

AAL Guidelines for Ethics, data privacy and security

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Abstract

The AAL Guidelines for Ethical Excellence provide the AAL Community with a model that integrates general law compliance with an ethical dialogue. It also provides reflections on how to set up ethical excellence for solutions targeting active and healthy ageing through digital technologies.

Statement of originality

This document contains original unpublished work except where clearly indicated otherwise. Acknowledgement of previously published material and of the work of others has been made through appropriate citation, quotation or both.

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1. INTRODUCTION AND SCOPE

What is the aim of these AAL Guidelines?

The main aim of this document is to provide the Active and Assisted Living (AAL) Community of stakeholders with guidelines for ethics, data privacy, and security regarding digital solutions for the Active and Healthy Ageing (AHA) domain, fostering two main aspects:

- to be compliant with existing regulations, standards, etc.
- to strive for ethical excellence, that is to try to go “beyond the call of duty” by implementing an iterative ethical dialogue with all relevant stakeholders as a way to develop the best possible product or service, at that time.

Who are these Guidelines aimed at?

This document is designed for all researchers, developers, primary, secondary and tertiary end-users, policymakers, start-ups, and enterprise innovators in the AAL domain. It can support the successful adoption and use of their solution by integrating an ethical and basic legal perspective right from the development stage of products and services. In the different application areas covered by AAL, there is a wide set of technologies and innovations with every project having its own specificity. This is why the approach taken in these guidelines is not "one-size fits all", but instead a guidance perspective on how to achieve more towards societal good.

Why are the Guidelines important?

As technology is rapidly progressing, very often the final users of AAL solutions face difficulties, such as a lack of digital skills or a sense of rejection towards new technologies¹. This means that gaps in information and communication for instance about (health) benefits, risk-mitigating measures, instructions for use, their rights and privacy need to be thoroughly addressed, throughout the complete cycle of development, from ideation to market launch and use.

Human-machine interaction needs to be designed to respond to the highest ethical, legal, and privacy/data management standards and requirements. This is essential to protect the older citizens, but also to guarantee the viability of the business solutions, ensuring they are legally compliant and match European and national regulations.

However, besides this technological human-machine interaction ethics, there is also the need to anticipate the complex settings where the AAL products and services will be used, which involve stakeholders, as well as organisational and budgetary challenges that compose the broad AAL market.

The specificities of the main beneficiaries of the AAL solutions – the older adults – may include increasing physical, mental, and functional impairment and thus also increasing risks of (accidental) use error, misuse, harm, unacceptance, lack of adaptation or lack of access, among others.

¹ <https://www.activeadvice.eu/news/concept-projects/aal-test-regions-austria/>

This specific ethical challenge that AAL solutions face implies the need for a more robust method, including not only compliance with legal regulations, but also the search for excellence in ethics, beyond what should already be expected for the general public.

Ethical excellence is not a 'nice to have' but a 'must have', not only for human and societal reasons but also for success in the market.

Most of the AAL solutions are not purchased by the older adults themselves, but by the secondary users - all kinds of organisations in the regulated market, such as municipalities, health care and social care organisations, and even informal caregivers. Most stakeholders in the AAL Community are familiar with EU regulations applicable to AAL products and services. And several European Programmes (e.g., H2020, Eurostars) have adequate and solid guides for regulatory compliance, that project partners should follow and that can be easily accessed and used.

AAL goes one step further and demands more than just legal compliance and ethical responsibility, – it proposes **Ethical Excellence**, by fostering the implementation of the ethical dialogue and integrating relevant values (more on values later) in an iterative process of discussion and action. Not only from the ideation and during projects' lifetime but also for solutions already in the market.

Thus, these Guidelines intend to go beyond the (legal) state-of-the-art by providing the Community with a simple guide towards excellent ethical behaviour:

Doing the right thing, at the right time, in the right way.

2. THE AAL MODEL FOR EXCELLENCE

Ethical excellence in all stages – conceptualisation & (co)creation; development & testing; market entry & scale-up - can leverage the trust of citizens and organisations, fostering the adoption of AAL solutions and services. To this aim, a two-fold complementary model of ethical excellence is proposed, that integrates compliance (left columns of the picture) with the ethical dialogue (right column of the picture); further details are in the next sections and in Figure 1:

