Personalized ICT solution to reduce re-hospitalization rates in heart failure elderly patients suffering from comorbidities

WP2: Platform development and tuning

D2.5: Developing the ELSI criteria and catalogue

Project acronym	**PerHeart**
Project full name	**Personalized ICT solution to reduce re-hospitalization rates in heart failure elderly patients suffering from comorbidities**
Dissemination level	Restricted
Type of deliverable	Report
Contractual Date of Delivery	M12
Actual Date of Delivery	
Deliverable Number	2.5
Deliverable Name	Development of the ELSI criteria and catalogue
Workpackage / Task	WP 2 / T 2.5
Work package responsible / Task responsible	ISO
Number of Pages	
Contributors	ISO; CITST, MUW, ECO, WUT, BZN

Version	5

Abstract
This deliverable is presenting the ELSI criteria catalogue which has been established based on consortium discussion, the findings of the focus groups with professionals and caregivers as well as the patient interviews. The ELSI criteria which could have been formulated cover the dimensions of autonomy, participation, justice and accessibility, (data) privacy, informed consent, liability and responsibilities, avoidance of discrimination, stereotyping and standardization and the usability of the PerHeart platform and close with contractual terms. The catalog presented here is not considered exhaustive but will be evaluated during the course of the project and adapted and expanded as needed.

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ABBREVIATIONS

AAL	Ambient assisted living
HF	Heart failure

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1 Executive summary

The aim of this deliverable is to describe the approaches followed to develop the ELSI criteria catalogue.

2 Introduction and Theoretical Background

In technology development, a human-centered approach within the framework of good scientific practice, including ethical principles and data protection aspects, has become increasingly prevalent.[1] In this approach, future users are involved in the development process from the very beginning in order to align the technology with user needs and thus increase user-friendliness and acceptance. The aspects to be considered in human-centered technology development extend to ethical as well as legal and social aspects (ELSI). ELSI research aims to accompany the development of new technologies from the very beginning within the framework of 'responsible research and innovation' (RRI) to analyze the potential and risks of new technologies and innovations to promote the development of human-centered and value-based technology.
These aspects change depending on the intended user group and are particularly relevant for vulnerable user groups such as ill or cognitively impaired groups. For this reason, the formulation and elaboration of an ELSI criteria catalog within the framework of the PerHeart project with the inclusion of the user groups through social science research methods is of particular importance.
The PerHeart project is employing Information and Communication Technology (ICT) to address all four aspects of personalized medicine (PMed), in order to reduce re-hospitalization rates in discharged heart failure (HF) patients and to elucidate specific risk factors the : predictive, preventive, personalized and participatory (4P). Predictive: Gathered data within WP3 will be analyzed in WP4 in order to elucidate specific risk factors and develop predictive models to help health professionals by revealing new physiological targets or characteristic patient profiles for focused intervention and hence reduced re-hospitalization. Gender [1] and socio-economic aspects can be considered in the data analysis for the exploration of risk factors, patterns of symptom evolution and identification of high-risk subgroups. Preventive: PerHeart supports home monitoring of essential health parameters and patient behavior (e.g. mobility models) in order to timely identify decompensation signs. It also supports maintaining a suitable level of activity and following often complex medication regimen to prevent worsening of the disease. While primary prevention should be the ultimate goal for all chronic diseases, secondary preventions are also essential components of PMed. In addition, preventing re-hospitalization of HF patients requires a deeper understanding of the risk factors and mitigating solution, which comes from employing data analysis and data integration. Personalized: The PerHeart platform is adaptable to each patient both hardware wise (through modularity) and software wise (Artificial Intelligence –AI– models trained with patient specific data). Professionals will be able to input a personal profile for each patient (e.g. acceptable health parameters, desired exercise level) while the underlying AI software (Task 2.3) will further tune this profile while adapting the platform's response to his evolution. Also, professionals will be able to optimize treatment and interventions based on real-time data received from remote monitoring. Participatory: PerHeart enables disease self-management and helps patients to identify underlying causes associated with a worsening of their condition. The platform also allows a multidirectional flow of health information between patients, health professionals and other stakeholders (e.g. family), which is an essential aspect of participatory medicine.
Predicting who will be re-hospitalized is difficult and cannot be generalized [5]. While hospital therapy and the length of stay play a decisive role in reducing re-hospitalization rates, self-management (including medication) of the disease and life-style changes (exercise, diet, etc.) also play an important role. The presence of multi-morbidity makes self-management even more complex for those with HF. Diabetes is a common co-morbidity in the HF population and the experience of living with both HF and diabetes is extremely challenging for patients and their family caregivers. Cognitive impairment which occurs in 30%-80% of HF patients is also impacting the capacity for self-management and disease understanding, thus contributing to

increasing rates of re-hospitalization. Mood disorders such as anxiety and depression which are common among HF patients can also affect cognition and are often underestimated and undertreated.[1]
Personalized medicine puts the HF patient at the very center of health care enabling self-management of the disease while, (at the same time,) allowing professional health providers to optimize treatment and understand risk-factors based on real-time reports and behavior of patients. Our approach will spur the ability of patients to play a more active role in managing their health thus supporting the current trend in sustainable care. The application of AI (for personalized care) and data analysis techniques (for relationships, patterns, risk prediction) will support and enhance medical decision making. Continuous monitoring will provide access to real-time patient data during the interval between visits by health professionals. All this wealth of information has the potential to play a decisive role in reducing re-hospitalization rates and in contributing to understanding the often-complex pallet of factors influencing the progress and outcome of HF patients. In addition, current health care models for HF patients can be transformed.
Including the future users into the study design can be highly beneficial and expands the participatory approach because the special and individual needs and requirements of HF patients as potential users of the PerHeart platform must be considered in a user-centred approach.

