Circulation: Genomic and Precision Medicine

AHA SCIENTIFIC STATEMENT

Data Interoperability for Ambulatory Monitoring of Cardiovascular Disease: A Scientific Statement From the American Heart Association

Antonis A. Armoundas, PhD, Chair; Faraz S. Ahmad, MD, MS; Derrick A. Bennett, PhD; Mina K. Chung, MD; Leslie L. Davis, RN, PhD, FAHA; Jessilyn Dunn, PhD; Sanjiv M. Narayan, MD, PhD; David J. Slotwiner, MD; Kevin Keith Wiley Jr, PhD, MPH; Rohan Khera, MD, MS, Vice Chair; on behalf of the American Heart Association Data Science and Precision Medicine Committee of the Council on Genomic and Precision Medicine and Council on Clinical Cardiology; Council on Cardiopulmonary, Critical Care, Perioperative and Resuscitation; Council on Cardiovascular and Stroke Nursing; Council on Lifestyle and Cardiometabolic Health; Council on Peripheral Vascular Disease; Council on Quality of Care and Outcomes Research; and Stroke Council

ABSTRACT: Wearable devices are increasingly used by a growing portion of the population to track health and illnesses. The data emerging from these devices can potentially transform health care. This requires an interoperability framework that enables the deployment of platforms, sensors, devices, and software applications within diverse health systems, aiming to facilitate innovation in preventing and treating cardiovascular disease. However, the current data ecosystem includes several noninteroperable systems that inhibit such objectives. The design of clinically meaningful systems for accessing and incorporating these data into clinical workflows requires strategies to ensure the quality of data and clinical content and patient and caregiver accessibility. This scientific statement aims to address the best practices, gaps, and challenges pertaining to data interoperability in this area, with considerations for (1) data integration and the scope of measures, (2) application of these data into clinical approaches/strategies, and (3) regulatory/ethical/legal issues.

Key Words: AHA Scientific Statements ■ ambulatory care ■ cardiovascular diseases ■ electronic health records ■ International Classification of Diseases ■ wearable electronic devices

A rapidly growing portion of the population currently uses wearable devices to track health and illnesses. These devices span smartwatches, smart rings, and remote monitors of ECG and oximetry, among others. In 2021, there were >100 million users globally of a single smartwatch, the Apple Watch, with >455 million wearables shipped across the globe.[1] In the United States, during 2019 to 2020, 29% of the US adult population reported using a wearable device for monitoring health and activity.[2]

Given these trends, a health care ecosystem of interoperable ambulatory medical devices may enable the integration of information from sensors, devices, and software applications (apps) to facilitate innovation in preventing and treating cardiovascular disease (CVD). Yet, the ambulatory medical technology ecosystem consists of systems that do not permit such goals, in particular because of challenges with interoperability and limited integration into existing clinical workflows (Figure). The proliferation of multiparameter, multiple-function ambulatory devices with multiple discrete data streams can provide information on several physiological and pathophysiological elements that may enable better patient care and outcomes.[3,4] However, strategies for data quality assurance and the appropriateness of clinical content (also known as technical requirements), which would help guide the design of clinically acceptable ambulatory monitoring systems, as well as the approach toward accessing and incorporating these data into clinical workflows, remain of limited efficacy.[5,6]

This scientific statement aims to address the best practices, gaps, and challenges pertaining to the need

Supplemental Material is available at https://www.ahajournals.org/journal/doi/suppl/10.1161/HCG.0000000000000095.

Circulation: Genomic and Precision Medicine is available at www.ahajournals.org/journal/circgen

Clinical Vignette

A 62-year-old woman receives an alert from her smartwatch indicating that she may have had an episode of atrial fibrillation. If she has granted permission for the health application of her smartwatch to upload data to her primary care professional's patient portal, and if the smartwatch and health application support the same vocabulary and communication protocols used by the patient portal and electronic health record, the system might then interpret this information in the context of her overall health to determine whether she may be at increased risk of an embolic stroke. The system could prompt her primary care professional to consider prescribing anticoagulation. To enable this workflow, syntactic and semantic interoperability between ambulatory and electronic health record data formats is key.

for data interoperability in this area, with considerations for (1) data integration and the scope of measures, (2) application of these data into clinical approaches/strategies, and (3) regulatory/ethical/legal issues.

DISEASE APPLICATIONS

Overview

Because several key physiological metrics are readily sensed and quantified, ambulatory monitoring of CVD is at an inflection point of growth, driven by a confluence of novel sensors, advanced analytics capable of processing massive amounts of data, and well-curated databases.[7]

Arrhythmia Detection and Monitoring

Arrhythmia monitoring is the best-established paradigm for novel ambulatory monitors, with wearable and handheld devices adding value to conventional Holter, event, patch, and implantable monitors.[8]

Atrial fibrillation (AF) is the most studied use case for detecting arrhythmias by novel devices. Two main sensor classes are used to detect AF: photoplethysmography and electrocardiographic recordings. A systematic review of smartphone photoplethysmography apps showed fair sensitivity, specificity, and negative predictive value for AF detection but low positive predictive value.[9] Electrocardiogram-based monitors are increasingly preferred over photoplethysmography sensors for AF monitoring and have been used to assess AF burden after medical therapy or ablation[10–12] or to guide anticoagulation.[12] Apps combining both sensors[13] have shown reduced time to diagnosis in individuals suspected of AF.

Ambulatory monitors can detect other supraventricular or ventricular tachyarrhythmias or bradycardia[8] and may facilitate risk stratification of patients for sudden cardiac death such as after myocardial infarction (MI) or those with hypertrophic cardiomyopathy by detection of complex ventricular ectopy or ventricular tachycardias. Detection of the AF burden and high ventricular rates may also aid in diagnosing tachycardia-induced cardiomyopathy.

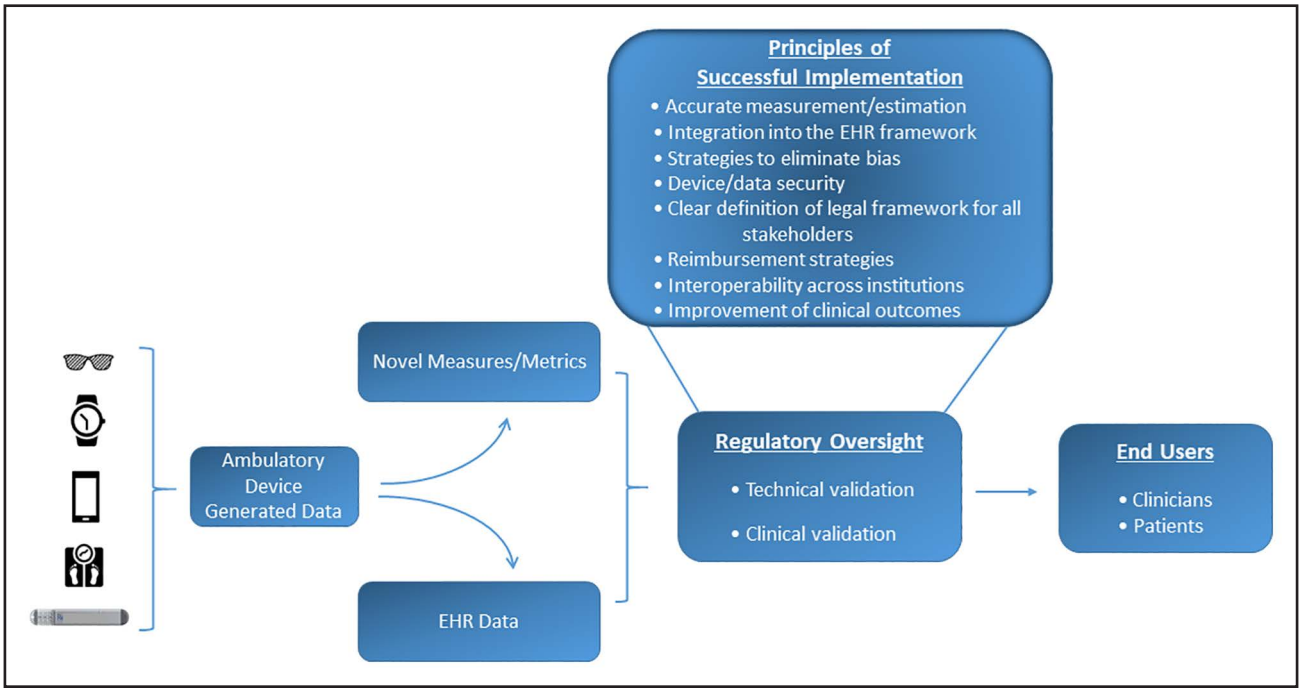

Figure. Overview of the approach to implementation of data derived from ambulatory monitoring devices.
EHR indicates electronic health record.

Blood Pressure

Blood pressure measurement is a key measurable disease entity for which photoplethysmography-based sensors are well suited. Photoplethysmography-based blood pressure assessment uses mapping of pulsatile peripheral arterial waveforms, which are calibrated to central (aortic) pressure with various algorithms and machine learning technologies.[14,15] Nevertheless, the diagnostic accuracy[16] of such sensors for blood pressure measurements must be broadly defined, including demographic groups with a predilection for hypertension, those with comorbidities such as heart failure (HF) and stroke, and other vulnerable populations.[17] Devices for ambulatory blood pressure measurement are described in the Spectrum of Physiological and Pathophysiological Measures: Wearable/Implantable Devices section.

Heart Failure

Remote sensors can be used to manage HF by quantifying vital signs, weight, lung congestion (using thoracic impedance from implantable or wearable sensors), hemodynamics (from several implanted devices), and activity, with varying success.[18] Recent studies show that direct pulmonary artery pressure monitoring with percutaneously implanted, leadless sensors may help reduce HF admission rates.[18–20]

Ischemic Heart Disease

Wearable sensors coupled with machine learning algorithms may be able to precisely detect changes in the electrocardiographic ST segment related to acute ischemia, even in the presence of noise. In early-phase studies, 2-lead wearable devices using smartphone-associated sensors at sequential sites have been shown to approximate the accuracy of the standard ECG, exhibiting 89% sensitivity, 84% specificity, 70% positive predictive value, and 95% negative predictive value for ST-segment–elevation MI compared with the 12-lead ECG.[21] Such devices could expedite the management of patients suspected to have an acute coronary syndrome, particularly in remote areas.[22] However, several issues remain, including the need to replicate these data when obtained by patients as opposed to expert clinician users.

In the future, minimally invasive wearable devices using various biosensors (eg, optical, electrochemical, magnetic, and microRNA-based biosensors) offer promise. For example, electrochemical biosensors measuring troponin levels have shown high predictive performance in risk-stratifying patients with myocardial damage/tissue necrosis, which could provide the basis for a home-based care solution in the field of biomarker assays.[23]

Detecting and Monitoring Pulmonary Disease

Pulse oximetry monitors and similar wearable devices are increasingly used to detect normal and worsening pulmonary conditions. A recent systematic review of 12 studies on wearable sensors that used statistical and machine learning algorithms to detect SARS-CoV2 infection[24] exhibited areas under the curve that ranged from 0.52 to 0.92 and accuracy for detecting presymptomatic infection of 20% to 80%. Indices primarily associated with COVID-19 diagnosis were increased heart rate, changes in skin temperature, and reduced activity, each with modest specificity alone. However, these early studies had limitations, including a lack of racial diversity in recruitment,[25] device-type variability, and a lack of standardized analyses.[26] Another review of 28 studies aiming to detect deterioration in patients diagnosed with COVID-19[27] found that oxygen saturation as measured by pulse oximetry (Spo_2) <95% and respiratory rate >30 breaths/min were the most common indicators, whereas respiratory rate, Spo_2, heart rate, and home temperature were the strongest indicators of hospitalization.