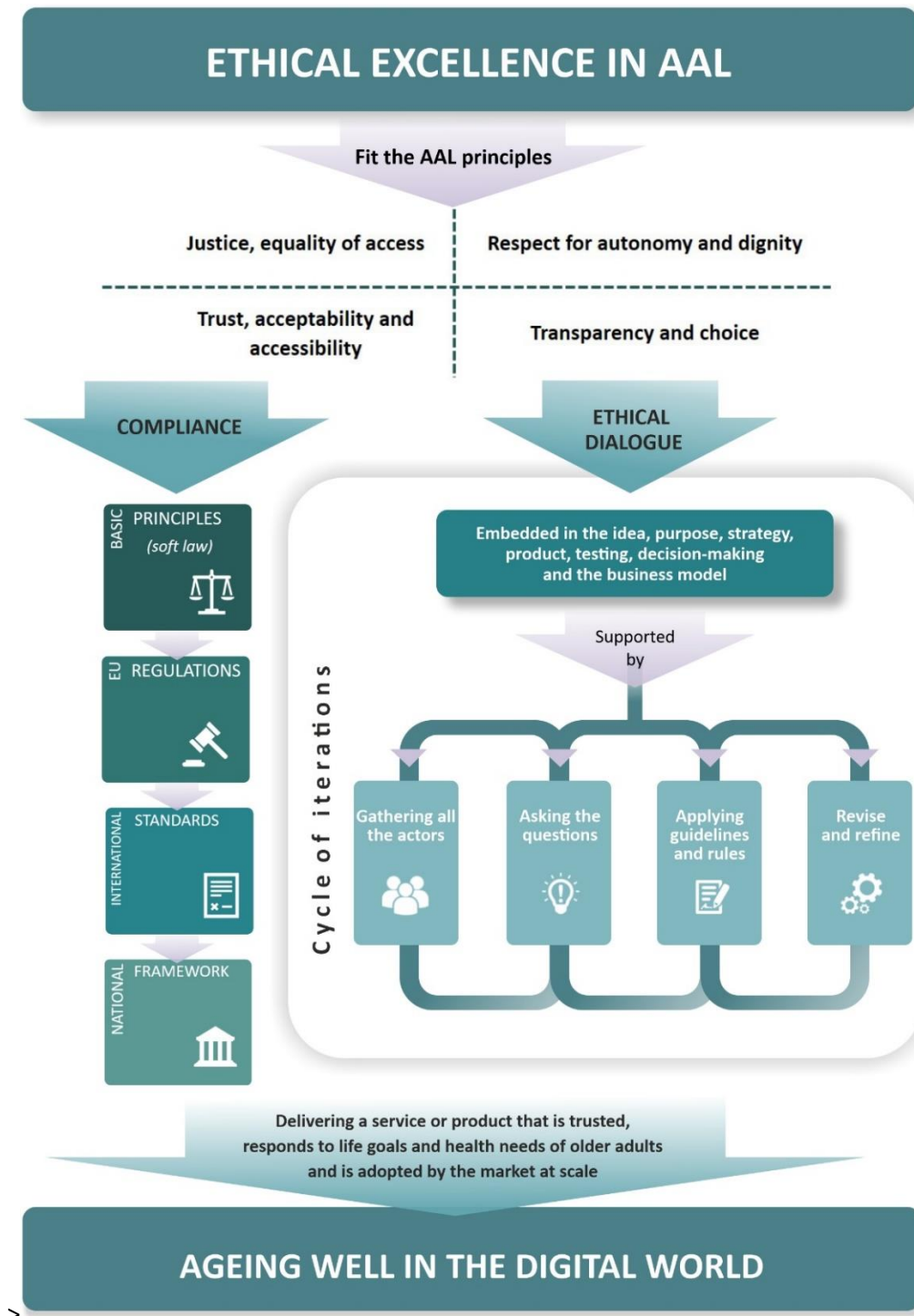
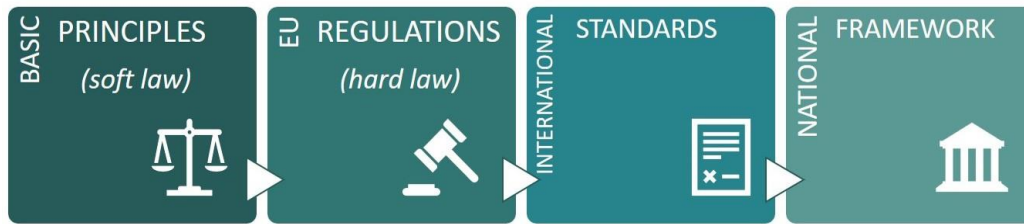


Figure 1 - The ethical excellence model

3. FRAMEWORK FOR COMPLIANCE



The AAL framework for compliance comprises four steps:

1. Basic principles (soft law)

Fundamental Ethical principles indicate that an intent to do good or provide help must always be the underlying motive for action. However, intent to do good is not sufficient. The potential for good must sufficiently outweigh the potential for harm.

Soft law includes a series of ethical codes of conduct, texts, and principles to guide the protection and respect of the human rights and dignity of human beings, based on 4 principles (beneficence, non-maleficence, autonomy, and justice). These principles are translated by AAL in Figure 3. Click [here](#) for the related Charter of fundamental rights of the European Union.

Research in AAL projects is often subject to ethical approval. Depending on medical device classification clinical research may be required for CE marking and market access. Ethical boards are especially mindful of vulnerability in users and the indicated balance in the potential for good versus the potential for harm. The ethical dialogue, which is discussed later and application of the AAL principles (see figure 3) can help prepare well for ethical approval, market access and market success.

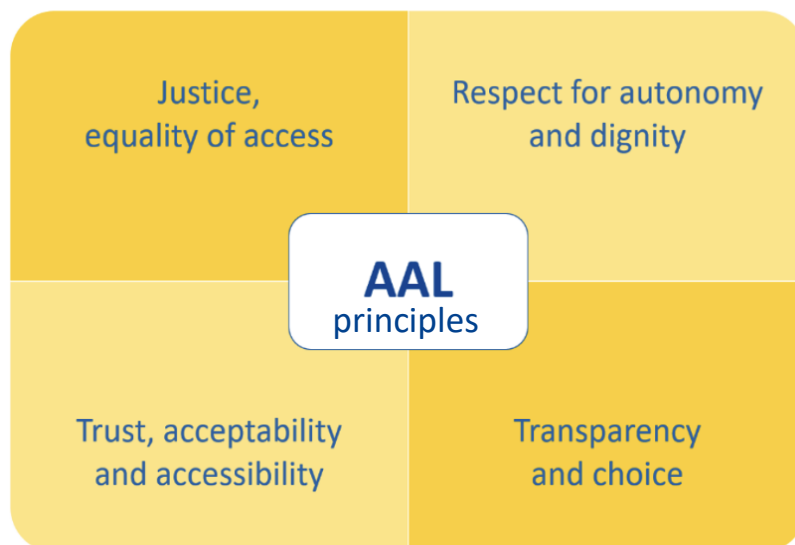


Figure 2 - The AAL principles

2. EU Regulations (hard law)

Relevant EU regulations for AAL products include data privacy and security (i.e., GDPR: General Data Protection Regulation) including the upcoming ePrivacy Regulation, and medical devices (i.e., EU MDR: Medical Device Regulation).

