

Artificial intelligence in cardiac amyloidosis: Expert insights on adoption challenges, opportunities and best practices for developing effective tools

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ASPIRE (Amyloidosis Stakeholder Partnerships for Impact, Reach, and Equity) is a collaboration among biotech and pharmaceutical companies committed to advancing solutions, improving diagnosis and care systems, and addressing obstacles to health equity for patients with amyloidosis.

1. INTRODUCTION

Cardiac amyloidosis (CA) is a serious and often underdiagnosed condition characterized by the deposition of amyloid fibrils in the heart. The two most prevalent forms of CA are light chain (AL) amyloidosis and transthyretin amyloidosis (ATTR), which includes both wild-type (ATTRwt) and variant (ATTRv) caused by mutations in the transthyretin gene. Survival for untreated patients varies between 2 to 5 years from the time of diagnosis, depending on the type of CA [1]. This underscores the critical need for early and accurate diagnosis, as timely intervention can dramatically improve patient prognosis, enhance quality of life, and increase survival rates. By identifying and treating CA at earlier stages, clinicians can prevent or mitigate irreversible cardiac damage, which is often associated with delayed diagnosis.

2. STUDY OBJECTIVES

2.1. Problem definition

Cardiac amyloidosis (CA) remains a diagnostic challenge due to its complex and varied presentation, often requiring a combination of laboratory tests, non-invasive imaging and biopsy. The American Society of Nuclear Cardiology (ASNC) highlights the increasing use of cardiac amyloid radionuclide imaging (CARI) as a valuable non-invasive diagnostic tool [2]. This approach utilizes tracers, such as technetium-99m-based pyrophosphate (Tc99m-PYP) and hydroxymethylene diphosphonate (HMDP), which offer sensitivity and specificity for detecting transthyretin amyloid cardiomyopathy (ATTR-CM).

Although imaging advancements have reduced the need for invasive procedures, tissue biopsy remains crucial in certain cases for diagnosing cardiac amyloidosis (CA) [3]. In all cases of CA, a biopsy is required to confirm amyloid deposition, especially when the monoclonal protein screen is positive. Cardiac involvement is most often assessed through abnormal cardiac biomarkers or imaging findings, though these are often non-specific and may appear later in disease progression. Clinical imaging, particularly imaging with ionizing radiation, requires clinician judgement to consider and order, leading to limited consideration of key imaging tests. Non-invasive methods such as bone scintigraphy may not provide definitive results. While bone scintigraphy, in conjunction with clonal dyscrasia rule-out test can approach sensitivity and specificity upwards of 90% for ATTR [4], variability in PYP sensitivity—such as that introduced by incidental monoclonal gammopathies (MG)—affects diagnostic accuracy. As a result, up to 40% of patients may still require an endomyocardial biopsy (EMB) to confirm CA diagnosis [5]. Specificity may also be impacted in cases where MG or other conditions lead to false-positive results, complicating the differentiation between CA and other disorders.

The integration of multiple diagnostic tests, including imaging, biopsies, and biomarker assessments, often contributes to significant diagnostic delays. This is especially problematic given that no single test, other than cardiac biopsy, can definitively diagnose cardiac amyloidosis.

2.2. Objectives

Recent advances in artificial intelligence (AI) offer significant potential to address the diagnostic challenges of cardiac amyloidosis (CA) by utilizing data from non-invasive imaging techniques like echocardiography and electrocardiograms (ECGs). AI tools can detect subtle patterns that may be missed by traditional methods, thereby enhancing early diagnosis and management.

In the U.S., more than 500 FDA-cleared AI algorithms are available, with the majority focused on medical imaging [6]. So far, approximately 27 AI tools have been approved by the FDA for cardiovascular applications, primarily as diagnostic aids.. A curated list of these AI tools is provided in Appendix 1. AI and machine learning-based tools have the potential to transform CA diagnosis, offering promising avenues for improved screening, diagnosis, and critical clinical insights.

This whitepaper explores the challenges, barriers, and opportunities in adopting AI-driven solutions for CA detection. It also shares expert insights from cardiology and AI specialists, proposing best practices for the development and integration of AI tools into clinical practice.

