Requirements for Human-Centered Artificial Intelligence: A Heart Failure Study Across Europe and Latin America

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***Abstract*— This paper explores the requirements for human-centered artificial intelligence (AI) tools for heart failure (HF) management, focusing on the needs of diverse healthcare settings in selected European countries (Netherlands, Spain, Czech Republic) and a Latin American country (Peru). Clinicians, patients, ethicists, and technical experts were engaged through co-creation workshops, local groups, narrative interviews, and surveys to gather clinical, ethical, and regulatory requirements for AI implementation in HF care. These activities provided input on the intended clinical use of AI tools, as well as patient data privacy and security concerns. Clinical requirements revealed regional differences in AI tool preferences and key predictors. European clinicians favored integration into secondary and tertiary care, focusing on quality of life and comprehensive follow-up measures, while clinicians in Peru prioritized secondary care with an emphasis on treatment adherence and complication management. Ethical considerations, such as data privacy and bias mitigation, were universally important but some context-specific differences emerged. European stakeholders emphasized mitigating biases related to sex, ethnicity, and socioeconomic status under European regulations, whereas Latin American stakeholders focused on context-specific ethics and robust national oversight. By aligning these insights with FUTURE-AI principles, the study ensures the development of effective, human-centered AI tools. This research highlights the importance of continuous stakeholder engagement and contextualizing AI applications to enhance their relevance, usability, and adoption across diverse healthcare settings.**

Keywords—Heart failure, human-centered AI, stakeholder engagement, trustworthy AI, FUTURE-AI.

I. Introduction

Cardiovascular diseases, including heart failure (HF), remain the leading cause of morbidity and mortality globally [1]. Despite continuous advances in cardiovascular research, HF management remains a major public health challenge, particularly in low- and middle-income countries (LMICs) where resources are restricted.

Artificial intelligence (AI) has emerged as a transformative technology in cardiology, offering promising solutions for early HF diagnosis, treatment planning, and management [2,3]. However, the development and validation of AI tools have predominantly occurred in high-income countries, where healthcare systems have advanced infrastructure and resources. Consequently, these models may not be directly applicable or suitable for LMICs, which face distinct healthcare challenges and resource limitations [4]. Moreover, the development of AI in HF has often occurred without adequate engagement of key stakeholders, leading to AI solutions that are misaligned with local practical needs and ethical considerations [5].

To address these challenges, we advocate for a human-centered and context-specific approach to AI in HF management, involving comprehensive stakeholder engagement from day one. This approach ensures that AI solutions not only meet technical standards but also resonate with the clinical, ethical, legal, and social implications (ELSI) of their use. Our initiative, the AI4HF project, funded by the European Commission (No. 101080430; 2023-2027) and involving 16

institutions from Europe, Latin America and beyond, seeks to pioneer AI-powered clinical tools for HF risk assessment. By integrating stakeholder feedback from inception and adhering to the FUTURE-AI guideline on trustworthy AI [6,7], we aim to develop AI solutions tailored to diverse healthcare settings and which will be trusted and adopted in real-world practice.

This study aims to bridge the gap between advanced AI technologies and the practical healthcare needs of underserved populations, ultimately improving HF management.

II. METHODS

A. Overview: Stakeholder identification

This study was conducted in collaboration with clinical sites from the Netherlands, Spain, Czech Republic and Peru, as detailed in Table I.

TABLE I. CLINICAL SITES INCLUDED IN THE STUDY.

Country	*Name of clinical site*	*Type of clinical site*
Netherlands	*Amsterdam Universitair Medisch Centrum*	University hospital
Netherlands	*Universitair Medisch Centrum Utrecht*	University hospital
Spain	*Fundació Hospital Universitari Vall d'Hebron*	University hospital
Czech Republic	*Fakultní nemocnice u sv. Anny v Brně*	University hospital
Peru	*Instituto Nacional Cardiovascular Peru*	Specialized cardiology center

In collaboration with social innovation experts, we conducted a detailed stakeholder mapping to identify the key stakeholders for our study. We identified seven groups: (1) healthcare professionals, (2) patients and caregivers, (3) hospital administration, (4) ethics and regulators, (5) policymakers and health authorities, (6) AI developers and industry and (7) payors. Representatives from each group were selected based on their experience and expertise. Upon selection, they participated in stakeholder engagement activities, including co-creation workshops, local groups, narrative interviews, and surveys to ultimately compile a list of requirements for our study.