This is particularly important for people in vulnerable situations, which can be the case of some older adults or people with disabilities. In the AHA domain, AAL has become expert in the Research & Development of new innovative solutions and their readiness for the market and, thus, gives high relevance to data protection regulations. Complying with these key requirements is a must!

GDPR: General Data Protection Regulation key points

The GDPR is a set of data protection rules for all organisations operating in the EU, wherever they are based or wherever their data processing activities are taking place. Stronger rules on data protection mean people have more control over their personal data.

Personal data is defined in the GDPR as “any information relating to an identified or identifiable natural person (‘data subject’); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural, or social identity of that natural person”. Special categories of personal data include racial or ethnic origin, political opinions, religious or philosophical beliefs, trade union membership, genetic data, biometric data, data concerning health, and data concerning a natural person's sex life or sexual orientation. Special categories of personal data have further restrictions.

Personal data shall be (a) processed lawfully, fairly, and transparent for the data subject, (b) collected for specified, explicit and legitimate purposes, (c) adequate, relevant, and limited to what is necessary for the purposes for which they are processed, (d) accurate and where necessary kept up to date, (e) kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the personal data are processed, and (f) processed in a manner that ensures appropriate security of the personal data, including protection against unauthorised or unlawful processing and against accidental loss, destruction or damage, using appropriate technical or organisational measures.

Processing personal data - e.g., through health apps, mobile data, payment transfers, ePlatforms, tracking or sensors for guidance, surveillance, domotics - is subject to the GDPR. If the data is anonymised and not traceable at any point in time, even with justifiable automated decision-making, the GDPR does not apply.

The GDPR is directly applicable in EU countries. The GDPR does not exclude Member State law that sets out the circumstances for specific processing situations, including determining more precisely the conditions under which the processing of personal data is lawful.

Click [here](#) to find the full text of the GDPR in your own language..

ePrivacy Regulation

The MDR aims to ensure the smooth functioning of the internal market as regards medical devices, taking as a base a high level of protection of health for patients and users, and taking into account the small- and medium-sized enterprises that are active in this sector. At the same time, this Regulation sets high standards of quality and safety for medical devices in order to meet common safety concerns as regards such products.

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:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment, or alleviation of disease,
- diagnosis, monitoring, treatment, 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,

Of significant importance is the classification of a medical device. Manufacturers of class I devices declare the conformity of their product themselves after drawing up the required technical documentation. Medical devices class IIa, IIb, and III are subject to a conformity assessment by a notified body, which generally has a significant effect on timelines and budgets. Lack of notified bodies and lack of regulatory staff can amplify these effects. Contact with a notified body early in the process of development is recommended to secure a slot and keep effects on time to market to a minimum.

Rule 11 of the EU MDR concerns the classification of software. Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes is classified as class IIa, except if such decisions have an impact that may cause:

- death or an irreversible deterioration of a person's state of health, in which case it is in class III; or
- a serious deterioration of a person's state of health or a surgical intervention, in which case it is classified as class IIb.

Software intended to monitor physiological processes is classified as class IIa, except if it is intended for monitoring of vital physiological parameters, where the nature of variations of those parameters is such that it could result in immediate danger to the patient, in which case it is classified as class IIb. All other software is classified as class I.

Among other, manufacturers shall establish, document, implement and maintain a system for risk management, conduct a clinical evaluation in accordance with the MDR requirements, draw up and keep up-to-date technical documentation that allows the conformity of the device with the requirements of the MDR to be assessed, and establish, document, implement, maintain, keep up to date and continually improve a quality management system that shall ensure compliance with the MDR in the most effective manner and in a manner that is proportionate to the risk class and the type of device. International standards such as IEC 62304 (Software life cycle processes), ISO 13485 (Quality management systems), and ISO 14971 (Risk management) are recommended and generally used in the process. The Medical Device Coordination Group (MDCG) documents provide among other further guidance for classification, clinical evaluation, and cybersecurity for new technologies.

Click [here](#) to find the full text of the MDR in your own language and [here](#) to access Medical Device Coordination Group (MDCG) guidance. The international standards referred to are available at a fee [here](#).

Declaration of Helsinki

The MDR refers to the World Medical Association Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects with regard to clinical investigations. The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data. The declaration is addressed primarily to physicians. However, the medical association encourages others who are involved in medical research involving human subjects to adopt these principles. It is applicable to most of the AAL systems and their various solutions. National legislation may go beyond encouraging others and require everyone involved in research to comply.

The most general and relevant principle of the Declaration of Helsinki is **respect for the individual and the protection of their health and rights**. Medical research involving human subjects may only be conducted if the importance of the objective outweighs the risks and burdens of the research subjects. Some groups and individuals are particularly vulnerable and may have an increased likelihood of being wronged or of incurring additional harm. All vulnerable groups and individuals should receive specifically considered protection.

It means that the rights and interests of the participants cannot be left aside as they are more important than the research itself. The researcher's duty is solely to the patient or volunteer, and while there is always a need for research, the subject's well-being must always take precedence over the interests of science and society. (Article 8)

As part of an individual's rights, researchers must protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information (Articles 9 and 24). Another important point is informed consent (Article 25). This document integrates or should be provided alongside relevant information concerning the participant's rights, such as the right of information, in order to decide on participation (art. 26). The recognition of the increased vulnerability of individuals and groups calls for special vigilance and protection is also foreseen. Non-vulnerable groups are always preferred if it is possible to achieve the research aims (Art. 19, 20). Lastly, it is important to indicate that the Helsinki Declaration highlights that ethical considerations must always take precedence over laws and regulations (Article 23).