In recent years, it has become increasingly clear that the consideration of ethical, legal and social aspects (ELSI) plays an important role in the development and use of socio-technical systems. The ethical impact of technology can be seen as an "interplay between a technology and human beings that raises normative, value laden, concerns"[2]. Therefore, the focus of the Horizon program initiated by the European Commission focuses particularly on ethical and legal implications in innovative research.[3] Given the enormous individual as well as overall societal importance of health data, ELSI criteria are also in focus at PerHeart. Values such as privacy, well-being, user-friendliness, informed consensus, autonomy, equity of access and trust, and even gender aspects as part of the ethical implications, are to be systematically considered in the design and incorporated into the development of the PerHeart platform. To this end, ethical, legal and social or socio-economic issues will be identified and jointly discussed at an early stage. The ethical technology assessment relates not only to the individual perspective of the users, but also to aspects on societal and organizational level. The different ethical perspectives with sometimes conflicting moral needs and requirements reveal the complexity of the area. Therefore, a careful discussion is needed because correct answers cannot always be found. But delving into the ethical challenges of technology engineering raises awareness of engineers and researchers and shall therefore be understood as a facilitator in the development process due to the prediction and prevention of potential ethics-related issues at a later stage of the project cycle and not as a barrier.

In addition to that, human-related research must respect not only human rights but also the rights of humans as research participants. Data protection, privacy rights, accessibility, availability, acceptance and informed consent are some ELSI keywords. Responsible technology development must consider the needs and requirements of humans as targeted users which has led to various research projects focusing on different aspects of ELSI criteria in technology

[1] Celano, C. M., Villegas, A. C., Albanese, A. M., Gaggin, H. K., & Huffman, J. C. (2018). Depression and Anxiety in Heart Failure: A Review. *Harvard Review of Psychiatry*, *26*(4), 175–184. https://doi.org/10.1097/HRP.0000000000000162

[2] Grüber, K., & Loevskaya, E. Instrumente für die ethische Reflexion über Technik im Alter. Retrieved from https://www.imew.de/fileadmin/Dokumente/Volltexte/Instrumente_zur_ethischen_Reflexion_31092020_UA.pdf

[3] Horizon Magazine (2022, March 7). Digital age 'desperately' needs ethical and legal guidelines. Retrieved from https://ec.europa.eu/research-and-innovation/en/horizon-magazine/digital-age-desperately-needs-ethical-and-legal-guidelines

research. The current state of research shows how multi-faceted and multi-layered the topic is and how application-specific the ELSI are.
Including aspects of ethical, legal, and social issues into the research process means to formulate potential ELSI criteria before starting the development process. This enables the research group to continuously review, evaluate, assess, and adapt the defined criteria throughout the complete project cycle. In contrast, ex-ante or ex-post evaluations mostly lead to imprecise and incorrect predictions or conclusions instead of taking the complete development cycle into account. Consequently, technical innovations are customized to the targeted user group and comply with legal and judicial regulations and social or even societal requirements. A user-centered development process guarantees a higher acceptance of digital or technological innovation.

3 Methodology

With the increased use of technology, digitization has also reached nursing and therapeutic care. The increasing technologization of care work for vulnerable persons, from technology-based assistance to autonomous and self-learning systems, opens up new areas of tension in the context of the duty of care to protect the individual.[4] The aim is to improve patient care through the "modernization" of nursing to counteract the shortage of nursing staff, and to meet the challenges of demographic change. With increasing computing power and the help of appropriate algorithms, large volumes of data (Big Data) can be analyzed more and more effectively and increasingly detailed user profiles can be created. Data-driven processes are identifying ever finer differences between individuals when analyzing contexts, enabling greater consideration of highly personal characteristics and circumstances, for example in diagnostics, prognosis and therapy. A few years ago, the so-called P4 medicine was therefore defined as a new major goal for the medicine of the future: Predict, Prevent, Personalized, Participate. If the information gained in this way can be used to improve patient care and avoid rehospitalizations, it will open up enormous opportunities for everyone involved. However, if the information is used to sanction undesirable behavior, it will have serious consequences for the constitutionally enshrined rights of freedom and direct consequences for the options for action in (real) everyday life. The individual needs of people with HF differ greatly in some cases. Due to a variety of factors, such as the family situation or the patient's own preferences, completely different care settings may be preferred even for a comparable clinical picture. In addition, there are often different therapeutic approaches between which the patient must decide and each of which is associated with specific opportunities and risks. From an ethical point of view, this gives rise to numerous questions, for example regarding freedom of choice between different forms of therapy. In addition, the very possibility of (albeit voluntary) monitoring can lead to changes in patients' own behavior and restrict their right to self-determination. The Hawthorne effect, for example, describes the phenomenon that awareness of participation in a study can already lead to a bias in subjects' behavior change and perception that is not intended by the study.[5] In addition, despite the increasing digitized penetration of the living and working environment, social, cultural and national differences have an influence on the perception of and interaction with technology.[6]. With all the possibilities that come with the use and evaluation of data, it therefore quickly becomes clear that the highest demands must be placed on the responsible handling of data. Accordingly, the generally high level of acceptance of digital applications in healthcare reaches its limits whenever users can no longer

[4] Hülsken-Giesler, M., Kreutzer, S., & Dütthorn, N. (Eds.) (2021). *Pflegewissenschaft und Pflegebildung: Band 18. Neue Technologien für die Pflege: Grundlegende Reflexionen und pragmatische Befunde* (1st ed.). Göttingen: Vandenhoeck & Ruprecht. Retrieved from https://ebookcentral.proquest.com/lib/kxp/detail.action?docID=6836961

[5] Roethlisberger, F. J., & Dickson, W. J. (1970). *Management and the worker: An account of a research program* (15th printing). Cambridge/Mass.: Harvard Univ. Press.

