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Integrating participatory research and literature review to identify social and ethical requirements for responsible AI in heart failure treatment

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Abstract— The rapid advancement of Artificial Intelligence (AI) in healthcare raises significant social and ethical concerns, particularly in cardiovascular care, the leading cause of death worldwide. Addressing these challenges requires a multidisciplinary, multi-stakeholder approach to ensure the responsible development and implementation of AI-driven solutions. First, a literature review examined how key ethical principles – namely, autonomy, confidentiality, data privacy, and equal treatment – are integrated into AI applications for heart failure care. These findings informed an online workshop with patient representatives, clinicians, and experts on ethical, legal, and social issues to discuss ethical concerns and practical implications. A team of requirements engineers and digital health experts synthesized insights from the literature review and workshop, specifying an initial set of requirements. Following multiple iterations with a multidisciplinary review team, the final set of 25 requirements was established. These were translated into software or system specifications where applicable or used to define guidelines for real-world implementation. This study provides a structured approach to embedding ethical and social considerations into AI-driven healthcare solutions. Its methods and key requirements are transferable to other AI applications in public health, promoting responsible and equitable adoption.

Keywords— *Artificial Intelligence, Stakeholder Engagement, Cardiovascular Disease, Ethical Legal and Social Implications, Requirements Engineering, Mixed-Methods Research*

I. INTRODUCTION

The rapid advancement of Artificial Intelligence (AI) in digital public health calls for structured approaches to identify and address ethical and social challenges. Cardiovascular diseases remain the leading cause of death globally [1], driving growing interest in applying AI to this field. Emerging evidence suggests that AI has the potential to enhance risk prediction and improve patient outcomes [2]. However,

several challenges persist, including integrating AI into clinical decision-making, mitigating algorithmic bias, and ensuring strict data governance [3], [4].

While the topic of AI ethics has gained increasing attention in the social sciences [5], the effective design and implementation of AI-driven innovations in healthcare requires a multidisciplinary effort. Bringing together expertise from clinicians, technologists, ethicists, and social scientists is essential to developing AI tools that are not only technologically advanced but also ethically sound and socially acceptable [3]. Participatory approaches can help bridge this gap by fostering inclusive discussions and co-designing solutions that align with public health priorities and patient needs [6].

In this study, we employ a mixed-methods approach, combining a literature review and a multi-stakeholder consultation, to examine key ethical and social considerations in the design and implementation of an AI-driven tool for personalized risk assessment and care planning in chronic heart failure. The insights gathered from these activities are systematically translated into a set of requirements providing a structured pathway for the responsible development and real-world integration of this AI-driven tool in healthcare settings. This work was performed within the context of the Horizon Europe project *Trustworthy Artificial Intelligence for Personalised Risk Assessment in Chronic Heart Failure* (AI4HF) [7].

Beyond its immediate clinical application, this approach offers valuable contributions to the field of digital public health, where AI is increasingly used for population-level interventions such as disease surveillance, early warning systems, health resource allocation, and pandemic modelling. Embedding ethical and social dimensions into the development and deployment of such tools is essential to ensure trust, equity, and societal acceptance, especially in

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situations when public health decisions are informed or automated by algorithmic systems.

II. METHODS

We employed the mixed-methods stepped approach shown in Figure 1 to address the challenge of identifying social and ethical requirements for AI-driven tools in healthcare. First, we conducted an umbrella review, i.e., a review of review articles without restrictions on the type of review [8], focusing on the integration of key ethical principles in AI-driven tools for heart failure treatment. Specifically, we examined how the principles of autonomy, confidentiality and data privacy, and equal treatment have been incorporated into such technologies. To identify relevant literature, we developed a comprehensive search string aimed at the intersection of ethics, artificial intelligence, and heart failure treatment. The search was performed in the PubMed, Scopus, and Web of Science databases with results up to September 2023. The findings from this literature review served as the foundation for discussions with ethicists in the workshop described below.

Second, we applied participatory research methods in an online workshop on ethical considerations for AI-driven tools in heart failure treatment. This session was part of a broader series of multi-stakeholder consultations designed to facilitate a bottom-up approach to developing trustworthy AI-driven tools for personalized risk assessment in chronic heart failure [9]. Stakeholders were identified through a context-specific stakeholder analysis using an adapted version of the Involvement Matrix proposed by Smits et al. [10]. For this session in particular, we invited representatives of patients from a patient association in the cardiovascular domain, clinicians involved in heart failure care, and social scientists in the network of the research team to explore ethical concerns related to AI-driven tools.