Other international legislation

Other international legislation to be evaluated for relevance, with the objective of protection and compliance of the ethical aspects includes:

- Nuremberg Code (RAVINDRA, 2011): created more than 70 years ago following the World War II experiments, This written document established 10 ethical principles for protecting human subjects, such as:
 - The voluntary consent of the human subject is absolutely essential
 - There must be a scientific justification for experimentation

- Participants must be protected from all unnecessary physical and mental suffering, and injury
- Universal Declaration of Human Rights (UN, 1948)
- European Convention on Human Rights (ECHR, 1950)
- Charter of Fundamental Rights of the European Union, and in particular:
 - Article 1 (Human dignity)
 - Article 3 (Right to the integrity of the person)
 - Article 7 (Respect for private and family life)
 - Article 8 (Protection of personal data)
- Treaty on European Union, and in particular Article 6 of the common provisions concerning respect for fundamental rights (EU, 1992)
- Convention of the Council No. 5 for the protection of human rights and fundamental freedoms (ECHR, 1950), namely Article 8 (Right to respect for private and family life)
- Universal Declaration on Bioethics and Human Rights (UNESCO, 2005)

3. International Standards

Standards are the silent foundation of the EU Single Market and global competitiveness. Standards are an invisible but fundamental part of our daily life. They help manufacturers ensure the interoperability of products and services, reduce costs, improve safety, and foster innovation. Standards give confidence that a product or a service is fit for purpose, is safe and will not harm people or the environment. Compliance with harmonised standards guarantees that products are in line with EU law.²

Standards to be considered for the AAL community include:

- [ISO TC314](#) Ageing Societies
- [EN 301 549 V3.2.1 \(2021-03\)](#) Accessibility requirements for ICT products and services
- [CEN-ISO/TS 82304-2:2021](#) Health and wellness apps – quality and reliability
- [IEC 62304:2006](#) Medical device software – Software lifecycle processes
- [IEC 62366-1:2015](#) Medical devices – Application of usability engineering to medical devices
- [ISO 13485:2016](#) Medical devices – Quality management systems – Requirements for regulatory purposes
- [ISO 14971:2019](#) Medical devices – Application of risk management to medical devices
- [ISO 14155:2020](#) Clinical investigation of medical devices for human subjects – Good clinical practice
- [ISO/IEC 27001:2022](#) – Information security management

² https://ec.europa.eu/commission/presscorner/detail/en/ip_22_661

4. National framework and regional regulations

After ensuring that a product or service complies with EU regulations and conforms to standards, it is still necessary to ensure that it also complies with national or regional regulations and market access requirements of the countries where it will be used or commercialised, namely ethical approval for studies when applicable and any specific authorisation from municipalities, regions or national agencies.

4. THE ETHICAL DIALOGUE

At the heart of the AAL model for ethical excellence is the ethical dialogue. The ethical dialogue can and is recommended to be used several times during the process from concept to (general) use of an AAL product or service:



Figure 3 - The ethical dialogue

The model has **three PHASES**:

1) Case: Technology in context

When starting a dialogue, be sure to present the technology, intended users, intended use and the context where it will be used. AAL solutions very often consist of a combination of different technologies and services (ICT and/or human). All these aspects can have their own ethical aspects, e.g., surveillance by sensors, GPS tracking, exchange of personal information etc. All these different aspects should be considered in the ethical dialogue about a solution.

2) Dialogue: Actors, Effects, Values

In a dialogue it is important to have the (diverse perspectives of) actors involved. Normally we look for contributions of patients, care professionals, management, and involved engineers. They all have different expectations about the effects of the technology: positive and negative, personal and societal. The aim is to get all hopes and worries to the table. Behind the expectations of the effects are values: what values are important to the different participants how does the project connect to these values.

Values often mentioned are: quality of care, privacy, work-pleasure, well-being, efficiency, etc.

3) Action opportunities: Technology, Context, User

After drafting a clear view on the technology, intended use, intended users, context and on the main – positive and negative – effects and the values in a (multi-)stakeholder dialogue, the main question is “What can we do to make it better?”

Actions to be taken in the last phase must consider the following 3 main dimensions:

- Technology: Ethics by DESIGN (e.g., engineering, design)
- Context: Ethics by CONTEXT (e.g., agreements, policy)
- User: Ethics by INDIVIDUAL (e.g., behaviour, awareness)

An ethical action dialogue is a new form to deal with ethics, as it is not just a dialogue, but also a call for action (innovation). It does not start top-down, but bottom-up.

The dialogue can be organised in the different stages of any development project:

- conceptualisation & (co) creation
- development & testing
- market entry & scale-up

In any phase, it is important to reflect on the values and effects of the service or product at stake and to find action opportunities to (ethically) improve it. With AAL solutions, there is often a specific focus on values connected to the protection of vulnerable people; therefore, it is necessary to be very familiar with the user’s needs, strengths, limitations, tasks, goals, and context.

In every new phase, the needs for improvement that resulted from the previous stage are implemented and tested and a new dialogue emerges, potentially also with new stakeholders. E.g., in the conceptualisation phase, there is the need for people who can conceptualize, who can understand what the effects are of an idea. In the market phase, there may be the need for people who understand business or marketing or safety measurements. A multidisciplinary team from the very beginning is the optimal solution for having different emphasis at various stages.

The Action opportunities may be part of a future library of ethical actions and as such useful for other AAL projects and initiatives.

At the end of this document a set of forms will be provided to implement the ethical dialogue, to assist in fulfilling legal compliance and driving to ethical excellence.

5. PRACTICAL EXAMPLE – a use case

There is a lot of variety in AAL projects. This is an example to clarify what it could mean to use the ethical dialogue for an AAL product.

2PCS: Personal protecting and caring system

Phase 1: Case

The 2PCS system is a mobile emergency- and location system, which was developed to address the requirements of healthcare professionals and ensure the independence of people in their care. This solution enables use in various life and care phases, both in inpatient and outpatient care. The 2PCS system consists of several specially developed units, which are combined to form a holistic system.

