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Review

Unlocking Tomorrow's Health Care: Expanding the Clinical Scope of Wearables by Applying Artificial Intelligence

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ABSTRACT

As an integral aspect of health care, digital technology has enabled modelling of complex relationships to detect, screen, diagnose, and predict patient outcomes. With massive data sets, artificial intelligence (AI) can have marked effects on 3 levels: for patients, clinicians, and health systems. In this review, we discuss contemporary AI-enabled wearable devices undergoing research in the field of cardiovascular medicine. These include devices such as smart watches, electrocardiogram patches, and smart textiles such as smart socks and chest sensors for diagnosis, management, and prognostication of conditions such as atrial fibrillation, heart failure, and hypertension as well as monitoring for cardiac rehabilitation. We review the evolution of machine learning algorithms used in wearable devices from random forest models to the use of convolutional neural networks and transformers. We further discuss frameworks for wearable technologies such as the V3-stage process of verification, analytical validation, and clinical validation as well as challenges of AI integration in medicine such as data veracity, validity, and security and provide a reference framework to maintain fairness and equity. Last, clinician and patient perspectives are discussed to highlight the importance of considering end-user feedback in development and regulatory processes.

RÉSUMÉ

Partie intégrale des soins de santé, la technologie numérique permet de modéliser des relations complexes pour détecter, dépister et diagnostiquer les maladies et prédire les issues pour les patients. En utilisant d'imposants ensembles de données, l'intelligence artificielle (IA) peut avoir des effets marqués tant pour les patients que pour les cliniciens et le système de santé. Dans cette revue, nous nous penchons sur les appareils portables contemporains utilisant l'intelligence artificielle qui font l'objet de recherches dans le domaine de la médecine cardiovasculaire. Cela comprend des dispositifs comme les montres intelligentes, les timbres d'électrocardiogramme et les textiles intelligents comme des chaussettes intelligentes et des capteurs thoraciques utilisés pour le diagnostic, la prise en charge et le pronostic de maladies comme la fibrillation auriculaire, l'insuffisance cardiaque et l'hypertension, ou qui sont utilisés pour le suivi de la réadaptation cardiaque. Nous avons passé en revue l'évolution des algorithmes d'apprentissage automatique utilisés dans les dispositifs portables depuis les modèles de forêt aléatoire jusqu'à l'utilisation de réseaux de neurones à convolution et de réseaux autoattentifs. Nous étudions aussi les systèmes utilisés pour les technologies portables comme le processus de vérification V3, de validation analytique et de validation clinique, de même que des défis d'intégration de l'IA en médecine comme la véracité, la validité et la sécurité des données. Enfin, nous proposons un cadre de référence pour maintenir l'équité et l'impartialité. Pour terminer, les perspectives des cliniciens et des patients sont abordées pour souligner l'importance de tenir compte des rétroactions des utilisateurs finaux dans les processus de développement et de réglementation.

In this contemporary era of personalized health care, there is a growing imperative to integrate consumer health technology products to empower clinicians and patients. The ubiquitous nature of wearable devices is evident, with an estimated 15%-25% of Canadians, and more than 25% of those in the United States owning a device that tracks fitness or monitors health.[1] This translates into > 72 million US users alone within the past year. The global market for smart wearables is projected to reach CAD$70 billion by 2025, underscoring the vast potential for harnessing these data and the significant potential for improving health.[2]

Wearable technology encompasses devices designed for use while worn. These are specialized devices comprising a sensor

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with a computer small enough to be worn or carried by individuals, enabling the measurement of physical parameters such as step count and heart rate, among a few inputs.[3] Ranging from smartwatches to subcutaneous sensors, wearables can sense, record, store, and transmit data, using sensors such as barometers, gyroscopes, accelerometers, and magnetometers in addition to optical, electrical, temperature, and visual sensors. These sensors facilitate the monitoring of health-related metrics such as heart rate, blood pressure, oxygen saturation, body temperature, sleep, physical activity level, electrocardiogram (ECG), and biochemical parameters (eg, serum glucose level). Physiologic data obtained from wearables are of limited clinical utility when viewed in isolation. Clinicians have historically reported concerns with providing timely and accurate interpretation of these data.[4,5]

Advancements in artificial intelligence (AI) can potentially unlock this wealth of wearable data alongside clinical, laboratory, and imaging modalities.[6] Multimodal AI-powered approaches have transformative potential particularly for longitudinal layered data that can enhance prognosis, diagnosis, and improve treatment strategies.[7] Traditional linear models for building prediction tools on the basis of limited patient-level information are being surpassed by machine learning algorithms capable of recognizing new patterns of data and learning without requiring retraining. Novel AI applications have the potential for identification of digital signatures using multimodal inputs to phenotype patients with cardiovascular disease.[8,9]

Despite the potential use of these devices in cardiovascular disease, there are limited examples of successful clinical applications. Many current AI applications rely on antiquated labels to predict outcomes (eg, International Classification of Diseases, ninth revision codes) and primitive decision tools that hinder their ability to unlock new insights. Additionally, disparities in the underutilization in the elderly, ethnic minority, and less educated populations and lower income households need to be addressed to ensure equitable access to the benefits of wearable technology.[10] Currently AI-based tools have yet to demonstrate improved patient outcomes at scale.[11] Yet, we stand at a pivotal moment in the evolution of AI because its role will evolve to further enhance the work of clinicians by improving acumen and streamlined work flows that alleviate administrative burdens, thereby affording more time to dedicate to patient care. Additionally, AI-driven insights will empower patients with greater understanding and involvement in their health care journey.

In this review, we discuss the current application of machine learning algorithms in wearable devices, wearable monitoring of various cardiovascular conditions, and challenges in integrating this technology in medical practice. Last, we highlight the patient and clinician perspectives, and barriers that limit equitable adoption of these devices in vulnerable groups.

Contemporary Case Use in 2024

Ms S. is a 50-year-old patient with heart failure (HF). Over the past 2 weeks, she has noted worsening lower limb edema and weight gain. She awoke during the night experiencing shortness of breath and was unable to rest comfortably. The next morning, she called her primary care provider, who scheduled a clinic appointment in 1 week. By the time of the appointment, Ms S.'s condition had worsened, precipitating an urgent visit to the emergency department in acute decompensated HF requiring positive pressure ventilation and intravenous diuretic administration.

