides the expected technical and clinical data (International Medical Device Regulators Forum (IMDRF) 2017; European Commission 2016).

Under the European regulation, it is important to clarify that according to MEDDEV 2.6/1 from July 2016, software 'is defined as a set of instructions that processes input data and creates output data' and stand-alone software '… means software which is not incorporated in a medical device at the time of its placing on the market or its making available' (European Commission 2016). Stand-alone software must have a medical purpose to be qualified as medical device. When used in

healthcare settings, these types of software can run on all types of operating systems and may have several applications, from directly controlling an apparatus (e.g. radiotherapy treatment) to providing support for healthcare professionals (e.g. X-ray interpretation) (European Commission 2016). A myriad of solutions in AAL will fall under the qualification criteria of stand-alone software as medical device. Following decision trees similar to those used in medical devices classification, stand-alone software guidelines allow developers to qualify their technology according to regulatory rules (MEDDEV 2.1/6 from July 2016, decision diagrams) (European Commission 2016) and determine if the developed AAL solution is a stand-alone software as medical device. If so, the life cycle of the ALL solution will be ruled by the regulation applied to medical devices.

These features are well expressed, for example, in a mobile application for processing electrocardiograms (ECGs). Such an application will be classified as stand-alone software as medical device if it uses signal data from an external source that can be received wirelessly, for example, from an AAL system and processes it to an ECG waveform – performing an action on data – for medical benefit of an individual patient. This will provide timely and accurate diagnosis and treatment. This software application will fall under the scope of the MDR and will be qualified as medical device, and its classification will be ruled by Rule 11 of Annex VIII of MDR (Medical Devices Expert Group on Borderline and Classification 2018).

Another example is software developed with the purpose of treating a variety of neurodisorders. The combination of several software applications allows the physician to establish rehabilitation plans based on interactive games and exercises, for cognitive stimulation, and to access patient's progress. Assuming an AAL context and depending on its autonomy, the patient – alone or with the support of a caregiver – can perform the planned tasks at home and the clinician can plan, monitor and assess the patients' progress throughout the treatment plan, at distance in the comfort of its office. Depending on the intended purpose identified by the manufacturer – treatment of disease, injury or handicap – this software can be easily integrated in a AAL solution and should be qualified as medical device and classified by means of Rule 11 of Annex VIII of MDR (Medical Devices Expert Group on Borderline and Classification 2018).

The same considerations could not be extended to a mobile application for storing pictures of skin moles, in a smartphone, as no data manipulation occurs, a prerequisite for a software to be qualified as stand-alone software as medical device. If the same application, besides storing pictures of moles, can also assess them with the help of an algorithm that classifies the mole as a melanoma, supporting diagnosis of skin cancer, it can be qualified as medical device and classified according to Rule 11 of Annex VIII of MDR (Medical Devices Expert Group on Borderline and Classification 2018). Applications that just store data and do not perform any action on it, with impact on an individual patient, are generally not medical devices. Healthcare information systems, normally dedicated to manage data, by storing, archiving and transferring, are not qualified as medical devices. However, specific modules of software may be qualified as medical devices (e.g. a medication module) (European Commission 2016).

Another technology of interest is bone-anchored hearing aids. The product comprises a titanium implant and a sound processor that relies on an electric power source. The question is whether the system is an active implantable medical device or only a medical device. The key for the classification is based on the fact that the implanted part (titanium) is not active and that the active element (sound processor) is not implanted. Thus, the system is not an active implantable medical device but rather a medical device as both components are classified as such (Medical Devices Expert Group on Borderline and Classification 2018). While this example is not per se an obvious AAL solution, wireless solutions that can be connected with the sound processor can fall under AAL. If the AAL solution (e.g. smartphone application) is developed with a medical purpose, it will probably fall under MDR with a particularity: if it is commercialized as a single system comprising the implant, the sound processor and the software application, the risk classification will be the highest of the three components, and all parts must comply with the general safety and performance requirements set for that classification.