The online workshop, held in November 2023, began with an introduction to the project, followed by a keynote presentation on the importance of addressing Ethical, Legal, and Social Issues (ELSI) in the design of AI-driven healthcare tools. Participants were then divided into three groups – patients, clinicians, and ELSI experts – for in-depth discussions among homogeneous groups. The subgroup discussions were followed by a plenary session where participants shared their insights. Although not formally requested, three patients continued the discussions via email after the session and those were also taken into consideration in the requirements specification.

A team of experts in requirements engineering and digital health analysed the findings from both the literature review and the workshop. These insights were translated into multistakeholder requirements using a structured template adapted from van Velsen et al. [11] containing the following fields: *id*, *type*, *requirement description*, *rationale*, *source*, *priority*, *author*, *status* (proposed, clarify, accepted or rejected), and *history*. The initial requirement list underwent multiple iterations based on feedback from the multi-stakeholder engagement lead, the clinical lead, the technical lead, and the external ethics advisor of the project.

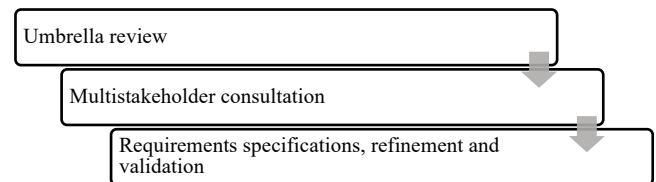


Fig. 1. Stepped approach to gather, specify, and validate ELSI requirements in multidisciplinary projects.

III. RESULTS

A. Umbrella review

A total of 127 articles were retrieved, and 25 reviews were analyzed in full. Below, we summarize the key findings for each ethical principle investigated.

Right to Autonomy: While AI-driven health solutions are sometimes seen as dehumanizing, they can also reduce administrative workload, allowing for more clinician-patient interaction [12]. One important issue to be considered is that, even if the accuracy of the AI models matches the clinicians' judgement, the lack of ability to assess the consequences of their decisions, makes clinician oversight essential [13], [14]. Explainability is another critical factor supporting clinicians in their right to autonomy, as both clinicians and patients need to understand how AI reaches conclusions [15]. In this line, regulatory frameworks, such as the General Data Protection Regulation mandates the 'right to explanation' during informed consent [13].

Confidentiality and data privacy: The literature highlights concerns about absence of clear globally accepted regulations on AI safety and efficacy in healthcare [12]. In particular, secure storage and transmission of clinical data are crucial, particularly with the growing use of remote monitoring technologies [15]. In the cardiovascular domain, the broad use of implantable devices, widely accepted by patients and physicians, offers clinical and economic benefits but also raises legal and privacy concerns [16], [17]. Additionally, the use of wearable devices in remote patient monitoring requires specific consent mechanisms that are often overseen, increasing the risk of personal data exposure [18]. While data sharing is essential for the implementation and validation of AI-driven solutions, safeguards must prevent unauthorized commercial exploitation and cyber threats [19].

Equal Treatment: The usage of AI in healthcare aims to improve efficiency and fairness, yet bias remains a significant challenge [20]. Existing literature reporting AI applications usually have retrospective designs and small sample sizes, which can potentially lead to bias [21]. As data volume increases, so does the risk of bias [19], [22]. Only 19% of heart failure prediction models reviewed by Di Tanna et al. [23] had a low risk of bias. Bias can stem from several issues, including unrepresentative datasets, non-random missing data, or even automated bias, as clinicians may over-rely on AI recommendations [13].

B. Participatory approach

In total, 17 external people to the project team participated in the ethical consideration workshop, namely 2 experts in Health Technology Assessment, 7 ELSI experts, 3 clinicians, and 5 patients.