[6] Lupton, D. (2015). *Digital sociology*. London, New York: Routledge Taylor & Francis Group.

directly influence or control personal data flows or are restricted in their self-determination and are thus dependent on comprehensive information regarding data use.
ELSI aspects are often not directly visible and have a rather hidden effect. Nevertheless, the consideration of the relevant issues is essential for acceptance by society as a whole. PerHeart is therefore oriented towards the "ELSI-Co-Design", which was developed within the framework of the EU project BRIDGE. this means that the development process is used to explore the ELSI fields of activity and the design of the technology is adapted to this, instead of first addressing data protection, social or ethical aspects in a downstream step and, in a sense, developing the technology past people. In an iterative approach, technology and ELSI are continuously monitored, adapted, checked and approved.[7] This approach has been further elaborated by the MEESTAR project with particular focus on moral issues in human-centered technology designs. Among other things, MEESTAR model can be used to evaluate the socio-technical system.[8] Since the effects of the technologies used often only become apparent in practice (Suchman 2007), the ELSI criteria catalog developed at the beginning of the project will be evaluated together with the different user groups and, in the sense of an iterative development approach, further developed.

3 phases:
- Literature review and analysis of current user practices based on focus groups.
- Development of an ELSI criteria catalog
- Evaluation and further development of the criteria catalog

The first two phases as part of the work package will be depicted in more detail in the following.
An extensive literature search of relevant ELSI-related literature and research publications was conducted. In the course of the literature review, the ethically relevant dimensions that could entail ELSI implications were identified.
Basic findings and procedures for establishing a catalog of ELS implications could be obtained and made usable. Together with the consortium partners, the conduct of the focus groups was discussed and determined. The advantage of focus groups is to illuminate and contrast the complex requirements of the PerHeart platform from different angles and in the creative potential that arises from the interaction of the different stakeholders. A guideline for the focus groups was created and a semi-structured questionnaire to guide the discussion was developed. A standardized questionnaire was designed to gain a deeper insight into the specific user needs of HF patients. In addition to demographic data, this questionnaire also included individual technology-related attitudes. In a next step, the focus groups were conducted in Poland and Denmark with physicians and caregivers. HF-patients were interviewed separately using the questionnaires provided. In a next, step, personas and scenarios were created, because purely participatory methods often fail because of the so-called task-artifact circularity.[9]
In order to match technically innovative artifacts to the user, it is necessary to start from examples of use (tasks), which in turn are initiated by the requirements of technical artifacts.[10] To address this problem, the key users are first translated into personas and scenarios. Personas are fictional characters that embody idealized user groups. They are used to help actors involved in the service process understand needs, to justify design decisions, and to better translate the background, desires, needs, and knowledge of subsequent users into technical requirements. These personas become "live" in scenarios. These are descriptions that are told from the perspective of the

[7] Liegl, M., Boden, A., Büscher, M., Oliphant, R., & Kerasidou, X. (2016). Designing for ethical innovation: A case study on ELSI co-design in emergency. *International Journal of Human-Computer Studies*, *95*, 80–95. https://doi.org/10.1016/j.ijhcs.2016.04.003

[8] Manzeschke, A., & Rother, E. (2013). *Ethical questions in the area of age appropriate assisting systems: Results of the Study* (Stand: Januar 2013). Berlin: VDI/VDE Innovation + Technik.

[9] Cooper, A., Reimann, R., & Cronin, D. (2012). *About Face 3: The Essentials of Interaction Design*. John Wiley & Sons.

[10] Carroll, J. M., & Rosson, M. B. (1992). Getting around the task-artifact cycle. *ACM Transactions on Information Systems*, *10*(2), 181–212. https://doi.org/10.1145/146802.146834

potential user and describe his or her social, emotional and motivational situation. Scenarios are at the same time concrete and flexible and offer the possibility to depict even complex processes in an easily understandable way. [11] In PerHeart, so-called problem scenarios were used to show possible conflicts in the use of the system. It is important to note that a problem scenario does not contain any solutions, but merely describes the requirements for the system. These requirements are collected and based on them, solution scenarios are developed that describe how the identified problems can be solved using the PerHeart platform. Finally, the specific requirements for the PerHeart system were extracted, sorted, and prioritized from the final solution scenarios. The personas and scenarios to be developed in the project are created in an iterative process and are based on the findings of the focus groups and the expert knowledge of the project partners.

The PerHeart-platform to be developed in the course of the project can be classified in the category of assistive systems or ambient assisted living (AAL). AAL technology includes technical systems that are used to support people in need of assistance, and thus often older people as well. Even if these systems serve to improve the quality of life, preserve self-determination and maintain an independent lifestyle, ethical issues must be taken into account when using technology. In order to ensure the greatest possible acceptance among users, ethical aspects should already be considered during technology development.[12] Based on a research project initiated by the German Federal Ministry of Education and Research to explore ethical implications of technology use, a set of guidelines and an evaluation model (MEESTAR) were developed. The MEESTAR model serves as a tool for reflecting on ethical and moral issues in the application of a socio-technical system. Even though the model and its evaluation dimensions are designed for the concrete application of an already system and thus are not designed for the development process, the MEESTAR dimensions can already be made usable during the design process.[13]
The guiding questions in the application of MEESTAR are:

- "Is the use of a given age-appropriate assisting system ethically doubtful or is it harmless?
- Which specific ethical challenges arise from the use of one or more age-appropriate assisting systems?
- Can those ethical problems that arise from the use of age-appropriate assisting systems be mitigated or even resolved altogether? If so, what are the potential ways of resolving them?
- Are there certain elements in the use of an age-appropriate assisting system which are ethically so dubious that the whole system should not be installed or used at all?
- When a system is being used, do new and unexpected ethical problems arise which were unforeseeable when planning and designing the system?
- What are the aspects and functions of a given age-appropriate assisting system which need special attention from an ethical point of view? "[14]

The model intends the critical reflection of ethically relevant questions from the individual, organizational and societal perspective. The model provides for the consideration of seven

[11] Rosa Gudjonsdottir (2010). *Personas and scenarios in use*. Unpublished. https://doi.org/10.13140/RG.2.1.1145.3922

[12] Augusto, J. C. (Ed.) (2012). *Ambient intelligence and smart environments: Vol. 11. Handbook of ambient assisted living: Technology for healthcare, rehabilitation and well-beeing*. Amsterdam: IOS Press.