B. Co-creation workshops

Four online co-creation workshops, each lasting two hours, were conducted with clinicians from the Netherlands, Spain, Czech Republic, and Peru between June and November 2023. Using the online platform MURAL (Fig. 1), clinicians used digital sticky notes to map the care pathways for HF patients at each site. Clinicians specified per category (pre-diagnosis, diagnosis, management and hospitalization) the care pathway steps, stakeholders involved, healthcare institutions, timing and the intended use of AI-driven prediction tools. Specifically, for the pre-diagnosis step, different entry-points were specified, allowing for the differentiation between 1) diagnosis suspicion at primary care facilities, 2) general etiology assessment and confirmation through tests at secondary care facilities, and 3) complex and special HF-diagnosis at tertiary care facilities.

Between September and October 2023, patient-focused workshops were held in Lima (n=15 patients) for the Latin American site and in Brussels (n=14 patients) for the European sites. These sessions were structured to 1) define patient needs, 2) identify preferences of use for AI tools in HF treatment and 3) gather input on data privacy, human-into-the-loop approaches and educational support.

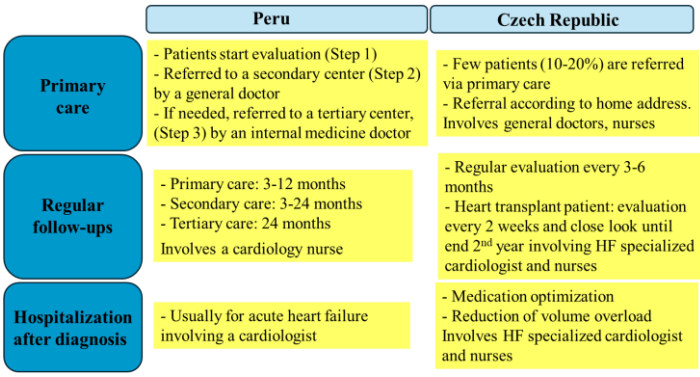

Fig. 1. Scheme of a section of the MURAL for Peru and the Czech Republic, as an example.

In November 2023, an online workshop on ELSI of the AI tool was held with 2 Health Technology Assessment (HTA) experts, 7 ELSI experts, 3 clinicians, and 5 patients. Tailored breakout sessions for each group fostered in-depth discussions to gather regulatory requirements, while a plenary session provided patients with insights into the ethical and regulatory dimensions of AI.

Finally, in May 2024, a multi-stakeholder workshop was held in Lisbon with 28 experts, including 12 healthcare professionals, 6 social scientists, 6 patients, and 4 AI experts. The workshop presented the main clinical, patient, and ethical requirements gathered over the past year and focused on interactive sessions (e.g., subgroups with Mentimeter questionnaires and collaborative boards) to further assess AI-driven tools for HF treatment.

C. Local sessions with patients and healthcare professionals

We established multi-stakeholder local groups in the Netherlands, Spain, Czech Republic, and Peru, primarily consisting of healthcare professionals and patients. Each site conducted an initial in-person meeting at their clinical locations and will continue to meet three times per year until 2027 to re-evaluate gathered requirements. In total, the groups included 19 patients, 12 cardiologists, 7 clinical nurses (including 4 specializing in HF), 2 family members/caregivers, and 1 research assistant.

D. Narrative interviews

We conducted 1-hour online interviews with 6 European HTA experts specialized in medical devices and European health regulations. After an introductory presentation on our study, each expert was asked a series of 9 questions. These questions sought feedback on our study approach and the optimal methods for evaluating our AI tool. Discussions included identifying key predictors, strategies for calibration and ensuring the tool's generalizability, and measures to mitigate biases. Importantly, experts provided insights on adapting the AI tool to different contexts (e.g., Netherlands vs. Peru) and integrating it into existing HF care pathways.

E. Surveys

A questionnaire was evaluated by HF experts using a 1-to-5 scale to determine key clinical priorities, needs, and

expectations. This assessment refines the requisites to engage HF specialists effectively and gather authentic feedback on preferred settings for using HF prediction tools, while matching each requirement to the FUTURE-AI principles.