The difficulties of the development of software as medical device do not end with qualification and classification; challenges also emerge during clinical evaluation. International Medical Device Regulators Forum suggests a three-step process for clinical evaluation of software as medical device:

1. Valid clinical association (Is there a valid clinical association between your software as medical device output, based on the inputs and algorithms selected, and your software as medical devices' targeted clinical condition?);
2. Analytical validation (Does your software as medical device correctly process input data to generate accurate, reliable and precise output data?);
3. Clinical validation (Does use of your software as medical devices' accurate, reliable and precise output data achieve your intended purpose in your target population in the context of clinical care?) (International Medical Device Regulators Forum (IMDRF) 2017).

Borderline issues regarding medical devices and medicinal products, in vitro diagnostic medical devices, cosmetics and biocides are also a topic of concern that deserves careful debate. AAL is not by excellence a field for this type of products, but several examples of borderline questions can be studied in the *Manual on Borderline and Classification in the Community Regulatory Framework for Medical Devices* (Medical Devices Expert Group on Borderline and Classification 2018).

The discussion around borderline products is a mirror of the technological advances in the field of medical devices. It gains particular importance in the scope of AAL due to the exponential emergence of products with the specific purpose of increasing the quality of life of the targeted population. Manufacturers must be aware of these challenges, and regulators have the obligation to create guidelines and recommendations to assure sustainable, harmonized and secure development of novel products.

6.5 The Medical Device Regulatory Pillar in the Development of AAL Solutions

In a context of continuous growth and constant innovation, the medical device sector faces big challenges regarding mainly the safety of products. Scientists and manufacturers have the responsibility of creating quality products, according to the market needs, while guaranteeing conformity with regulations and safety for users. eHealth and borderline products add strains to this context, as classification and research demands might be unclear or misinterpreted.

In the scope of AAL, this becomes even more significant as products shall not only fulfil the needs of the target population but also be designed and manufactured in such a manner that utilization poses minimum doubts and risks and guarantees usability. Specific milestones can be introduced in the development chart of a AAL solution. By answering in the initial steps of the project – sometimes already at the initial brainstorming of the concept – to question like 'Does my product have a medical purpose?', 'What type of medical device it is?' and 'What is its inherent risk to the user?', the developer will be armed with data that enables a more efficient research and development process, by ensuring correct application of resources and decreasing the time to market. When developing a medical technology, the developer must have in mind that the four stages (T1, T2, T3 and T4) needed to technology translation from an idea to a product are also answers to regulatory demands. In Europe, MDR, with its demands for safety, performance and post-market activities, obligates the developer/manufacturer to respond to the four translation stages to maintain the product available for the user in a healthcare setting.

These demands can only be attended if all stakeholders actuate under the same base of principles and according to the same rules. A solid, comprehensive regulatory basis must be available, and its application shall be assured and inspected. Thus, competent authorities are obliged to identify the evolution of research and of the market and support/inspect manufacturers during the development and commercialization processes.

The new MDR is introducing changes in the medical technology sector with strict measures to increase transparency, traceability and security while demanding more clinical evidences and the involvement of experts in the evaluation process. This context must be integrated in AAL projects, if a medical purpose is identified, and, by default, project management policies must contemplate regulatory affairs specialists (employed or subcontractor) since this is the best way to ensure the sustainability of the regulatory pillar and the success of the project.

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Chapter 7
Use of WHO-FIC to Structure Information in Ambient Assisted Living

Joaquim Alvarelhão

7.1 Introduction

Demographic changes in the western countries constitute a societal challenge due to an increase of aged population. At the same time, these demographic changes are an opportunity to develop solutions, such as information and communication technologies, and changes in the various support services, namely, in health systems. It is also clear that raising the general publics' awareness of the importance of living healthily and functionally in the last period of the life cycle, preferably in community contexts, contributes to the development of policies that respond to these aspirations (Pin and Spini 2016). Independent living and community care appear to be a lower cost for health and welfare systems (Watson et al. 2018), even in situations of loss of autonomy, while providing better quality of life outcomes (Seah et al. 2018).