[13] Weber, K. (2015). MEESTAR – ein Modell zur ethischen Evaluation sozio-technischer Arrangements in der Pflege und Gesundheitsversorgung. In K. Weber, D. Frommeld, A. Manzeschke, & H. Fangerau (Eds.), *Wissenschaftsforschung: Band 7. Technisierung des Alltags: Beitrag für ein gutes Leben?*. Stuttgart: Franz Steiner Verlag.

[14] Manzeschke & Rother (2013)

different ethical dimensions, some of which conflict with each other, from the aforementioned perspectives: Care, autonomy, safety, justice, privacy, participation and self-conception. Each of these dimensions can be viewed from three different perspectives: the individual, the organizational and the social perspective, the combination of which is in turn assigned to a so-called ethical escalation level, the status of which is intended to reflect the need for action. The four ethical escalation levels range from level I as "ethically unobjectionable" to level IV "to be rejected". A graphic representation of the model is shown in Figure 1.

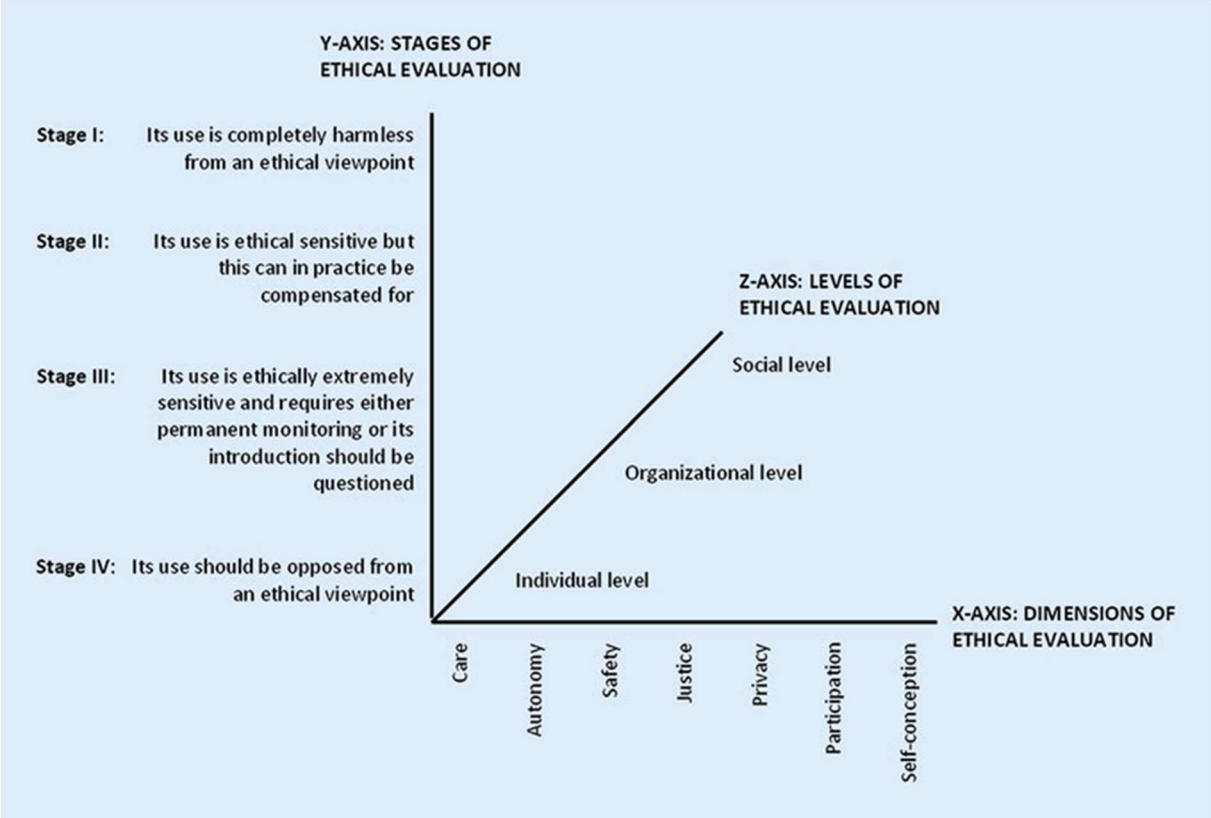

Figure 1 MEESTAR a model for the ethical evaluation of socio-technical arrangements adapted from Manzeschke et al. 2015

In the course of the extensive literature research conducted at the outset and the review of the relevant primary literature as well as the topic areas identified in the project discussions, particularly in the context of the preparation of the focus groups, the following ELSI dimensions were considered relevant:

Care

The concept of care implies support for the person in need in activities that are difficult for them, pose a risk for them (e.g. risk of falling) or that they are no longer able to do and can be seen as an extension of self-determination. This support can also be technology-based.

Guiding questions:

“At which point does technically assisted care for needy people become problematic because it changes their relationship with themselves and with the world in a way they do not want, or in a way which we should not want for them?

What degree of dependency in care structures is still acceptable or desirable, and at which point does a well-intended caregiving attitude become a patronising or negatively paternalistic approach which, under certain circumstances, might be technically supported or brought about?"[15]

Autonomy

The right to self-determination or autonomy is considered a fundamental human right and is part of human dignity.

