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THE IMPACT OF ARTIFICIAL INTELLIGENCE (AI) INNOVATIONS IN CARDIOLOGY: A COMPREHENSIVE REVIEW OF CLINICAL EFFECTIVENESS, ETHICAL CHALLENGES, AND SOCIO-SYSTEMIC IMPLICATIONS

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ABSTRACT

The aim of this review article is to provide an in-depth analysis of the current state of knowledge on the use of Artificial Intelligence (AI) in cardiology. We place particular emphasis on actual clinical effectiveness and the technological, ethical and social consequences of its implementation in healthcare systems. The review is based on carefully selected literature from 2018–2025, which was searched in the PubMed, Scopus and Web of Science databases, focusing on four key dimensions: technology, clinical practice, ethics and healthcare systems. AI (ML, DL) algorithms offer revolutionary potential in diagnostics (e.g., LVEF automation) and risk prediction (e.g., identification of hidden phenotypes in ECG). However, their implementation has often stalled due to critical non-clinical barriers. Among these, we identified: the problem of Explainability (XAI), which undermines legal accountability (especially with adaptive SaMD models); Algorithmic Bias, resulting from underrepresentation of training data, carrying the risk of exacerbating health inequalities (Health Equity); as well as serious systemic obstacles related to the need for continuous regulatory oversight (e.g., AI Act) and staff retraining. In order for us to reap the medical benefits of AI in a fair and safe manner, we urgently need policy recommendations on model validation across diverse cohorts, the development of transparent XAI architectures (rather than post-hoc methods), and the creation of flexible regulatory frameworks and educational programmes at the system level.

KEYWORDS

Artificial Intelligence (AI), Cardiology, Explainable AI (XAI), Algorithmic Bias, Health Equity, Healthcare Systems

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1. Introduction

1.1. Context and Medical Issues: Global Burden of Cardiovascular Diseases

Cardiovascular diseases (CVD) remain the greatest public health challenge worldwide, being the leading cause of death (World Health Organisation, 2024). The growing burden of CVD is the result of a complex interaction of demographic factors, such as ageing populations, and behavioural and environmental factors, including increases in obesity, diabetes and sedentary lifestyles. This multifactorial etiology requires innovative, radical changes in the ways we diagnose, predict and manage risk. Effective control of NCDs today requires not only pharmacological advances, but above all early, accurate diagnosis and personalised risk assessment (Johnson et al., 2024).

Contemporary cardiology, especially in advanced healthcare systems, faces the problem of information overload (Big Data). This data comes from advanced imaging techniques (ECHO, CT, MRI), continuous ECG monitoring, wearables, and extensive Electronic Medical Records (EMR). Even the best and most experienced clinicians find it difficult to efficiently process these huge data sets to draw optimal clinical conclusions. Therefore, there is an urgent, systemic need for tools that can aggregate, process and interpret this data on an unprecedented scale and complexity.

1.2. The Rise of AI as a Technological Innovation and a Tool Changing the Face of Medicine

Artificial Intelligence (AI), specifically its subfield of Deep Learning (DL), has emerged as a natural response to these challenges. These methods have revolutionised the analysis of complex biological signals and medical images, offering the opportunity to transform cardiology from a reactive model to a predictive model (Maron et al., 2023; Ristovski et al., 2023).

Groundbreaking research in recent years has shown that DL algorithms are capable of achieving, and in some cases even surpassing, the accuracy of a cardiologist in tasks such as the automatic detection and classification of arrhythmias in ECG recordings (Attia et al., 2021) and the precise segmentation and

quantification of cardiac parameters in echocardiography (Ouyang et al., 2020; Topol, 2024). The potential of AI goes far beyond automation alone. AI allows for the discovery of subtle, hidden biomarkers (so-called hidden phenotypes) in standard tests (e.g., in a seemingly normal ECG), enabling the prediction of cardiovascular events (e.g., the development of heart failure or atrial fibrillation) long before clinical symptoms appear (Attia et al., 2021). This dynamic technological progress makes AI a transformative technology. However, like any technological revolution in medicine, its full implementation is a multidimensional process, generating serious challenges at the intersection of technology, ethics and social sciences (Ouyang et al., 2020; Topol, 2024).

1.3. Research Gap: From Effectiveness to Social Justice

Despite undoubted clinical progress, the lion's share of the literature to date is highly technical, focusing on the validation of the algorithms themselves — their AUC, sensitivity and specificity. This focus on algorithmic performance metrics has led to a critical research gap in the systematic analysis and synthesis of non-medical and non-clinical challenges (Topol, 2024). The introduction of autonomous decision-making systems in a field as crucial as cardiology raises fundamental dilemmas:

Ethical and Legal: Who is actually responsible for algorithmic error? How can explainability (XAI) be ensured and patient and clinician trust maintained?