Ambient assisted living (AAL) concept embraces the use of information and communication technologies systems in straight conjunction with social and healthcare in daily life, which, at individual level, aims to facilitate independence, autonomy and social involvement throughout ageing (AAL Association 2016). The contribution of AAL to healthcare systems is expressed in indicators of economic efficiency, effectiveness and quality improvement (Haux et al. 2016) in new ways of living and healthcare (Mayora et al. 2014) with a particular focus on the current concepts of active aging. A wide variety of technologies are used for this purpose, from simple devices to home automation systems including fall prevention strategies, distance rehabilitation exercises or medication management (Siegel and Dorner 2017). In this sense, the breadth of action of AAL encompasses health interventions in a range that covers preventive measures, changes in behaviours and maintenance or improvement of body functions. In recent times, clinical assessment

J. Alvarelhão (✉)
Health Sciences School, University of Aveiro, Aveiro, Portugal
e-mail: jalvarelhao@ua.pt

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data have increased in published work, but most continue to focus on the technical and engineering characteristics of the AAL projects (Queirós et al. 2015), and a gap between the areas still exists.

International standard classifications from health field may offer a starting point for bridging the different stakeholders together into the desired changes in community-based health support (Zelmer and Hagens 2014). In addition, as a tool to improve communication between two fields of knowledge, through a common language and a common conceptual framework, the use of these classifications allows the comparison of data between different countries, systems or projects. Health information is essential for measuring effectiveness and efficiency, but it also helps to improve the quality of the system in terms of accessibility and equity. International classifications are crucial for scientific purposes emphasizing relevant information for understanding individual needs, services and systems (Jakob et al. 2007).

This work describes briefly the reference classifications from the World Health Organization Family of International Classifications (WHO-FIC) that can contribute for explaining the process of different types of AAL systems, guided by the health procedural reasoning cycle (Higgs 2008). To illustrate the potential of using WHO-FIC for this purpose, an AAL service is used as an example.

7.2 World Health Organization Family of International Classifications

The WHO-FIC is a group of classification products that could be used in an integrated manner to compare health information in a wide range of settings, at international, national or local levels (Kim and Coenen 2011). The various classifications of the WHO-FIC are the result of several years of international development efforts and comprise three major types of classifications named related classifications, reference classifications and derived classifications. The reference classifications include the International Classification of Functioning, Disability and Health (ICF), the International Classification of Diseases and Related Health Problems (ICD) and the underdevelopment International Classification of Health Interventions (ICHI). These classifications cover the main parameters of health and the health system, such as death, disease, functioning, disability, health and health interventions (Jakob et al. 2007). Being a product of international consensus, WHO-FIC is recommended as guideline for international reporting on health (Madden et al. 2007).

7.2.1 International Classification of Functioning, Disability and Health

The ICF is a standardized classification with more than 1,400 categories, where functioning is understood as the operationalization of the health state representing the result of the interaction of the health condition of an individual with its

contextualizing factors (World Health Organization 2015a). Thus, the overall purpose of ICF is to describe health components and health-related states through a unified and standardized 'language' corresponding to a unified and standardized conceptual framework. In this framework, disability is a broader concept that includes impairments (body structure or/and body function components), activity limitation and participation restriction (activities and participation component). If the description of the concept of disability is implicit in the categories related to the functions and structures of the body, the ICF defines activity as the accomplishment of an action or task and participation as the involvement in a life situation. In this component, the ICF differentiates the concepts of performance and capacity, the first one regarding the realization in real context and the capacity related to the realization in an ideal context (Jette et al. 2007). Each ICF category assumes valuation through the assignment of qualifiers. The first qualifier in each category expresses the extent of the disability within the body functions and structures or the limitation in the case of activities or the restriction for participation construct. Approximately 190 countries adopted ICF with different applications across scientific and professional fields.

7.2.2 International Classification of Diseases and Related Health Problems

The ICD is the standard diagnostic tool for epidemiology and health management (World Health Organization 2011). This classification makes possible to analyse the general health situation of the population and to monitor the prevalence and incidence of diseases and other health problems (World Health Organization 2018a). The main objective of the ICD is to categorize diseases, health conditions and external causes of disease in order to provide useful statistics on mortality and morbidity. The classification is also an informative tool for decision support systems and reimbursement systems and used as some minimal common denominator to be used in language-independent documentation of medical information (Jakob et al. 2007).