The different 2PCs products/parts are:

- 2PCS SAFETY WATCH: a mobile alarm and location system
- 2PCS PERSONAL TRANSMITTER: a mobile alarm and location system
- 2PCS ANTENNA
- 2PCS SOFTWARE PLATFORM

The 2PCS software platform is part of the 2PCS system, a mobile call and location system. On this platform, emergencies and warnings triggered, for example, by the 2PCS safety watch or the 2PCS personal transmitter, are displayed or forwarded to compatible alarm systems.

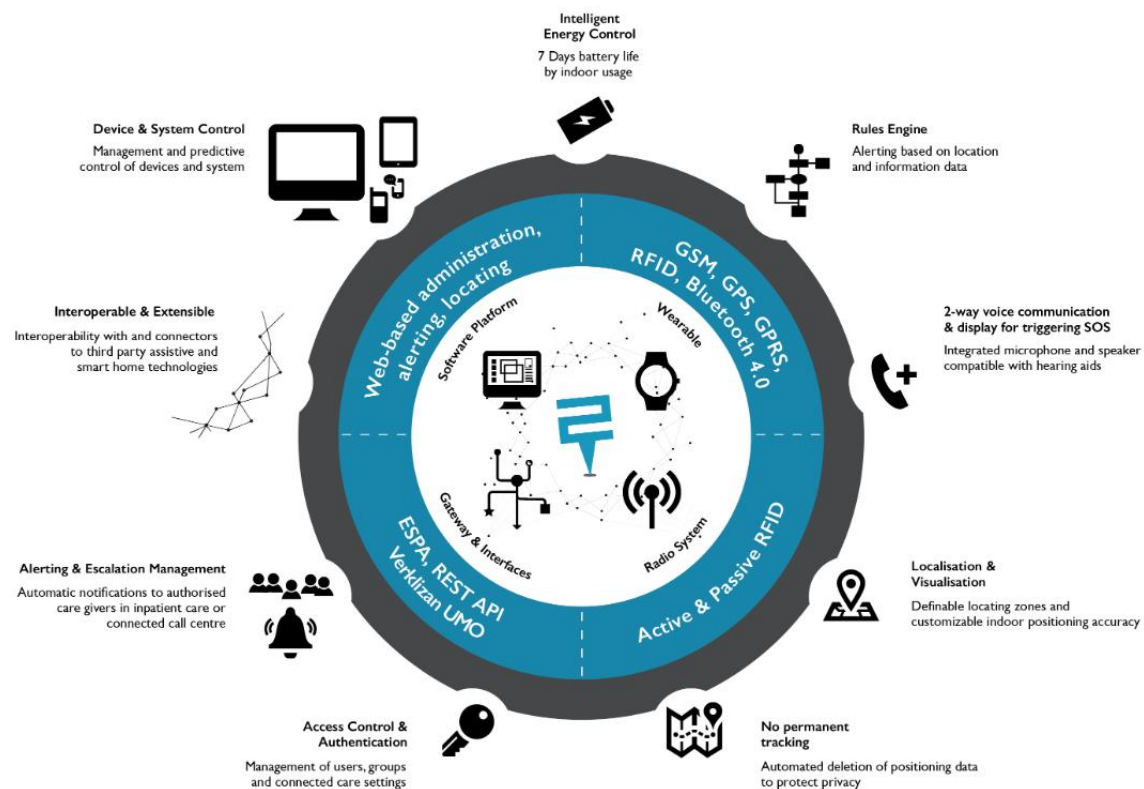


Figure 4 - P2CS architecture

Phase 2: Dialogue

Actors: Potential participants in the dialogue include older adults, caretakers, family, designers, healthcare professionals, (call center workers), managers of care organisations, ...

Effects: Potential positive and negative effects and questions include:

- People feel more secure?
- People dare to go further away from their home?
- How many 'false positives'? What are the effects: not listening anymore, panic?
- A call center function should be organized
- Who is getting a signal when something is wrong: family? caretakers?
- Who solves technological problems or malfunctions?
- People have to wear a device. Do they have to be trained?
- Who is going to pay for the device? And for the back end?
- What is the targeted market for this product?
- Are there standards to follow in this area?
- What effects can tracing have on privacy?

Values: Security, freedom, safety, closeness, independence, cost-efficiency, usability, beauty (design), ...

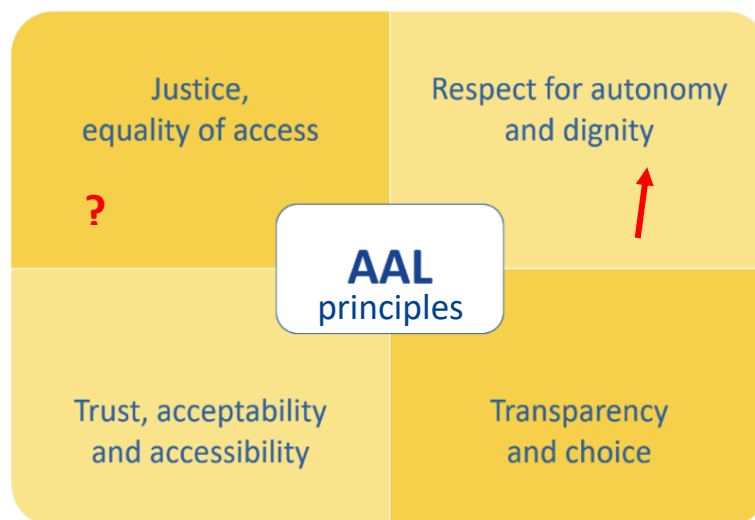


Figure 5 - The AAL principles employed in ethical dialogue (in this case with red arrow and question mark)

AAL principles: Autonomy is enhanced, is it accessible though to those with lower incomes?