Social and Equity: How can algorithmic error in training data exacerbate health inequalities and exclusion?

Organisational and Regulatory: How should healthcare systems integrate costly technology into existing infrastructure, and how should regulations be adapted to certify adaptive AI models?

It is this interdisciplinary gap, lying at the intersection of technology and society, that is the main focus of this article.

1.4. Purpose and Structure of the Article

The purpose of this Synthetic Review Article is to provide a comprehensive synthesis of the literature that not only critically analyses the clinical effectiveness of AI in cardiology, but above all focuses on the technological, ethical and socio-organisational implications of its implementation at the system level, providing a solid knowledge base for clinicians, policy makers and researchers alike. The structure of the article is presented in a way that allows for easy navigation and provides a clear overview of the main points of the article. ethical and socio-organisational implications of its implementation at the system level, providing a solid knowledge base for clinicians, policy makers and researchers alike. The structure of the article is as follows:

Section 2 (Methodology): Describes in detail the structured literature review strategy that led us to these conclusions.

Section 3 (Clinical Applications): Maps the main areas of AI transformation in cardiology (imaging, electrophysiology), establishing the context for further discussion.

Section 4 (Key Implications): Constitutes the core of the analysis, discussing in detail the ethical (XAI, accountability), social (algorithmic error, inequality) and organisational (costs, digital literacy, regulation) challenges.

Section 5 (Conclusions): Provides a synthetic summary, discusses the limitations of the review, and formulates key recommendations for future research and public policy on AI technology management in health.

2. Methodology

This review article is synthetic and narrative, based on qualitative criteria and focusing on the interdisciplinary implications of implementing Artificial Intelligence (AI) in cardiology.

2.1. Time Criteria and Databases

The review is based on literature published between 2018 and 2025. The choice of this time frame is strategic, as these years represent a period of rapid growth and commercialisation of Deep Learning (DL) techniques in medicine. The analysis focuses on publications indexed in three major databases: PubMed, Scopus, and Web of Science.

2.2. Search Strategy

To ensure comprehensiveness and relevance, a combination of keywords focusing on four main dimensions (technology, clinical practice, ethics, healthcare systems) was used:

Technology and Clinical Practice: (“Artificial Intelligence” OR “Machine Learning” OR “Deep Learning”) AND (“Cardiology” OR “Cardiovascular Disease” OR “Electrocardiogram” OR “Echocardiography”).

Ethics and Equity: AND (‘Ethics’ OR ‘Algorithmic Bias’ OR ‘Fairness’ OR ‘Explainable AI’ OR ‘XAI’).

Healthcare Systems: AND (‘Healthcare Systems’ OR “Implementation” OR ‘Cost-Effectiveness’ OR ‘Physician Trust’).

2.3. Inclusion and Exclusion Criteria

Inclusion Criteria: We included full research articles, comprehensive systematic reviews, meta-analyses, and positions of ethics committees and cardiology societies (e.g., JACC, AHA, ESC) that directly discussed the use of AI (ML/DL) algorithms in the diagnosis, prognosis, or treatment of CHD, with a clear emphasis on implications beyond pure technical effectiveness.

Exclusion Criteria: Conference abstracts, unreviewed preprints, articles focusing exclusively on basic IT techniques without clinical application, and publications outside the specified time frame were excluded.

2.4. Data Selection and Extraction Process

The literature selection process was conducted according to a structured screening procedure. The initial phase consisted of reviewing titles and abstracts for their relevance to technological, clinical, and societal issues. In the next stage, a full evaluation of selected articles was performed.

Data extraction involved identifying key information: type of AI application (e.g., ECG, Echo), effectiveness measures obtained (e.g., AUC, Accuracy), identified ethical/social barriers (e.g., black box problem, algorithmic error), and systemic challenges (e.g., costs, staff competencies). The collected data was used to create a synthetic narrative synthesis.

3. Clinical Applications of AI: Potential for Innovation

The application of artificial intelligence in cardiology – especially deep learning (DL) methods – is essentially a paradigm shift that goes beyond simple process improvement. It enables real standardisation, automation and, most importantly, the discovery of pathophysiological patterns that have remained hidden until now. This section of the article takes an in-depth look at where exactly AI's transformative potential is greatest in cardiac diagnostics.

3.1. AI in Cardiac Imaging Analysis (Echocardiography, CT and MRI)

Cardiac imaging – including echocardiography (ECHO), computed tomography (CT), and magnetic resonance imaging (MRI) – is a pillar of diagnostics, but it has its traditional drawbacks: it is time-consuming, highly operator-dependent, and inevitably burdened by subjective measurement variability (Ristovski et al., 2023). The implementation of DL is a direct response to these issues, introducing much-needed standardisation and automation of the entire analytical process (Gevaert et al., 2023).

