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## ИСКУССТВЕННЫЙ ИНТЕЛЛЕКТ В КАРДИОЛОГИИ: СРАБОТАЛ ЛИ ОН?

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### РЕЗЮМЕ

Искусственный интеллект (ИИ) позиционируется как технология, меняющая парадигму и «правила игры» в медицине. Существует ли он в кардиологии? В этой статье мы обсудим некоторые области кардиологии, в которых достигнут определенный прогресс во внедрении технологий искусственного интеллекта. Несмотря на перспективы искусственного интеллекта, сохраняются проблемы, включая кибербезопасность, трудности с внедрением и управлением изменениями. В этой статье обсуждается использование ИИ, встроенного в качестве технологии «черного ящика» в существующие диагностические и интервенционные инструменты, ИИ в качестве дополнения к диагностическим инструментам, таким как ЭХО, компьютерная томография или МРТ, ИИ в коммерчески доступных мобильных устройствах и ИИ в чат-ботах и других технологиях взаимодействия с пациентами. При этом, несмотря на определенный прогресс, правовая, нормативная, финансовая и этическая базы по-прежнему находятся в процессе эволюции на национальном и международном уровнях.

**Ключевые слова:** болезни сердечно-сосудистой системы, искусственный интеллект, кардиология, кибербезопасность, новые диагностические возможности, пациент-ориентированный интерфейс, смарт-технологии.

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# ARTIFICIAL INTELLIGENCE IN CARDIOLOGY: DID IT TAKE OFF?

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## ABSTRACT

Artificial intelligence (AI) has been touted as a paradigm shifting, game-changing development in medicine. Did AI in cardiology take off? In this paper, we discuss some areas within cardiology in which there has been progress in the implementation of AI technologies. Despite the promise of AI, challenges remain including cybersecurity, implementation and change management difficulties. This paper discusses the use of AI embedded as a 'black box' technology in existing diagnostic and interventional tools, AI as an adjunct to diagnostic tools such as echo or CT or MRI scans, AI in commercially available wearables, and AI in chatbots and other patient-facing technologies. Lastly, while there has been some progress, the legal, regulatory, financial and ethical framework remains a work in evolution at national and international levels.

**Key words:** artificial intelligence, cardiology, cardiovascular disease, cybersecurity, new diagnostic capabilities, patient-oriented interface, smart-technology.

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## INTRODUCTION

Artificial intelligence (AI) has been touted as a paradigm shifting, game-changing development in medicine. It was supposed to make diagnoses, facilitate tests, chat with patients better than real doctors can, automate difficult processes and even power robots to operate without humans. Of course, no one expected this to happen overnight. Yet with the increasing use of AI and related technologies in other industries eg. Weather prediction, self-driving cars, detection of fraud, hotel booking chatbots, the question is: where are we in medicine specifically in cardiology? Did AI in cardiology take off?

## WHAT DOES AI NEED FOR IT TO WORK?

For AI to work, first, there has been to large amounts of data; more precisely, large amounts of good quality and accurate data. Second, there needs to be access to significant computing processing power. Currently, such massive compute power is easily available — most smart phones have compute capabilities that exceed most computers a decade ago. Related to these two key ingredients are second-order needs that directly affect the promise of AI: (1) storage capacity, (2) access to the Cloud, (3) cybersecurity and patient confidentiality/privacy needs, (4) integration or connectivity with hospital operational systems including electronic health records, pharmacy systems and administrative systems, and (5) requisite regulatory, legal and societal landscape. As large volumes of data are processed, storage costs increase. The need for immediacy and to be ‘online’ or near-online most times add to the cost. The Cloud is a natural solution to this need with scalable and elastic resources and use-dependent costing. However, use of the Cloud for healthcare is significantly regulated in most developed countries. These regulations often require that the Cloud server be hosted in the home country. Lastly, cyberattacks by all sorts of actors have made cybersecurity a major consideration in the use of AI, cloud computing and even the mechanism of data storage [1–3]. Cyberattacks can range from malware that corrupt databases and algorithms, denial-of-service attacks, exfiltration of personal, operational and research data, implantation of fake data that corrupt algorithms, adversarial attacks, amongst others. It should be noted that cybersecurity issues are already a known problem with implantable cardiac devices [4–7]. The need to defend from cyberattacks and other nefarious activities significantly impedes the deployment of AI in hospital systems. The need for integration with hospital operational systems, when taken in the context of cybersecurity, is an increasingly complex and expensive process.

Importantly, an accurate AI algorithm does not necessarily make a successful AI deployment. AI, like any tool, needs to be implemented at the right place, by the right people and at the right time. This entire process of change management, implementation and validation is both an art and a science. For AI to work, it has to be embedded into clinical care processes. The new workflow must not incur additional work for nurses, doctors, allied health staff or administrators; and if it does, it has to be so easy, so logical that the healthcare provider will do so intuitively. AI solutions that do not fit into the normal workflow or which incurs additional effort on the part of the care provider will be doomed to failure [8].