The Evolution of Machine Learning

Machine learning, a set of computational techniques, can identify intricate patterns within vast data sets, and subsequently produce precise and tailored outputs (Table 1). In cardiovascular health, reliance has traditionally been on rules-based algorithms and probabilistic models for clinical decision-making. For example, a blood pressure remote monitoring platform might suggest uptitration of an antihypertensive medication on the basis of preset thresholds.

In recent years, machine learning in cardiology has increasingly used deep learning algorithms, rooted in supervised learning, a subcategory of machine learning that uses labelled data sets to train algorithms to predict patterns and outcomes, and labelled ground truths, which are targets for training or validating the model with a labelled data set. Supervised learning involves making predictions on the basis of provided data and comparing them with human-labelled data. The algorithm computes the discrepancy between predicted and actual labels, known as the loss, and minimizes it through iterative adjustments to the model's learned features. This iterative process allows the model to glean insights directly from raw data, including high-dimensional modalities like ECG, images, echocardiography video, and textual data.

Deep neural networks (DNNs) have emerged as a powerful tool for learning features and predictions from raw data in cardiology.[12] DNN is a complex artificial neural network with multiple layers of input and output that is used to manage unlabelled and unstructured data. Their capacity to extract features from diverse, high-dimensional data sources facilitates data-driven discoveries. Contemporary examples of these clinical applications in cardiology include the use of ECGs to predict left ventricular dysfunction or future development of atrial fibrillation (AF).[13-16] However, these conventional approaches limit scalability and adaptability with challenges related to real-time data variances and catastrophic forgetting, which occurs when the network "forgets" how to effectively perform the earlier tasks.[17]

Wearable data present an ideal opportunity for deep learning models, incorporating diverse sensor parameters like cuffless blood pressure, heart rate, oxygen saturation, temperature, activity, 1-lead ECG, and blood glucose levels. The widespread use of wearable sensors and the lack of enhanced data aggregation capabilities pose new challenges in managing, interpreting, and integrating such data. Addressing these challenges necessitates multimodal AI solutions that capture the complexity of health and disease.[18] Currently, AI integration into medical care has been limited, with the progress mainly observed in the applications of medical imaging interpretation. However, because clinicians routinely handle data from multiple sources and modalities, there is a pressing need to develop AI models that effectively integrate multimodal data.

Machine Learning Algorithms for Smart Wearable Devices

Early wearable AI models primarily used traditional machine-learning techniques suitable for time-series analysis, such as support vector machine, logistic regression, and

Table 1. Glossary of terminologies related to artificial intelligence

Terminology	Definition
AI	Simulation of human intelligence processes such as data acquisition, reasoning, and data processing by machines and computer systems
Machine learning	A subset of AI that involves algorithms and models capable of revising output on the basis of experience and improving performance without being explicitly programmed
Deep learning	Subset of machine learning that focuses on algorithms inspired by the structure and function of human brain, known as ANNs. It is commonly used for applications such as image and speech recognition and language processing
ANN	Deep learning models are based on ANNs, which are layers of interconnected nodes processing data and passing it to the next layer
DNN	A type of ANN with multiple layers between the input and output capable of modelling complex and abstract features of the data
CNN	A subtype of DNNs designed to process structured grid data (ie, images) using pattern recognition techniques
FCNN	Also known as feed-forward neural network, FCNN is a type of ANN in which each neuron in one layer is connected to every neuron in the next layer
RNN	A type of ANN designed for sequential data processing. Unlike the feed-forward neural network, RNNs have connections that form a cycle, allowing them to exhibit dynamic temporal behaviour
LSTM	A subtype of RNN designed to model sequential data and overcome limitations of traditional RNNs by capturing long-term dependencies
SVM	A supervised machine learning model used for classification and regression analysis.
Random forest	An ensemble learning method used for classification and regression tasks in machine learning that uses decision trees during training
Transformers	A type of deep learning model architecture capable of effectively capturing long-range dependencies and contextual information in text data
Segmentation	Process of partitioning image or data into multiple segments

AI, artificial intelligence; ANN, artificial neural network; CNN, convolutional neural network; DNN, deep neural network; FCNN, fully connected neural network; LSTM, long-short-term memory network; RNN, recurrent neural network; SVM, support vector machine.

random forest (Table 1).[19] These methods handled structured data well and performed adequately even with relatively small data sets. However, because these models require single-value aggregations from the wearable, such as mean, median, and aggregate statistics, they need to be more comprehensive in providing insights into the complex temporal dynamics inherent in most wearable data streams. As shown in Figure 1A, the sequential nature of time-series data was often overlooked, because each data point was treated independently (Fig. 1).[20]

Deep learning pipelines were later introduced to wearables, and their success in various time-series forecasting tasks offers a solution for addressing wearable data challenges.[21] These challenges include the large volume of data generated by wearables, the complex temporal dynamics inherent in most wearable data streams, and the need to capture temporal dependencies. These models demonstrate exceptional proficiency in decoding the intricate nonlinear relationships embedded within large quantities of data, thereby addressing these challenges. Fully connected neural networks (FCNNs) marked a significant shift by using deep learning for wearables' data, enhancing the ability to model nonlinear relationships within larger data sets. Although more potent than support vector machine or random forest in handling complex patterns, FCNNs still needed to explicitly account for the order of data points in time series, which is crucial for capturing temporal dependencies (Fig. 1).

As the field progressed, recurrent neural networks (RNNs) were developed to model time-series data, to explicitly address the limitations of FCNNs.[22] RNNs have successfully integrated large quantities of wearable data, processing sequences by maintaining a hidden state that captures information about previous data points, thus preserving temporal dependencies. However, they often face challenges with long sequences. Long-short-term memory networks were introduced to overcome these challenges, and they can learn long-term dependencies without the vanishing gradient problem.