3.1.A. Echocardiography (ECHO) – Automation and Standardisation

Echocardiography, while the most readily available and non-invasive imaging method, is also the most prone to subjective interpretation (Johnson et al., 2024). AI models, trained on huge, diverse video datasets, now achieve accuracy that is comparable to, and sometimes even better than, that of highly experienced sonographers (Ouyang et al., 2020; Cheng et al., 2023).

Automatic Segmentation and Parameter Measurement: DL algorithms, typically using convolutional neural networks (CNN), can segment heart chambers (LV, LA, RV) in near real time. Systems such as EchoNet-Measurements dramatically reduce the time required for post-processing, enabling almost immediate acquisition of key geometric and functional parameters (Ouyang et al., 2020).

Left Ventricular Ejection Fraction (LVEF) Assessment: This is the most critical parameter for assessing cardiac systolic function. Since traditional methods are prone to high variability, AI introduces necessary standardisation here. Studies show that DL-assisted LVEF assessment achieves an intraclass correlation coefficient (ICC) exceeding 0.90, effectively reducing discrepancies with technician assessments and

approaching the ‘gold standard’ — cardiac magnetic resonance imaging (CMR) (Narayanaswami et al., 2023). From an organisational perspective (Krittanawong et al., 2023), this allows for significantly faster analysis of large patient cohorts.

3.1.B. Computed Tomography and Cardiac Magnetic Resonance Imaging (CT/MRI) – Efficiency and Risk Assessment

For more advanced techniques such as CMR and CT, AI focuses primarily on improving the efficiency of data acquisition and detecting prognostic biomarkers (Slomka et al., 2022; Wu et al., 2023).

Automatic Analysis and Reduction of Examination Time: In the case of MRI, DL is used to reconstruct images from incomplete data (undersampling) (Slomka et al., 2022). Reducing the acquisition time of MRI images is absolutely crucial for patient comfort and laboratory efficiency, which has a direct impact on operating costs.

Detection of Unstable Plaques and MACE Risk: AI algorithms are revolutionising the analysis of Coronary Computed Tomography Angiography (CCTA). The models can automatically segment coronary vessels and, more importantly, accurately quantify the characteristics of atherosclerotic plaques, enabling the identification of unstable plaques (Williams et al., 2024). Machine learning (ML) models combine CCTA and MRI data to build personalised models for predicting major adverse cardiovascular events (MACE), achieving an AUC above 0.85, which means higher precision than traditional risk scales (Williams et al., 2024).

Opportunistic Detection of Systemic Diseases: Interestingly, AI opens up opportunities for the incidental detection of significant non-cardiac changes (such as lung nodules, fatty liver, or spinal osteoporosis) on standard chest CT and MRI scans. This opportunistic detection has broad implications for public health (Topol, 2023).

3.2. AI in Electrophysiological Diagnostics and Risk Stratification

The analysis of electrocardiograms (ECG) – a basic, non-invasive tool – has gained a whole new depth thanks to deep learning (Pienta et al., 2023). In this area, AI is not limited to automating interpretation, but has primarily demonstrated the ability to detect hidden phenotypes and prognostic patterns that are simply invisible to the human eye (Johnson et al., 2024).

3.2.A. Automatic Arrhythmia Detection and ECG Interpretation

Cardiologist Effectiveness in Arrhythmia Detection: DL models (often RNN or CNN), trained on millions of ECG recordings, match or exceed experienced cardiologists in the automatic detection and classification of various arrhythmias, including Atrial Fibrillation (AF) (Attia et al., 2021). Groundbreaking research has shown that a DL algorithm designed to detect 12 types of arrhythmias achieved an AUC of 0.97, which is an expert-level result (Attia et al., 2021; Johnson et al., 2024).

Detection of Preclinical Condition (Hidden AF): The most exciting application is the unique ability of algorithms to identify patients who will develop atrial fibrillation (AF), even though their ECG is in normal sinus rhythm at the time of testing (Attia et al., 2021; Johnson et al., 2024). The mechanism involves capturing subtle, irregular ECG features that are early signals of impending AF. In a cohort study, an impressive AUC of 0.87 was achieved in predicting incident AF, which is crucial for early stroke prevention (Attia et al., 2021).

3.2.B. Hidden Phenotypes and Risk Prediction

AI treats ECGs as a rich source of systemic data, going beyond simple rhythm classification to predict complex medical conditions (Johnson et al., 2024).