3. BARRIERS AND ENABLERS OF AI ADOPTION

Overall, gaps remain in how to standardize optimal use of AI devices and how to address cost-effectiveness, implementation, ethics, privacy, safety, equitable access and more. To understand the key barriers and enablers to adoption of AI tools for detecting and screening CA, we facilitated an advisory board of leading cardiologists and AI developers who are pioneers of AI-driven diagnosis. These insights reveal that four primary factors are closely interconnected and serve as key determinants in the process.

3.1. Clinician factors

Adopting AI for CA screening hinges on effectively integrating AI into clinical workflows. Challenges include ensuring that AI tools are user-friendly and seamlessly embedded in daily practices. Trust and reliability in AI performance are crucial; physicians need confidence that AI tools perform comparably to traditional diagnostics, without unintended consequences like false positives. While explainability remains important, especially in building trust and equipping clinicians to interpret outputs, the applicability of AI—its impact on decision-making, clinical practice, and patient pathways—has become equally critical. Key Drivers Analysis (KDA) may support explainability by clarifying diagnoses and

addressing physician concerns. Training and education are critical, equipping clinicians to interpret AI outputs confidently, with explainability playing a key role in education. Awareness, knowledge and feedback about existing and emerging AI technologies for CA are necessary, supported by collaboration and communication between clinicians and AI developers to ensure ongoing improvements and effective tool integration.

3.2. Institutional factors

The integration of AI tools for CA screening is influenced by various institutional factors. Cost and personnel allocation are significant considerations, with financial implications and resource constraints, such as budget limitations and the availability of a tech support team, playing key roles in the adoption process. Adoption at the departmental level can be challenging, as budget impacts and cross-departmental coordination, including cross-charging, often need to be addressed. Reimbursement challenges for AI-based screening can vary depending on the tool, disease, and practice setting, complicating widespread implementation. Having an AI champion within the institution is crucial for advocating the business case and facilitating the onboarding of these tools. Data accessibility, compatibility, and quality are also critical, as physicians require high-quality, interoperable data to effectively utilize AI-driven diagnostics. Furthermore, institutions must ensure they have the necessary resources for follow-up after an AI-driven diagnosis and address any limitations that might arise. The choice between cloud-based or on-premises deployment platforms depends on institutional preferences and existing infrastructure, and managing version upgrades is essential for sustainable and efficient AI tool use.

3.3. Ethical/ regulatory factors

Ethical and regulatory factors may influence the adoption of AI for detecting and screening CA. Compliance with current and evolving regulatory requirements can be challenging for healthcare providers, requiring careful navigation of guidelines and standards. Cybersecurity is a significant focus within the regulatory landscape, with the maintenance of secure systems adding to device connectivity dependencies. Data privacy and security are also crucial, with patients concerned about how their health information is handled and protected. Ensuring robust measures for data protection and clear communication about AI's role in diagnosis are essential. Additionally, addressing legal and ethical considerations, such as liability and patient consent, helps maintain trust and ensure that patients are fully informed about how AI is used in their care.

3.4. Patient factors

To gain a comprehensive understanding of the barriers and enablers to AI adoption, we also explored patient perspectives by organizing a patient advisory board with CA patients to capture their insights.

Patients expressed a strong desire for clear visibility and sufficient knowledge about the use of AI in diagnosing CA. They believe it is essential for the use of AI to be clearly communicated, ensuring they understand how these tools contribute to their diagnosis—not only to provide informed consent but also to grasp how the technology is being utilized. This transparency is vital for building trust and ensuring patients are comfortable with AI integration into their healthcare. However, trust can be undermined by factors such as fear of data misuse, lack of digital literacy, accessibility issues, and the perceived reputation of clinicians.

According to the ARC patient advisory board, there is a strong consensus that consent for AI use in diagnosing CA should be incorporated into standard medical forms, treating AI as a routine part of modern medical practice. This would streamline the process, allowing healthcare providers to integrate AI without additional barriers while keeping patients informed and engaged in their care. Additionally, patients expressed a desire to be informed of AI-generated risk scores or predictive values, regardless of the results, emphasizing the importance of transparency. Notably, patients with ATTRw amyloidosis showed a greater willingness to receive this information compared to those with hereditary forms of the disease. As expressed by the patients: “I think it comes down to one thing, I'd rather be scared about nothing than oblivious to something” and “Yes, I want the data then we can figure out if it is accurate. It is also stressful not knowing.”