As RNNs became popular, convolutional neural networks (CNNs) also competed in the space by adding a novel layer to processing time-series data. CNNs use convolutional layers to capture spatial features from sequences. They are suitable for segmenting and analyzing time-bound signal patterns and assessing wearable data as a 1-dimensional signal, like how they process images as 2- or 3-dimensional signals. Because of their efficiency and capacity to "understand" spatial correlations, they are the most used algorithm in wearable devices. CNNs usually have multiple processing blocks. Typically, each block first filters a signal with a kernel, processes through a nonlinear function that helps encode the features, and then pools (subsamples) the signal such that each feature represents an increasingly larger unit of time. Thus, in each block, the kernel understands relationships across a fixed amount of time, and pooling is used to summarize samples, thereby increasing the temporal length of the relationships measured in the next block.

More recently, transformers have revolutionized the field by using self-attention mechanisms to identify relationships across much longer sequences, significantly improving processing efficiency and model performance over earlier models.[23] This architecture allows for parallel processing of sequences and can manage longer dependencies with greater efficiency. Transformers in wearables signify a move toward models that require substantial data sets but offer remarkable accuracy and speed. Looking ahead, the integration of AI in wearable technology is expected to continue to evolve, with advancements in areas such as real-time health monitoring, personalized health recommendations, and early disease detection.

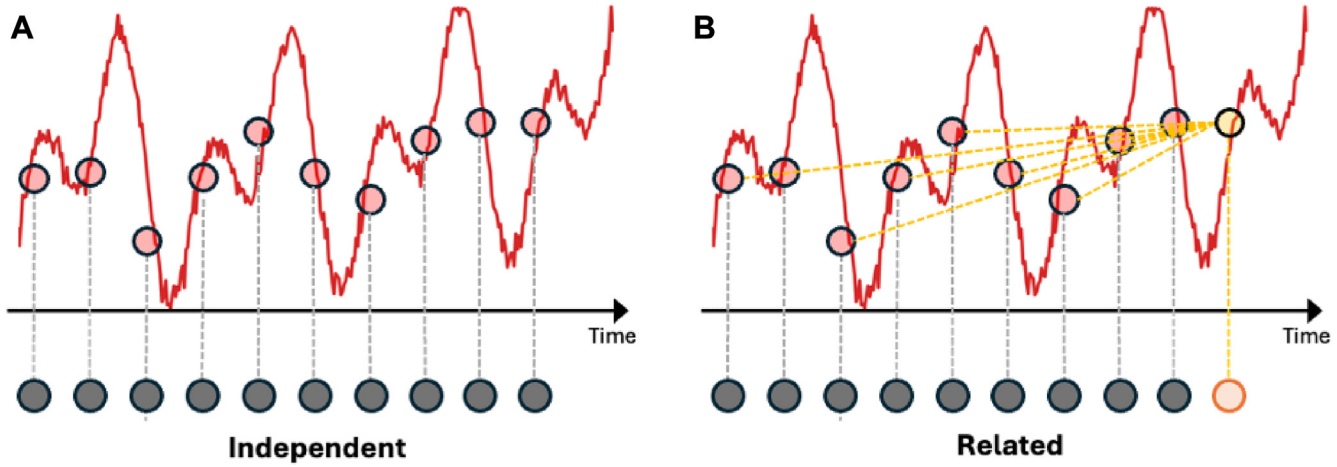


Figure 1. Comparison of model treatments of a heart signal over 60 seconds. (**A**) Key points (circled in **blue**), indicating that each point is treated independently by models such as support vector machine and random forest (**B**) The same heart signal with connections (example of 1 point [**orange**] and its related connections in **yellow dashed lines**) between sequential data points, showing the approach of advanced models like convolutional neural networks, long-short-term memory networks, and transformers that consider temporal relationships within the data. The horizontal time line (x-axis) beneath both panels indicates the sequence of heartbeats.

Wearables in Disease Screening and Management

A recent survey to assess the uptake of utilization patterns of wearable devices showed that 49% reported using wearable devices every day and 82% of users expressed willingness to share their health data with clinicians. However, among individuals with, or at risk of cardiovascular disease, fewer than 18% of those with established cardiovascular disease and 23% at risk reported using wearable devices, compared with 29% of the general population. Sociodemographic factors such as older age, lower educational status, and lower household income were associated with a lower odds of wearable usage. These findings highlight the potential for wearable devices but also underscore that these devices are underused among those with cardiovascular disease. Key barriers to the broader use of these devices is the need for rigourous evidence that unequivocally establishes their role in disease monitoring. In the next section we provide seminal examples of applications of wearable technologies for patients with cardiovascular disease.

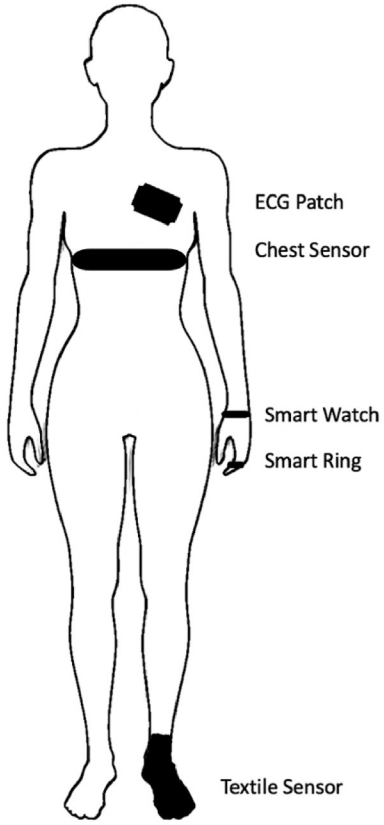
Atrial fibrillation with photoplethysmography monitoring

AF is associated with a high global burden of cardiovascular disease and stroke. The detection of AF using smartwatches is arguably the most successful application wearables in current clinical practice. The Apple Heart Study, the largest study of wearable devices for AF detection, investigated whether photoplethysmography (PPG)-enabled devices such as the Apple Watch (AW; Apple Inc, Cupertino, CA) can detect AF in individuals with no known history of cardiovascular disease.[12] The PPG waveform is synchronous with heartbeats and therefore can be used to assess the heart rate. Using AI, such waveforms are assessed with periodicity and if a pulse irregularity is detected in 5 of a series of 6 tachograms (periods of 1 minute length) the irregular pulse might suggest AF. The DNN algorithm trained base off of the AW PPG sensor data has shown excellent prediction of AF compared with the gold standard 12-lead ECGs (c-statistic, 0.97; 84% positive predictive value).[24] The Heartline trial,[25] a randomized clinical trial on the significance of detection of AF using the AW, has started recruitment of more than 150,000 individuals. The primary objective is identifying and diagnosing AF, evaluating improvement in cardiovascular outcomes, improving anticoagulant adherence, and identifying predictors of disease. The results of this study are anticipated in 2025. Additionally, other types of devices are being evaluated for similar purposes, including a "smart ring" that measures PPG and was shown to have 96.9% diagnostic accuracy in detecting AF.[26] A summary of sensor technology and machine learning algorithm used in various wearable devices is shown in Figure 2. Furthermore, a comparison of features of commonly available wearable watches and rings are listed in Supplemental Table S1.