Heart Failure (HF) Prediction: Studies have shown that AI models can analyse ECGs and predict future heart failure (HF), even in a group of patients whose traditional ECG recordings showed no abnormalities (Khera et al., 2023). This was achieved by detecting subtle, almost imperceptible changes in signal morphology and complexity.

Stratification of Sudden Cardiac Death (SCD) Risk: Work is underway to use AI to improve patient risk stratification, especially after a heart attack, to more accurately predict who is at highest risk of Sudden Cardiac Death (SCD) (Noseworthy et al., 2022; Jollis et al., 2023).

Predicting Non-Cardiac Conditions: AI models can analyse ECGs to detect, for example, elevated blood potassium levels (hyperkalaemia) (Topol, 2023) (e.g. with AUC 0.85) or the risk of diabetes. This ability to extract systemic information from a single routine ECG test best illustrates the transformative potential of AI.

3.3. AI in Telecardiology and Remote Monitoring

The rise in popularity of wearables and remote patient monitoring (RPM) has created a huge new stream of data for AI in cardiology. This technology enables continuous, passive data collection, taking diagnostics beyond the hospital walls (Topol, 2023; Al-Ghamdi et al., 2024).

Incidental Detection and Screening: AI algorithms play a key role in filtering the vast, often unstructured data streams generated by RPM (Johnson et al., 2024). They enable the effective detection and screening of critical conditions such as atrial fibrillation (AF) (Attia et al., 2021), often in patients who remain asymptomatic.

Data Quality Challenges: Data from wearable devices is characterised by high noise and variable quality (Topol, 2023). For this reason, AI models must be particularly robust and resilient, which requires the use of advanced DL techniques.

Personalisation of Interventions: In the long term, AI can use this continuous data to build ultra-sensitive, dynamic risk models that allow interventions to be tailored in near real time (Maron et al., 2023). This is the essence of personalised precision medicine.

4. Technological, Ethical, and Social Implications of Implementing AI in Cardiology

Implementing AI in cardiology requires a holistic approach that goes beyond dry clinical accuracy metrics. This section, which forms the core of this review, analyses in detail the intersection of technology, ethics, and society.

4.1. Ethical Challenges and the Problem of Trust

The rapid integration of AI systems in cardiology—from automated ECG interpretation to risk prediction—raises fundamental ethical questions about accountability, clinical trust, and algorithmic transparency. We must resolve these issues before this technology becomes the standard of care (Jollis et al., 2023).

4.1.A. The Fundamental Problem of Explainability ('Black Box')

The most serious dilemma concerns the issue of Explainable Artificial Intelligence (XAI). Deep learning (DL) models, which demonstrate the highest clinical effectiveness in cardiology, often function as a 'black box,' generating a diagnosis or prognosis without providing the cardiologist with an understandable and auditable decision path (Topol, 2024). In clinical practice, this lack of transparency undermines the confidence of medical staff (Holst et al., 2024).

Technical Aspects of XAI in Cardiology: Post-Hoc Methods and Their Limitations: Currently, the dominant approach uses post-hoc methods, i.e., tools that attempt to explain the model's decision after it has been made. The most commonly used in ECG analysis and imaging are SHAP (SHapley Additive exPlanations) and LIME (Local Interpretable Model-agnostic Explanations) (Holst et al., 2024). These methods allow for the visualisation of which pixels in an image (e.g. ECHO/MRI) or time points in a signal (e.g. ECG) contributed most to the final diagnosis (so-called saliency maps). However, these techniques have serious ethical and clinical limitations. Saliency maps often indicate only a region rather than a pathophysiological mechanism. For example, in ECG analysis, the model may focus on artefacts rather than the actual pathology. Furthermore, post-hoc methods do not guarantee that the explanation reflects the actual operation of the 'black box'; they can be unstable and susceptible to manipulation.

Critical Challenge: Quantifying Uncertainty: To maintain clinical trust, AI must provide not only an explanation but also a measure of its uncertainty. In cardiology, an AI decision about the risk of an event (e.g., heart attack, stroke) must be supported by the algorithm's confidence interval. The lack of this information forces the clinician to make a critical decision based on a single, binary (yes/no) or probabilistic (X%) answer, without knowledge of the tool's degree of certainty, which is ethically problematic.

The evolution of XAI – from post-hoc to proper explainability: The physician has an ethical obligation to justify their decision to the patient. Currently used XAI methods are often techniques added after the fact (e.g., saliency maps), which only visualise regions of activation without providing a complete understanding of the mechanism. Ethics and procedural safety require that XAI solutions evolve towards inherently interpretable models that provide clinically relevant attributes and measures of uncertainty quantification, which actually support clinical judgement rather than replace it (European Commission, 2021; Holst et al., 2024).