Currently, evidence for using wearable oxygen saturation monitors for patients diagnosed with COVID-19 is modest,[28] with conditional recommendations for using high-quality and reliable devices at home and integrating home oximetry data into the health care system.

Other Clinical Applications

Virtual care that incorporates novel sensors has promise beyond CVD. It has already improved health care access in rural and other underresourced areas and may even accelerate clinical trial recruitment and event classification.[29] The COVID-19 pandemic[30–32] illustrated that the virtual care model can provide near–hospital-grade oxygen saturation and electrocardiographic monitoring at home and thus reduce the need for urgent and inpatient care.[33,34] Emerging apps include perioperative monitoring at home to expedite discharge after surgery,[35] tracking of cardiac rehabilitation, monitoring for diabetes[36] and metabolic disease,[37] and cautious engagement of patients with innovations such as chatbots.[38] Future work must identify patients and diseases best suited to this approach and then test practical workflows that minimize bias and ensure data privacy and integrity (Table 1).

SPECTRUM OF PHYSIOLOGICAL AND PATHOPHYSIOLOGICAL MEASURES: WEARABLE/IMPLANTABLE DEVICES

Overview

Emerging wearable systems focusing on validated pathophysiological indices and providing actionable data to guide care are expected to advance cardiovascular

Table 1. Disease Applications

Best practices	Description
1. Use of wearable systems with published and actionable end points in clinical studies	Clinical studies of wearables include detection of AF to triage for anticoagulation or detection of elevated PA pressure to manage HF
2. Make available the raw data, data splits, algorithm version, and training/test results	Replication of AI-based studies is difficult, particularly if the underlying hardware (sensors, software versions) differs. Publishing details may facilitate reproducibility, FDA review, and patient safety
Gaps and challenges	**Background**
1. Sensors and algorithms linked to clinical tasks need to be clearly defined as most or least appropriate	Wearable systems may not provide equally effective or actionable end points for all CVD end points. Strengths and limitations of each need to be defined.
2. Calibration of sensors and algorithms is needed for each application	Sensor-algorithm pairs are optimized and then calibrated to a consensus (ground) truth per task, for example, detecting AF or sensing PA pressure or activity
3. Standardization of sensor types and algorithmic approaches is needed	Comparisons between wearable systems are enabled for each clinical task. One approach is to develop sensor and data interoperability standards.

AF indicates atrial fibrillation; AI, artificial intelligence; CVD, cardiovascular disease; FDA, US Food and Drug Administration; HF, heart failure; and PA, pulmonary artery.

practice. This process requires that each system is tested rigorously in well-characterized populations for hard clinical end points (Table 2), as well as actionable clinical surrogates such as tachycardia or alterations in blood pressure. The monitoring landscape is transitioning from a past in which all measurements were intermittent toward a future in which many will be continuous. However, the cut points for treating continuous metrics and whether these improve outcomes for any disease have yet to be determined in clinical trials and are beyond the scope of this document.

Physical Activity

Physical activity may inform care in those with or at risk for CVD and can be tracked by wearable devices more continuously and passively during daily activities than by 6-minute walk distance in controlled settings and more objectively than by a subjective recall. Sensors of movement (accelerometer), position (by GPS, gyroscope, barometer, and altimeter), or heart rate can be processed by algorithms to indicate physical activity type, activity level, and energy expenditure[39]; other biosignals and surface electromyography (eg, smart socks) also hold promise.[39] However, several challenges exist. There is a lack of standardization of sensing and analytics among systems and external validation.[40] Clinical challenges include difficulties for clinicians in integrating patient-generated physical activity data into a care plan. In contrast, patient difficulties include cost, setup, and data sharing with the clinical team.

Table 2. Spectrum of Physiological and Pathophysiological Measures: Wearable/Implantable Devices

Best practices	Description
1. Identification of physiological indices that are best measured by wearable systems	Physiological indices reflect several clinical signals, but not all are detected with equal accuracy by wearables, and not all wearables are equally effective at this measurement
2. Establishment of clinical trials of device studies that define diagnostic accuracy	Wearable systems translate the detection of physiological indices to improve clinical care by requiring that result accuracy be prospectively tested in clinical workflows aiming to guide diagnosis or therapy
3. Actionability of detected physiological indices	Wearable systems that enable automated and manual physiological measurements inform timely, accurate clinical decision-making
Gaps and challenges	**Background**
1. Development and testing of wearable systems to ascertain undetected but clinically important physiological indices	Most wearable devices concentrate on readily measured indices such as the ECG or activity, but sensors that detect and measure novel metrics may also provide clinical value (eg, AI of the ECG to track serum potassium or data from wearables for several metabolic markers)
2. Development of methods to digitize symptoms scores	Symptoms (eg, nausea, palpitations, dyspnea, chest symptoms) are a key factor in clinical evaluation but are underemphasized in digital medicine. Wearable system development should address this gap.
3. Development of standards to serve as a foundation for comparing sensor systems	A framework of processes that enables systems to be independently evaluated and compared is needed and may be facilitated by the development of nonproprietary, reference datasets

AI indicates artificial intelligence.

Prescription, referral and measurement standardization of physical activity, is fundamental for patient care, and having physical activity assessment in electronic health records would be an important addition to our national surveillance systems. A multi-organizational effort led by the American Heart Association and Physical Activity Alliance has created a Physical Activity FHIR Implementation Guide[41] (version 1 for Standardized Use) in Health Level 7 International, that is now in the public domain for implementation and uptake by health systems, qualified exercise professionals, digital health technology, medical fitness centers, and evidence-based programs. In July 2023, measures for physical activity assessment were incorporated into the US Core Data for Interoperability version 4,[42] so they will be included into EHRs when version 4 of USCDI becomes part of federal regulation, in about 2–3 years. A reference implementation for the Implementation Guide will be developed by Fall 2024, and the USCDI physical activity assessment measures will be incorporated into the US Core. These developments will enhance the opportunity for digital exchange of patient-level data for physical activity prescription, referral and assessment.

Fall Detection

Wearable devices that use movement (eg, gyroscope, accelerometer), vision (surveillance cameras), or other sensors in the ambient environment are examples of technology aiming to detect falls.[43] Current best practices for detecting falls combine sensors, typically placed on the waist, with wireless data transmission to an information processing center for analysis and alerting.[43] Such systems can detect falls with ≥94% accuracy, depending on technical specifications, although most studies have been performed in relatively young, healthy subjects. Emerging technologies such as smart textiles in garments are gaining interest because of their cost and practicality.[43] Challenges include sensor noise (eg, motion artifact), poor connectivity, delays in transmitting alerts to key parties, and interoperability with current electronic health records (EHRs).[43,44]

Vital Sign Monitoring

Monitoring heart rate, blood pressure, blood oxygen, and core temperature can facilitate real-time clinical decisions in hospitalized or ambulatory patients.[45] Data may be transmitted continuously or when a designated event such as an abnormal heart rhythm occurs. Pulse oximeters can provide feedback on oxygen saturation at home, but a recent study suggested that they did not improve outcomes without supplemental text messaging data.[46,47] Challenges include the risk of exacerbating disparities in care such as the relative lack of validation of pulse oximetry devices in patients with darker skin color,[48] low-bandwidth environments, and lack of hardware. Other challenges include data integrity and privacy. Although some vital signs such as temperature are included within the classification of EHR and thus are subject to existing regulations on data integrity and confidentiality,[49] other clinical surrogates such as steps and activity level are not. It is likely that as digital databases and clinical evidence grow, there will be reconsideration of these historical classifications. Such reclassifications would ideally be based on evidence from clinical trials of actionable workflows.

Heart Rate and Rhythm

The Disease Applications section discussed mobile device detection of heart rate and rhythm to predict the risk of CVD. Although ECGs and photoplethysmographies can diagnose arrhythmias such as AF from a limited number of leads, the lack of validated algorithms limits their ability to accurately diagnose complex arrhythmias, MI, or other abnormalities.[50] A framework that enables the external validation of such systems and data standards to enable competing systems to be compared requires data interoperability. Such an approach may also facilitate patient-led data review and verification after appropriate alerts.

Devices for Hemodynamic Measurement

Several devices can measure pulmonary artery and left atrial pressures. Pulmonary artery pressure devices have a Class IIB recommendation for patients with symptomatic HF in the European Society of Cardiology and American College of Cardiology/American Heart Association[51] guidelines, with American College of Cardiology/American Heart Association guidelines further restricting devices to patients in New York Heart Association class III. Meta-analyses suggest that pressure monitors are more effective than impedance monitors in guiding therapy.[19]

In the COMPASS-HF trial (Chronicle Offers Management to Patients with Advanced Signs and Symptoms of Heart Failure), patients randomized to a pressure sensor (mounted in the right ventricular outflow tract) did not have a lower incidence of HF events than those receiving standard care. Still, they experienced a longer time to first HF hospitalization ($P<0.03$).[52] In the CHAMPION study (CardioMEMS HF System Post Approval Study) of 1114 patients, another sensor guided care to reduce HF hospitalization by 28% at 18 months and was cost-effective.[53]

Because pulmonary artery pressure may not accurately reflect left atrial pressures,[54,55] devices are being developed that monitor left atrial pressures directly. LAPTOP-HF (LA Pressure Monitoring to Optimize Heart Failure Therapy)[56] was terminated early because of complications relating to its transseptal placement. However, in already-enrolled patients, HeartPod was associated with a 41% reduction in HF hospitalizations at 12 months ($P=0.005$), and newer devices are being tested in this space. Other sensors can sense chest wall impedance using straps[57] or respiratory rate using a chest patch.[58] Ballistocardiography[59] and seismocardiography mechanoacoustically record micromovements from cardiac motion at the body's center of mass and the chest, respectively.[60] Devices based on phonocardiography have recently been cleared by the US Food and Drug Administration (FDA) to assess murmurs[61] and could potentially indicate filling pressures.

Devices for Measuring Sleep and Indices of Pulmonary Health

There is increasing awareness of the link between sleep-disordered breathing and CVDs, including HF, AF, and mortality.[62] Several devices are being tested to measure sleep-related physiology in the ambulatory setting to simplify diagnosis and to augment or potentially replace polysomnography in selected cases.[63] Emerging devices use electrocardiographic and phonocardiographic sensors, oxygen sensors that can detect desaturations,[64] photoplethysmography to detect abnormalities in pulse waveforms, and sound sensors to detect snoring, as well as electroencephalographic and electromyographic sensors.[62]

DATA FORMAT

Overview

Analogous to human language, which is built on defined grammatical structures and vocabularies, data interoperability requires information to be communicated in a structure recognized by both sender and receiver (known as syntactic interoperability) and requires that both sender and receiver understand the meaning of the information (known as semantic interoperability). If these conditions are met, the systems can transmit, receive, and process the information for further use. In this section, we outline commonly used tools for structuring and communicating health care information, introduce the most widely used collection of medical terms and concepts, and touch on the Open mHealth initiative dedicated to making mobile health data interoperable with the use of existing clinical vocabularies and communication protocols.