Atrial fibrillation with 1-lead ECG monitoring

Wearables with ECG monitoring capability have also been evaluated for the detection of AF. In the **m**Health **S**creening **t**o **P**revent **S**trokes (mSToPS) study continuous 1-lead ECG monitoring was evaluated using the Zio patch (iRhythm, San Francisco, CA) to detect new AF diagnosis up to 1 year.[27] This study showed that ECG monitoring analyzed by a deep learning model led to a higher rate of new AF diagnosis than standard methods, and was associated with increased initiation of anticoagulation therapy and cardiology referral. The Amazfit Health Band (Zepp Health, Hefei, China), which records PPG and 1-lead ECG data, has a sensitivity 96%, specificity of 98%, and 97% accuracy for the detection of AF.[28]

Wearable technology can be also used in managing patients with established AF. Noninvasive continuous rhythm monitoring provides the opportunity to assess the burden of arrhythmia and the need for ongoing anticoagulation and rhythm control strategies. Reliable wearable technology can guide patients to time use of anticoagulation with episodes of



Wearable Device	Sensors	Measurements	Machine Learning Algorithms	Clinical Indications	Clinical Study or Trial
Smart watch (ie, Apple Watch, Garmin Watch)	PPG GPS Barometer Accelerometer ECG sensor Blood oximetry	HR HR recovery SaO2 pVO2 Rhythm Step count Calories burned	Deep learning algorithm using CNN, recurrent neural networks, and long-short-term networks, and transformers	Arrhythmia screening Heart failure management and prognosis Uptitration of β-blockers Long QTc screening	Apple Heart Study HEARTLINE trial TRUE-HF study
Smart ring (ie, Oura Ring)	PPG GPS Accelerometer Thermometer Blood oximetry	Step count Speed Exercise Cardiac output SaO2 Temperature Sleep stages	Deep learning algorithm using CNN	Physical activity Arrhythmia screening Cardiac telerehabilitation	Sel et al.[26]
ECG patch (ie, Cardiopatch)	Single lead ECG Continuous ECG Seismocardiography Radiofrequency	Single lead ECG ECG variable intervals HR variability Pulmonary congestion Cardiac output	Deep learning algorithm using CNN	Arrhythmia screening Electrolyte abnormalities Heart failures screening	mSToPS study iCare-AF study
Textile sensors (ie, Smart Socks, chest strap)	Barometer Accelerometer Stretch sensor ECG Seismocardiography	HR R-R Weight change Body vibrations Step count Calories count	Support vector machine, one hidden layer neural network, multihidden layers neural network	Heart failure congestion Weight loss Cardiac rehabilitation	Singhal et al.[37] Abraham et al.[43]

Figure 2. Use of wearable technology sensors, underlying machine learning algorithms, and their clinical indications in cardiovascular medicine. Apple Watch is from Apple Inc (Cupertino, CA); Garmin Watch is from Garmin Ltd (Olathe, KS); Oura Ring is from Oura Health Ltd (Oulu, Finland); Cardiopatch is from Novosense Ab (Lund, Sweden); and Smart Socks are from Sensoria (Redmond, WA). CNN, convolutional neural network; ECG, electrocardiogram; HR, heart rate; iCare-AF, Continuous Anticoagulation theRapy in patiEnts with Atrial Fibrillation; mSToPS, **m**Health **S**creening **t**o **P**revent **S**trokes; PPG, photoplethysmography; pVO2, estimate of oxygen consumption; QTc, corrected QT interval; SaO2, oxygen saturation; TRUE-HF, **T**ed **R**ogers **U**nderstanding **E**xacerbations of **H**eart **F**ailure.

paroxysmal AF. For instance the **iC**ontinuous **A**nticoagulation the**R**apy in pati**E**nts with **A**trial **F**ibrillation (iCARE-AF) study,[28] showed in patients with paroxysmal AF that on-demand use of anticoagulation on the basis of 1-lead ECG recordings is safe and feasible and can also help improve patient adherence to therapy. Currently, a large clinical trial of rhythm-guided treatment with direct oral coagulants and use of smart watches is under way by Turakhia et al., and is sufficiently powered to account for superiority of major bleeding events vs ischemic stroke.[29]

In the absence of large-scale clinical trials among multiple populations and external validation of 1-lead ECG devices, the validity of such devices remains unknown. For instance, in the mSTOP trial, the information from the device was communicated to the patient and their primary physician, which led to higher rates of cardiology visits and follow-up investigations. A new study published by our group has shown validity and feasibility of AF detection in elderly HF patients using the AW. The AW readings compared with the expert panel's consensus, showed an agreement (κ) of 0.52 ($P < 0.05$). This is one of the many validity studies under way to show how wearables can be used in the real world and lead to improvement in cardiovascular care outcomes in patients from a diverse range of backgrounds.[30] Although the data from these trials have yet to be integrated into cardiovascular societies' guidelines, clinical use of AI-integrated wearable devices such as the smartwatches in the formal diagnosis and management of AF are currently being reviewed by multiple Canadian, European, and American cardiovascular societies.