The standardization of the nomenclature and systematization for the names of diseases is the basic concept of ICD, which defines the universe of diseases, disorders, injuries and other related health conditions, these entities are listed comprehensively in order to cover the diversity of the phenomena (World Health Organization 2015b), with approximately 12,700, of which about 8,000 are valid as underlying cause of death. However, the classification does not differentiate other conditions present at patient admission (Kurbasic et al. 2008). ICD is one of the oldest and most important classifications in healthcare covering all fields of medicine, and despite some limitations (Volkmar et al. 2012; Villanueva and Cohen 2018) is used in more than 100 countries and is translated in 43 languages (World Health Organization 2015b).

7.2.3 International Classification of Health Interventions

The purpose of ICHI is to provide a common tool for analysing and reporting health interventions for statistical purposes (World Health Organization 2017), not only for local initiatives like comparisons between two or more countries but also for global initiatives such as Sustainable Development Goals and universal health coverage (World Health Organization 2018b) or Rehabilitation 2030. The definition of health intervention in ICHI is 'an act performed for, with or on behalf of a person or a population whose purpose is to assess, improve, maintain, promote or modify health, functioning or health conditions' (World Health Organization 2017). In this sense, health interventions included actions at individual level for diagnosis or treatment but also at population level such as vaccination programs (Jakob et al. 2007) and across different sectors of the health system – community care, medical and surgical, primary care and rehabilitation (Fortune et al. 2018). Each intervention is described around three axes: 1) target, the entity on which the action is carried out; 2) action, the deed done by an actor to the target; and 3) means, the processes and methods (includes approach or technique) by which the action is carried out. Each axis consists of a coded list of descriptive categories. Additional information about an intervention can be added using extension codes, including, for example, codes for therapeutic and assistive products and medicaments (World Health Organization 2017). With categories of targets, in addition to the section on body functions and systems, which are already present in many national level classifications, ICHI includes three further sections dealing with interventions at the level of activities and participation, interventions on environment and interventions in health-related behaviours (Fortune et al. 2018). The development of ICHI started in 2007, and a beta version is now accessible online through the classifications page of WHO website.

7.3 AAL and Health Procedure Reasoning Cycle

Within AAL, many concepts are advocated and acting on a wide range of subjects, the literature on AAL developments is not easy to systematize. For instance, the idea of ambient intelligence deals with paradigms of natural interactions between the person and the context where the person is acting. This brings a challenge about measuring the meaningful effects of these services and systems in health at individual and population levels (Cedillo et al. 2018). However, an effort has been made to structure the different information on the topic. It is possible to find proposed AAL frameworks from the technological point of view by grouping the published works under this perspective into architectures, components (e.g. physical devices, context awareness, user interaction or privacy and security (Queirós et al. 2015)) and systems or services. Other revisions look for the impact on user's quality of life, stating the lack of good methodologic studies about this outcome in the field (Siegel and Dorner 2017), due to the complexity of interventions but also due to difficulties in measuring some health outcomes, such as participation, or because outcomes are

intangible (Nicolson et al. 2012). Concerning the type of support provided to AAL users, the systematic review of Chap. 2 identified six major categories (medication, activity recognition, healthcare, falls detection, participation and monitoring), which can be further subdivided. For instance, a systematic review (Calvaresi et al. 2017) refers to multimedia analysis, data analysis, data sharing and communication for functions that were classified in Chap. 2 as healthcare (Calvaresi et al. 2017).

To merge these approaches, we consider that AAL services and systems use the same steps recognized in the health procedural reasoning cycle (Table 7.1). This process can be generally described in six groups of information: 1) define initial situation of the person; 2) collect information; 3) process information; 4) identify problems and establish goals; 5) take action; and 6) evaluate outcomes and update information. For each of these steps, it will be possible to make a correspondence with an AAL process. The description of the AAL process could rely on the type of support provided to the user like 'data storage' or 'activity recognition', having a close relationship with the kind of technology that gives purpose to the action or task. Finally, it will be possible to make a correspondence with a reference classification of WHO: the individual health experience in general can be described using the dimensions of the ICD and ICF (Madden et al. 2007) and AAL interventions using ICHI (World Health Organization 2017).