Syntactic Interoperability (Controlled Vocabularies)

Controlled vocabularies allow clinical content in EHRs to be represented in a standardized way that can be understood by humans and captured, stored, and interpreted by computers. There are several widely used controlled vocabularies for medical terms and concepts. SNOMED CT (Systematized Nomenclature of Medicine Clinical Terms) is the single largest collection of medical terms, organized hierarchically to provide definitions, synonyms, and relationships and containing >350 000 concepts.[65] It includes clinical findings, symptoms, diagnoses, procedures, body structures, organisms, substances, pharmaceuticals, devices, and specimens.

Each term in SNOMED CT is organized into 3 primary core components: concepts, descriptions, and relationships.[65] The fundamental building blocks are concept codes. These are clinical terms that are then assigned a numerical code. For example, the concept of AF has been assigned the code 49436004. Each concept is organized into an "is-a" hierarchy. For example, AF "is-an" arrhythmia.

Furthermore, each concept code has textual descriptions divided into 2 groups: a fully specified name and synonyms. Each concept has only 1 fully specified name, but each may have many (or no) synonyms. A relationship describes the association between 2 concepts. The relationship is used to define the meaning of a concept in a way that a computer can process.

Semantic Interoperability

Controlled vocabularies provide the building blocks for the interoperability structure, but a common organizational structure is needed to exchange and interpret the information. Health Level 7 International has developed 2 of the most widely used structures: Structured Reports/Consolidated-Clinical Document Architecture (C-CDA) and Fast Healthcare Interoperability Resources (FHIR).

Structured Reporting/C-CDA

A major effort toward developing standards for exchanging data between hospital information systems has been the development of the Clinical Document Architecture, which is a standard that provides structure to electronically stored medical information by specifying the way that data elements are captured, stored, accessed, displayed, and transmitted. Clinical Document Architecture includes a common architecture, coding, semantic framework, and an extensible markup language (XML)–based markup language that is human readable and machine interpretable. Along with Clinical Document Architectures, Implementation Guides were released by multiple standards development organizations such as Health Level 7 International as case studies to demonstrate the use of Clinical Document Architectures in specific scenarios and to serve as document templates. Implementation guide consolidation has been achieved through the C-CDA effort led by the US Office of the National Coordinator for Health Information Technology. The C-CDA satisfies "meaningful use," the minimum US standards for EHRs that eligible health care professionals and hospitals must meet in adopting and using EHR technology to qualify for Medicare and Medicaid incentive payments. Despite the acceptance of C-CDA as the primary standard for clinical document exchange in the United States, challenges underlying the goals of meaningful use remain.[66,67]

Fast Healthcare Interoperability Resources

FHIR builds on the static C-CDA data organization standards by providing not only a clinical data structure but also a standard for the exchange, including sending, transmission, delivery, and receipt of such clinical data, which are critical tasks when it comes to ambulatory monitoring data. Through FHIR, data are stored and accessed as individual elements rather than full documents, and these elements are described by FHIR resources. The FHIR data representation and bundling standards are based on JavaScript Object Notation, XML, and Resource Description Framework. The key solution that FHIR brings to interoperability is the app programming interface (API) that can perform the packaging, transfer, and unbundling of the data. The FHIR API follows existing internet standards, using the HTTP-based RESTful protocol (an API architectural style that uses HTTP requests to access and use data) for sharing information packets and OAuth (an authentication protocol that allows one to approve 1 app interacting with another on their behalf without giving away their password) for authentication (Substitutable Medical Applications and Reusable Technologies on FHIR). This makes

data sharing easy between various technologies, from legacy health systems to modern digital tools. Furthermore, FHIR APIs enable clinical data sharing and health data originating from other sources such as devices that can be used outside the clinical setting.

Observational Medical Outcomes Partnership Common Data Model

The Observational Medical Outcomes Partnership Common Data Model plays a crucial role in facilitating collaboration across systems using federated data models. It provides a standardized structure that allows different health care systems to harmonize their data and includes standardized vocabularies and terminologies such as SNOMED CT. Flags/variables in the Observational Medical Outcomes Partnership Common Data Model serve as essential metadata that identify the data source, assess data quality, enable data integration and comparison, facilitate data filtering, and support data auditing.

Open mHealth

Open mHealth is the leading mobile health data interoperability standard. The Open mHealth standard is indexed to existing clinical vocabularies (SNOMED for diagnoses, the Logical Observation Identifiers Names and Codes, a database and universal standard, for identifying medical laboratory observations) or SNOMED for laboratory tests and the normalized naming system for generic and branded medications and integrates with FHIR. Open mHealth enables both pulling ambulatory data into an EHR and harmonizing the data by using common data schemas, which support defining meaningful distinctions between data types (eg, a heart rate measurement from a smartwatch versus an electrocardiographic patch), and this metadata-supported context increases the clinical utility of the ambulatory data (Table 3).

Table 3. Data Format

Best practices	Description
1. C-CDA	A standard that satisfies "meaningful use" by providing structure to certain aspects of electronically stored medical information by specifying the way that data elements are captured, stored, accessed, displayed, and transmitted
2. FHIR	Provides a clinical data structure but also provides a standard for the exchange, including sending, transmission, delivery, and receipt, of such clinical data
3. OMOP CDM	A CDM for collaborating across systems using federated data models that provides a standardized data structure, promotes interoperability, facilitates vocabulary mapping, enables federated data analysis, supports collaborative research, and ensures data privacy and governance
4. Open mHealth	Enables both pulling ambulatory data into an EHR and harmonizing the data by using common data and metadata schemas
Gaps and challenges	**Background**
1. Lack of syntactic interoperability	The ability of computer systems to communicate with one another because of the use of common data formats and common communication protocols
2. Lack of semantic interoperability	The ability of computer systems to exchange data with unambiguous and common meaning among them
3. Lack of data digestibility	The transformation of large data streams into information elements that are rapidly understandable and actionable by a human reader

C-CDA indicates consolidated clinical document architecture; EHR, electronic health record; FHIR: Fast Healthcare Interoperability Resources; and OMOP CDM, Observational Medical Outcomes Partnership Common Data Model.

Verification and Validation

Verification and validation are key aspects of quality management. The International Organization for Standardization 9000 standards provide specific guidelines for verification and validation, which have been adapted by various industries, including the medical devices industry (International Organization for Standardization 13485). The software and hardware industries also have their own verification and validation processes outlined by the Institute of Electrical and Electronics Engineers standard (1012-2016), and the FDA describes verification and validation processes required for software and hardware products that are submitted for their approval.[49,68] Goldsack et al[69] recently developed the V3 Framework for applying these concepts directly to digital health technologies, also known as biometric monitoring technologies, in which the validation process is further divided into analytical validation and clinical validation, similar to the validation framework used for "wet lab" biomarkers following the BEST (Biomarkers, EndpointS, and other Tools) resource developed by the FDA–National Institutes of Health Biomarkers working group.[70]

INTEGRATION INTO EHR AND INTO PATIENT HEALTH REPOSITORIES

Overview

Integration of patient-generated health data (PGHD) into EHRs and personal health records is essential to leveraging these data for clinical care and quality improvement. Although much progress has been made toward enabling PGHD integration, more work is needed to define best practices.

EHRs and Personal Health Records

The passage of the Health Information Technology for Economic and Clinical Health Act in 2009 enabled the

rapid adoption of EHRs across the United States.[71] Office-based adoption of EHRs has more than doubled since 2008, with 78% of practices having an EHR certified by the Office of the National Coordinator for Health Information Technology and 88% with any EHR.[72] Personal health records are electronic apps in which the individual manages health information from diverse sources that can be securely shared with additional individuals or third parties in a secure environment.[73] Patient portals are electronic personal health records directly tethered to institutional EHRs.[74] Each of these apps has the potential to play an integral role in integrating PGHD into promoting and preserving cardiovascular health.

Legislative Support for Data Sharing

Passed in 2016, the 21st Century Cures Act included specific policies to protect and promote the rights of patients to access their digital health data and to promote interoperability between institutions.[75] Multiple stakeholders have been involved in promoting the adoption of standards for the interoperability of digital health data, including Health Level 7 International FHIR[76] and Open mHealth, as discussed previously in more detail.

Guidance on Data Standards and Interoperability

The US Office of the National Coordinator for Health Information Technology publishes and regularly updates the United States Core Data for Interoperability, with the most recent version published in July 2022. This guidance specifies several classes of data relevant to the integration of PGHD into EHRs, personal health records, and patient portals, including patient demographics/information to enable patient identification and matching and vital signs, which include several physiological measurements related to cardiovascular health (eg, blood pressure, heart rate, body weight, and height). As noted, another key group is Open mHealth, which promotes the adoption of mobile health data interoperability standards. Since the passage of the Cures Act, the US Office of the National Coordinator for Health Information Technology has released additional guidance on standardized APIs for patient and population services, including details for authentication and authorization of sharing data among devices, apps, and institutions.[6,77]

Status of Data Integration

The integration of PGHD into each of these apps has been limited for various reasons. These include the need for more widely used data standards for storing and exchanging PGHD and the limited capability of health care institutions and EHR platforms to receive such digital health data (Table 4). A 2020 scoping review found PGHD integration into EHRs to be in the early stages and identified recurring concerns about resource requirements, efficient data delivery to the EHR, and workflows and dashboards for reviewing PGHD that would not contribute to alert fatigue and would enable efficient data review.[7,78]

Table 4. Integration Into EHR and Patient Health Repositories

Best practices	Description
1. Leverage USCDI standards and standardized FHIR APIs for data exchange and integration into EHRs and PHRs	With the passage of the Cures Act and continued evolution of USCDI standards and APIs, stakeholders need to leverage standards in data exchange and integration
Gaps and challenges	**Background**
1. Evaluate the readiness of EHRs, FHIR, and FHIR APIs for PGHD data exchange and presentation	The existing rigid interface of most EHRs is not amenable to the continuous nature and large scale of PGHD. Increased flexibility in the EHR structure could enable re-envisioning of how PGHD could be integrated effectively for health care. The use of FHIR and FHIR APIs continues to evolve and expand. However, more formal evaluation of FHIR and FHIR APIs in diverse populations, including those from historically experiencing disadvantage groups and underresourced communities, is needed to ensure equitable and effective integration of PGHD into EHRs and PHRs.
2. Develop best practices for presentation of PGHD to patients and integrate them with tools to promote and preserve cardiovascular health	The integration of PGHD into PHRs and other apps is relatively new; therefore, identification of best practices is needed, including how to leverage SMART on FHIR tools, for presenting PGHD to patients and building tools to promote and preserve cardiovascular health.
3. presentation of PGHD to clinicians and population health stakeholders and integrate them with workflows aiming to improve and promote cardiovascular care	Research and development incorporating principles from design thinking experts on how to best present data to clinicians and population health stakeholders are needed, eg best practices for integrating dashboards and tools into clinical workflows and how to best leverage tools such as SMART on FHIR apps.

API indicates application programming interface; app, application; EHR, electronic health record; FDA, US Food and Drug Administration; FHIR, Fast Healthcare Interoperability Resources; PGHD, patient-generated health data; PHR, personal health record; SMART, Substitutable Medical Applications and Reusable Technologies; and USCDI, United States Core Data for Interoperability.

REGULATORY

Overview

Data interoperability is fundamental to integrating ambulatory health technologies into clinical care. Regulatory agencies, in particular the US FDA, recognize the potential of digital health to transform health care and to establish new approaches to promote innovation in the field (Table 5).