Guiding questions:

"How can people be assisted in their autonomy on the basis of practices oriented consistently around the individual's right to autonomy?

How can people be supported in their autonomy when their usual criteria of autonomous decision-making and action have become questionable or even untenable?

How do we deal with the fact that ascribing autonomy can conflict with the right to care and support?"[16]

Safety

The concept of safety and security should be understood in the context of the PerHeart platform as an AAL system in such a way that the use of the socio-technical system should enable the users to lead the best possible self-determined life. Regular self-monitoring can increase the subjective sense of security, but it can also de facto improve objective security.

Guiding questions:

"How can we counter the fact that establishing safety can sometimes reduce existing capabilities? In other words, when people begin to rely on technology they may stop taking care of certain things themselves in a productive sense.

How should we evaluate technical assistance which increases the subjective feeling of safety without increasing safety objectively?

How do we resolve conflicts between safety and privacy and between safety and autonomy (freedom)?"[17]

Data protection and privacy

Privacy can be seen here as the inherent human right to independently develop and exercise one's own individual lifestyle and to protect it, which in turn includes the social environment. In

[15] Manzeschke & Rother (2013)
[16] Manzeschke & Rother (2013)
[17] Manzeschke & Rother (2013)

addition, personal information and data are to be protected within the framework of privacy. Especially AAL systems, which genuinely serve to improve the general living situation, independence, and self-determination, realize this primarily by collecting, processing and evaluating sensitive personal data. For this reason, the aspect of privacy and data protection is of particular importance in this context.

Guiding questions:

"How can the privacy of the individual over and above informational autonomy be upheld as a moral right when designing age appropriate assisting systems?

How can we protect the privacy of cognitively impaired people?

How do we deal with cultural differences when evaluating private and public spheres – such as when introducing age-appropriate assisting systems among people with a migration background?"[18]

Justice

The dimension of equity refers in particular to access to health care structures. On the one hand, this is determined by social status, but it also varies from country to country depending on the established health care system. Equal access to AAL systems, some of which are cost-intensive, is therefore a key issue.

Guiding questions:

"Who gets access to age-appropriate assisting systems?

How should age-appropriate assisting systems be financed (who pays how much)?

What is our understanding of intragenerational and intergenerational justice?"[19]

Participation

The concept of participation (International Classification of Functioning, Disability and Health (ICF)) aims at the equal participation of all people in social and societal life and their integration into societal structures. Particular attention must therefore be paid to vulnerable groups such as the elderly or the sick.

Guiding questions:

"What participation is possible for older people who are no longer or should no longer be integrated into working life? What kind of participation do they wish for?

What manner of participation is a) envisaged and b) actually promoted by age appropriate assisting systems?

[18] Manzeschke & Rother (2013)
[19] Manzeschke & Rother (2013)

To what extent do technical assistance systems prevent or impede certain types of participation?"[20]

Self-conception

The perception and evaluation of one's own self result in the self-image, which in turn influences one's own self-image. One's own self-image can also differ from the perception of one's own person by others (external image). When and to what degree a person considers himself or herself old, ill or vulnerable also depends on the social context and discourse and can vary from culture to culture. In most cases, aging processes and health problems have negative connotations, which is why there is a risk that the negative connotation will be reinforced or that the self-image will deteriorate, which counteracts the actual intention of AAL systems.

Guiding questions:

"How is the question of meaning which tends to pose itself more in old age given space and perspective within socio-technical arrangements?

To what extent does the tendency to medicalize life also changes our attitude to age and aging?

Which social constraints, direct or indirect, arise because of the dominant images of medicalized and technically assisted age and aging?

To what extent are standardization routines established through age-appropriate technology?"[21]

The seven ethical dimensions will each be analyzed at three levels to consider the different perspectives of each dimension. The individual level should cover the perspective of the individual user. The organizational level aims to include the responsibilities of institutionalized structures, while the social level includes societal and social structures as well as social responsibility. All ethical evaluation results can be classified on four escalation levels, from unobjectionable to complete rejection.

In project-internal expert discussions, the ethical evaluation dimensions were discussed critically. In addition to that, a requirement analysis was conducted in the expert consortium in several meetings. Questions regarding the definition and description of the users and their requirements for the platform usage were included. Inclusion and exclusion criteria of HF patients were defined. A data management plan was established in order to fulfill the GDPR. The user needs were targeted in focus groups and patient interviews by guiding questions.

[20] Manzeschke & Rother (2013)
[21] Manzeschke & Rother (2013)

3.1 Study Participants

People with heart failure (HF) are usually of an older age (from 59 – 86 years) and the disease is similarly prevalent in both genders.[22] But women are older than men when hospitalized.[23] Due to a higher age and other risk factors, every fifth to every second patient with HF typically has several noncardiac comorbidities which increase the hospitalization rate. [24][25] Typical comorbidities of HF patients are COPD, renal disease, depression, sleep disordered breathing, anemia, liver abnormalities, diabetes mellitus and others like cancer or frailty.[26]

Depending on the level of HF and the severity of the individual comorbidities, patients need more assistance in daily life, a more comprehensive medical treatment and care and thus a closer interaction with physician and/or caretaker. In addition to that, the level of social support is related to the quality of life.[27] Higher social support can even reduce hospitalization and mortality.[28] Age is another factor which has a strong impact on the level of independence of people with heart failure. The individual clinical picture must be taken into account accordingly when planning and conducting the study.

The protection of the study participants is considered to be the guiding principle. In addition to the avoidance of psychological and physical harm, the avoidance of further negative consequences of the subjects is also taken into account. This includes economic, social and legal aspects.

Psychological harm might be caused by the study setting, the technology usage (stress caused by misusage or stress though the setting itself),the data collection and the data transfer by researchers and the data sharing with physicians or caretakers. Potential causes of physical harm are collected and shall be reduced. Social harm might be caused by pilot phase and the visibility of the devices. Economic harm may arise by additional costs caused by the project (e.g. electricity).