Patient discussions and follow-up conversations revealed both optimism and concern regarding the integration of AI into heart failure care. A key apprehension was the fear of

receiving less personalized care, and in the patients' perspective "lower-quality care", due to AI-driven decision-making. Patients emphasized that healthcare must account for individual needs, including cultural and social factors, rather than relying solely on generalized AI models. This aligns with the principle of autonomy, as patients stressed the importance of being fully informed about the risks and limitations of AI-based decisions. Transparency and explainability were seen as critical, with participants expressing that their trust in AI systems was largely dependent on their trust in the clinicians using them. Notably, there was strong resistance to commercial AI solutions, with patients preferring AI tools embedded within clinician-led care pathways rather than corporate-driven innovations. Concerns around equal treatment were also raised, particularly regarding potential biases in AI algorithms. Patients recognized that AI models depend on existing data, which may not always represent diverse populations, leading to inequities in care. They called for quality assurance mechanisms, standardized guidelines, and evidence-based validation to ensure fairness. Additionally, accountability for AI-driven errors was a major topic, with participants questioning who should take responsibility if an AI system contributes to misdiagnosis or inappropriate treatment. This reinforced the necessity of maintaining a strong human element in AI-assisted healthcare, ensuring that clinicians retain decision-making authority rather than relying blindly on algorithmic outputs. Finally, regarding confidentiality and data privacy, patients were cautious about the security of their health data, particularly in remote monitoring applications. While acknowledging the potential benefits of continuous symptom tracking, some patients shared personal experiences where symptom monitoring led to increased stress rather than reassurance. The discussion underscored the evolving nature of AI in healthcare and the need for a balanced, transparent approach that prioritizes patient welfare and data security. Participants recognized that AI development is an ongoing process requiring continuous learning, updates, and validation. Some acknowledged that early adopters would play a crucial role in refining AI tools but stressed that robust safeguards must be in place to protect patient rights and well-being.

Clinicians highlighted several challenges regarding the integration of AI into heart failure care. A major concern was the impact on consultation time, as the use of AI tools would add to an already demanding workflow that includes reviewing anamnesis, lab results, and heart function measurements. They emphasized that AI should enhance, rather than complicate, clinical decision-making. Additionally, they stressed the need for structured protocols in high-pressure situations, such as emergency alerts for nurses and families, ensuring that AI serves as a support tool rather than an added burden. Training was another key issue, as clinicians acknowledged the necessity of education on AI-driven decision support tools. However, they raised concerns about the additional workload and questioned how much trust should be placed in AI-generated recommendations. This links to the right to autonomy, as clinicians must retain final decision-making authority, ensuring that AI complements rather than overrides their expertise. The discussions also touched on confidentiality and data privacy, particularly the risks of reverse patient de-identification when using AI

models. Clinicians debated the necessity of secure data-sharing protocols and privacy-preserving techniques like differential privacy to prevent unauthorized data exposure. Overall, they underscored that AI must be implemented with clear guidelines, human oversight, and transparency to ensure safe and ethical use in clinical practice.

ELSI experts emphasized the complexity of equal treatment in AI-driven healthcare, questioning what makes data truly representative in this specific context. They highlighted that fairness is not just about equal access but also about ensuring that AI accounts for demographic diversity from the design phase. Bias, a central ethical concern, should be addressed early through collaboration with technologists. Experts debated whether equality or appropriate treatment should be the goal, as in some cases, positive discrimination might be necessary to ensure equitable care. Additionally, they stressed that access to AI-driven treatments must be considered; if a solution is too expensive, it risks reinforcing existing inequalities rather than reducing them. On confidentiality and data privacy, experts raised concerns about data governance, particularly in regions like South America, where there is fear of data being accessed by unauthorized parties. They questioned whether privacy as we understand it today will still be viable in the future, given the increasing reliance on data-driven healthcare. A key distinction was made between consent for treatment and consent for data use in research, emphasizing the need for clearer frameworks that respect both patient autonomy and data protection principles. Ensuring transparency and accountability in AI-driven healthcare will be crucial to maintaining public trust.

C. Requirements specification and validation

Thirty-three ELSI requirements were specified based on the workshop and literature review, with 18 requirements gathered from the workshop and follow-up discussions and 15 from the literature review. Each of these requirements was analysed by the lead of stakeholder engagement activities, Clinical lead, Technical Lead, and external Ethics Advisor of the project. The involvement of the external ethics advisor was crucial for quality assurance.

A few iterations were performed to solve unclarity. After this, each abovementioned party approved or rejected each requirement. Disagreements were discussed leading to the rejection of 8 requirements and resulting in a final list of 25 requirements, provided in Table 1. Requirements were rejected if they were deemed out of scope for the intended context, lacked sufficient clarity, or could not be adequately supported by a clear rationale. Multiple requirements conveying overlapping concepts were consolidated into one.