Table 5. Regulatory

Best practices	Description
1. Engage with the FDA early in product development	Early engagement of the FDA's CDRH can help stakeholders determine whether their product requires FDA review and how the regulatory approval process can be facilitated by adopting processes that reduce the barriers to approval (eg, by using data standards recognized by the agency)
2. Digital Health Center of Excellence	The Digital Health Center of Excellence was created by the FDA's CDRH to empower stakeholders to advance health care by fostering innovation in the digital health space by connecting innovators in order to accelerate digital health advancement, build partnerships, and share knowledge
3. Recognized data standards	The FDA supports interoperability by collaborating with stakeholders including hospitals, health care providers, manufacturers, and standards development organizations such as Health Level 7 and others to promote the development of interoperability tools and their use in clinical care
4. Understand the difference between FDA cleared and FDA approved	Medical devices that are FDA cleared have gone through the premarket notification [510(k)] process. Medical devices that are FDA approved have gone through the premarket approval process
Gaps and challenges	**Background**
1. CDRH's regulatory powers are limited to device approval	Although the FDA can encourage stakeholders to develop products that use existing standards and make data interoperable, their regulatory power ultimately is limited by their mandate from Congress; for example, if a device is demonstrated to be safe and effective for its intended use, the agency cannot withhold approval and require it to be interoperable with other health IT systems.
2. International digital health tools development and sales	Unlike most medical devices, digital health tools are sold over the counter and across international boundaries. This means that a US consumer must be aware of potential risks when purchasing a digital health device from a country that does not adhere to internationally accepted definitions of safety and efficacy as outlined by the International Medical Device Regulators Forum.

CDRH indicates Center for Devices and Radiological Health; FDA, US Food and Drug Administration; and IT, information technology.

FDA Definition of Digital Health

Digital health refers to the use of technology such as smartphones, computers, and the internet to improve health care.[79] This can include EHRs, telemedicine, wearables, mobile health apps (mHealth), and health informatics, among other things. The goal of digital health is to make health care more efficient, accessible, and convenient for patients while improving the quality of care. This can include remote monitoring, virtual consultations, and the ability to access patient data quickly and easily.

Role of the FDA

It is the mission of the FDA's Center for Devices and Radiological Health to protect and promote public health by ensuring that patients and clinicians have timely access to safe, effective medical devices. It exercises this mission primarily by its authority over the regulatory approval process. The new domain of digital health has allowed the agency to advance its mission by developing innovative pathways for the approval of digital health devices and thinking about medical devices in new, creative ways such as considering software as a medical device (SaMD).[80,81]

FDA Regulatory Approval Versus Clearance

The Center for Devices and Radiological Health regulates medical devices through several pathways, which are beyond the scope of this overview. However, many digital health technologies receive the FDA label "cleared" versus "approved." "Cleared" is assigned when a device is reviewed under the premarket notification [510(k)] pathway, which is used for low- to moderate-risk devices that are similar to devices already on the market. This often results in devices being labeled as FDA cleared. Examples of the types of devices that have received FDA clearance through the 510(k) pathway include pulse oximeters, ultrasound imaging systems, and smartwatches capable of detecting AF. Premarket approval is used for high-risk devices. Manufacturers must submit a premarket approval application to the FDA demonstrating that the device is safe and effective through clinical trials and a more rigorous review process. This results in the device being FDA approved. Examples of the types of devices that receive FDA approval include implantable pacemakers and defibrillators, deep-brain stimulators, and artificial heart valves. Many digital health devices such as smartwatches fall outside of the remit of the FDA, which classifies them as wellness devices and therefore does not regulate them. At the time of writing, several devices combine functionalities that are FDA regulated (eg, AF detection) and others that are not (eg, Spo_2 measurement). For low- to moderate-risk medical devices with no valid predicate for establishing substantial equivalence, the FDA Modernization Act created the de novo pathway. This may apply to innovative digital health tools. The de novo pathway provides a regulatory route for innovative devices that are relatively low risk without the burden of the premarket approval process. If the FDA determines that a device meets the criteria for de novo classification, it assigns the device a risk category (class I or II) and establishes special controls, if necessary, to ensure its safety and effectiveness.

FDA's Approach to Interoperability

The ability of systems to share, interpret, and act on data is fundamental to the widespread adoption of digital

health technologies. Although the FDA does not have the authority to regulate data interoperability, it can encourage the creation and adoption of standards in powerful ways.

The FDA supports interoperability by collaborating with stakeholders, including hospitals, health care professionals, manufacturers, and standards development organizations such as Health Level 7 International and others, to promote the development of interoperability tools and the use of these tools in clinical care.[82] One important example is the 2017 document Design Considerations and Pre-Market Submission Recommendations for Interoperable Medical Devices.[3] This gives nonbinding guidance to manufacturers to design and develop safe and effective interoperable medical devices by outlining important design considerations and clarifying the agency's recommendations for submitting interoperability-related information in premarket submissions.

Standards are the backbone of reliable, interoperable medical devices. In 2013, the FDA published an initial set of standards, and the agency continues to recognize and encourage the use of consensus standards that are relevant to the design and development of interoperable medical devices. The agency has a database listing its recognized standards.[83]

The FDA categorizes software into 3 groups[84]: (1) software that can perform a medical task on its own, without being part of a hardware medical device (known as SaMD); (2) software that is integral to a medical product (software in a medical device); and (3) software that is used in the manufacturing or maintenance of a medical device.

Software as a Medical Device

Because digital health tools can be sold over international boundaries, unlike traditional medical devices, regulatory agencies have recognized that they needed to develop a common framework and set of principles for digital health, particularly SaMD, that would enable all stakeholders and regulators to promote safe innovation while protecting patient safety. The International Medical Device Regulators Forum is an international organization that strives to harmonize medical device regulations among its member countries. Established in 2011 by the regulatory authorities of Australia, Canada, the European Union, Japan, and the United States, it develops regulatory guidelines and standards for medical devices. Its primary objective is to promote global regulatory convergence and cooperation, to improve the safety and effectiveness of medical devices, and to increase international trade in medical devices.

In 2013, the International Medical Device Regulators Forum formed the SaMD working group to develop guidance supporting innovation and timely access to safe and effective SaMD. The working group, chaired by the FDA, agreed on 4 key components: definitions for SaMD, a framework for risk categorization, the quality management system for SaMD, and a framework for clinical evaluation of SaMD.[81]

Digital Health Center of Excellence

In September 2020, The Digital Health Center of Excellence was created by the Center for Devices and Radiological Health to empower stakeholders to advance health care by fostering innovation in the digital health space.[85] The objectives are to connect innovators to accelerate digital health advancement, build partnerships, share knowledge, increase awareness, and drive synergy to advance best practices while simultaneously developing an innovative regulatory approach that is least burdensome, promotes efficiency, yet still meets the FDA standards for product safety and efficacy.

Two recent documents issued by the FDA will influence the adoption of digital health technologies for cardiovascular health. First, in January 2021, the Center for Devices and Radiological Health published "Artificial Intelligence/Machine Learning (AI/ML) Software as a Medical Device Action Plan," in which they summarize feedback from key stakeholders on this topic and delineate 5 steps to facilitate innovation through artificial intelligence/machine learning–based SaMD.[86] Second, in September 2022, the FDA issued guidance on clinical decision support software, which outlines 4 criteria that lead to the categorization of clinical decision support software as a SaMD.[87]

CLINICAL WORKFLOWS AND OPERATIONAL STRATEGIES

Overview

A national survey has found that <10% of US clinicians reported that data from wearables and other ambulatory devices were integrated into the EHRs.[88] This key barrier to the impact of these rich data on health care reflects limitations in relying on patients sharing this information during clinical encounters or clinicians obtaining it from patients. A systematic study of the integration process, with inference based on successful deployments, is drawn primarily from pilot assessments at a few select institutions.[89] A few key principles and strategies are outlined here and in the Figure. Examples of the potential workflows for integrating data from ambulatory monitoring to clinical care are presented in the Supplemental Figure.

Information Classification and Summarization

As described previously, novel devices offer a plethora of data streams. Broadly, these may represent (1) well-recognized elements of a subject's health record such

as measures of the heart rate, blood pressure, and single-lead ECGs and (2) newer data streams captured predominantly through novel ambulatory devices by providing measures of activity, sleep, or symptoms.

For quantitative measures that correspond to existing clinical elements in the EHR, additional measures obtained from ambulatory data streams can be added after the standardization of measurement units. However, for the more complex measures such as those focusing on unstructured data or qualitative measures, existing clinical workflows do not have an existing process of integration that is readily accessible to clinicians. These may include patient narratives of their physical or mental health or reports from the device outputs that are available as images. Therefore, there is a need for direct access to these data streams and their summary measures that may provide the required information, with the prioritization of data streams dictated by evidence of an effect on patient outcomes.[39] The summaries of the data streams would need to be synthesized to effectively communicate the health status of patients without overwhelming clinicians; this would require dedicated development in clinically appropriate and relevant information summarization strategies.

Focus on Established Clinical Relevance

A series of prospective evaluations of wearable-driven monitoring strategies have demonstrated improvements in detecting undiagnosed cardiac conditions.[12,90] Several of these medical devices have been approved or are under consideration for approval by regulatory agencies.[91] The evaluation of data that are deemed suitable to be incorporated into clinical care must require the same level of evidence as any clinical assay, including technical reliability, valid and reproducible results, and clinical utility, defined as information that meaningfully alters the care and outcomes of patients.[91] Whether the additional role of patient-led data sharing results in increased engagement with their health care professional requires evaluation as an independent outcome. The issues are amplified by the fact that these devices are increasingly used in individuals without any CVD or risk factors.[2]

Support for Clinical Practice Guidelines

The rapid evolution of ambulatory device technology and the growing body of evidence supporting their clinical potential have surpassed the lengthy process of developing clinical practice guidelines. Consequently, as patients and clinicians increasingly rely on data from wearable devices to inform their decisions, there remains a notable absence of comprehensive medical guidance for when and how to initiate clinical action based on ambulatory device data. This underscores the urgent requirement for regularly updated guidance that contextualizes the clinical significance of metrics derived from wearables and synthesizes the available evidence to support informed clinical decision-making.

Incentives and Disincentives

There is currently little incentive to incorporate ambulatory data into existing health care workflows, with clinical inertia often further hindering adoption of new technology. There are some notable exceptions such as during lockdowns during the COVID-19 pandemic that prompted technology adoption on multiple fronts. However, given the voluminous data and increasing time required for data interpretation and entry into the EHR, there is an urgent need for professional societies to work with payers and regulatory agencies to define use and reimbursement criteria. Furthermore, the accurate integration and security protection of the derived data of wearables and implantable devices in the EHR are likely to require additional effort and the hiring of additional information technology staff, which translates into additional health care overhead cost. This should reflect the demonstrated benefit for each device and may inform the design of trials for each device. Ongoing efforts are focusing on developing new Common Procedural Terminology codes that accurately reflect work performed by ambulatory devices and novel technologies and the interpretation of their data.[92]

The Centers for Medicare and Medicaid Services' Medicare Access and CHIP Reauthorization Act of 2015 and Merit Based Incentive Payments System regulations grant the Centers for Medicare and Medicaid Services authority to mandate EHR interoperability and provide a strategic lever to incentivize EHR manufacturers to implement standardized protocols for ambulatory device data collection, reporting, and data sharing. To excel in Merit Based Incentive Payments System performance measures and meet the Medicare Access and CHIP Reauthorization Act of 2015 requirements, EHR manufacturers would be compelled to develop systems that seamlessly integrate data from ambulatory devices, aligning with Centers for Medicare and Medicaid Services–mandated standards. This ensures that EHR systems effectively capture and communicate information from wearables and other ambulatory devices, fostering data consistency and interoperability and ultimately enhancing the ability of health care professionals to access and use patient-generated data in a standardized manner for improved clinical decision-making and patient care.