Taking into account the findings from the expert discussions, the focus groups and the literature review, initial ELSI criteria were formulated. For this purpose, the MEESTAR guidelines were used. The ethical criteria catalog is regarded as a dynamic tool and is continuously reviewed in

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[22] Marti, C. N., Georgiopoulou, V. V., & Kalogeropoulos, A. P. (2013). Acute heart failure: Patient characteristics and pathophysiology. *Current Heart Failure Reports*, *10*(4), 427–433. https://doi.org/10.1007/s11897-013-0151-y

[23] Galvao, M., Kalman, J., DeMarco, T., Fonarow, G. C., Galvin, C., Ghali, J. K., & Moskowitz, R. M. (2006). Gender differences in in-hospital management and outcomes in patients with decompensated heart failure: Analysis from the Acute Decompensated Heart Failure National Registry (ADHERE). *Journal of Cardiac Failure*, *12*(2), 100–107. https://doi.org/10.1016/j.cardfail.2005.09.005

[24] Braunstein, J. B., Anderson, G. F., Gerstenblith, G., Weller, W., Niefeld, M., Herbert, R., & Wu, A. W. (2003). Noncardiac comorbidity increases preventable hospitalizations and mortality among medicare beneficiaries with chronic heart failure. *Journal of the American College of Cardiology*, *42*(7), 1226–1233. https://doi.org/10.1016/s0735-1097(03)00947-1

[25] Mentz, R. J., & Felker, G. M. (2013). Noncardiac comorbidities and acute heart failure patients. *Heart Failure Clinics*, *9*(3), 359-67, vii. https://doi.org/10.1016/j.hfc.2013.04.003

[27] Bennett, S. J., Perkins, S. M., Lane, K. A., Deer, M., Brater, D. C., & Murray, M. D. (2001). Social support and health-related quality of life in chronic heart failure patients. *Quality of Life Research : An International Journal of Quality of Life Aspects of Treatment, Care and Rehabilitation*, *10*(8), 671–682. https://doi.org/10.1023/a:1013815825500

[28] Luttik, M. L., Jaarsma, T., Moser, D., Sanderman, R., & van Veldhuisen, D. J. (2005). The importance and impact of social support on outcomes in patients with heart failure: An overview of the literature. *The Journal of Cardiovascular Nursing*, *20*(3), 162–169. https://doi.org/10.1097/00005082-200505000-00007

the course of the project and knowledge progress and adapted if necessary.

4. ELSI Criteria

Autonomy and restricted autonomy

Users must be able to act on their own and independently. The system must not restrict them. Alarms and warnings must be agreed with the users. It must be possible to terminate the application at any time and this process must be known to all users, and the legal consequences must be communicated clearly and understandably. Patients need to know how to use the system. Use in cognitively impaired persons requires separate consideration and should be represented by their authorized representatives in their best interests and legally safeguarded by specific living wills. Careful consideration must be given to whether these patients are included in the study.

The criteria listed here are not exhaustive, as the ELSI topic areas and the formulation of the criteria will be further developed based on the results of the focus groups, as well as discussions in the project group and other stakeholders, as mentioned above. Changes, reformulations or extensions of the already formulated criteria are therefore also possible at any time. The ELSI criteria will only be fully formulated after the first year of the project and the results of the associated work packages, so that they can be adjusted and adapted as necessary after the pilot phase. Furthermore, the criteria cannot be exclusively formulated since there are sometimes conflicting perspectives of the same criteria.

Participant-related criteria	Documents and guidelines to be provided	Provided
Vulnerable people (HF patients) are involved in the study	- Details of type of vulnerability - Clearly defined inclusion and exclusion criteria and recruitment process - Personalized system modification - Informed consent - Information material	- Recruitment and inclusion and exclusion criteria - Personalization in pilots - Informed consent sheet -Information presentation
Are patients involved who are unable to give informed consent	- Details of the procedures for obtaining approval from the guardian/legal representative - Measures to avoid coercion - Assessment whether the participants have the mental capactity to participate - Assessment whether the participants can perform regular activities of daily living	ADL and MMSE test were conducted in Denmark, none failed (limits must be set)
Technology usage	- Training program must be established - System shut down: clear guidelines, responsibilities and accountability shall be established including liability and consequences	
	- What should an end-user do, if measurements are out of range, e.g. high or low blood pressure, gaining weight in a short period of time etc.? Should they contact their primary care physician? A doctor who referred them for the PerHeart project? The PerHeart team?	
Resisting behavior	- How will we deal with resistance, inappropriate behavior and usage	

Personalization	PerHeart platform is customizable both in terms of hardware (through modularity) and software (through AI models trained with patient-specific data). Personal profiles can be created for individual patients (e.g., acceptable health parameters, desired level of training), which can be reviewed and modified by the underlying AI software. Based on real-time data, the patient's treatment can also be monitored and adjusted remotely.	
	Personalized solution in terms of: - Medication - Measurements - Contact person (physician, caretaker, nurse) - Cultural aspects	In preparation for the pilots
Technology-related criteria		
Alarms	- Alarm type (sound, light, vibration) to be selected: The possibility of choice strengthens the sense of autonomy.	
Pill dispenser	- Measurement of lifting or opening the medication box is not enough. How to make sure that the end-user actually took prescribed medications?	Very difficult to ensure because even when watching the person can pretend to perform the swallowing
Monitoring walking abilities	- Number of steps could be a good indicator of the overall performance and exercise capacity	
Glucometer	- Relevant for diabetics, but not for HF patients. Some have both, but here, they usually have their own device, and would not want to replace it with a new one.	