Heart failure

Despite significant advances with guideline-directed therapy, HF still remains one of the most significant progressive cardiac conditions and affects the life of more than 7.5 million patients in North America.[31] Wearable technology provides a unique opportunity to improve symptom management and reduce hospitalization, narrowing the equity gap in cardiac care access by facilitating the diagnosis, prognosis, and remote monitoring.[32]

Heart failure diagnosis. AI-empowered wearable and digital technologies have made significant advances in diagnosis and management of HF. Recent work using 1-lead ECGs to detect cardiomyopathies supports the notion of scalability for HF screening. Although recordings of 1-lead ECGs are often noisy and prone to artifact, strategies were applied and used to train a 1-lead CNN.[33] The algorithm's inputs included voltage data, aggregating information from patterns and identifying outputs of left ventricular systolic dysfunction, correctly identifying abnormalities in 90% of the ECGs analyzed. The

algorithm in question showed robust performance even when the clinical ECG signal was augmented with typical noises from 1 wearable ECG sensor. Their noise-adapted model has an area under the receiver operating characteristic curve of 0.87, which is a robust performance compared with clinical ECGs. This highlights the potential of leveraging advanced machine learning techniques to enhance the accuracy and efficiency of cardiomyopathy detection. Attia et al. used 1-lead ECGs from an AW coupled with an AI algorithm to detect patients with left ventricular dysfunction with an area under the curve of 0.885.[16]

Heart failure prognosis. In patients with HF, data from wearable devices such as heart rate variability (HRV) and physical activity are some of the parameters that can be used for prognostication. HRV is a measurement of the fluctuation of time between each heartbeat. Patients with HF have autonomic dysfunction, which might play a role in pathophysiology. In the **U**nited **K**ingdom **H**eart Failure **E**valuation **a**nd **R**isk **T**rial (UK-HEART), patients with low HRV quantified using a standard deviation of all normal R-R intervals during a 24-hour period had a lower survival rate particularly if < 50 ms. Wearable monitoring devices capable of estimating HRV show promise and might identify those who benefit from cardiac resynchronization therapy.[34,35] Although pedometers can typically be used for administering the 6-minute walk test, for AW users, monitoring can occur via the HealthKit (Apple Inc) interface because it can integrate an AI algorithm for calculating the 6-minute walk, which is also validated by heart rate data and mean daily step count algorithms.

Heart failure Hospitalization Prediction Models

Traditionally, clinicians have relied on static snapshots to determine HF prognosis. Noninvasive cardiac monitoring using wearable sensors could provide dynamic data to accurately predict hospitalization in HF patients. In the Multisensor Non-invasive Remote Monitoring for Prediction of Heart Failure Exacerbation (LINK-HF) study, a disposable biosensor provided continuous physiologic data uploaded to a cloud database for analyzing trends and designing prognostic algorithms for prediction of HF exacerbation in patients with HF with reduced ejection fraction.[36] To do this, a wearable sensor (Vital Connect; VitalConnect, San Jose, CA) was attached to the participants' chest for 1-lead ECG detection, skin impedance, temperature, and continuous 3-axis accelerometer. The sensor data was then paired via Bluetooth to an android phone and uploaded to a cloud analytic platform (PhyslQ; physIQ Inc, Chicago, IL). The cloud-based data were then analyzed using similarity-based modelling, which is a machine learning analytic that learns tandem patterns. Over a 3-month follow-up, differences between a baseline model estimate of vital signs and actual monitored values were used to generate a clinical alert. The platform was able to successfully predict hospitalization for HF exacerbation with 76%-88% sensitivity and 85% specificity.

Currently, the **T**ed **R**ogers **U**nderstanding **E**xacerbations of **H**eart **F**ailure (TRUE-HF) study has completed enrollment of patients with HF. This study is aimed to determine whether continuous data gathered by the smartwatch paired with a transformer AI model can predict acute decompensation. Additionally, this study will compare wearable-generated estimates of oxygen consumption with traditional cardiopulmonary exercise testing, which is the current gold standard of assessment but remains inaccessible to most Canadians living with HF.

Heart failure Congestion

Wearable devices can also be used to detect worsening congestion in those with HF. For instance, the ZOLL uCor patch (ZOLL Medical Corp, Pittsburgh, PA) equipped with ECG monitor and radiofrequency sensor has the ability to measure pulmonary fluid content and is currently being evaluated in a clinical trial for its ability to predict congestion.[37] Another patch that uses seismocardiography techniques has been able to detect congestion on the basis of measurement of chest wall vibration correlating with the movement of the heart in the chest and blood flow.[38] Finally, one of the latest developments in wearable technology for detection of worsening edema involves textile-based sensors such as "smart" socks that have been developed to detect worsening edema via data from built-in accelerometer and stretch sensors to measure changes in ankle circumference (Fig. 2).[37]

The Heart Failure Society of America in collaboration with the Canadian Heart Failure Society and the European Cardiovascular Society, are currently working on a document for clinical recommendations for standardized reporting of noninvasive remote patient monitoring interventions and key clinical workflow components for processing such data in patients with HF. We anticipate that similar clinical guides and standards of reporting will soon become available through other cardiovascular societies as well. At this time, there are no established clinical standards of care for wearable sensors.

Blood Pressure Monitoring and Treatment

Hypertension screening is fundamental in the primary care setting for cardiovascular disease prevention. Cuffless PPG wearable wristbands using features such as pulse transit time have been shown to accurately measure continuous blood pressure and screen for hypertension using AI.[39] Pulse transit time is defined as the amount of time for a pulse to propagate between 2 arterial sites, and pulse arrival time, which refers to the time between 2 ECG R waves and the peak of the PPG signal. Transit time can be calculated by using PPG signs from 2 sensors at different locations or PPG and the electrocardiographic signal. An alternative strategy that combines deep learning and retinal imaging has also been used to diagnose hypertension. The clinical significance of such devices needs to be further investigated in clinical trials. Multimodal AI that integrates clinical and laboratory features can further improve personalized management of hypertension.[40]

In the context of secondary prevention and monitoring of blood pressure, the **CO**mbined-device, **R**ecovery **E**nhancement (MiCORE) study showed improved adherence to guideline-directed therapy in patients with

coronary artery disease via self-management programs using integration of an AW and a Bluetooth blood pressure cuff to assess blood pressure and activity level.[41] In their study, a 43% reduction in 30-day rehospitalization and significant health-related cost reductions were reported.[41]

Cardiac Rehabilitation

Cardiac rehabilitation is a comprehensive guideline-directed prevention strategy that applies to many cardiovascular conditions. Remote rehabilitation programs have demonstrated significant cost savings and patient convenience. A meta-analysis of 23 randomized clinical trials of patients who underwent cardiac rehabilitation after myocardial infarction showed home-based cardiac rehabilitation was as effective as a centre-based approach in improving clinical quality of life outcomes.[42] One such trial used the REMOTE-CR (Android), a real-time remote rehabilitation platform that includes the use of a chest-worn sensor and showed improved activity level with cost effectiveness compared with centre-based programs.[43] In this study, physiologic parameters such as heart rate, and respiratory rate via the chest sensor BioHarness 3 (Zephyr Technologies, Annapolis, MD), as well as single-lead ECG data collected via smartphone devices collect and upload data to the cloud for multimodal analysis and monitoring of exercise adherence and improvements in cardiopulmonary fitness.