4. PROPOSED SOLUTIONS

4.1. Action items to overcome barriers to AI adoption

4.1.1. Integration into workflow

The integration of AI tools into existing clinical workflows is a critical challenge. It is essential to ensure that AI tools are well-coordinated with the work of specialists. With multiple platforms often being disease-specific, IT resources can become overwhelmed, highlighting the value of a single interoperable AI vendor to streamline technical integration and simplify engagement with central purchasing. Clinicians must be fully informed about the AI processes and express active engagement to ensure a smooth transition and effective use of these technologies [7, 8]. Improving clinical care, diagnostic yield and early detection while improving efficiencies in daily clinical care should be clearly defined goals. New tools need to avoid increasing unnecessary tasks for clinicians when using the electronic medical record. Additionally, several technical, clinical, and budgetary stakeholders are involved, making it crucial to have a cross-departmental decision-maker actively engaged in the adoption process.

4.1.2. Provide clear value proposition

The application of AI within healthcare provides an opportunity for clinicians to deliver a more personalized approach to medical care by accounting for confounders, interactions, and the rising prevalence of multi-morbidity [9]. Clinicians should clearly communicate their preferences regarding the AI modalities used (e.g., echocardiography, ECG) and the user interface (e.g., electronic health records (EHR) systems or specific applications). Any required improvements in design should be addressed to ensure the AI tool meets clinical needs and enhances usability [7, 8].

4.1.3. Understand institutional requirements for AI adoption

The threshold for AI uptake can vary widely among institutions, particularly in complex diagnostic pathways like CA. A common barrier cited by many institutions is a lack of confidence in governance, as they grapple with regulatory risks associated with evolving guidelines and new AI regulations proposed by government agencies. Ethical and reputational risks, particularly those related to bias and explainability, also pose challenges, as the absence of a gold standard complicates the creation of effective policies. Privacy and data risks are among the most critical concerns, with advanced AI models raising heightened privacy and security issues. The need to govern data is not new, but AI has increased access to unstructured data, such as images, voice, and text, and these must now be explicitly covered in governance, audit, process, and storage standards [10, 11]. It is crucial to recognize and address risks, ensuring that AI tools are tailored to meet the specific needs and standards of each institution [8].

4.1.4. Centralization of AI

Many institutions are moving towards a centralized implementation of AI tools to streamline data management and reduce redundancy. Centralization becomes increasingly important as the size and complexity of real-world data grow. AI developers must find optimized solutions for AI deployment which will facilitate more efficient implementation and recognition, and maintain high confidence levels in AI outputs, while preserving confidentiality of data used [7].

4.1.5. Identification of AI champions

One effective way to accelerate AI adoption is by identifying and empowering AI champions within organizations. Specialists or super specialists with AI expertise can play a crucial role in driving the integration of AI tools. These champions can lead the way by educating others about AI technologies, starting with the data already available. Over time, they can introduce more diverse datasets and advocate for the inclusion of underrepresented groups in AI studies, ensuring a more comprehensive and equitable approach to AI implementation. [12].

4.1.6. Partnerships with regulatory bodies

Building strong partnerships between AI vendors, software developers, and life sciences companies with regulatory bodies like the FDA is essential. These collaborations can bring valuable business cases to health systems, accelerate AI adoption timelines, and shape market dynamics. The evidence required by the FDA depends on the regulatory pathway. For instance, the 510(k) clearance pathway often relies on retrospective validation, which may satisfy regulatory requirements but may fall short in garnering clinician buy-in or inclusion in clinical guidelines and consensus documents. Aligning with best practices and standardized systems will be crucial for broader adoption [8, 13].

A more significant challenge is the need to resubmit AI algorithms for approval by the FDA and regulatory bodies with every update, making it even more difficult to ensure seamless integration into clinical workflows. Establishing a regulatory framework could enable more flexible real-time updates under predefined guidelines. This could involve approaches like “locked algorithms” or predetermined change control plans [14, 15].