Monitoring subjective signs related to heart failure	-	End-users should fill in short questionnaires on daily basis including the most important signs of heart failure, e.g. dyspnea, oedema (swollen legs), general wellbeing, performance of daily tasks, exercise limitation, walking distance, sleep disturbances	Must be agreed on with pilot sites and questionnaires must be established accordingly
Indoor position and fall detection	-	Is relevant, but the extra installation tasks and added complexity urges a cost and benefit appraisal	To be discussed
Disease-related requirements			
Standardization	-	E.g. standard protocols for measurement processes	

Participation

Criteria		
Measurements	- Is there any flexibility in the way measurements are carried out in terms of time and frequency?	
Communication	- How are critical incidents communicated? - Ways of communication between caregiver/physician/researcher and patient	
Mobility	- Is the terminal device permanently installed in one location? - Does the PerHEart platform reduce mobility and if yes, how will this issue be tackled? - Can the test persons take the measuring devices with them?	
Protocols and standardizations		
Disease-related technology requirements	Technology-related aspects must be included in a human-centered development approach. Here, the specific disease-related requirements for the technology must be given special consideration.	

Use of the PerHeart platform should be supportive, not restrictive, of HF patients' participation in social life. In this context, the individual needs of the subjects should be addressed to enhance the user experience. Caregivers and researchers should also be considered in this aspect.

Justice and accessibility

Access to and use of the PerHeart platform should be designed to be as non-discriminatory as possible. This means that PerHEart should be available to all people regardless of age, gender, ethnic origin, level of education and technical experience. The target group of people with heart failure should not be denied access to Technology due to technology and use-related barriers. Therefore, care should be taken to tailor the technology to the needs of this patient group in order to fulfill the accessibility aspect in advance.

Criteria		
Financial implications	- What are the costs of the use? - How do we deal with additional costs caused by the use?	
Educational background	- Is the system easy to use? - Is the system language easy to understand?	
Age-related implications	- Is the font large enough for older people or people with impaired vision to read?	
Attitudes towards technology	- Will the system also be applicable with people with low/no interest in technology or a lack of experience?	
Data Access	- We will strive to implement fair access to the data	GDPR regulations open access repository General Public Licence (GPL/A)
Language	- Wherever language is used in the project (i.e. questionnaires, informed consent, display announcements etc.), the native language of the individual users should be used	
Cultural differences	- Cultural differences should be considered	
Training	Before the introduction of the technology, the test person should be trained in the use of the platform and the associated instruments. A training manual should be	

	created for this purpose. The training measures should be carried out with both patients and professionals. The manual should be adapted to the respective target group.	
	- Patients	
	- Professionals	
	- PerHeart representatives	

Privacy and data privacy

The data collected, processed and evaluated in the course of using the PerHeart platform must be prepared in such a way that data linkage, data forwarding, or information derivation is possible.

	Critical Incident	**Measure**
GDPR and privacy	Compliance with GDPR must be guaranteed, privacy regulations must be established	Data Management Plan GDPR agreement to be discussed
Data processing	Data processing must be depicted in detail	Data Management Plan
AI model management	Should be clarified and responsibilities must be defined	
Data retention	Length of retention must be described	Data Management Plan
Data transfer to professionals	Which data will be transferred to caregivers/researchers?	Data Management Plan
Will the project reuse data	Access to the existing data must be depicted	Data Management Plan
Collection of new data	New data collection and long-term management must be justified	Data Management Plan
	Training of all persons involved must be established	
	Consortium level policy on data collection and storage should be defined - Individual storage solution deviating from the CLP must be reasonably explained and detailed	
	Documentation must be ensured, i.e. collection protocol, methodology	
Data storage	How data are stored, backed-up managed and curated must be defined	Data Management Plan
	Anonymization of metadata	Data Management Plan

Data preservation	Plans and place for long-term storage, preservation and planned retention period and preservation standards must be described	Data Management Plan
Metadata	Additional metadata must be described and clarified	Data Management Plan
	Precise translation must be provided	
Methodology	Must be depicted	Data Management Plan
	Health and monitoring - Number of daily steps for activity monitoring - The indoor localization (Positioning system) - Gait monitoring device - Sleep data - Calendar entries - Smart pill dispenser - Blood pressures - Heart rate - ECG - Oxymeter - Glucometer - A&D weight scale - Wearable tags, anchor nodes, system controller	To be depicted further and agreed on in preparation of the pilots
Data access	Further agreements regarding data access to make data accessible	
Data quality from devices	Compliance with CE certification where possible	

Deliverables/ scientific publications	Length and place of storage - EU regulations - National regulations - Institutional regulations	Data Management Plan
Data sharing/ data repository	Methods/ software tools must be specified	Data Management Plan
	Restrictions /delays to sharing including planned actions should be identified and described	Data Management Plan
	Suitability of data for sharing should be explained (e.g. raw data, AI models, publications etc.)	Data Management Plan
	Institutional, departmental and study policies - Within the consortium - Public domain - Data Management Policy and procedures - Data security policy - Data sharing policy - Institutional information policy	
FAIR data management	Costs must be identified and forecasted.	Data Management Plan
Formal information standards	Define standards the study complies with	Data Management Plan
Risks to data security	A risk forecast and countermeasures should be created	Data Management Plan
Discovery by potential users of the research data and governance of access	Data sharing policy should be established	Data Management Plan
Regulation of responsibilities of users	How external users are bound by data sharing agreements etc. must be indicated	Data Management Plan

Alerts and critical alerts	Who will receive alerts and critical alerts? 1. End-users? 2. Caregivers? 3. PerHeart team? **4.** Health care professionals?	

Safety

The use of the PerHeart platform must not represent a risk for the users, neither in the normal, intended use situation nor in the case of malfunctions or error messages, system crashes, connection problems or other technical defects. Furthermore, the use of the system should in no case cause additional psychological or cognitive strain or stress.