4.1.B. Complex Legal Responsibility and Physician Autonomy

The lack of algorithmic transparency directly complicates the determination of legal and ethical responsibility in the event of a misdiagnosis (Meskó et al., 2023). In the event of an error, it is difficult to determine whether the fault lies with:

The manufacturer/developer (errors in training data or algorithm).

The medical facility (improper implementation, lack of local validation).

The cardiologist (ignoring AI warnings or blindly following an incorrect suggestion).

The ethical consensus is that the ultimate responsibility lies with the cardiologist who exercises clinical supervision (human-in-the-loop) (European Society of Cardiology, 2024). However, this position generates psychological burden (automation bias – the tendency to over-rely on automated results), which essentially undermines the clinician's autonomy. There is an urgent need for a new regulatory framework that clearly defines the division of responsibility, including the certification and auditing of adaptive AI models that change over time (Meskó et al., 2023).

Regulatory Challenges for Adaptive AI Models (SaMD): Regulations such as the European AI Act (European Commission, 2021) and the FDA guidelines for Software as a Medical Device (SaMD) classify AI algorithms in cardiology as high-risk medical devices. However, traditional certification processes (approval of a fixed product version) are inadequate for adaptive models (learning systems) that learn and change their behaviour after clinical implementation (Liu et al., 2023; Meskó et al., 2023). This challenge requires continuous regulatory oversight. In practice, this means that developers must prove not only the initial effectiveness but also the safety of the model's evolution over time, which entails the need for regular audits (e.g., every 6 months) and recertification, which is both costly and logistically complex (Liu et al., 2023). This impact is most evident in MACE prediction systems, where patient data changes dynamically over time.

4.1.C. Privacy Protection, Sensitive Data and Patient Consent

AI models in cardiology are extremely 'data hungry'; they need access to huge, highly sensitive data sets (Topol, 2023). The collection, aggregation and processing of this data poses serious privacy risks and requires strict compliance with standards such as the European GDPR.

Re-identification Risk: Even after anonymisation, the complexity and uniqueness of cardiology data (e.g., specific ECG patterns or unique heart anatomy in images) pose a risk of patient re-identification, especially when the data is combined with other datasets (a so-called de-anonymisation attack) (Vokinger et al., 2023; Secemsky et al., 2023). This risk is particularly high in telecardiology and wearable devices, which generate a constant, unique stream of location and biological data (Secemsky et al., 2023).

Ethics of Informed Consent: Informed consent must be expanded. Patients must understand what data will be used by AI, by whom, and what the potential risks are – including the risk of misdiagnosis, privacy violations, and potential algorithmic discrimination (Secemsky et al., 2023). Conceptualising consent for data use in machine learning is more complex than traditional consent for a medical procedure because it is not known in advance how the algorithm may evolve and what new research goals may emerge. Therefore, ethicists are calling for a shift to dynamic consent, which gives patients ongoing control over their data (Zhang et al., 2024).

4.2. Social Issues and Data Equality (Health Equity)

The implementation of AI in cardiology, although technologically progressive, carries the risk of unknowingly exacerbating existing health inequalities, thus becoming the subject of critical analysis.

4.2.A. Algorithmic Bias and Discrimination

The most significant social challenge is the problem of algorithmic bias (Algorithmic Bias) (Ghassemi et al., 2023). These errors almost always result from uneven and historically biased distribution of training data (European Commission, 2021).

Mechanisms of Error in Cardiology: Error is not a problem inherent to AI itself, but rather a problem with the data on which it is trained. In cardiology, the lack of representation is multidimensional:

Geographical/Economic Error: Models are often trained on data from highly specialised, large academic centres (e.g., the US/Western Europe). This data does not reflect the diversity of the global population, nor does it take into account differences in hardware infrastructure and data acquisition protocols in smaller hospitals (Wu et al., 2023; Rajkomar et al., 2024).

Ethnic/Racial Bias: Studies have shown that ECG and imaging algorithms may exhibit lower sensitivity and specificity in ethnic minorities because training sets were predominantly based on Caucasian populations (Ghassemi et al., 2023; Wu et al., 2023). For example, differences in cardiac anatomy and CHD evolution between racial groups (related to genetic factors, but mainly socioeconomic factors) can lead to model decalibration.

Clinical Error (Labeling Bias): If the input data (e.g., ECHO image) is clinically labelled (e.g., ‘heart failure’) by clinicians who themselves use traditional, error-prone methods, then AI learns and perpetuates this historical error (Zeleznikow et al., 2023).

Clinical Consequences of Inequality: The result is poorer performance and lower accuracy of AI in diagnosing and predicting risk in marginalised groups. This disparity leads to unequal quality of care and is a clear violation of health equity (Wu et al., 2023).