Other concerns involve the legal implications of the omission of information available from these devices in clinical decision-making and whether using device-driven decision-making may cause harm. Moreover, the legal issues surrounding the response of clinicians receiving data from such devices that require urgent medical action, despite issues with the reliability and consistency of these data inputs, merit dedicated evaluation.

Table 6. Clinical Workflows and Operational Strategies

Best practices	Description
1. Identification of clinically relevant measures	The measures chosen for inclusion in clinical workflows need to be validated and useful for clinical care
2. Standardization of clinical response	The care of patients in response to information derived from ambulatory devices requires standardized approaches from clinical practice guidelines
3. Reduction of clinical burden	A focus on standardization and summarization of data inputs can ensure appropriate processing by clinicians without the requirement of addition clinical resources
Gaps and challenges	**Background**
1. Lack of accepted management strategies	There is a paucity of both data and clinical guideline support to define how clinicians and health systems should respond to growing data from ambulatory devices
2. Lack of clear incentives	Most clinical time and effort spent reviewing and evaluating data from these devices currently do not represent compensated effort and have unclear effect on patient outcomes
3. Lack of local population performance	The algorithms that infer information from ambulatory devices, particularly those based on AI, are often proprietary without any transparency in their development and therefore have unknown generalizability to new populations

AI indicates artificial intelligence.

Local Optimization

A critical issue that has received limited attention is the institution-specific application of technology and the limited availability and validity of such tools outside of major health systems. Therefore, although wearable-driven care strategies may be effective at a specific institution, this does not guarantee that the strategy will generalize to a different institution. Consequently, there is likely a need for both proof of performance and continuous monitoring of the output of these ambulatory devices, given the required high bar of clinical care (Table 6).

Administrative Burden

Incorporating data from ambulatory monitoring provides significant benefits to patients, as noted previously, but even with optimal integration into the EHR, it requires significant oversight from clinicians to monitor for abnormalities, communicate with patients, and update treatment strategies on the basis of the new information. For clinicians and health care systems to incorporate these technologies into clinical practice, it will be necessary for the administrative burden to be recognized by payers and compensated appropriately. This will be a major challenge for EHRs built on legacy systems without interoperability and adaptability and for smaller organizations that may not have the resources to permit the modernization of their EHR systems.

ISSUES PERTAINING TO PATIENT DATA

Ensuring Health Equity in Implementation

A potential concern arising from using information from wearables in decision-making is the socioeconomic barriers to access and knowledge about the features of these devices. This may result in unintentionally creating or exacerbating disparities in health outcomes.[93] Therefore, if indications for these devices are identified that substantively alter the course of illness, there should be a mechanism to incorporate them as medical devices, with coverage as part of the overall health coverage system. Similarly, technological literacy must be incorporated into the larger health education of patients and our communities (Table 7).

Patient Rights/Ethics

The Health Insurance Portability and Accountability Act of 1996 and General Data Protection Regulation or the Data Protection Act of 2018 impose privacy and security standards on organizations that collect and use consumer data.[94] Device developers, device manufacturers, and data

Table 7. Issues Pertaining to Patient Data

Best practices	Description
1. Use of common and local standards of data quality	Collection of contextual information is expected to aid in the understanding of the specific needs for the assessment of wearable data quality. The framework provided by Findability, Accessibility, Interoperability, and Reuse is a proposed starting point.
2. Promoting standards for data governance, documentation, and sharing in the spirit of open science	A federated system enables legal data control to remain within the domain from which the data originate, yet details pertaining to differences with respect to the repositories in which the data are held, the relationships in which data are exchanged, and the type of data that are shared are clearly elucidated
Gaps and challenges	**Background**
1. Interoperability standards are required to facilitate secure data exchange between devices and EHR systems	Data ownership by different stakeholders, rights, and governance from wearables need to be clearly defined. When manufacturers do not restrict access to the raw data, interoperability standards will enable data sharing and audit between clinical stakeholders.
2. Evolution of regulatory boundaries	Health care wearable devices are developing rapidly, and the data security and privacy issues in their specific domains are complex. A regulatory framework for all stakeholders, including patients, needs to be established.
3. Health inequality	There is potential for digital and technological divides because some participants may not be able to access or use wearable devices due to cost, innumeracy, and technical illiteracy
4. Representation and fairness	The current use and features of wearables disproportionately target some members of the general population and exclude others, thus creating issues of a lack of representativeness and fairness

EHR indicates electronic health record.

brokers are not subject to the Health Insurance Portability and Accountability Act of 1996 or General Data Protection Regulation requirements that may threaten security of consumer data.[95] Innovation has outpaced commensurate regulation to ensure thorough consent and protections for data transmission. Contemporarily, patients' rights are being prioritized and affirmed by law, and data should be anonymized to avoid identification if shared beyond the reasons for which they were collected, although how to achieve bona fide anonymization is not always clear.[96]

Cybersecurity

Wearable devices are prone to attack and require secure exchange of information.[97] Lack of authentication, location monitoring, and security holes are problems associated with these devices.[98] The attributes of blockchain computing used in trading digital currency and the advanced analytics applied in financial markets could also be applied to health care. Storage and management of health records on blockchain platforms protects patient data and allows patients to access their data on request, thus maintaining the privacy of patient data generated by wearable devices, enhancing interoperability of data storage systems, and improving medical information management between and across health care facilities.[99] However, although both infrastructural and algorithmic measures are needed, through interdisciplinary teams at every stage of design and implementation, no defense is 100% effective,[100] and possible security vulnerabilities have to be continually assessed.

Data Ownership

The main challenge of data protection involves the safeguarding of an individual's privacy and autonomy to control their data without limiting the benefits of their use. However, established mechanisms for individual control of data such as informed consent, a duty of confidentiality and deidentification, may not be sufficient and may interfere with positive uses.[101] Another concern about the use of health data in research involves user-generated data obtained from digital devices and wearables or data supplied by users to social media, resulting from "lack of international boundaries when using the internet" and because the "online information industry has failed to self-regulate."[102] The growing economic importance of secondary use of data makes it increasingly seen as a powerful commodity and a major driver of transformation at a national level[103] or at the market capitalization and revenue streams of data-intensive companies.[104]

Research

Dense data collection from patients using wearables may change how randomized clinical trials are designed and conducted, introducing fewer obstacles for patients to enroll (eg, remote enrollment) and increased patient outreach.[105] Compared with traditional randomized clinical trial data, the data infrastructure for sensor data are different and consist of multiple layers: raw unfiltered data, raw filtered data to eliminate invalid data in accordance with their respected algorithms, and data derived from the secondary derivatives for interpretation.

There is evidence that cloud computing, in conjunction with fast-expanding technologies such as big data analytics, artificial intelligence, and the internet of medical things, improves efficiencies, resource availability, and interoperability and reduces costs.[106–108]

A low level of interoperability makes the integration of wearable data with other health data difficult.[109] In addition, the integration of wearables into health services is currently challenging because the additional staff required to assist patients with the technology might need to be trained differently because software and hardware solutions are different between devices, and manufacturers may refuse to make their raw data accessible to patients and institutions that own them. In turn, interoperability standards are also crucial for data storage in order to integrate wearables into health services, which is currently costly.[110]

Ambulatory monitoring devices may reduce the need for clinic visits, which subsequently may reduce the time and logistical burden on patients. Furthermore, wearable technology is uniquely positioned to achieve one of the goals of digital health: expanding access to health services and thus enabling precision medicine and improving health equity. However, large and extended wearable datasets usually target specific age, social, and economic groups while excluding important and large parts of the general population, resulting in biased and unrepresentative datasets.[111] Thus, issues of fairness raise concerns about using and recommending wearable technology for health in the general population.

Last, it is necessary to establish which is the right device for the research question of interest. This may involve a priori investigations of measure validation and the potential impact on risk factors and clinical outcomes.

Legal

Patient consent constitutes a mechanism to ensure that patients' interests are protected.[112] Regulations produced and supported by the US Office of the National Coordinator for Health Information Technology govern specified actors or entities.[104] However, data produced by these wearable devices may not be subject to existing laws and regulations.[101] The Trusted Exchange Framework and Common Agreement was published to establish an infrastructure and governance model for data exchange across networks.[109] Violating protections in

the General Data Protection Regulation/Data Protection Act of 2018, Health Insurance Portability and Accountability Act of 1996, or 21st Century Cures Act may result in serious consequences, including substantial penalties and potentially criminal liability.[112]

CONCLUSIONS

A functional interoperability framework for ambulatory monitoring devices is essential to facilitate a reliable and seamless interaction between different devices during health care delivery but remains elusive.

Because the primary objective of incorporating data streams from such devices into clinical settings is to improve care and outcomes, clinical needs and priorities are critical to defining the requirements and approach to ambulatory medical device interoperability. Therefore, clinical use cases with precise descriptions of workflows and human-device and device-device interactions are expected to drive the development of robust interoperability standards. The impact of data streams that need to be prioritized in this framework would best be determined by the strength of the associated evidence-based health benefits. To achieve these aims, a consistent view of which data and functions of a medical device can safely contribute to health care improvements in an interoperable system must be shared across stakeholders embodied in the system. This view should include the architectural framework for interactions between components of the ambulatory system, as well as a robust and transparent process for capturing and defining ambulatory device vocabularies and communication protocols.

ARTICLE INFORMATION

The American Heart Association makes every effort to avoid any actual or potential conflicts of interest that may arise as a result of an outside relationship or a personal, professional, or business interest of a member of the writing panel. Specifically, all members of the writing group are required to complete and submit a Disclosure Questionnaire showing all such relationships that might be perceived as real or potential conflicts of interest.

This statement was approved by the American Heart Association Science Advisory and Coordinating Committee on October 12, 2023, and the American Heart Association Executive Committee on January 26, 2024. A copy of the document is available at https://professional.heart.org/statements by using either "Search for Guidelines & Statements" or the "Browse by Topic" area. To purchase additional reprints, call 215-356-2721 or email Meredith.Edelman@wolterskluwer.com

The American Heart Association requests that this document be cited as follows: Armoundas AA, Ahmad FS, Bennett DA, Chung MK, Davis LL, Dunn J, Narayan SM, Slotwiner DJ, Wiley KK Jr, Khera R; on behalf of the American Heart Association Data Science and Precision Medicine Committee of the Council on Genomic and Precision Medicine and Council on Clinical Cardiology; Council on Cardiopulmonary, Critical Care, Perioperative and Resuscitation; Council on Cardiovascular and Stroke Nursing; Council on Lifestyle and Cardiometabolic Health; Council on Peripheral Vascular Disease; Council on Quality of Care and Outcomes Research; and Stroke Council. Data interoperability for ambulatory monitoring of cardiovascular disease: a scientific statement from the American Heart Association. *Circ Genom Precis Med.* 2024;16:e000095. doi: 10.1161/HCG.0000000000000095

The expert peer review of AHA-commissioned documents (eg, scientific statements, clinical practice guidelines, systematic reviews) is conducted by the AHA Office of Science Operations. For more on AHA statements and guidelines development, visit https://professional.heart.org/statements. Select the "Guidelines & Statements" drop-down menu, then click "Publication Development."