III. RESULTS

A. Clinical requirements for AI tools

Through the local group discussions and co-creation sessions, we gathered clinical requirements for AI tools in HF management. This included identifying preferred settings of use, desired outcomes, and relevant predictors specific to the AI tool across the four study countries (Table II).

TABLE II. CLINICAL REQUIREMENTS FOR AI-DRIVEN HF PREDICTION ACROSS COUNTRIES.

	Care Settings	Focus Areas	Suggested Key Predictors
Netherlands	Secondary and Tertiary	Treatment response, quality of life, mortality, hospitalization, adverse cardiac events, identify undiagnosed HF patients and referral	Clinical laboratory imaging (general and specific) and multi-disciplinary team discussions
Spain	Primary, Secondary and Tertiary	Mortality, adverse cardiac events, identify undiagnosed HF patients, prognostic tests, and various follow-up measures	Clinical laboratory imaging (general and specific), demographics, comorbidities, electrocardiogram, blood and chest X-ray tests, and patient reported outcome measures
Czech Republic	Primary, Secondary and Tertiary	Mortality, hospitalization, renal failure, and advanced HF progression	Clinical laboratory imaging (general and specific) and laboratory, and oedemas, crackles
Peru	Secondary	Mortality, hospitalization, adverse cardiac events, renal failure, need for heart transplant or device, and adherence to medication	General clinical laboratory tests and imaging

Clinicians in the Netherlands, Spain, and Czech Republic propose to integrate the AI tool across various care settings, emphasizing secondary and tertiary care, while those in Peru focused on secondary care only. Clinicians in European countries show a broader range of focus areas, such as quality of life, identifying undiagnosed patients, and specific follow-up measures. In contrast, clinicians in Peru prioritize assessing the need for heart transplant or devices and the patient adherence to medication. Clinicians in European countries use a diverse set of key predictors, including demographics, comorbidities, and detailed imaging tests, whereas those in Peru rely more on general clinical laboratory tests and imaging, with less diversity in predictive parameters. In addition, in Europe, there is a significant emphasis on integrating these tools within the existing clinical workflow to ensure incorporation into daily practice. Furthermore, the tools need to be flexible, allowing for personalization to meet individual patient needs and integrating diagnostic, prognostic, and monitoring functionalities.

It is worth noting that minor variations are also apparent across the three European countries (e.g., focus areas, suggested key predictors), which shows the critical importance of contextualizing the requirements for effective, usable and impactful AI tools in every local health context.

B. Ethical and regulatory requirements

Similarities and differences in ethical and regulatory requirements for expected use of AI-based HF treatment tools have been identified between Europe and Latin America (Table III).

TABLE III. DESCRIPTION OF ETHICAL AND REGULATORY RISKS BETWEEN EUROPE AND LATIN AMERICA.

General similarities between Europe and Latin America		
Data Privacy	***Trust and Reliability***	***Accessibility***
Concerns about data privacy and the need for control over patient information	Preference of tools endorsed by health organizations and with regulatory oversight	Easy-to-use AI tools with clear benefits in disease managing (e.g., reminders) for universal use
Specific differences between Europe and Latin America		
Europe: • Mostly focused on sex, ethnicity and socio-economic status as sources of bias • Ensuring data privacy by regulations (e.g., AI act, General Data Protection Regulation (GDPR)) • Increase data sharing to improve AI algorithm for prediction		
Latin America: • Altitude is a potential source of AI bias • Context-specific ethics and strong national oversight • Ensure data security by maintaining confidentiality and prohibiting unauthorized data sales or data misuse • Improve patient digital/healthcare literacy to make informed decisions		

The results show that stakeholders in both Europe and Latin America prioritize data privacy, trust in health-endorsed AI tools, and accessible disease management through user-friendly interfaces. Regarding potential AI biases, stakeholders in Europe mainly focus on mitigating biases related to sex, ethnicity, and socio-economic status. In contrast, stakeholders in Latin America identified altitude as a potential source of AI bias due to the country's specific geography, while emphasize context-specific ethics and robust national regulatory oversight to prevent data misuse. Enhancing patient digital literacy was also identified as a priority for informed decision-making in healthcare.