Furthermore, a meta-analysis of 9 trials that evaluated wearable monitors of physical activity in patients with cardiovascular disease showed that exercise prescription and monitoring via a wearable device was superior to no device, and increased adherence to rehabilitation plans.[44]

Challenges of Incorporating AI in Health Care

Software algorithms that deploy AI to analyze sensor-collected data have the capability of collecting and processing large amounts of data. However data privacy, operability, and integrity present challenges to scaling wearable devices in clinical medicine. There is also a critical need for ongoing rigour to assess these algorithms and ascertain the generalizability with prospective data, clinical trials, and feasibility studies to improve workflow.

A Framework to Development of More Robust Technologies

Goldsack and colleagues have proposed a 3-stage process of verification, analytical validation, and clinical validation (V3), in which verification evaluates that the sensor-level data generates accurate data, analytical verification evaluates the performance of the algorithm, and clinical validation predicts a meaningful clinical, biological, and physical experience in the specified population (Fig. 3).[45,46] A successful V3 (ie, does the tool measure what it claims to measure? Is the measurement appropriate for the target population?) process might be challenging because each component of the framework might be built by a different company and most applications might not be broadly transferable to different populations (ie, AW parameters to detect oxygen consumption were derived from healthy populations and are not necessarily relevant in sick populations).

Bias and Inequity

AI-generated algorithms can be used in diagnosis and management of many health conditions. Bias in AI affects the applicability and interpretation of data generated through such algorithms. One source of bias is "data bias," when algorithms are trained on previously existing biased data. Obermeyer et al. have reported evidence of significant racial bias in widely used AI-generated algorithms in health care. For instance, in the US-based algorithm at any given risk score, Black patients had to be deemed much more ill than White patients to be recommended the same treatment by AI. This is because the algorithm was trained on health care spending data rather than illness. Because unequal access to care means less money is spent for Black patients, this introduces bias when using health care spending as a means to estimate care needs. Despite the fact that health care costs can be an effective proxy for health; large racial biases arise as a result of unequal access to care.[47]

Racial bias has been observed in the measurement of oxygen saturation level by pulse oximetry devices. Because of the greater presence of melanin, Black patients have falsely elevated peripheral oxygen saturation detected via pulse oximetry compared with arterial oxygen saturation measured in arterial blood gas.[48] Within the HF population, the oxygen saturation is used to estimate the cardiac index using the Fick equation. During hospitalization, these calculations guide patient care. Because of the discrepancy in peripheral vs arterial oxygen saturation level, use of the Fick cardiac index in Black patients might underestimate the peripheral oxygen saturation level via pulse oximetry. This might significantly affect the course of HF management in Black patients and lead to suboptimal care.[49] Ensuring that these sensors are generalizable across skin tones is of paramount importance. In recent studies, there was an absolute error of 30% during activity than at rest in those with darker skin tone.[50] This raises the need for systematic validation of wearables under various conditions and across a wide range of skin tones before further integration of such devices in consumer products.

Bias in AI is a significant source of concern in machine learning and AI-generated technology. These biases usually reflect widespread societal views about race, gender, biological sex, and ethnicity. Currently, researchers are focused on identifying such biases because AI should be used to mitigate rather than perpetuate inequalities.

Recently, Jain et al. have proposed a framework of 6 equitable AI algorithm principles to maximize performance while minimizing bias. These 6 principles focus on identification of clinically relevant equity criteria, development of algorithms on the basis of diverse data sets to allow for comprehensive representation, inclusion of demographically sensitive features to address disparities, careful choice of prediction targets to avoid imperfect proxies (ie, health care costs for health care needs), caution using uninterpretable algorithms and finally, emphasize that clinical algorithms should remain complementary and not in replacement of clinical judgement.[51] This framework as a necessary equity lens should be applied to all clinically focused

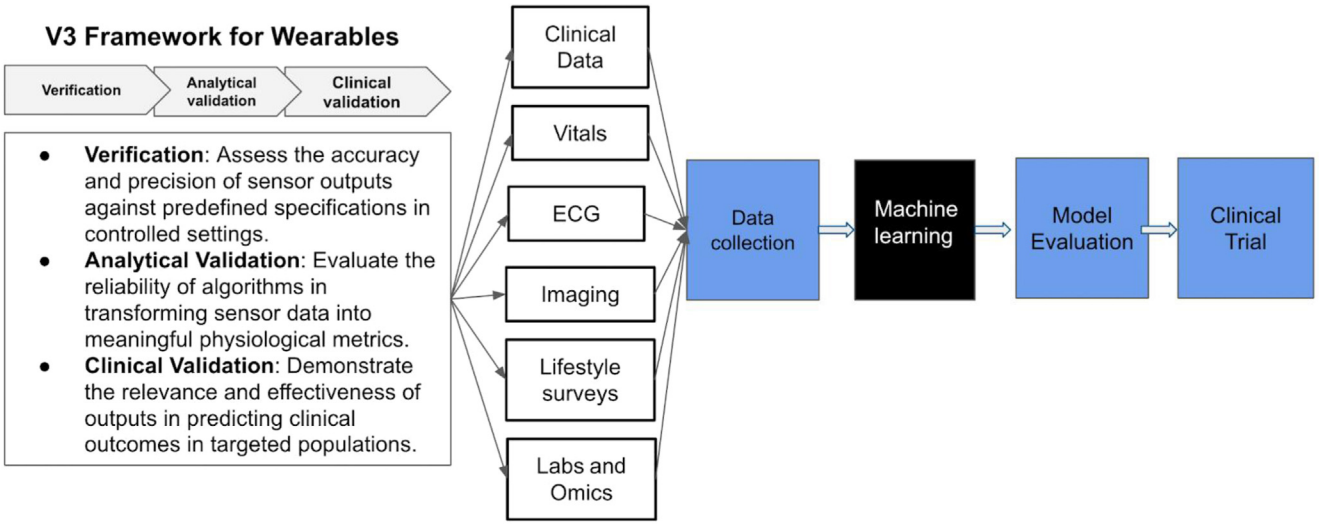


Figure 3. The V3 framework is essential for ensuring wearables deliver accurate, reliable, and clinically relevant data, facilitating their safe and effective application in health care. This framework informs all aspects of clinical medicine, underlining the necessity for rigourous model evaluation and clinical trials to guarantee generalizability, regardless of the complexity of machine learning algorithms involved. ECG, electrocardiogram.