Disclosures

Writing Group Disclosures

Writing group member	Employment	Research grant	Other research support	Speakers' bureau/ honoraria	Expert witness	Ownership interest	Consultant/ advisory board	Other
Antonis A. Armoundas	Massachusetts General Hospital	AHA (17UNPG33840017)†; The RICBAC Foundation†; NIH (1 R01 HL135335-01, 1 R01 HL161008-01, 1 R21 HL137870-01, 1 R21EB026164-01, and 3R21EB026164-02S1)†	None	None	None	None	None	None
Rohan Khera	Yale School of Medicine	NHLBI (K23)†; Doris Duke Charitable Foundation (Clinician Scientist Development Award 2022060)†; Bristol Myers Squibb (research grant through Yale)†	*JAMA* (associate editor)†	None	None	Evidence-2Health LLC*; Ensight-AI, Inc*	None	None
Faraz S. Ahmad	Northwestern University Feinberg School of Medicine	NIH/NHLBI (K23HL155970)†; AHA (grant No. 856917)†	None	None	None	None	None	None
Derrick A. Bennett	University of Oxford (United Kingdom)	None	None	None	None	None	None	None
Mina K. Chung	Cleveland Clinic	NIH (R01 HL158071, P01HL158502)†; American Heart Association (Atrial Fibrillation Strategically Focused Research Network grants 18SFRN34110067, 18SFRN34170013, 20SCG35490449)†	None	None	None	None	None	None
Leslie L. Davis	University of North Carolina at Chapel Hill	None	None	None	None	None	None	None

(*Continued*)

Writing Group Disclosures Continued

Writing group member	Employment	Research grant	Other research support	Speakers' bureau/ honoraria	Expert witness	Ownership interest	Consultant/ advisory board	Other
Jessilyn Dunn	Duke University	None	None	None	None	None	None	None
Sanjiv M. Narayan	Stanford University	None	None	None	None	None	None	None
David J. Slotwiner	Cornell University	None	None	None	None	None	None	None
Kevin Keith Wiley Jr	Medical University of South Carolina	None	None	None	None	None	None	None

This table represents the relationships of writing group members that may be perceived as actual or reasonably perceived conflicts of interest as reported on the Disclosure Questionnaire, which all members of the writing group are required to complete and submit. A relationship is considered to be "significant" if (a) the person receives $5000 or more during any 12-month period, or 5% or more of the person's gross income; or (b) the person owns 5% or more of the voting stock or share of the entity, or owns $5000 or more of the fair market value of the entity. A relationship is considered to be "modest" if it is less than "significant" under the preceding definition.

*Modest.

†Significant.

Reviewer Disclosures

Reviewer	Employment	Research grant	Other research support	Speakers' bureau/ honoraria	Expert witness	Ownership interest	Consultant/ advisory board	Other
Paul E. Drawz	University of Minnesota	None	None	None	None	None	None	None
Michael E. Ernst	University of Iowa	None	None	None	None	None	None	None
Paolo Palatini	University of Padova (Italy)	None	None	None	None	None	None	None
Jagmeet Singh	Massachusetts General Hospital, Harvard Medical School	None	None	None	None	None	None	None
Michael Smolensky	University of Texas Health Science Center	NIH Division of Minority Health (assessment of the clinical utility of data derived from 48-h blood pressure monitoring in combination with those derived from a unique home blood pressure monitoring device on progression of chronic kidney disease to kidney failure and need of dialysis)*	None	None	None	Circadian Ambulatory Technology & Diagnostics*	Circadian Ambulatory Technology & Diagnostics*	None

This table represents the relationships of reviewers that may be perceived as actual or reasonably perceived conflicts of interest as reported on the Disclosure Questionnaire, which all reviewers are required to complete and submit. A relationship is considered to be "significant" if (a) the person receives $5000 or more during any 12-month period, or 5% or more of the person's gross income; or (b) the person owns 5% or more of the voting stock or share of the entity, or owns $5000 or more of the fair market value of the entity. A relationship is considered to be "modest" if it is less than "significant" under the preceding definition.

*Modest.

REFERENCES

1. Peterson M. Apple Watch continues domination of growing smartwatch market with 100M users. 2021. Accessed March 13, 2023. https://appleinsider.com/articles/21/08/26/apple-watch-continues-domination-of-growing-smartwatch-market-with-100m-users
2. Dhingra LS, Aminorroaya A, Oikonomou EK, Nargesi AA, Wilson FP, Krumholz HM, Khera R. Use of wearable devices in individuals with or at risk for cardiovascular disease in the US, 2019 to 2020. *JAMA Netw Open*. 2023;6:e2316634. doi: 10.1001/jamanetworkopen.2023.16634
3. US Food and Drug Administration. Design Considerations and Pre-Market Submission Recommendations for Interoperable Medical Devices, guidance for industry and Food and Drug Administration staff. 2017. Accessed xxxx. https://www.fda.gov/media/95636/download
4. Robkin M, Weininger S, Preciado B, Goldman JM. Levels of conceptual interoperability model for healthcare frame-work for safe medical device interoperability. Paper/poster presented at: Proceedings IEEE Symposium on Product Compliance Engineering (ISPCE); May 1-8, 2015; Rosemont, IL.
5. Boxwala AA, Rocha BH, Maviglia S, Kashyap V, Meltzer S, Kim J, Tsurikova R, Wright A, Paterno MD, Fairbanks A, et al. A multi-layered framework for disseminating knowledge for computer-based decision support. *J Am Med Inform Assoc*. 2011;18:132–139. doi: 10.1136/amiajnl-2011-000334
6. Bilici E, Despotou G, Arvanitis TN. The use of computer-interpretable clinical guidelines to manage care complexities of patients with multimorbid conditions: A review. *Digit Health*. 2018;4:2055207618804927. doi: 10.1177/2055207618804927
7. Sana F, Isselbacher EM, Singh JP, Heist EK, Pathik B, Armoundas AA. Wearable devices for ambulatory cardiac monitoring: JACC state-of-the-art review. *J Am Coll Cardiol*. 2020;75:1582–1592. doi: 10.1016/j.jacc.2020.01.046
8. Steinberg JS, Varma N, Cygankiewicz I, Aziz P, Balsam P, Baranchuk A, Cantillon DJ, Dilaveris P, Dubner SJ, El-Sherif N, et al. 2017 ISHNE-HRS expert consensus statement on ambulatory ECG and external cardiac monitoring/telemetry. *Heart Rhythm*. 2017;14:e55–e96. doi: 10.1016/j.hrthm.2017.03.038
9. Hermans ANL, Gawalko M, Dohmen L, van der Velden RMJ, Betz K, Duncker D, Verhaert DVM, Heidbuchel H, Svennberg E, Neubeck L, et al. Mobile health solutions for atrial fibrillation detection and management: a systematic review. *Clin Res Cardiol*. 2022;111:479–491. doi: 10.1007/s00392-021-01941-9
10. Halcox JPJ, Wareham K, Cardew A, Gilmore M, Barry JP, Phillips C, Gravenor MB. Assessment of remote heart rhythm sampling using the AliveCor heart