Requirement for Fairness Audits and Mitigation Measures: It is necessary to establish social and regulatory interventions (Zeleznikow et al., 2023). The AI model should undergo a Fairness Audit before and after implementation to assess whether its calibration and precision are consistent across all relevant demographic subgroups (Zeleznikow et al., 2023). This includes validation for equal opportunity and equal true positive rates across different groups. Error mitigation strategies include techniques such as data re-weighting, data synthesis to better balance training sets, or the use of fairness-aware algorithms that minimise discrimination during training (Ghassemi et al., 2023).

4.2.B. Unequal Access to Technology (Digital Divide)

AI is an expensive technology based on advanced digital infrastructure, which carries the risk of widening the digital divide in access to healthcare (Sacks et al., 2023).

Geographical and Economic Disparity: The latest AI-based diagnostics are often only available in large, affluent urban centres or in high-income countries (Zeleznikow et al., 2023). This excludes residents of rural areas or low-resource regions, where not only equipment is lacking, but also the high network bandwidth necessary to transfer large image data sets to the cloud. This barrier is one of the key determinants of global health inequality in terms of access to advanced cardiology (Rajkomar et al., 2024).

Digital Competence Barrier: Digital exclusion affects older people and those with lower digital literacy (Sacks et al., 2023). This hinders the implementation of AI-based telecardiology and monitoring solutions that require active interaction with a device or application (Secemsky et al., 2023). Social acceptance and successful implementation of AI require health policy to actively invest in digital infrastructure and patient education (Maron et al., 2023).

4.2.C. Social Acceptance and Patient Trust

The ultimate success of AI implementation in cardiology depends on public trust and acceptance by patients and medical staff (Al-Ghamdi et al., 2024).

I. Risk Perception and Patient Education: Patients often perceive AI systems as a “black box”, which naturally leads to concerns about lack of control and accountability (Al-Ghamdi et al., 2024). If patients do not trust the security and purposes of processing their sensitive cardiological data (Zhang et al., 2024; Holst et al., 2024), they may actively refuse to participate in AI-based diagnostic tests. Educational interventions (increasing digital health literacy) are essential to clearly explain to patients how AI works, its benefits, and its limitations (Althubaiti, 2024).

II. The Role of Organisational Culture and Ethical Design: Equally important is the acceptance of AI by physicians. Physicians do not trust systems that do not provide explanations (XAI) or that are not adapted to the clinical workflow (Attia et al., 2021; Williams et al., 2024). Cardiologists must believe that an algorithm that has been trained at another centre will remain effective in a local, diverse population (Topol, 2023).

The Human-in-the-Loop Challenge: Effective ethical AI interface design must take into account the role of the clinician as the ultimate decision-maker (human-in-the-loop). Software must support critical judgement rather than encourage errors resulting from over-reliance on automation (automation bias) (Holst et al., 2024). Achieving this balance requires research into the psychology of medical decision-making so that the AI interface properly calibrates the physician's level of attention and critical thinking, minimising the risk of both negligence (failing to notice an AI error) and overconfidence (Holst et al., 2024).

4.3. Impact on the Healthcare System and Required Competencies

The implementation of AI in cardiology is a process that requires profound organisational changes. It generates significant challenges in terms of health economics, IT integration and the redefinition of the professional roles of medical staff (Maron et al., 2023).

4.3.A. Health Economics and Implementation Challenges (ROI)

Investments in AI infrastructure are significant and constitute a natural barrier to entry (Krittanawong et al., 2023).

Initial Costs vs. Long-Term Savings: A key organisational challenge is proving return on investment (ROI) (Althubaiti, 2024). Although AI can generate significant savings through automation (e.g., reducing image analysis time) and improved risk prediction (e.g., preventing costly MACEs), the initial costs of purchase, integration, and local validation (necessary due to potential bias) are high (Krittanawong et al., 2023). Decision-makers must make a precise economic assessment, focusing on the total cost of ownership (including licensing, maintenance, training and auditing costs).

Integration with Electronic Health Records (EHR): The main organisational barrier is the integration of AI systems with existing, often incompatible or fragmented IT systems (legacy EHR systems) (Wang et al., 2024). For an AI model to work effectively, it needs continuous access to high-quality, structured data from EHRs, which often requires costly and time-consuming modifications to interfaces and standardisation of coding standards (e.g., SNOMED CT, LOINC). The lack of seamless integration not only discourages implementation, but also creates a technological 'island' effect that minimises the clinical usefulness of AI in everyday work.

4.3.B. Redefining Roles and Required Competencies (Digital Literacy)

The introduction of AI leads to an inevitable professional transformation in cardiology, requiring medical staff to acquire new digital skills and competencies (Chen et al., 2023).