Method: Consider checking the AAL principles, attaching for instance post-its, arrows, or question marks to indicate positive, negative, or yet unknown effects. See Figure 6.

Phase 3: Action opportunities

Ethics by DESIGN (e.g., technology, engineering, design)

- Making technology more reliable (how many missed emergencies, how many unnecessary?)
- Create a way to put off the device and/or to switch off certain functionalities, if wanted
- Can it be more beautifully designed, do people have choices of colours?

- Make it easily repairable
- Is tracking necessary?
- Where does the data go to, who is in control of that choice?

Ethics by CONTEXT (e.g., agreements, policy)

- Define what people (health professionals, family) do when the alarm sounds (the protocol)
- Create a technical helpdesk? (how many: one per country, one per care company?)
- Who is going to pay for the device and for the system?
- Will it be mandatory?

Ethics by INDIVIDUAL (e.g., behaviour, awareness)

- Create a program for users to learn about the device: the use, the effects
- Organise workflows of communication on use and problems of the device

Method: Consider creating a table with rows per individual effect and columns for effects, the related values, (3 types of) action opportunities, actual actions (in case of negative effects also known as mitigating measures), and (for the effects that matter most) outcome measures, study outcomes, analysis of acceptability (if not acceptable then a feedback loop is needed), real world use outcomes and follow-up actions. This effort can be especially useful in efforts to obtain and maintain EU MDR compliance.

APPLYING THE GUIDELINES IN PRACTICE

Examples of guiding questions:

- Is the project compliant with hard and soft law, existing standards and guidelines in the area?
- Did the project plan the research study that is being conducted to evaluate the product and/or service under development with all the relevant stakeholders?
- Did the project foresee ethical clearance approval in due time, collect informed consents and provide privacy notices as required in the different project phases?
- Did the consortium assess if an approval from an ethical board needs to be received in all pilot countries? If decided that it is not applicable, what were the steps undergone by the consortium to decide it?

Read [DOC 1 Compliance and GDPR](#) and [DOC 6 AAL and the new EU Medical Device Regulation \(MDR\) – Annex to this document](#)

ACTION NEEDED! fill in [DOC 2 Checklist for research with users](#)

Participants

How many participants did you involve in your ethical dialogue sessions? From which categories?

- Primary (older adults)
- Secondary (caretakers)
- Tertiary (policy, financial)

ACTION NEEDED! Fill in [FORM 1 Participants template](#)

Dialogue: effects

- Please share the list with positive and negative effects of using the technological solution generated during the workshop.

Dialogue: values

- Please share the list with values generated during the workshop.
- What were the top three most relevant values?

Action: opportunities

- Please share the list with action opportunities for technology (ethics by design).
- Please share the list with action opportunities for the context (e.g. agreements, policy measures) technology.
- Please share the list with action opportunities for human behaviour (e.g. education, communication).

ACTION NEEDED! Fill in [FORM 2 – SECTIONS A Technology in context](#) | [B Implementing the dialogue](#) | [C Defining the actions](#), considering the sections applicable to the project depending on its stage.

Reflections for further developments

What (results): The results of the workshop are a list of effects, values and action opportunities on technology, context and human behaviour. What did you do with these results after the workshop? Which action opportunities turned into actions? What values and effects are newly considered? Were some actions taken up?

How (process): How did people react after the workshop? Did it lead to new connections, new ideas?

How (methodology): The ethical dialogue is a new form of getting technology into the process of innovation. Can you help us with your reflections? Where was the methodology helpful? What functioned well? What could be improved?

ACTION NEEDED! Fill in [FORM 3 Further reflections](#)

6. FORMS

a. GUIDING DOCUMENTS

DOC 1

COMPLIANCE AND GDPR

Research involving the use of personal information (information or an opinion about an identified individual, or an individual who is reasonably identifiable) must comply with applicable privacy legislation. The EU General Data Protection Regulation (GDPR) Regulation 2016/679 (EU, 2016) is the most important change in data privacy regulation in 20 years. Its main objectives are to harmonize data privacy laws across Europe, to protect and to empower all EU citizens' data privacy and to reshape the way organizations across the region approach data privacy. Guaranteeing that all the data collected is complying with what is required by the GDPR is fundamental to comply with the ethical principles. The GDPR has an extended jurisdiction - extraterritorial applicability. It applies to all organisations processing the personal data of data subjects residing in the European Union, regardless of their location. (GDPR, 2018).

The GDPR sets out seven key principles that shall lie at the heart of projects processing personal data:

PRINCIPLES	EXPLANATION
Lawfulness, fairness and transparency	It is necessary to demonstrate a lawful basis for obtaining personal data to process it: there are 6 possible conditions for processing. The collection of personal data must be conducted in a fair manner, ensuring it was not obtained under false pretence and satisfying reasonable expectations as to how the data will be used. Transparency includes the right to be informed.
Purpose limitation	Data collected only for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes; Exception: further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes shall not be considered to be incompatible with the initial purposes.
Data minimisation	The data collected must be adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed.
Accuracy	The data collected must be accurate and, where necessary, kept up to date. Every reasonable step must be taken to ensure that personal data that are inaccurate, having regard to the purposes for which they are processed, are erased, or rectified without delay.
Storage limitation	Data must be kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the personal data are processed.
Integrity and confidentiality (security)	The data must be processed in a manner that ensures appropriate security of the personal data, including protection against unauthorised or unlawful processing and against accidental loss, destruction, or damage, using appropriate technical and organisational measures
Accountability	Data controllers have to be able to demonstrate they are GDPR compliant, for instance by adherence to an approved code of conduct or an approved certification mechanism.

This document does not intend to provide a deep overview of the GDPR, but focused guidelines, that directly impact AAL projects. A GDPR checklist is suggested <https://gdpr.eu/checklist/>.