To illustrate the use of AI in cardiology, we will describe several use cases. These include AI embedded as a ‘black box’ technology in existing diagnostic and interventional tools, AI as an adjunct to diagnostic tools such as echo or CT or MRI scans, AI in commercially available wearables, and AI in chatbots and other patient-facing technologies. Of note, AI is used in other healthcare related activities such as back-end processes for operational, claims and other financial purposes. However, these use cases are not specific to cardiology and will not be discussed.

## AI AS EMBEDDED AS A BLACK BOX IN EXISTING DIAGNOSTIC AND INTERVENTIONAL TOOLS

AI as complex algorithms guiding procedural imaging is already embedded in software platforms such as those by Philips Echo-Navigator [9]. The Echo-Navigator allows real time fusion and overlap of trans-esophageal echo images with fluoroscopy. Such technology allows an interventionalist to better understand the anatomical relationships of cardiac structures so as to guide structural heart valve procedures. However, usage of such technologies have not been main stream yet. Other than the cost of adoption, most proceduralists have internalized the procedures and adding on a layer creates an unnecessary overlay. Of course, the hope is that this technology will improve the safety and procedural speed for less experienced proceduralists as the underpinning structural heart intervention becomes more common place. In the case of Echo-Navigator, the underlying AI works, but the adoption of the technology is limited by the lack of compelling need.

On the other hand, the use of algorithms and AI in intravascular optical coherence tomography (OCT) is so well embedded and internalized that most people do not even think of the underlying intelligence processing the images [10]. When OCT was first introduced, it produced stunning images at high resolution beyond what

intravascular ultrasound could generate. Now, newer generations of OCT can create 3-dimensional reconstructions of the vessel wall including stent struts and identifying areas of malapposition. The speed at which the acquired light signals are processed into these clear images is only possible because of the underlying algorithms and processing power. In this instance, the use of AI is invisible to users, and the AI has been so well embedded that users do not have to activate the AI to use it — it is already automatic. Such use of the AI represents successful use of AI in a way that improves the useability of the base technology to physicians without any significant burden of additional effort.

### AI AS AN ADJUNCT TO DIAGNOSTIC TECHNOLOGIES

Perhaps one of the most studied use cases for AI is in the field of cardiovascular imaging [11]. In CT [12, 13] and in cardiac MRI, AI is already embedded to automate many of the processes. For example, in cardiac MRI, multiple machine learning algorithms have been developed that can do segmentation of cardiac chambers [14–17]. Industry has embedded AI into their technology and this includes CT scans and MRI machines, amongst others [18–20]. Where this is successfully done, it is usually behind the scenes and not obvious to the users. In that sense, this would represent successful integration of AI technologies into everyday imaging platforms.

Where the use of AI requires changes in workflow (as opposed to automation of existing processes), it becomes much harder to execute. In the sphere of echocardiography, many companies have attempted to do so. Technology by Caption (Caption Guidance), GE Healthcare (Vivid Ultra Edition), Ultramics (EchoGo), and US2.AI are all FDA approved for use in facilitating echocardiography [21]. In September 2021, the US2.AI technology received FDA clearance for the first fully automated solution measuring both 2D and Doppler cardiac ultrasound images to produce a complete patient report. The company now has to work with hospitals and clinics to determine the workflow for such a technology. There are several important questions and considerations: (1) will the technology work in the patient population? How should validation be performed?; (2) in what scenarios will the technology be inaccurate, and therefore trigger human intervention? What imaging quality is required? (3) what kind of training is required for the echocardiographer and what is the role of the echocardiographer? (4) who is responsible for the echo report? (5) what is required for audit? In a paper by Tromp et. al., the authors describe some of the underlying technology for US2.AI, including the use of

automated deep learning-based workflow to automate the view classification, annotation, and interpretation of cardiac volumes, LVEF, and E/e' ratio [9].

### AI IN COMMERCIALLY AVAILABLE WEARABLES

One of the greatest promises for AI in cardiology is its use to facilitate wearable sensor technology. Of course, the use of wearables to measure steps has been around for some time. Smart watches and wearables are also useful for the measurement of physical activity intensity, step counts and heart rate. Studies have shown comparable accuracy for the Apple watch, Fitbit for heart rate and step counts but appeared to underestimate moderate-to-vigorous activity minutes [22].

However, commercial consumer technology companies like Apple, Fitbit, and Samsung have incorporated ECG recordings into the smart watches. Apple was able to demonstrate for the first time that such consumer grade technology was able to detect irregular heart rhythms and the possible presence of atrial fibrillation. Among participants in the Apple Heart Study who received notification of an irregular pulse, 34 % had atrial fibrillation on subsequent ECG patch readings and 84 % of notifications were concordant with atrial fibrillation [23]. Initially, there was both hope and consternation: hope that such technology would make for much easier detection of atrial fibrillation; and consternation that doctors' offices and emergency rooms would be flooded with worried patients having an 'irregular heart rhythm'. As it turned out, the truth is probably somewhere in between. In clinical practice, the Apple Watch identified and alerted some patients of their AF and this resulted in the necessary and appropriate care. But these numbers were not huge and there was no tidal wave of worried patients. Nonetheless, this illustrated the challenge of such technology: how can it be embedded in routine daily use, operate in the background and yet provide accurate information to the patient and the care providers when needed.