4.1.7. Other factors

It is crucial to establish clear guidelines and protocols to ensure that AI tools are used ethically and that patient rights are protected. One of the major barriers to AI adoption is the lack of robust prospective research and clinical trials that validate AI's effectiveness in real-world settings. Developing and conducting such studies is essential to building trust in AI tools and ensuring they are safe and effective for widespread use. The used platform should be Cybersecurity safe [16]. A cloud-based platform for a non-profit system is essential to accommodate large volumes of data that is easily accessible, particularly in academic settings conducting research. The AI tool needs to be integrated with existing hospital systems, such as EHRs, which can incur additional costs for IT services, custom development, and data migration. Regulatory bodies like the FDA are still developing frameworks for the approval and reimbursement of AI in healthcare. This evolving landscape can make institutions hesitant to invest in AI due to the risk that their tools might not be reimbursed or may face future regulatory hurdles.

4.2. Best practices for AI tool development and implementation

While understanding the barriers and enablers to adoption by an end-user perspective is important, it is equally important to create benchmarks for AI tool developers, to ensure future products are robust, reliable, and equitable in real-world clinical settings. Implementing these strategies will help overcome many of the common barriers to AI adoption and pave the way for broader acceptance and usage of AI in healthcare.

4.2.1. Ensure seamless integration into hospital systems

AI tools must integrate smoothly into existing hospital systems, including EHRs and imaging modalities, to minimize disruption. This requires collaboration with clinicians during the design phase to ensure the tools align with real-world needs and practices. AI tools must adhere to established interoperability standards. This ensures that AI systems can communicate effectively with other hospital systems, reducing technical barriers to adoption [8]. Dedicating health coordinators to facilitate the onboarding and training process for hospital system staff can ensure effective integration.

4.2.2. Conduct post-market studies for real-world validation

After deployment, AI tools should undergo continuous monitoring in real-world settings to validate their effectiveness and safety. These post-market studies are crucial for identifying any discrepancies between controlled trial results and real-world performance and any unintended downstream effect they may cause. Lessons learned should be used to iteratively improve the technology by refining algorithms, enhancing user interfaces, or adjusting deployment strategies to better meet clinical needs [7]. For instance, consistently monitoring the relevance of alerts to healthcare providers after deploying a tool is crucial to ensure they remain engaged and continue using it effectively.

4.2.3. Prioritize high-quality data curation

The success of AI in cardiac disease diagnosis relies heavily on the quality of the data used to train and validate the algorithms. It is crucial to prioritize the curation of high-quality, annotated datasets that accurately represent the clinical scenarios AI tools will encounter. This is particularly important for the selection of reference standards to create the labels. Developers must ensure that data is collected, stored, and utilized in compliance with ethical standards and regulations, including patient consent and data privacy. This builds trust in AI tools and ensures compliance with legal requirements [7]. Prioritizing data curation has proven to significantly enhance the use of AI in cardiac disease diagnosis. Some organizations have developed centralized repositories that aggregate vast amounts of real-world data, including echocardiograms and outcome-assessed studies from multiple international sites. Others collaborate with leading institutions, utilizing clinical trial data and real-world datasets to ensure that AI models are trained and validated on clinically relevant information, improving both accuracy and reliability. Additionally, some efforts focus on applying advanced data collection and annotation strategies in cardiovascular applications, emphasizing standardized data gathering and rigorous validation processes. These steps ensure that algorithms are capable of generalizing across diverse patient populations and clinical environments.

4.2.4. Embrace data diversity

To avoid biases in AI tool performance, it is essential to train algorithms on data from diverse patient populations to ensure the AI tool is broadly applicable and equitable [8]. In practice, some organizations

curate large volumes of relevant real-world data using cloud-based AI solutions, adapting designs to address inconsistencies in imperfect data inputs. Others prioritize diversity in datasets, focusing on racial and gender representation, while also integrating seamlessly with electronic health record (EHR) systems to deliver real-time value at the point of care. Additionally, some initiatives obtain data from multiple healthcare systems across different regions and settings, introducing real-world variability and focusing on seamless integration into healthcare infrastructure, effectively navigating bureaucratic and IT challenges for efficient implementation. Potential bias must be monitored during and after implementation of AI tools.