AI algorithms in development and enforced by organizations responsible for their approval.

Lack of Regulatory Policies

Regulatory oversight governing wearable devices is lacking, allowing the emergence of numerous products of unknown safety and efficacy. Currently, the US Food and Drug Administration has a new digital health innovation plan that proposes a pragmatic risk-based approach to regulate software and wearable medical devices through precertification programs that aim to assess and determine appropriate product development.[52] This is done using the international medical device regulators risk categorization framework that allows regulatory oversight of companies in production and premarket pathways that are appropriate and require solicitation of feedback from stakeholders such as clinicians, scientists, and industry leaders. In the absence of such regulatory oversight policies, data obtained from wearable devices cannot be widely accepted in clinical settings. However, presence of such bodies are critical at the levels of national organizations to hospitals and front-line clinicians.

Data Quality

Because incorrect data is more harmful than no data, scientific validation studies are under way to assess accuracy of the raw data obtained by algorithms used in smart wearable devices. Data quality is a crucial feature of scientific data, which is the foundation of device development and validation. It is one of the fundamentals of research ethics. However, variability of sensors is one of the challenges in assessing data quality obtained by wearables. For instance, oxygen saturation could vary on the basis of location of assessment (ie, wrist or finger) and the type of device used (ie, smart watch vs ring). One way to mitigate this challenge to ensure data quality is to perform clinical validation studies.[53] Even after clinical validation of data, data storage practices can play a significant role in quality and reliability of data. Regulatory hurdles for accessing proprietary archives could also widen the gaps and lead to inequity in medical research and development. However, the presence of such bodies are critical at the levels of national organizations to hospitals and front-line clinicians. The clinicians require knowledge of the AI systems and ability to integrate such systems effectively into existing workflows. As such, skills related to understanding AI systems in health care should become a priority in medical education.[54]

Data Security and Patient Confidentiality

Sensitive patient data via wearable technology is subject to breaches. As such, specific attention has to be paid toward data security in this field. Deidentification of data is a possibility to protect data, however, because of the extent of available data for each user, they can theoretically be reidentified.[55] Next-generation cybersecurity tools such as block chain have been proposed as a means for secure storage and prevention of such data breaches.[56] Furthermore, there should be reassessment of Health Insurance Portability and Accountability Act policies to account for increasing availability and heterogeneity of patient technological data and more transparent privacy policies that can help improve patient trust and engagement.[57]

In Europe, the General Data Protection Regulation states that everyone has the right to control and protect their own personal data and as such manufacturers should allow for integration of privacy and security options in all wearable devices.[58] However in many cases, users have to "opt out" of certain settings to restrict the use of their information by manufacturers. From the patient perspective, such options create trust and empower the users. In one study, patients who were willing to share their health data with their physician (72%) but fewer with their health insurer or manufacturing companies (53%).[57] Therefore, defining better security options and a more transparent approach for opting out of data collection by manufacturers is needed for building trust in transition to digital care.

Table 2. Ongoing clinical trials for wearable devices in cardiovascular medicine

Study name or trial identifier	Study title	Primary objective	Condition	Study design	Estimated duration
Strong Hearts	Strong Hearts: A Remote, App-Enabled, Exercise Program for Patients With Congenital Heart Disease (Strong Hearts App)	To create a remote, mobile application-enabled exercise program for patients with congenital heart disease	Congenital heart disease	Interventional	January 2024 to December 2025
WB-AF	Portable Measurement Methods Combined With Artificial Intelligence in Detection of **A**trial **F**ibrillation (WB-AF)	To develop state of the art PPG- and ECG-based methods for long-term AF monitoring	AF	Observational	June 2021 to December 2024
RADAR-HF	Remote Dielectric Sensing (ReDS) Assisted Diuresis in Acute Decompensated Heart Failure	To evaluate the use of a wearable vest capable of noninvasively measuring lung fluid content in hospitalized patients with HF	HF	Interventional	December 2018 to 2025
NCT06009718	Artificial Intelligence (AI) Analysis of Synchronized Phonocardiography (PCG) and Electrocardiogram (ECG)	To develop an artificial intelligence analysis system to identify dLVEF (EF < 50%) using PCG and ECG	HF	Observational	June 2020 to 2028
RECAMO	**RE**mote **CA**rdiac **MO**nitoring by the Corsano CardioWatch 287-2 Evaluation Study	To compare the number of episodes of AF detected using the Corsano CardioWatch 287-2 (Health BV, The Hague, The Netherlands) during 28 days of use with the number of episodes of AF detected using conventional Holter monitoring during 48 hours of use	AF	Observational	June 2023 to December 2024
Nanosense Study	Nanowear Heart Failure Management Multi-sensor Algorithm	To develop and validate a multiparameter algorithm for the detection of HF before an HF event	HF	Observational	August 2021 to December 2024
SAFER Wearables Study	A Study of the Acceptability and Performance of Wearables for Atrial Fibrillation Screening in Older Adults	To determine the feasibility of measuring interbeat intervals using a wristband	AF	Observational	February 2023 to May 2025
NCT04835857	Comparison of Cuff-Less Wrist Wearable Blood Pressure Device to Cuff Based Blood Pressure Measuring Devices	To compare cuffless wrist wearable radial artery blood pressure measurements using ViTrack (developed by Dynocardia Cambridge, MA) with the cuff-based commercially available blood pressure device, in healthy volunteers with normal or high blood pressure	Hypertension	Observational	January 2021 to May 2024
CONGEST-HFEX	Correlation of Non-invasive CPM Wearable Device With Measures of Congestion in Heart Failure in Exercise	To investigate if changes in measures derived using a CPM wearable device correlate with changes in B-lines between dialysis sessions and with the difference in weight between dialysis sessions	HF	Observational	March 2023 to 2025

AF, atrial fibrillation; CONGEST-HFEX, Correlation of Non-invasive CPM Wearable Device With Measures of Congestion in Heart Failure in Exercise; CPM, continuous passive motion; dLVEF, depressed left ventricular ejection fraction; ECG, electrocardiogram; EF, ejection fraction; HF, heart failure; RADAR-HF, Real-Time Electrogram Analysis for Drivers of Atrial Fibrillation and Heart Failure; PCG, phonocardiography; PPG, photoplethysmography; WB-AF, Portable Measurement Methods Combined With Artificial Intelligence in Detection of **A**trial **F**ibrillation.