	Critical incidents	**Measure**
Alarms	Critical alerts should be set and related interventions described specifically	
Out of range results	Algorithms should be created describing actions in case of out of range results	
Functional breakdowns		
Process Interruption		
Network Problems		
Faults		
Error-prone measurements due to wrong operation	e.g. blood measurements in home setting, pill dispenser	
Training		
Standardization	Protocols for acquiring the data will try to ensure that the measurements performed during the pilots are done in a correct manner	
Personalized measurements	e.g. glucometer relevant for diabetics	
Interventions	Which interventions are planned/ can occur	Non-interventional study

Informational self- determination/ Informed Consent

The users of the PerHeart platform must be comprehensively and understandably informed about all usage-related areas of the technological assistance system. This includes the duration, scope, sequence, area of use and goals of the assistance system. Information must also be provided about any limitations of the system and possible risks associated with its use. In addition, data use, data processing and data storage must be explained in an understandable manner. Instruction in the use of the system must also be listed. Only after complete clarification the consent to participation should be obtained. The end-users must give a consent to use functionalities with no benefit to them.

Additionally, the informed consent must describe who is responsible for monitoring the data during pilots. Acceptance of all technical solutions and functionalities must be ensured beforehand

Informed consent must state:

- Purpose, aims and benefit of the PerHeart platform
- Measurements with potential benefit for the end-users (e.g. weight or blood pressure measurement) and list data collected for research purposes only (e.g. position determination).
- Differentiating functionalities providing direct or indirect benefit to the end-users (e.g. display of results, alerts) from functionalities collecting data for future analyses with no benefit to the end-users.
- Limitations
- Training procedures
- Information on alarm thresholds for measurements and activities and display of alarms on the end-user devices
- Shut down procedures
- Risks and hindrances through usage
- Information on all the functionalities and their potential application in monitoring of their health status
- Data collection, processing and transfer (anonymization)
- People involved in the processing of personal health data, e.g. who will administer the PerHeart platform and who will check the incoming results from the end-users
- Responsibilities
- Statement that the PerHeart team is not responsible for medical interventions during the pilots
- Statement that the end-user remains within the health care system according to country regulations (e.g. in Poland it means services provided by the National Health Fund)
- Liability, responsibilities and accountabilities, and liability risks must be detailed and defined.
- That the end-user remains within the health care system according to country regulations
- Health data will be collected from different medical devices and includes timestamp of the measurement, blood pressure, heart rate, ECG parameters, glucose and oxygen levels, weight and segmental body weight analysis data, tag identifier.

Liability and responsibilities

Liability, responsibilities and accountabilities, and liability risks must be detailed and defined. The role of the researcher in the study and the pilots should be clearly formulated, rights and duties should be defined. Especially when planning the piloting, the researcher should be prepared for their future role and made aware of the task. Here, particular emphasis should be placed on the importance of informing the subjects to increase their commitment and engagement. Possible patient concerns should be identified in advance and specifically addressed when approaching patients. A relationship of trust between patient and researcher is essential for the positive course of the study.

- Comprehensive informed consent

- What should an end-user do, if measurements are out of range, e.g. high or low blood pressure, gaining weight in a short period of time etc.? Should they contact their primary care physician? A doctor who referred them for the PerHeart project? The PerHeart team?
  - there is no direct collaboration between PerHeart and primary health care or specialist health care.
- Responsibility of the PerHeart teams in countries performing pilots for monitoring data transferred to the platform
  - Exacerbation of heart failure is possible in all users and might result in unfavorable outcomes.
  - Sudden events may occur, e.g. falls
  - No responsibility is not accepted. Justification: members of the PerHeart team are physicians and they must follow the principles of ethical conduct, which means they must take some level of responsibility for the end-users taking part in the PerHeart pilots.
- Responsibilities for system maintenance and care #as well as troubleshooting and the frequency of maintenance work should be defined

Avoidance of discrimination, stereotyping and standardization

In order to avoid discrimination, the general principle of equality should of course be applied in the PerHeart project. Furthermore, the image of a person suffering from cardiac insufficiency should be realistic and in no way judgmental, either negatively or positively. Deficits in comparison to healthy persons should be avoided. Rather, the use of technology should serve as support in dealing with the disease, maintaining quality of life and enjoyment of life, and a good attitude toward life. Technology use should not restrict or dictate the exercise of daily routines, and measurement results should not entail control mechanisms. Accordingly, care should be taken to ensure that the individual's lifestyle is not perceived as being restricted by the use of technology.

Usability

Use of the PerHeart platform should be designed to be as simple, intuitive, and comprehensible as possible, and should be based on the specific needs of patients, whose usage requirements should be considered in technology development. In addition, possible age-related competence limitations in technology use should also be included in technology development. The use of the platform as well as the associated devices should be simple and clearly arranged. Usability should be regularly reviewed by adequate means during development.

- Disease related requirements
- Interface for different user groups
- Colors
- Font size
- Barrier-free usage should be targeted
- Creation of a usability test to asses ease of interaction with technology

Contractual terms

Users should be able to exit the project and terminate the collaboration at any time. Reasons for this do not have to be given and the person should not suffer any disadvantage as a result. Coercion to continue must not be exercised under any circumstances.

5. Conclusion

The catalog presented here is not considered exhaustive but will be evaluated during the course of the project and adapted and expanded as needed. Following the Co-design approach, the ELSI criteria are subject to further modifications and will therefore be finally formulated by the end of the project. Especially in terms of usability, the pilot studies will provide sound input for further implications.

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Date	Changes	Version	Author
25.10.2021	First draft	1	Kathrin Bierwirth
05.11.2021	Second draft	2	Kathrin Bierwirth
16.12.2021	Third draft	3	Kathrin Bierwirth
02.02.2022	Fourth draft	4	Kathrin Bierwirth
18.02.2022	Final version	5	Kathrin Bierwirth