4.2.5. Engage with regulatory agencies

To stay informed and plan for future regulatory advisories; maintaining awareness and early ongoing communication with regulators can help to anticipate and address potential regulatory hurdles [8]. Developers can protect intellectual property by using “Registered Know-How” and creating IP to protect innovations and account for regulatory challenges by staying compliant and informed. Seeking pre-submission meetings with the FDA and other relevant regulatory bodies may facilitate the regulatory approval process.

4.3. Future data and knowledge generation initiatives

Although developers and end-users can collaborate to enhance the development and adoption of AI tools, there remains a need for increased awareness, education, and improved resources for AI tool development. Several potential initiatives aimed at addressing these needs are highlighted, and ARC is actively involved in many of them. The following strategies can significantly enhance awareness, education, and the practical application of AI tools.

4.3.1. Dissemination through peer-reviewed and point of view (POV) articles for to generate greater awareness and education

Publishing research papers in leading peer-reviewed cardiology and AI journals, and POV articles focusing on the successes and challenges of implementing AI and offering detailed case studies and analysis to guide future applications can elevate the understanding of AI's role in diagnosis and the benefits, limitations, and ethical considerations of AI in cardiac care. The Amyloidosis Research Consortium (ARC), the Amyloidosis Stakeholder Partnerships for Impact, Reach and Equity (ASPIRE) is a collaboration among biotech and pharmaceutical companies that are committed to advancing solutions, improving diagnosis and systems of care, and addressing obstacles to health equity on behalf of amyloidosis patients. ARC established ASPIRE as a strategic initiative to drive evidence-based programs that shape the rapidly evolving amyloidosis landscape for the benefit of patients. Several ASPIRE-ARC initiatives were implemented to organize educational discussion panels, webinars and online courses that explore AI applications in cardiology, targeting both clinicians and AI developers. These platforms

can be used to discuss the latest research, share practical insights, and answer questions from practitioners who are new to AI technology.

4.3.2. Develop an implementation plan model

Development of a model implementation plan using a successful AI tool in cardiology as an example, would provide a practical example of how AI can be implemented in real-life settings. This would involve selection of a well-documented and effective AI tool currently used in cardiology and creation of a comprehensive implementation plan including data requirements, model training, validation processes, regulatory compliance, and clinician training into a blueprint plan from vision to reality. When implemented, it is essential to collect feedback from clinicians and patients to refine the tool and the implementation process [8].

4.3.3. Establish a registry of federated data for CA to evaluate AI models and increase diverse populations

Establish a registry that pools de-identified patient data from multiple institutions, creating a large and diverse dataset which allows institutions to share data while maintaining patient privacy and adhering to data protection regulations. The registry can be updated with new data as it becomes available to ensure that researchers and clinicians have access to the latest datasets for their work. Transparency in data management practices and identifying gaps is crucial for maintaining the widespread participation of such a registry [7].

These data and knowledge generation initiatives are vital for advancing the understanding and application of AI in the diagnosis of CA. By publishing research, developing model implementation plans, and creating a robust data registry, the medical community is maintaining trust and encouraging AI tool use in disease detection which can drive forward the integration of AI tools, ultimately improving patient outcomes and advancing the field of cardiology.

5. CONCLUSIONS

There is an urgent need to advance implementation science for AI tools to establish practical, cost-effective workflows for AI/ML-driven precision medicine that effectively address key unmet clinical needs. Enhancing and implementing AI tools to support CA diagnosis could benefit both the patients and clinicians, lead decision-making, and accelerate patient access to the appropriate treatment. Those efforts may promote significant advancement in addressing the challenges of early detection and treatment of this rare disease. Best practices offer a better development and implementation of AI-based solutions particularly AI-tools for screening of ATTR-CA.

Presented insights from clinicians and AI developers offer the potential to improve patient outcomes by enabling earlier, more accurate diagnoses, and reducing the costly consequences of delayed treatment.

Ultimately, these insights will impact both large academic institutions and community practices with cardiology departments. The goal is to enable faster, earlier, and more efficient detection of CA from routine tests like echocardiograms and ECGs, ultimately benefiting patients.

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Appendix

Appendix 1. List of FDA-Authorized AI Tools Relevant to Cardiovascular Screening and Diagnosis as of Jan. 5, 2025

“This table includes FDA-authorized AI tools relevant to cardiovascular applications as of Jan. 5, 2025. Tools are included based on their potential relevance to cardiovascular screening or diagnosis, even if their regulatory labeling describes broader or non-specific applications (e.g., general-purpose measurement tools). For tools that are not explicitly labeled as screening devices, this table highlights their relevance to cardiovascular use cases.”