DOC 2

CHECKLIST FOR RESEARCH WITH USERS

MAIN STAGES	TASKS	Yes/No/Other	Description
USER REQUIREMENTS	Which type of users (primary, secondary, tertiary) are predicted? Ageing can affect abilities. Consider for reasons of accessibility and quality also people with for instance vision problems, motor disabilities and low (digital) literacy or cognitive challenges. For more on accessibility consult the Web Content Accessibility Guidelines (WCAG) . The blueprint personas provide for inspiration personas for different ages and health conditions		
	When (early in the project) are a representative sufficiently large group of users consulted about their goals, tasks, environment, abilities and resulting requirements for the AAL product and its delivery? Consider beyond a single moment in time for input, co-creation (using the ethical dialogue), and user-centred evaluation.		
	Are they individual or group sessions?		
	Who will perform the sessions?		
	What are the recruitment criteria for this phase (inclusion, exclusion)?		
	Which instruments are used? For instance, interview scripts, (validated) questionnaires, templates etc. Consider the AAL Toolbox: http://www.aal-europe.eu/wp-content/uploads/2015/02/AALA_ToolboxA5_online.pdf		
	Is personal data collected? Is sensitive data collected? Is collection of data minimised? Is data where possible anonymised? Ask users for consent in an appropriate manner.		
	Is secondary data (previously otherwise collected data) available of good quality and in sufficient quantity to answer the research questions?		
	Who will collect, store, and process the data? Ensure data security.		
	Will the data be transferred to other partners? Inside or outside the European Economic Area (member countries EU plus Iceland, Liechtenstein, and Norway)? If so, is it anonymised? Aggregated data? Protected? Detail the process. Create and maintain a Data Management Plan. If applicable have research data transfer/processing agreements and ensure data security and alignment with user consent.		
What are the main study goals, hypothesis, and research questions?			
STUDY DESIGN FOR THE PILOT	What are the (primary, secondary, tertiary) (validated) outcome measures? What will be the appropriate statistical analysis?		
	What is the methodology used? What is the rationale behind the methodology?		
	What is the duration of the pilot? What is the rationale behind the duration?		

	<p>Which digital tools or devices will be used? Are these prototypes tools or devices already in the market? If existing devices, find CE mark or other certifications and check if the intended use, intended users and context of use in the study match the certification. If prototype, please gather a full description of the architecture. Check with ethics committee procedures.</p>		
	Who are the participants (inclusion/exclusion criteria)?		
	Is there a control vs. intervention group? Will the participants be randomised? If yes, what are the randomisation procedures?		
	How was the number of participants calculated (statistically valid rationale for sample size)?		
	How is the sample recruited?		
	What are the potential risks for participants and preventive/mitigation measures?		
	Is this study subject to clinical trial procedures or non-clinical trial procedures? What are the study requirements given medical device classification?		
	Is submitting a clearance request to a regional ethics committee or to a national authority required?		
	What is the study protocol (including specific objectives, (validated) outcome measures, instruments, timeline, evaluation plan)?		
	Is there a model for the informed consent?		
	Is personal data collected? Is sensitive data collected? Etc. see above. If so, is there a privacy and data organisational policy and a Data Protection Officer (DPO) with sufficient expertise and authority?		
	What are the data protection procedures? Consider a (standardized format for) a Data management plan.		
ETHICS AND DATA	What are the data collection procedures (by any digital system and also through other sources - e.g., Instruments of the evaluation protocol)?		
	What are the data storage procedures?		
	What are the data transfer procedures?		
	What are the data processing and reporting procedures?		
	Will there be use of secondary data?		
	What is the exit strategy for the pilot participants?		
	Is there a project board? E.g., Ethics Board or User Advisory Board?		
	Ethical approval from competent authority granted before recruitment?		
	An adequate Technology Readiness Level (TRL) for piloting?		
	Are there mobilisation strategies for participants established (increase recruitment, prevent drop-out)?		
Are there project presentation sessions and training sessions foreseen before recruitment (mandatory)?			
Is the equipment for end users insured?			
PILOT REQUIREMENTS	Is there insurance for participants' personal risks?		
	Which type of users (primary, secondary, tertiary) are predicted? Ageing can affect abilities. Consider for reasons of accessibility and quality also people with for instance vision problems, motor disabilities and low (digital) literacy or cognitive challenges. For more on accessibility consult the Web Content Accessibility Guidelines (WCAG) .		

	The blueprint personas provide for inspiration personas for different ages and health conditions		
PILOT IMPLEMENTATION	When (early in the project) are a representative sufficiently large group of users consulted about their goals, tasks, environment, abilities and resulting requirements for the AAL product and its delivery? Consider beyond a single moment in time for input, co-creation (using the ethical dialogue), and user-centred evaluation.		
	Are they individual or group sessions?		
	Who will perform the sessions?		
	What are the recruitment criteria for this phase (inclusion, exclusion)?		

DOC 3

GUIDANCE ETHICS APPROACH

<https://ecp.nl/wp-content/uploads/2020/11/Guidance-ethics-approach.pdf>

DOC 4

INSTRUCTION MANUAL APPROACH GUIDANCE ETHICS FOR DIGITAL CARE
(as an annex to this document)

b. MANDATORY FORMS

FORM 1

PARTICIPANTS TEMPLATE

Depending on the stage of the project, some of these activities may be already undertaken, only planned or not even applicable.

MAIN STAGES	CATEGORY	SESSIONS	PRIMARY	SECONDARY	TERTIARY
USER REQUIREMENTS	NUMBER				
	DESCRIPTION				
USER TESTING	NUMBER				
	DESCRIPTION				
PILOTS/TRIALS	NUMBER				
	DESCRIPTION				
ETHICAL DIALOGUE	NUMBER				
	DESCRIPTION				

FORM 2

A | TECHNOLOGY IN CONTEXT

1. Sketch the solution enabled by technology

In AAL, there are different kinds of solutions enabled by technologies in areas such as, health & care, living & building, safety & security. For the dialogue it is important that all stakeholders understand what the solution is about.