monitor to screen for atrial fibrillation: the REHEARSE-AF study. *Circulation*. 2017;136:1784–1794. doi: 10.1161/CIRCULATIONAHA.117.030583
11. Svennberg E, Friberg L, Frykman V, Al-Khalili F, Engdahl J, Rosenqvist M. Clinical outcomes in systematic screening for atrial fibrillation (STROKESTOP): a multicentre, parallel group, unmasked, randomised controlled trial. *Lancet*. 2021;398:1498–1506. doi: 10.1016/S0140-6736(21)01637-8
12. Rizas KD, Freyer L, Sappler N, von Stulpnagel L, Spielbichler P, Krasniqi A, Schreinlechner M, Wenner FN, Theurl F, Behroz A, et al. Smartphone-based screening for atrial fibrillation: a pragmatic randomized clinical trial. *Nat Med*. 2022;28:1823–1830. doi: 10.1038/s41591-022-01979-w
13. Avram R, Ramsis M, Cristal AD, Nathan V, Zhu L, Kim J, Kuang J, Gao A, Vittinghoff E, Rohdin-Bibby L, et al. Validation of an algorithm for continuous monitoring of atrial fibrillation using a consumer smartwatch. *Heart Rhythm*. 2021;18:1482–1490. doi: 10.1016/j.hrthm.2021.03.044
14. Watanabe N, Bando YK, Kawachi T, Yamakita H, Futatsuyama K, Honda Y, Yasui H, Nishimura K, Kamihara T, Okumura T, et al. Development and validation of a novel cuff-less blood pressure monitoring device. *JACC Basic Transl Sci*. 2017;2:631–642. doi: 10.1016/j.jacbts.2017.07.015
15. Xiao H, Qasem A, Butlin M, Avolio A. Estimation of aortic systolic blood pressure from radial systolic and diastolic blood pressures alone using artificial neural networks. *J Hypertens*. 2017;35:1577–1585. doi: 10.1097/HJH.0000000000001337
16. Kollias A, Stergiou GS. Automated measurement of office, home and ambulatory blood pressure in atrial fibrillation. *Clin Exp Pharmacol Physiol*. 2014;41:9–15. doi: 10.1111/1440-1681.12103
17. Lewis TT, Parker R, Murden R, Spikes T, Erving C, McKinnon II, Van Dyke ME, Booker B, Quyummi A, Vaccarino V, et al. Network stressors, personal stressors, and ambulatory blood pressure in African-American women: does superwoman schema play a role? *Health Psychol*. 2023;42:485–495. doi: 10.1037/hea0001309
18. Mohebali D, Kittleson MM. Remote monitoring in heart failure: current and emerging technologies in the context of the pandemic. *Heart*. 2021;107:366–372. doi: 10.1136/heartjnl-2020-318062
19. Halawa A, Enezate T, Flaker G. Device monitoring in heart failure management: outcomes based on a systematic review and meta-analysis. *Cardiovasc Diagn Ther*. 2019;9:386–393. doi: 10.21037/cdt.2019.01.02
20. Abraham J, Bharmi R, Jonsson O, Oliveira GH, Artis A, Valika A, Capodilupo R, Adamson PB, Roberts G, Dalal N, et al. Association of ambulatory hemodynamic monitoring of heart failure with clinical outcomes in a concurrent matched cohort analysis. *JAMA Cardiol*. 2019;4:556–563. doi: 10.1001/jamacardio.2019.1384
21. Muhlestein JB, Anderson JL, Bethea CF, Severance HW, Mentz RJ, Barsness GW, Barbagelata A, Albert D, Le VT, Bunch TJ, et al. Feasibility of combining serial smartphone single-lead electrocardiograms for the diagnosis of ST-elevation myocardial infarction. *Am Heart J*. 2020;221:125–135. doi: 10.1016/j.ahj.2019.12.016
22. Li K, Elgalad A, Cardoso C, Perin EC. Using the Apple Watch to record multiple-lead electrocardiograms in detecting myocardial infarction: where are we now? *Tex Heart Inst J*. 2022;49:e227845. doi: 10.14503/THIJ-22-7845
23. Redon P, Shahzad A, Iqbal T, Wijns W. Development of a new detection algorithm to identify acute coronary syndrome using electrochemical biosensors for real-world long-term monitoring. *Bioengineering (Basel)*. 2021;8:28. doi: 10.3390/bioengineering8020028
24. Mitratza M, Goodale BM, Shagadatova A, Kovacevic V, van de Wijgert J, Brakenhoff TB, Dobson R, Franks B, Veen D, Folarin AA, et al. The performance of wearable sensors in the detection of SARS-CoV-2 infection: a systematic review. *Lancet Digit Health*. 2022;4:e370–e383. doi: 10.1016/S2589-7500(22)00019-X
25. Cho PJ, Yi J, Ho E, Shandhi MMH, Dinh Y, Patil A, Martin L, Singh G, Bent B, Ginsburg G, et al. Demographic imbalances resulting from the Bring-Your-Own-Device study design. *JMIR Mhealth Uhealth*. 2022;10:e29510. doi: 10.2196/29510
26. Nestor B, Hunter J, Kainkaryam R, Drysdale E, Inglis JB, Shapiro A, Nagaraj S, Ghassemi M, Foschini L, Goldenberg A. Machine learning COVID-19 detection from wearables. *Lancet Digital Health*. 2023;5:e182–e184. doi: 10.1016/S2589-7500(23)00045-6
27. Takahashi S, Nakazawa E, Ichinohe S, Akabayashi A, Akabayashi A. Wearable technology for monitoring respiratory rate and SpO(2) of COVID-19 patients: a systematic review. *Diagnostics (Basel)*. 2022;12:2563. doi: 10.3390/diagnostics12102563
28. World Health Organization. *Clinical Management of COVID-19: Living Guideline*. World Health Organization; 2023.
29. Sharma A, Mahaffey KW, Gibson CM, Hicks KA, Alexander KP, Ali M, Chaitman BR, Held C, Hlatky M, Jones WS, et al. Clinical events classification (CEC) in clinical trials: report on the current landscape and future directions: proceedings from the CEC Summit 2018. *Am Heart J*. 2022;246:93–104. doi: 10.1016/j.ahj.2021.12.012
30. Jain S, Workman V, Ganeshan R, Obasare ER, Burr A, DeBiasi RM, Freeman JV, Akar J, Lampert R, Rosenfeld LE. Enhanced electrocardiographic monitoring of patients with coronavirus disease 2019. *Heart Rhythm*. 2020;17:1417–1422. doi: 10.1016/j.hrthm.2020.04.047
31. Mishra T, Wang M, Metwally AA, Bogu GK, Brooks AW, Bahmani A, Alavi A, Celli A, Higgs E, Dagan-Rosenfeld O, et al. Pre-symptomatic detection of COVID-19 from smartwatch data. *Nat Biomed Eng*. 2020;4:1208–1220. doi: 10.1038/s41551-020-00640-6
32. Maille B, Wilkin M, Million M, Resseguier N, Franceschi F, Koutbi-Franceschi L, Hourdain J, Martinez E, Zabern M, Gardella C, et al. Smartwatch electrocardiogram and artificial intelligence for assessing cardiac-rhythm safety of drug therapy in the COVID-19 pandemic: the QT-Logs study. *Int J Cardiol*. 2021;331:333–339. doi: 10.1016/j.ijcard.2021.01.002
33. Krittanawong C, Rogers AJ, Johnson KW, Wang Z, Turakhia MP, Halperin JL, Narayan SM. Integration of novel monitoring devices with machine learning technology for scalable cardiovascular management. *Nat Rev Cardiol*. 2021;18:75–91. doi: 10.1038/s41569-020-00445-9
34. Krittanawong C, Johnson KW, Rosenson RS, Wang Z, Aydar M, Baber U, Min JK, Tang WHW, Halperin JL, Narayan SM. Deep learning for cardiovascular medicine: a practical primer. *Eur Heart J*. 2019;40:2058–2073. doi: 10.1093/eurheartj/ehz056
35. Amin T, Mobbs RJ, Mostafa N, Sy LW, Choy WJ. Wearable devices for patient monitoring in the early postoperative period: a literature review. *Mhealth*. 2021;7:50. doi: 10.21037/mhealth-20-131
36. Avram R, Olgin JE, Kuhar P, Hughes JW, Marcus GM, Pletcher MJ, Aschbacher K, Tison GH. A digital biomarker of diabetes from smartphone-based vascular signals. *Nat Med*. 2020;26:1576–1582. doi: 10.1038/s41591-020-1010-5
37. Dunn J, Kidzinski L, Runge R, Witt D, Hicks JL, Schussler-Fiorenza Rose SM, Li X, Bahmani A, Delp SL, Hastie T, et al. Wearable sensors enable personalized predictions of clinical laboratory measurements. *Nat Med*. 2021;27:1105–1112. doi: 10.1038/s41591-021-01339-0
38. Schario ME, Bahner CA, Widenhofer TV, Rajaballey JI, Thatcher EJ. Chatbot-assisted care management. *Prof Case Manag*. 2022;27:19–25. doi: 10.1097/NCM.0000000000000504
39. Bayoumy K, Gaber M, Elshafeey A, Mhaimeed O, Dineen EH, Marvel FA, Martin SS, Muse ED, Turakhia MP, Tarakji KG, et al. Smart wearable devices in cardiovascular care: where we are and how to move forward. *Nat Rev Cardiol*. 2021;18:581–599. doi: 10.1038/s41569-021-00522-7
40. Chan A, Chan D, Lee H, Ng CC, Yeo AHL. Reporting adherence, validity and physical activity measures of wearable activity trackers in medical research: a systematic review. *Int J Med Inform*. 2022;160:104696. doi: 10.1016/j.ijmedinf.2022.104696
41. Health Level Seven International. Physical Activity Implementation Guide. August 2023. Accessed March 4, 2024. https://build.fhir.org/ig/HL7/physical-activity/
42. Office of the National Coordinator. US Department of Health and Human Services. US Core Data for Interoperability (USCDI) Version 4. July 2023. Accessed March 4, 2024. https://www.healthit.gov/sites/isa/files/2023-07/Final-USCDI-Version-4-July-2023-Final.pdf
43. Wang X, Ellul J, Azzopardi G. Elderly fall detection systems: a literature survey. *Front Robot AI*. 2020;7:71. doi: 10.3389/frobt.2020.00071
44. Baig MM, Afifi S, GholamHosseini H, Mirza F. A systematic review of wearable sensors and IoT-based monitoring applications for older adults: a focus on ageing population and independent living. *J Med Syst*. 2019;43:233. doi: 10.1007/s10916-019-1365-7
45. Stevenson JE, Israelsson J, Petersson G, Bath PA. Factors influencing the quality of vital sign data in electronic health records: a qualitative study. *J Clin Nurs*. 2018;27:1276–1286. doi: 10.1111/jocn.14174
46. Lee KC, Morgan AU, Chaiyachati KH, Asch DA, Xiong RA, Do D, Kilaru AS, Lam D, Parambath A, Friedman AB, et al. Pulse oximetry for monitoring patients with Covid-19 at home: a pragmatic, randomized trial. *N Engl J Med*. 2022;386:1857–1859. doi: 10.1056/NEJMc2201541
47. Bressman E, Long JA, Honig K, Zee J, McGlaughlin N, Jointer C, Asch DA, Burke RE, Morgan AU. Evaluation of an automated text message-based program to reduce use of acute health care resources after hospital discharge. *JAMA Netw Open*. 2022;5:e2238293. doi: 10.1001/jamanetworkopen.2022.38293