C. Requirements for trustworthy

We systematically organized the gathered requirements according to the FUTURE-AI principles (*i.e.* fairness, universality, traceability, usability, robustness, explainability) [6] to facilitate the development of trustworthy, efficient, and human-centered AI tools in healthcare throughout Europe and Latin America. Table IV synthesizes the most essential recommendations for each guiding principle, as derived from the surveys, narrative interviews, co-creation workshops, and local group discussions conducted in both Europe and Latin America.

TABLE IV. SUMMARY OF THE MOST RELEVANT FUTURE-AI PRINCIPLES WITH REQUIREMENTS AND RATIONALES

FUTURE-AI principles		
Principle	***Requirement***	***Rationale***
Fairness	AI-based solutions must be non-discriminatory, ensuring inclusivity, transparency, and fairness in their decision-making processes	Meeting ethical imperatives ensures that AI operates ethically, securely and reliably
	Patients with low digital literacy shall not be discriminated in their treatment with clinical decision support system	Patients fear that those with low digital literacy may face discrimination with the use of new AI-driven care tools.
Universality	The AI tool should follow reporting guidelines based on the latest expert consensus methodologies (e.g., MI-CLAIM, MINIMAR)	Following consensus methodologies ensures AI tools meet universal standards of transparency, reliability, and reproducibility, promoting global consistency and trust in evaluation and reporting
Traceability	Patients using treatments with AI-driven tools want to be able to decide whether their data can be used for research purposes	Patient data has various uses, so patients must be well informed. Consent for treatment should be separate from research data consent
Usability	The decision on treatment should be made collaboratively between doctor and patient. AI should enhance the doctor-patient interaction, without replacing the human touch	Patients desire shared decision-making and believe doctors should oversee AI as a quality control measure, yet they fear technology may replace the human touch in healthcare
Usability	AI tools should undergo rigorous randomized clinical trials that include diverse patient populations, relevant clinical scenarios, and comprehensive assessment of safety, effectiveness, and performance metrics in real-world healthcare settings	Well-designed randomized clinical trials are essential to validate AI tools' safety and efficacy in real-world settings, requiring collaboration to enhance data diversity, patient representation, and integration of data types
Robustness	Clinicians adjust inputs such as electrocardiogram, lab results, patient history, and heart measurements. The AI tool must manage missing data and accurately assess performance across diverse inputs	Clinicians manage outputs from tools such as electrocardiograms, lab results, patient histories, and heart measurements, considering reliability across settings to determine values for risk prediction
Explainability	Clinicians must uphold the "right to explanation" under data regulations, starting with informed consent procedures and throughout the entire lifecycle	The AI must transparently explain decisions, adhering to data regulations and addressing the "right to explanation" in informed consent
	Patients expect their doctors to clarify the decisions made by AI tools	Patients are concerned about transparency with AI algorithms no longer set by humans, which complicates doctors' ability to explain decisions to patients

IV. DISCUSSION

Stakeholder engagement across Europe and Peru has clarified context-specific requirements crucial for successful AI integration in HF prediction. This effort highlighted regional nuances in healthcare delivery and universal priorities such as trustworthiness and accessibility in AI-driven solutions. Our study advocates a human-centered approach to AI development, aligning with local healthcare practices and patient needs, which is essential for enhancing HF management and addressing healthcare disparities to promote equitable access to effective solutions. Continuous involvement of diverse stakeholders throughout the project lifecycle—from proposal writing to AI tool deployment—is vital to ensure the usability and adoption of AI innovations by healthcare providers, maximizing their impact on patient outcomes.

Adhering to FUTURE-AI principles provides a structured framework for developing trustworthy AI for HF management, promoting fairness, universality, traceability, usability, robustness, and explainability. These principles, shaped by input from stakeholders including clinicians, patients, ethicists, and regulators, guide AI development to enhance clinical decision-making and ensure adherence to ethical standards essential for acceptance and integration into healthcare systems.

In conclusion, our approach bridges cutting-edge AI innovations with diverse healthcare needs, facilitating equitable access to effective HF management worldwide while addressing local disparities to improve global health outcomes. Differences with other Latin American countries may include varying healthcare infrastructures, cultural attitudes toward technology, and differing regulatory environments, impacting the implementation and effectiveness of AI solutions. Future research should be extended to other countries to further validate these findings and capture additional regional variations.

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