Define and describe your solution here:

2. Sketch the users and context where they will use the solution

What are the main characteristics of the target group, where do they live, how do they live, what interactions do they have? What organisations are involved?

E. g., older adults, at home, in residential units, cared for by professionals, neighbours, family, a lot of life experience, not that much life expectancy, not working, maybe volunteering, ...

For the dialogue it is important that all stakeholders understand where and by whom the solution will be used (primary and secondary users).

Define and describe your context here:

Method: Invite a technological expert and/or an expert of the context. Let him/her/them inform the group. Only informational questions will be asked, opinions are for later in the process.

FORM 2

B | IMPLEMENTING THE DIALOGUE

PARTICIPANTS

Invite relevant people for the ethical dialogue. This could be the developers of the solution, the users (clients), policymakers (in organisation or administration), care professionals, informal caregivers and/or others who have a role in the process or are influenced by the use of the solution. It is important that some of the participants also have the power to enforce improvements. If it is impossible to get all the right people around the table, try to ensure at least that all the perspectives are considered in the group.

EFFECTS

This is the start of the dialogue.

- a) **Ask the question: *what are the effects that could occur using this solution in this context?***

Explain that these effects can be positive or negative. Be sure to have enough room for both of them. They might be direct or indirect. Try to gather effects for the different stakeholders.

- b) **From the answers collected, try to focus on *what effects are most important: What are the intended effects? What are the non-desirable effects, the ones to be avoided?***

VALUES

Connect your reflections to values.

- a) **Ask the question: *Which values played a role in the dialogue in the previous phases?***

This can be asked directly to the group or a co-moderator could note the values and bring them into the dialogue at this new stage.

b) Ask the question: *Are the main AAL values well considered in this product/service?*

The question to be answered is what values are most important in this case, and how the AAL **main principles** presented below are addressed by the solution:

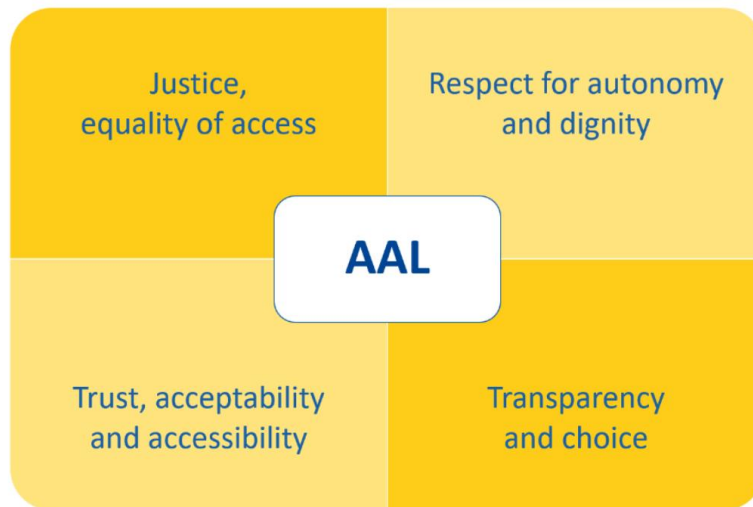


Figure 6 - The AAL principles

Method:

- Use a neutral moderator – even better if he/she is familiar with the method (and the context).
- This is not a discussion (who is right or wrong). It is a dialogue (exchanging of ideas and arguments): “we are trying to make something better, there are no winners or losers at the table, every input is important”.
- Ensure a ‘safe’ environment (Chatham House rules³).
- The goal of the dialogue must be made very clear to all participants, as well as the purpose - what will be done with the results.

³ <https://www.chathamhouse.org/chatham-house-rule#>

FORM 2

C | ACTION OPPORTUNITIES

Having completed the shared picture of the effects and the most important values, the last phase starts. How to make this solution have more positive and less negative effects, in accordance with the AAL values, supplemented by values of the participants. The actions shall be organised in 3 areas: the technology (ethics by design), the context and the behaviour of the individual.

ETHICS BY DESIGN (e.g. engineering, design)

a) *How can technology be improved - which actions will you implement?*

Examples: blurred camera's (privacy), anonymized data, data tuned on the user group, nice colours (attractiveness), washable (usability), universal design (easy to connect), accessibility, understandable information, a red button (when something goes wrong), etc.

ETHICS BY CONTEXT (e.g. agreements, policy)

b) *What can be improved in the AAL context - which actions will you implement?*

Examples: rules of use, agreements about who has access to data, and when, a helpdesk, technology innovation demands, standardisation, part of the payment protocol,

ETHICS BY INDIVIDUAL (e.g. behaviour, awareness, e.g. education, communication)

c) *What can be improved in user behaviour - which actions will you implement?*

People mostly have to learn how to use new technologies, at all different levels.

Examples: digital literacy, digital divide, ageing process, health professionals training to use the new product/service, communication about the (effects of) the new technology.

Method:

- This is a creative phase, so brainstorm is important.
- Conceptualize and make it as concrete as possible.
- Define what action opportunities can become actions.
- If people around the table can do an action, ask them to.
- For the other actions: define a first step.

FORM 3

FURTHER REFLECTIONS

WHAT (results):

- What values and effects are newly considered?
- Which action opportunities turned into actions?

HOW (process):

How was the workshop evaluated?

Were there new ideas presented? (yes/no, elaborate please)

Were there new connections in between stakeholders? (yes/no, elaborate please)

HOW (methodology):

The ethical dialogue is a new form of getting ethics into the process of innovation. Can you help us with your reflections?

Was the methodology (not) helpful?

What functioned well?

What could be improved?