The list of requirements includes a mix of prescriptive, normative, and descriptive elements, reflecting the multidisciplinary nature of the process, where insights from the literature review and the stakeholder consultation were integrated. Normative and descriptive statements were retained when they provided essential context or helped articulate stakeholder values and concerns, even if they were not immediately actionable. Where possible, these were translated into prescriptive system or software requirements or used to define guidelines for real-world implementation, at a later stage of the project. The requirements management process was documented with all versions available.

TABLE I. FINAL LIST OF ELSI REQUIREMENTS.

ID	Requirement
ELSI.1	The AI tool shall undergo rigorous validation and refinement processes to enhance its predictive performance in comparison to statistical models.
ELSI.2	Clinicians must ensure the "right to explanation" in accordance with the General Data Protection Regulation (GDPR) throughout the entire lifecycle, starting from the initial informed consent procedures.
ELSI.3	AI-based solutions must be non-discriminatory, ensuring inclusivity, transparency, and fairness in their decision-making processes.
ELSI.4	The AI tool must implement robust mechanisms to ensure the confidentiality and anonymization of clinical data of the patients.
ELSI.5	AI integrated with wearable devices for remote monitoring must ensure the proper acquisition of consent before collecting cardiovascular patients' data.
ELSI.6	AI integrated with wearable devices for remote monitoring must implement robust security measures to protect personal information, ensuring data confidentiality and preventing unauthorized access.
ELSI.7	AI must prioritize personal data privacy, implementing measures to prevent unauthorized commercial exploitation of clinical data.
ELSI.8	The AI tool must prioritize secure data transmission over the internet to mitigate the risks of cyberattacks and unauthorized use.
ELSI.9	The AI tool must undergo well-designed randomized clinical trials to rigorously evaluate its safety and effectiveness in real-world healthcare settings. The design of these trials should encompass diverse patient populations, relevant clinical scenarios, and a comprehensive assessment of the tool's performance metrics.
ELSI.10	The AI tool must be designed with consideration for digital literacy issues, particularly among older adults.
ELSI.11	Clinicians want that clinical AI-tool is integrated within a specific clinical process based on the intended-use of the novel algorithm.
ELSI.12	Clinicians should be able to control the level of input of various variables (e.g., EKG, laboratory results, anamnesis, and heart-value measurements). Additionally, the clinical AI-tool should be able to cope with missing data entries and provide an estimate on model accuracy, considering the different data entries.
ELSI.13	Clinicians should receive clear guidance on the education and training prior to the clinical use of novel AI-tools. The training sessions should include a plenary explanation session as well as an interactive session to use the novel AI tool and provide the ability to directly ask questions, before using the AI tool in daily clinical practice.
ELSI.14	Patients who opt for the treatment using the AI-driven tool want to be able to decide whether their data can be used for research purposes.
ELSI.15	The AI-driven tools shall be available to all patients. Inclusiveness principles should be considered not only at the development stage but also at implementation.
ELSI.16	The informational, educational, and training material shall be adapted to the values and fears of each culture.
ELSI.17	The patient shall be informed about who takes the responsibility for the decision on following, or not following the decision proposed by the AI-driven tool.
ELSI.18	The decision on the treatment to receive shall be taken collaboratively between doctor and patient. AI should be used to augment a doctor-patient encounter, not replace the human touch.
ELSI.19	The patient shall be informed of the risks of the use of the AI driven tools and the decisions proposed.
ELSI.20	Patients with low digital literacy shall not be discriminated against in their treatment with CDSS.
ELSI.21	Patients do not want AI-tools to be the sole item on which clinical decision making is based.

ELSI.22	Patients want their doctors to be able to explain the decisions proposed by the AI tools.
ELSI.23	The patient shall be able to decide whether their data is used in clinical decision support systems (e.g., AI driven tools).
ELSI.24	In case a patient decides to opt out of having their data in AI-driven tools, the attitude of the clinician towards the patient should not be compromised in any way.
ELSI.25	The AI tool shall undergo rigorous validation and refinement processes to enhance its predictive performance in comparison to statistical models.