Thus, the proposed correspondence between AAL process and WHO-FIC is the following: 1) define initial situation of the person, ICD and ICF; 2) collect information, ICHI; 3) process information, ICF; 4) identify problems and establish goals, ICF; 5) take action, ICHI; and 6) evaluate outcomes and update information, ICD and ICF. For each classification, appropriate categories are selected in detail to constitute a structured set of information (Table 7.1).

7.4 Discussion

This work's purpose is to use the WHO-FIC as a standard to structure information about the use of AAL services and systems. The recent availability of ICHI (as a beta version) is an opportunity for improving not only the classification itself but also to explore the use under multidisciplinary disciplines, like AAL field. The developments made at technological level in the AAL field are considerable with excellent and creative proposals, but measuring the impact and efficiency in real context still is the weakest factor of the area. The configuration of studies with a high methodological level to carry out measurements of efficacy and health efficiency, like randomized control trials, can encounter several problems (Lauriks et al. 2007). On the one hand, the number of users of the same AAL system with the corresponding financial value in infrastructures, equipment or devices and, on the other hand, the wide range of multidimensional services and activities to be tested are examples of these difficulties. Systematic collection of information, which can be aggregated into a common structure, relating users' characteristics to the contexts in which they live and carry out activities, with the different actions and

Table 7.1 Fall detection in AAL system and information correspondence with WHO-FIC in a fall due to slip in a wet floor (example)

Health procedural reasoning cycle[a]	ALL process fall detection	WHO-FIC	Information categories (examples)
1. Describe person initial situation	Data storage	ICD	ICD category – tendency to fall because of old age or other unclear health problems
		ICF	ICF body functions – mental functions, sensory functions and pain, neuromusculoskeletal and movement-related functions
			ICF activities and participation – mobility, self-care
			ICF environmental factors – context description
2 Collect information	Activity recognition	ICHI	Observation of changing and maintaining body position, observation of walking and moving, observation of going up- and downstairs, observation of moving around in different locations, observation of moving around using transportation
3 Process information	Data analysis	ICF	Qualifiers from categories of ICF activities and participation component
			Qualifiers from categories of ICF – environmental factors
4. Identify problems and establish goals	Data analysis	ICF	Qualifiers from categories of ICF body functions
			Qualifiers from categories of ICF activities and participation component
			Qualifiers form categories of ICF – environmental factors
5. Take action	Communication	ICHI	Practical support with communication (emergency call)
	Vital signs data sharing		Blood pressure monitoring, temperature monitoring, measuring body temperature, pain assessment
6. Evaluate outcomes and update information	Data storage	ICD	ICD category – fall on same level from slipping, tripping and stumbling
	Data analysis	ICF	ICF body functions – mental functions, sensory functions and pain, neuromusculoskeletal and movement-related functions
	Data sharing		ICF activities & participation – mobility, self-care

ICD International Classifications of Diseases, *ICF* International Classification of Functioning, Disability and Health, *ICHI* International Classifications of Health Interventions, *WHO-FIC* World Health Organization Family of International Classifications

[a]Adapted from Higgs (2008)

interventions provided by AAL services and systems, can contribute to a deeper understanding of their true impact on the daily lives of the users. The use of standard classifications for structure information also can contribute for comparison between different kinds of services or systems even if they are available in different locations which will be a valuable tool for use in policy, research and practice (Fortune et al.

2018). Naturally, in addition to the necessary updating of classifications, addressing eventual gaps, overlapping categories or ambiguities especially in ICHI, other types of developments will be necessary to improve the extraction of knowledge from the structured information. The definition of ontologies by a certain type of health condition or the elaboration of detailed semantic models of the different activities to study is an example for future work. Although the use of other WHO classifications in this work has not been explored, it is possible that information in AAL field makes sense to be mapped to one of these classifications such as medicines or technical aids. In conclusion, in order to enhance the needs and goal analysis from the users' perspective, the information about the impact of AAL services and systems should be mapped with WHO-FIC classifications.

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