### AI IN CHATBOTS, MEDICAL CONSULTATIONS AND OTHER PATIENT-FRONTING TECHNOLOGIES

Chatbots are used by banks, airports, governments, airlines, helpdesks, technology companies and a multitude of other industries. Some of them are intuitive and helpful, while others frustrate users. Regardless, chatbots and other patient-fronting human interfaces are here to stay, with several in the marketplace [24]. They can have several functions, from making or changing medical appointments, to triaging or facilitation of

medical consultations based on urgency or clinical presentation. However, for these technologies to function properly, there are two key requirements. One: the ability to interact with the human either in terms of typed or keyed data or spoken language. This means that the technology must be able to have different types of data input. In certain countries, this limits the usability of the technology. Of course, this is by no means a show-stopper as such a technology is never meant for everyone. Clinics and hospitals would need to provide multiple channels for communication. There is a possibility of duplication of work and need for multiple channels to coordinate —whether appointment slots or follow through of medical complaints. The second requirement is for the underlying intelligence embodied by the AI to be ‘smart’ enough to make the right decision, whether in triaging, ordering tests, or setting up appointments to see the right doctor. This underlying AI requires massive data for training, and there may be customization specific for each healthcare ecosystem when utilizing AI developed elsewhere.

Perhaps the most impressive demonstration of how AI has been used to transform healthcare is by China’s Ping An’s Good Doctor platform which has an entire ecosystem of online healthcare services from medical teleconsultation, pharmacy, laboratory testing [25–28]. As of June 2021, the platform reported more than 400 million users [26, 28].

For cardiology, there are various studies describing the use of machine learning algorithms to triage patients with chest pain [29, 30]. However, implementing such algorithms is a more complex problem and it remains unclear how it can fit into regular workflow in primary care or the emergency room.

## AI IN ELECTRONIC HEALTH RECORDS

Integration of AI in electronic health records (EHR) represents an area of huge promise [31]. AI has the potential to support clinical documentation and data entry, real-time monitoring, clinical decision support, data extraction, data organization and risk prediction. However, these tools are not specific to cardiology. Nonetheless, in a study of gastroenterologists, AI optimization was felt to save physicians time in extracting relevant clinical information from EHRs [32]. Together with advancements in monitoring sensors, AI-based technologies have also made inroads with algorithms that provide near-real-time diagnosis [33]. The use of biosensors can also offer the potential to detect deteriorating patients, especially when couple with algorithms that harness data from EHRs. However, in this entire area, much remains to be done. Integration of AI into EHR processes with feedback loops; integration of data

from biosensors and subsequent AI analysis etc, has yet to enter mainstream practice.

## REGULATORY AND LEGAL FRAMEWORK, INTERNATIONAL RULES REQUIRED

For AI to truly take-off, there has to be the right regulatory framework within each hospital, country and globally. This includes legal, ethical, insurance and financial considerations. Who certifies an AI algorithm fit for use? What standards apply? Are the standards and approvals interchangeable across nations? Are algorithms required to continuously improved? What are the quality control and audit requirements? Do physicians have the final say? Do patients and care providers understand the limitations and useability of AI? In Jan 2021, the US Food and Drug Administration published the “*Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) Action Plan*” from the Center for Devices and Radiological Health’s Digital Health Center of Excellence [34]. The Action Plan is a direct response to stakeholder feedback to the April 2019 discussion paper, “Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning-Based Software as a Medical Device” and outlines five actions the FDA intends to take. These include (abbreviated):

1. Develop an update to the proposed regulatory framework presented in the AI/ML-based SaMD discussion paper, including through the issuance of a Draft Guidance on the Predetermined Change Control Plan.
2. Strengthen FDA’s encouragement of the harmonized development of Good Machine Learning Practice (GMLP) through additional FDA participation in collaborative communities and consensus standards development efforts.
3. Support a patient-centered approach by continuing to host discussions on the role of transparency to users of AI/ML-based devices.
4. Support regulatory science efforts on the development of methodology for the evaluation and improvement of machine learning algorithms, including for the identification and elimination of bias, and on the robustness and resilience of these algorithms to withstand changing clinical inputs and conditions.
5. Advance real-world performance pilots in coordination with stakeholders and other FDA programs, to provide additional clarity on what a real-world evidence generation program could look like for AI/ML-based SaMD.

Other than the US FDA, other countries have also put forth their own guidelines, for example in EU, Australia and Singapore [35–37]. In many ways, the field



has progressed at a pace faster than current laws and regulations. Nonetheless, for AI in cardiology to truly take-off, there will have to be greater clarity on regulations and appropriate laws to govern its use and misuse.

## SUMMARY

AI is a reality in our lives. It has permeated many industries including medicine. However challenges remain in the implementation of AI technologies in medicine as a whole, and in the field of cardiology. For there to be successful AI implementation, the laws and regulations must catch up and society as a whole must learn to adapt to this new disruptive, yet enabling technology.

## Conflict of interest

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