Digital Competencies for Physicians: Cardiologists must possess advanced digital literacy to effectively supervise, interpret algorithm results, and critically evaluate their reliability and limitations (e.g., interpret confidence measures) (Chen et al., 2023). Medical curricula must be urgently updated to include topics such as the fundamentals of data science, AI ethics, and human-machine interaction. The new cardiologist is an 'AI-augmented clinician' who must be able to distinguish correlation from causation in algorithm results (Topol, 2023).

Impact on Support Staff: AI can take over a significant portion of technicians' routine tasks, giving staff the opportunity to shift their focus to direct patient interaction and more complex tasks (Wang et al., 2024). However, there is concern about automation and job losses, which requires active communication and staff retraining programmes.

4.3.C. Regulatory Challenges and Standardisation

The need for a stable and adaptive regulatory framework is a key organisational factor that determines the pace and safety of AI adoption (European Commission, 2021).

Certification and Validation of AI as a Medical Device: AI systems in cardiology are treated as medical devices (software as a medical device, SaMD) and must undergo rigorous validation and certification processes (e.g., by the FDA in the US, CE in the EU) (European Commission, 2021). The inadequacy of traditional certification paths for adaptive, learning AI models slows down innovation and forces new mechanisms of continuous regulatory oversight (European Commission, 2021). The AI Act (EU) classifies AI in medicine as a high-risk system, imposing an obligation of continuous monitoring and strict requirements for Explainability (XAI) and Data Quality Management (European Commission, 2021).

The need for data standardisation: Effective implementation of AI requires standardisation of methods for collecting, storing and labelling cardiological data at the international level. The lack of uniform protocols hinders data exchange, validation across different centres (crucial for detecting algorithmic bias) and increases integration costs (Wang et al., 2024). It is necessary to promote open, federated databases that allow AI training without the need for physical transfer of sensitive data (Federated Learning technology).

4.4. The Impact of AI on Interventional Cardiology and Surgical Procedures

The implementation of AI also affects those areas of cardiology that require precise planning and real-time support (Noseworthy et al., 2022).

Decision Support in Ablation: In electrophysiology, AI can analyse complex 3D electroanatomical maps, identifying critical points of inflammation, which increases the precision of the procedure and reduces the risk of complications (Noseworthy et al., 2022). AI models can analyse voltage maps and heart activation patterns with greater objectivity than the human eye, helping to locate the substrate of arrhythmia (Noseworthy et al., 2022). AI acts as an advanced decision support system (DSS) in this context.

Planning and Simulations (Structural Cardiology): In structural cardiology (e.g., TAVI valve implantation), AI analyses CT images to automatically measure the geometry and anatomy of the heart (Slomka et al., 2022; Tsiftaris et al., 2024). Deep learning models are used to precisely measure the dimensions of the aortic valve ring, the aortic angle and the distance from the coronary ostia, which is crucial for selecting the optimal size and type of implant and minimising the risk of complications (e.g. mitral valve damage or coronary stenosis). This enables precise planning and virtual simulations of the procedure (Slomka et al., 2022).

Safety Challenges: Introducing AI into the interventional environment places the highest demands on reliability and safety (safety-critical systems) (Meskó et al., 2023). An error in the planning algorithm or a mistake in real-time image interpretation can have immediate, catastrophic consequences for the patient, placing double emphasis on certification, validation and continuous supervision of these systems (Jollis et al., 2023). In this context, explainability (XAI) becomes not only an ethical requirement but also a procedural safety requirement, as the clinician must be able to quickly and logically understand why the system has made a particular suggestion in order to verify or reject it.

5. Conclusions, Limitations, and Suggestions

The implementation of Artificial Intelligence (AI) in cardiology is one of the most important breakthroughs in digital medicine, with the potential to fundamentally transform the diagnosis, risk prediction, and management of cardiovascular diseases (Jollis et al., 2023; Collins et al., 2023). This review confirms that AI algorithms are already achieving and even surpassing the competence level of cardiologists in routine tasks, paving the way for predictive and preventive medicine based on the discovery of hidden phenotypes (e.g., in ECG recordings and MRI images).

5.1. Summary of Key Findings and Bifocal Analysis

The main conclusions of the review focus on the bipolar nature of this innovation, highlighting both its technological maturity and the accompanying societal challenges:

Clinical and Organisational Potential: AI effectively automates and standardises diagnostic measurements, reducing variability in results (e.g., LVEF in ECHO) and reducing the workload on clinicians. This translates into direct organisational benefits – increased laboratory throughput, reduced diagnosis time and efficient use of resources. AI's proven ability to identify risk long before symptoms appear (e.g., occult AF in sinus rhythm) is changing the paradigm of care.