IV. DISCUSSIONS AND CONCLUSION

The work described in this paper highlights the complementary value of a literature review and multi-stakeholder consultation. While the literature review identifies key discussion topics, the workshops enabled in-depth engagement with diverse stakeholder groups, providing valuable insights into their needs, preferences, and concerns.

The findings from both the literature review and stakeholder consultations align in several key areas. Regarding the right to autonomy, AI systems should complement, not replace, human judgment, with clinicians remaining at the centre of decision-making [14], while ensuring empathy and the management of complex conditions. From the patients' perspective, it is essential to establish clear ethical standards and accountability mechanisms to safeguard patient autonomy. Confidentiality and data privacy are particularly critical in cardiovascular care, where implantable and wearable monitoring devices are widely used and where robust data security measures must be in place to protect sensitive patient information [16], [17]. Finally, equal treatment must also be a priority, requiring the prevention of discrimination due to biased training data [19], [21], [22]. To this end, transparency in AI decision-making and clear accountability for AI errors are essential to fostering trust and fairness.

Multiple frameworks for developing trustworthy AI have emerged for general AI (e.g., [24], [25]), as well as specifically for the healthcare domain [26]. These frameworks consider key concepts such as explainability, fairness, robustness, and transparency, but they are often developed by experts from industry and academia, with little or no involvement from end-users and other key stakeholders. The recently published STANDING Together consensus [27], which provides a set of recommendations to promote transparency in health datasets, offers a promising counterexample demonstrating how multi-stakeholder engagement, including Patient and Public Involvement, can enhance the relevance and legitimacy of AI governance frameworks. The lack of participatory input can hinder adoption in clinical practice, as AI tools may fail to align with real-world healthcare needs, workflows, and ethical considerations.

A key strength of the current work lies in the multidisciplinary expertise of those involved in gathering, refining and validating the requirements. Contributions from requirements specialists, technical experts, clinical experts, ELSI experts, patients and ethics specialists ensured that each requirement was both clear and ethically sound. These requirements were then prioritised following the MoSCoW prioritization technique (Must have, Should have, Could have, Won't have) [28] and translated into software or system

specifications, where applicable, or used to define guidelines for real-world implementation of an AI-driven tool for personalised risk predictions in the treatment of chronic heart failure.

Another strength of this study is its contribution to bridging the gap between technical development and social impact assessment in AI-driven healthcare solutions. While requirements specification is a well-established practice in technology development, it remains less familiar to social scientists, who may have limited exposure to its methods and standards. This study highlights the value of bringing together technical, clinical, and social scientists to ensure that the AI tools are technically robust, as well as ethically sound and socially responsive. This approach fosters a more inclusive and comprehensive pathway for the responsible development and implementation of AI in healthcare.

An umbrella review was chosen to synthesize existing literature reviews on the integration of key ethical principles in AI-driven tools for heart failure treatment, allowing us to capture a comprehensive, high-level overview of the current evidence base, identify common gaps, and avoid duplication of previous analysis. Given the fast-paced developments in the field of AI ethics in healthcare, along with the evolving regulatory frameworks at national and international levels, it is likely that new evidence will continue to emerge. It is, therefore, recommended that future research continues to monitor and update this synthesis regularly to ensure alignment with emerging evidence, policy shifts, and regulatory standards.

It should be acknowledged that the patients participating in the workshop were members of a patient association, meaning they are likely to have had a higher level of interest and engagement in the topic than the general patient population. Similar discussions should be performed with patients at the local clinical sites. In this line, in addition to high-level discussions, we are engaging with local groups of stakeholders in multiple countries in Europe, South America, and Africa, to assess whether the proposed AI tools and implementation pathways align with the cultural and healthcare organizational contexts of the clinical sites where the technology will first be deployed.

Future work will focus on the iterative development of both the technological tools and the pathways for real-world implementation, in collaboration with the stakeholders identified in this study, as well as policymakers, payors, and hospital administrators.

In conclusion, integrating ethical considerations into AI-driven healthcare tools is crucial for building trust among patients and healthcare providers, ensuring equitable access to advanced treatments, and protecting patient rights. This work contributes to these objectives by providing a framework for identifying and embedding social and ethical requirements into the development of AI tools for heart failure treatment, promoting their responsible and effective use in public health. The methods described here are transferable to the design of AI-driven solutions in various public health domains.

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