Perspectives in AI-Guided Digital Care

Patient perspective

There is a paucity of data on assessment of patient views and perspectives regarding the use of wearables and how those data are analyzed, stored, and shared. In a survey of > 500 individuals with AF, 79% were interested in using a mobile-based technology for detection of AF. The stated benefits of using such devices include fewer in-person visits to the hospital, reassurance and peace of mind, and more consistent follow-ups. Approximately two-thirds of the group were interested in continuing using the mobile-based monitoring system in the future for quality of life benefits.[59] The lower rate of use of wearable devices in individuals with health issues might be related in part to their perception that devices are more geared toward elite athletic performance, rather than monitoring of health status in those with disease. They might be less engaged or inclined to use these devices with regularity when framing their performance against healthy or more active individuals.[9]

Furthermore, in some patients, navigating wearable devices, particularly in patients with cognitive, visual, or hearing impairments, lack of non-English resources, cost of the device and internet access, and a complex interface can limit usability and compliance. Without consistent data, the effect and validity might be limited, and particularly affect those with unequal access to digital care and thus worsen health disparities. Research should continue to evaluate patient's perspectives on use of wearables and access to the data they record. Ongoing patient involvement and representation on guideline committees will remain crucial as well, to ensure issues around equity, data use, and health privacy are recognized and addressed.

Clinician perspective

From the clinician's perspective, wearable data offers potentially invaluable insights into risk-modifying factors, medication adherence, and disease progression that is independent of patients' self-reports. However, the successful adoption of such technology hinges on its ability to facilitate better decision-making leading to improved patient outcomes and experiences, rather than merely increasing the volume of data the clinician receives. Digital tools that require constant monitoring, often leading to false positive results, are prone to limited sustainability.[60]

According to a survey of health care professionals, lack of sufficient clinical infrastructure and personnel is the primary barrier to the use of health digital tools. AI-based algorithms must effectively address real-world clinical challenges and this requires meaningful use criteria, clinical guidelines, and regulatory oversight committees. Furthermore, clinicians report concern with regard to patient data privacy and potential legal liability with the use of new digital programs. In many cases, the use of wearable technology might be initiated by patients and providers might be asked to interpret data they are unfamiliar with in the setting of unclear reimbursement policies and legal liabilities. The lack of transparency in AI algorithms is another concern among clinicians, because it can be challenging to decipher the meaning of data and the sources of information derived from patient presentations. Some clinicians perceive AI-guided care as diminishing the role of human intelligence and expertise. Additionally, there is apprehension regarding the external validity and generalizability of the data, further complicating acceptance and integration of AI into clinical practice.[61,62] All of these factors might lead to delay in acceptance and implementation of AI-assisted care by the health care providers.

Conclusions

AI algorithms allow for multimodal analysis of data from various sensors and wearable technologies alongside patient's electronic medical records, biochemical, and imaging findings. Application of AI has helped play a key role in optimizing wearable technology performance and integration in the cardiovascular medicine and clinical setting. Accurate real-time continuous monitoring of health data could pave the way for enhancing prevention and management of cardiovascular diseases such as arrhythmias, HF, hypertension, and improved adherence to cardiac rehabilitation programs.

As sensor technologies advance alongside the refinement of AI processes, wearable devices will become increasingly sophisticated, potentially revolutionizing cardiovascular practice. Wearable devices have shown potential application in screening and monitoring of cardiovascular diseases as discussed previously. However, in the absence of extensive validation through large-scale clinical trials to verify effectiveness, their clinical implementation remains in infancy. This transition presents unique challenges such as ensuring accuracy and validity of biosensors embedded within these devices. Regulatory oversight spanning the entire life cycle of wearable technology development, from initial design to widespread implementation, is essential to safeguard patient safety and efficacy. All of the ongoing active clinical trials involving the use of wearable technologies in cardiovascular medicine among a diverse cohort of individuals (ie, from congenital heart disease to cardiovascular rehabilitation in the geriatric population) are shown in Table 2. The adoption of wearable technologies requires active engagement of clinicians and patients alike to ensure that wearable products meet their needs, are user-friendly, and inspire trust and confidence.

Establishing the necessary infrastructure is crucial to enabling decentralized health care delivery and ensuring equitable access to wearable technologies and associated AI algorithms. By harnessing real-time patient-generated data obtained from free-living environments, health care providers can gain valuable insight into individuals' cardiovascular health and deliver personalized care interventions.

Case Revisited—HF Care in 2028

Ms S. is a 50-year-old patient with HF. She is mildly symptomatic at the time, but has not noticed any weight change. She receives an alert via an integrated mobile-based application that collects bioimpedance data from a chest sensor, triggering a 1-lead ECG by her smartwatch. On the basis of data from the chest sensor and her smartwatch, an AI-generated message instructs Ms S. to increase her daily diuretic dose, ensure daily weight measurement, and to self-monitor for symptoms of HF. A simultaneous alert is automatically sent to the health team, suggesting a high risk of impending HF decompensation and recommendation for clinical

assessment. Arrangements are made for bloodwork and a clinic appointment with the primary care physician in 2 days. Data from Ms S.'s wearable devices, laboratory tests, and health records are integrated to provide a summary of her condition and a list of potential management recommendations for the physician to review and act upon at the appointment.

Ethics Statement

The research reported has adhered to the relevant ethical guidelines.

Patient Consent

Patient consent is not applicable because this is a review article.

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Disclosures

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Supplementary Material

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