Ethical, Social and Regulatory Barriers: The full, safe and fair implementation of AI is limited by significant non-clinical challenges that must be addressed at the level of public policy and health organisations:

Ethics (Trust and Accountability): The critical issue of explainability ('black box') undermines clinician trust and fundamentally complicates the determination of legal liability for algorithmic error (Topol, 2024; Meskó et al., 2023). The development of XAI is therefore not only an ethical requirement, but also a procedural safety requirement.

Society (Fairness): Algorithmic errors resulting from inequalities in training data pose a real risk of exacerbating existing inequalities in access and quality of care for marginalised groups, undermining the principle of Health Equity (Wu et al., 2023; Rajkomar et al., 2024). The need to conduct an Audit of Fairness is imperative.

Organisation (System): Systemic integration with existing EDM systems, high initial costs (ROI) and the urgent need to retrain medical staff in digital skills (Chen et al., 2023) remain key organisational barriers (Wang et al., 2024; Zeleznikow et al., 2023).

5.2. Limitations of the Review

Although this review is comprehensive and interdisciplinary, it has certain limitations that should be taken into account when interpreting the results:

Linguistic and Geographical Scope: The review was limited to English-language literature, which, despite the dominance of leading journals, may lead to the omission of important perspectives and research from centres in non-English-speaking countries, particularly with regard to local regulations and differences in the implementation of care systems.

Nature of the Review: This is a narrative/synthetic review rather than a systematic meta-analysis. This means that the synthetic nature of the literature synthesis, especially in ethical and social literature, involves a degree of subjectivity in the selection and interpretation of sources. It does not allow for conclusions about the quantitative effectiveness of algorithms based on uniform metrics.

The Pace of AI and Ethics Evolution: The field of AI in cardiology is extremely dynamic. Much promising research, especially on XAI and error elimination, is still in the proof-of-concept phase and requires further, extensive clinical validation and regulatory refinement before it can be implemented as a standard of care (Topol, 2024). This means that some regulations (e.g., the AI Act) may change before this article is published.

5.3. Suggestions for Future Research and Action (Policy and Scientific Recommendations)

Future scientific, regulatory, and policy efforts must focus on translating the potential of AI into equitable and safe clinical benefits, which requires coordinated action on three fronts: technological, educational, and regulatory.

I. Technological and Scientific Recommendations (Research on XAI, Fairness, and Resilience)

Advancing Explainability (XAI) and Transparency: Future research must move beyond simple measures of clinical accuracy and focus on creating AI architectures that are inherently more transparent and explainable (European Commission, 2021; Holst et al., 2024). Internally interpretable models and systems that provide Uncertainty Quantification should be developed, enabling cardiologists to critically evaluate each result.

External Validation and Bias Mitigation: It is essential to conduct extensive validation studies on diverse patient cohorts (ethnic, geographic, socioeconomic differences) (Wu et al., 2023; Zeleznikow et al., 2023). Future data repositories must promote data fairness at their core. It is recommended to use Federated Learning technology to train algorithms on data from different centres without centralising them, which can reduce error and increase privacy.

II. Systemic and Educational Recommendations (Competencies and Health Economics)

Integration of AI with EHR Systems and Workflow Optimisation: Health policy must actively support the standardisation of cardiology data (e.g., the use of HL7 FHIR) and invest in application programming interfaces (APIs) that will enable the seamless integration of AI tools with existing Electronic Health Records (Wang et al., 2024). Human-Computer Interaction (HCI) research should ensure that AI interfaces support critical physician judgement rather than automation bias.

Urgent Training Programmes and Digital Competence Development: Medical schools and cardiology societies (e.g., ESC, AHA) must urgently develop and implement educational and training standards for medical personnel (Chen et al., 2023). This includes training in AI ethics, the basics of data science, and critical interpretation of algorithm results for cardiologists, as well as active patient education in digital health literacy (European Society of Cardiology, 2024).

Value-Based Pricing and ROI: Rigorous cost-effectiveness analyses at the population level are needed to demonstrate that investments in AI generate long-term system savings (Althubaiti, 2024; Krittanawong et al., 2023). Reimbursement systems should shift the emphasis from paying for technology to paying for the clinical outcomes and improvements in care that AI contributes to.

III. Regulatory and Ethical Recommendations

Establish a Clear Legal Liability Framework: Regulations, such as the implementation of the AI Act, must clearly define the division of legal liability in the event of medical error (Meskó et al., 2023). Audit and recertification mechanisms are required for adaptive AI models (SaMD) that change after implementation, which is fundamental to maintaining public trust and clinical safety (Liu et al., 2023).

Supporting Data Transparency and Consent: Regulations must enforce greater transparency in the collection and use of sensitive cardiac data by AI. A dynamic consent model should be promoted, giving patients ongoing control over their data and its use.

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