AI Algorithm	Developer	FDA Submission Number	Cardiovascular Application	Modality	Year of Approval / Clearance
Invision Precision Cardiac Amyloid	InVision Medical Technology Corporation	K243866	Cardiac Amyloidosis	Echo	2025
EchoGo Amyloidosis	Ultromics Ltd	K240860	Cardiac Amyloidosis	Echo	2024
Real-time AI guidance	UltraSight	K223347	Heart disease	Echo	2024
DeepRhythm AI (DRAI)	Medicalgorithmics	K210822	Arrhythmias	ECG	2024
Invision Precision LVEF	InVision Medical Technology Corporation	K232331	Left Ventricular Dysfunction	Echo	2024
Aquilion Precision (TSX-304A/4) V10.14 with AiCE	Canon Medical Systems Corporation	K182901	Coronary Artery Disease	Cardiac CT	2023
Global Hypoperfusion	Edwards Lifesciences, LLC	K231038	Hypoperfusion	EHR	2023

AI Algorithm	Developer	FDA Submission Number	Cardiovascular Application	Modality	Year of Approval / Clearance
Index (GHI) Algorithm					
LVivo IQS	DiA Imaging Analysis Ltd.	K222970	HCM / RVH	Echo	2023
MPXA-2000	Medipixel, Inc.	K222036	Coronary heart disease (stent implant)	Angiography	2023
Rapid RV / LV	iSchemaView Inc.	K223396	RV / LV Ratio (Pulmonary Embolism)	CT Pulmonary Angiograms	2023
Viz AAA	Viz.ai	K223443	Abdominal Aortic Aneurysm	Cardiac CT	2023
Viz HCM	Viz.ai	DEN230003	Hypertrophic Cardiomyopathy (HCM)	ECG	2023
AI4CMR v1.0	AI4MedImaging Medical Solutions	K220624	Cardiomyopathy	CMR	2022
Aorta-CAD	Imagen Technologies, Inc.	K213353	Aortic Atherosclerosis	X-ray	2022
EchoGo HF	Ultromics Ltd.	K222463	HFpEF	Echo	2022
Viz LVO ContaCT	Viz.AI, Inc.	K223042	Large Vessel Occlusions	Cardiac CT	2022
Viz RV / LV	Viz.AI, Inc.	K221100	RV / LV Ratio (Pulmonary Embolism)	Cardiac CT	2022
BriefCase, RIB Fractures Triage (RibFx)	Aidoc Medical, Ltd.	K202992	RV / LV Ratio (Pulmonary Embolism)	Cardiac CT	2021
LVivo Seamless V2.0	DiA Imaging Analysis Ltd	K212466	HFpEF	Echo	2021

AI Algorithm	Developer	FDA Submission Number	Cardiovascular Application	Modality	Year of Approval / Clearance
Vantage Fortian 1.5T	Canon Medical Systems Corporation	K213305	HCM	CMR	2021
Caption Guidance	Caption Health	K201992	Cardiomyopathy	Echo	2020
EchoGo Pro	Ultromics Ltd.	K201555	CAD	Echo	2020
Kardia AI V2	AliveCor	K201985	HFpEF / Cardiomyopathy	ECG	2020
AI-Rad Companion (Cardiovascular)	Siemens Medical Solutions USA, Inc.	K183268	Coronary Artery Calcification	Chest CT	2019
EchoGo Core (1.0)*	Ultromics Ltd.	K191171	Left Ventricular Dysfunction	Echo	2019
EchoMD	Caption Health (now part of GE HealthCare)	K173780	Left Ventricular Dysfunction	Echo	2018
Arterys Cardio DL	Arterys Inc. (now part of Tempus AI)	K163253	HCM / HFpEF	CMR	2017

Abbreviations: AI, artificial intelligence; CAD, cardiac coronary disease; CMR; cardiovascular magnetic resonance; CT, computed tomography; ECG; electrocardiogram; Echo, echocardiography; EHR, electronic health records; HCM, hypertrophic cardiomyopathy; HFpEF, heart failure with preserved ejection fraction