48. Tobin MJ, Jubran A. Pulse oximetry, racial bias and statistical bias. *Ann Intensive Care*. 2022;12:2. doi: 10.1186/s13613-021-00974-7
49. US Food and Drug Administration. CFR - Code of Federal Regulations Title 21. 2022. Accessed December 23, 2023. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=820.30
50. Nelson BW, Allen NB. Accuracy of consumer wearable heart rate measurement during an ecologically valid 24-hour period: intraindividual validation study. *JMIR Mhealth Uhealth*. 2019;7:e10828. doi: 10.2196/10828
51. Iaconelli A, Pellicori P, Caiazzo E, Rezig AOM, Bruzzese D, Maffia P, Cleland JGF. Implanted haemodynamic telemonitoring devices to guide management of heart failure: a review and meta-analysis of randomised trials. *Clin Res Cardiol*. 2022;1:13. doi: 10.1007/s00392-022-02104-0
52. Bourge RC, Abraham WT, Adamson PB, Aaron MF, Aranda JM Jr, Magalski A, Zile MR, Smith AL, Smart FW, O'Shaughnessy MA, et al. Randomized controlled trial of an implantable continuous hemodynamic monitor in patients with advanced heart failure: the COMPASS-HF study. *J Am Coll Cardiol*. 2008;51:1073–1079. doi: 10.1016/j.jacc.2007.10.061
53. Desai AS, Bhimaraj A, Bharmi R, Jermyn R, Bhatt K, Shavelle D, Redfield MM, Hull R, Pelzel J, Davis K, et al. Ambulatory hemodynamic monitoring reduces heart failure hospitalizations in "real-world" clinical practice. *J Am Coll Cardiol*. 2017;69:2357–2365. doi: 10.1016/j.jacc.2017.03.009
54. Campbell P, Drazner MH, Kato M, Lakdawala N, Palardy M, Nohria A, Stevenson LW. Mismatch of right- and left-sided filling pressures in chronic heart failure. *J Card Fail*. 2011;17:561–568. doi: 10.1016/j.cardfail.2011.02.013
55. Drazner MH, Velez-Martinez M, Ayers CR, Reimold SC, Thibodeau JT, Mishkin JD, Mammen PP, Markham DW, Patel CB. Relationship of right- to left-sided ventricular filling pressures in advanced heart failure: insights from the ESCAPE trial. *Circ Heart Fail*. 2013;6:264–270. doi: 10.1161/CIRCHEARTFAILURE.112.000204
56. Maurer MS, Adamson PB, Costanzo MR, Eigler N, Gilbert J, Gold MR, Klapholz M, Saxon LA, Singh JP, Troughton R, et al. Rationale and design of the Left Atrial Pressure Monitoring to Optimize Heart Failure Therapy Study (LAPTOP-HF). *J Card Fail*. 2015;21:479–488. doi: 10.1016/j.cardfail.2015.04.012
57. Cardioset. 2022. Accessed February 21, 2024. https://finder.startupnationcentral.org/company_page/cardioset-medical
58. Qiu C, Wu F, Han W, Yuce MR. A wearable bioimpedance chest patch for real-time ambulatory respiratory monitoring. *IEEE Trans Biomed Eng*. 2022;69:2970–2981. doi: 10.1109/TBME.2022.3158544
59. Shao D, Tsow F, Liu C, Yang Y, Tao N. Simultaneous monitoring of ballistocardiogram and photoplethysmogram using a camera. *IEEE Trans Biomed Eng*. 2017;64:1003–1010. doi: 10.1109/TBME.2016.2585109
60. Balali P, Rabineau J, Hossein A, Tordeur C, Debeir O, van de Borne P. Investigating cardiorespiratory interaction using ballistocardiography and seismocardiography: a narrative review. *Sensors (Basel)*. 2022;22:9565: doi: 10.3390/s22239565
61. US Food and Drug Administration. Eko Devices Inc letter. Accessed February 21, 2024. https://www.accessdata.fda.gov/cdrh_docs/pdf19/K192004.pdf
62. Kwon S, Kim H, Yeo WH. Recent advances in wearable sensors and portable electronics for sleep monitoring. *iScience*. 2021;24:102461. doi: 10.1016/j.isci.2021.102461
63. Chung MK, Eckhardt LL, Chen LY, Ahmed HM, Gopinathannair R, Joglar JA, Noseworthy PA, Pack QR, Sanders P, Trulock KM, et al; on behalf of the American Heart Association Electrocardiography and Arrhythmias Committee and Exercise, Cardiac Rehabilitation, and Secondary Prevention Committee of the Council on Clinical Cardiology; Council on Arteriosclerosis, Thrombosis and Vascular Biology; Council on Cardiovascular and Stroke Nursing; and Council on Lifestyle and Cardiometabolic Health. Lifestyle and risk factor modification for reduction of atrial fibrillation: a scientific statement from the American Heart Association. *Circulation*. 2020;141:e750–e772. doi: 10.1161/CIR.0000000000000748
64. Sharma M, Kumar K, Kumar P, Tan RS, Rajendra Acharya U. Pulse oximetry *SpO2* signal for automated identification of sleep apnea: a review and future trends. *Physiol Meas*. 2022;43:11TR01. doi: 10.1088/1361-6579/ac98f0
65. Global spending on health: a world in transition. World Health Organization. 2019. Accessed December 6, 2022. https://apps.who.int/iris/bitstream/handle/10665/330357/WHO-HIS-HGF-HF-WorkingPaper-19.4-eng.pdf?ua=1
66. D'Amore J, Bouhaddou O, Mitchell S, Li C, Leftwich R, Turner T, Rahn M, Donahue M, Nebeker J. Interoperability progress and remaining data quality barriers of certified health information technologies. *AMIA Annu Symp Proc*. 2018;2018:358–367.
67. Rocha BH, Pabbathi D, Schaeffer M, Goldberg HS. Screening Consolidated Clinical Document Architecture (CCDA) documents for sensitive data using a rule-based decision support system. *Appl Clin Inform*. 2017;8:137–148. doi: 10.4338/ACI-2016-07-RA-0120
68. US Department of Health and Human Services. *General Principles of Software Validation: Final Guidance for Industry and FDA Staff*. US Food and Drug Administration, Center for Devices and Radiological Health and Center for Biologics Evaluation and Research; 2002.
69. Goldsack JC, Coravos A, Bakker JP, Bent B, Dowling AV, Fitzer-Attas C, Godfrey A, Godino JG, Gujar N, Izmailova E, et al. Verification, analytical validation, and clinical validation (V3): the foundation of determining fit-for-purpose for biometric monitoring technologies (BioMeTs). *npj Digital Med*. 2020;3:55. doi: 10.1038/s41746-020-0260-4
70. FDA-NIH Biomarker Working Group. *BEST (Biomarkers, Endpoints, and Other Tools) Resource*. US Food and Drug Administration; 2016.
71. Washington V, DeSalvo K, Mostashari F, Blumenthal D. The HITECH era and the path forward. *N Engl J Med*. 2017;377:904–906. doi: 10.1056/NEJMp1703370
72. HealthIT.gov. Office-based physician electronic health record adoption. Accessed February 16, 2023. https://healthit.gov/data/quickstats/office-based-physician-electronic-health-record-adoption
73. Tang PC, Ash JS, Bates DW, Overhage JM, Sands DZ. Personal health records: definitions, benefits, and strategies for overcoming barriers to adoption. *J Am Med Inform Assoc*. 2006;13:121–126. doi: 10.1197/jamia.M2025
74. Irizarry T, DeVito Dabbs A, Curran CR. Patient portals and patient engagement: a state of the science review. *J Med Internet Res*. 2015;17:e148. doi: 10.2196/jmir.4255
75. Lye CT, Forman HP, Daniel JG, Krumholz HM. The 21st Century Cures Act and electronic health records one year later: will patients see the benefits? *J Am Med Inform Assoc*. 2018;25:1218–1220. doi: 10.1093/jamia/ocy065
76. Mandel JC, Kreda DA, Mandl KD, Kohane IS, Ramoni RB. SMART on FHIR: a standards-based, interoperable apps platform for electronic health records. *J Am Med Inform Assoc*. 2016;23:899–908. doi: 10.1093/jamia/ocv189
77. HealthIT.gov. Standardized API for patient and population services. Accessed February 16, 2023. https://healthit.gov/test-method/standardized-api-patient-and-population-services#ccg
78. Tiase VL, Hull W, McFarland MM, Sward KA, Del Fiol G, Staes C, Weir C, Cummins MR. Patient-generated health data and electronic health record integration: a scoping review. *JAMIA Open*. 2020;3:619–627. doi: 10.1093/jamiaopen/ooaa052
79. US Food and Drug Administration. What is digital health? Accessed March 4, 2024. https://fda.gov/medical-devices/digital-health-center-excellence/what-digital-health
80. US Food and Drug Administration. Digital health software precertification (pre-cert) pilot program. Accessed March 4, 2024. https://fda.gov/medical-devices/digital-health-center-excellence/digital-health-software-precertification-pre-cert-pilot-program
81. US Food and Drug Administration. Software as a medical device (SaMD). Accessed March 4, 2024. https://fda.gov/medical-devices/digital-health-center-excellence/software-medical-device-samd
82. US Food and Drug Administration. Medical device interoperability. Accessed March 4, 2024. https://fda.gov/medical-devices/digital-health-center-excellence/medical-device-interoperability
83. US Food and Drug Administration. Recognized consensus standards. Accessed March 4, 2024. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/search.cfm
84. Bazoukis G, Hall J, Loscalzo J, Antman EM, Fuster V, Armoundas AA. The inclusion of augmented intelligence in medicine: a framework for successful implementation. *Cell Rep Med*. 2022;3:100485. doi: 10.1016/j.xcrm.2021.100485
85. US Food and Drug Administration. Digital Health Center of Excellence. Accessed March 4, 2024. https://fda.gov/medical-devices/digital-health-center-excellence
86. US Food and Drug Administration. Artificial intelligence and machine learning in software as a medical device. Accessed March 4, 2024. https://fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-software-medical-device
87. US Food and Drug Administration. Clinical decision support software – guidance. Accessed March 4, 2024. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-decision-support-software
88. Torrence R. Providers still skeptical about wearable accuracy, integration abilities. 2021. Accessed February 4, 2023. https://fiercehealthcare.com/tech/providers-still-skeptical-about-wearable-accuracy-integration-abilities
89. Smuck M, Odonkor CA, Wilt JK, Schmidt N, Swiernik MA. The emerging clinical role of wearables: factors for successful implementation in healthcare. *NPJ Digit Med*. 2021;4:45. doi: 10.1038/s41746-021-00418-3

90. Attia ZI, Harmon DM, Dugan J, Manka L, Lopez-Jimenez F, Lerman A, Siontis KC, Noseworthy PA, Yao X, Klavetter EW, et al. Prospective evaluation of smartwatch-enabled detection of left ventricular dysfunction. *Nat Med*. 2022;28:2497–2503. doi: 10.1038/s41591-022-02053-1
91. Gallas BD, Badano A, Dudgeon S, Elfer K, Garcia V, Lennerz JK, Myers K, Petrick N, Margerrison E. FDA fosters innovative approaches in research, resources and collaboration. *Nat Mach Intell*. 2022;4:97–98.
92. Frank RA, Jarrin R, Pritzker J, Abramoff MD, Repka MX, Baird PD, Grenon MS, Mahoney MR, Mattison JE, Silva E 3rd. Developing current procedural terminology codes that describe the work performed by machines. *NPJ Digit Med*. 2022;5:177. doi: 10.1038/s41746-022-00723-5
93. van Kessel R, Wong BLH, Clemens T, Brand H. Digital health literacy as a super determinant of health: more than simply the sum of its parts. *Internet Interv*. 2022;27:100500. doi: 10.1016/j.invent.2022.100500
94. GDPR.EU. What is GDPR, the EU's new data protection law? Accessed January 4, 2023. https://gdpr.eu/what-is-gdpr/
95. McGraw D, Mandl KD. Privacy protections to encourage use of health-relevant digital data in a learning health system. *npj Digital Med*. 2021;4:2. doi: 10.1038/s41746-020-00362-8
96. Chikwetu L, Miao Y, Woldetensae MK, Bell D, Goldenholz DM, Dunn J. Does deidentification of data from wearable devices give us a false sense of security? A systematic review. *Lancet Digital Health*. 2023;5:e239–e247. doi: 10.1016/S2589-7500(22)00234-5
97. Langone M, Setola R, Lopez J. Cybersecurity of wearable devices: an experimental analysis and a vulnerability assessment method. Paper/Poster presented at: 2017 IEEE 41st Annual Computer Software and Applications Conference (COMPSAC); July 4–8, 2017; Turin, Italy.
98. Lanka S, Ehsan S, Ehsan A. A review of research on emerging technologies of the Internet of Things and augmented reality. Paper/Poster presented at: 2017 International Conference on I-SMAC (IoT in Social, Mobile, Analytics and Cloud); February 10–11, 2017; Palladam, Tamil Nadu, India.
99. Krittanawong C, Aydar M, Hassan Virk HU, Kumar A, Kaplin S, Guimaraes L, Wang Z, Halperin JL. Artificial intelligence-powered blockchains for cardiovascular medicine. *Can J Cardiol*. 2022;38:185–195. doi: https://doi.org/10.1016/j.cjca.2021.11.011
100. Chen JH, Beam A, Saria S, Mendonça EA. Potential trade-offs and unintended consequences of AI. In: Matheny M, Israni ST, Mahnoor A, Whicher D, eds. *Artificial Intelligence in Health Care: The Hope, the Hype, the Promise, the Peril*. National Academy of Medicine; 2019.
101. Spector-Bagdady K, Armoundas AA, Arnaout R, Hall JL, Yeager McSwain B, Knowles JW, Price WN 2nd, Rawat DB, Riegel B, Wang TY, et al; on behalf of the American Heart Association Advocacy Coordinating Committee. Principles for health information collection, sharing, and use: a policy statement from the American Heart Association. *Circulation*. 2023;148:1061–1069. doi: 10.1161/CIR.0000000000001173. PMID: 37646159
102. Andanda P. Ethical and legal governance of health-related research that use digital data from user-generated online health content. *Inform Commun Soc*. 2020;23:1154–1169. doi: 10.1080/1369118X.2019.1699591
103. Statistics Canada. *The Value of Data in Canada: Experimental Estimates*. Government of Canada; 2019.
104. HealthIT.gov. Trusted Exchange Framework and Common Agreement (TEFCA). Accessed January 4, 2023. https://healthit.gov/topic/interoperability/policy/trusted-exchange-framework-and-common-agreement-tefca
105. Izmailova ES, Wagner JA, Perakslis ED. Wearable devices in clinical trials: hype and hypothesis. *Clin Pharmacol Ther*. 2018;104:42–52. doi: https://doi.org/10.1002/cpt.966
106. Javaid M, Haleem A, Singh RP, Rab S, Suman R, I.H. K. Evolutionary trends in progressive cloud computing based healthcare: ideas, enablers, and barriers. *Int J Cogn Comput Eng*. 2022;3:124–135.
107. Armoundas AA, Narayan SM, Arnett D, Spector-Bagdady K, Bennett DA, Celi LA, Friedman P, Gollob MH, Hall JL, Kwitek AE, et al; on behalf of the American Heart Association Institute for Precision Cardiovascular Medicine, Council on Cardiovascular and Stroke Nursing, Council on Cardiovascular Disease in the Young, Council on Cardiovascular Radiology and Intervention, Council on Hypertension, Council on Kidney in Cardiovascular Disease, and Stroke Council. Use of artificial intelligence in improving outcomes in heart disease: a scientific statement from the American Heart Association. *Circulation*. 2024;149:e1028–e1050.
108. Pearson T, Vitalis D, Pratt C, Campo R, Armoundas AA, Au D, Beech B, Brazhnik O, Chute CG, Davidson KW, et al. The science of precision prevention: research opportunities and clinical applications to reduce cardiovascular health disparities. *JACC Adv*. 2024;3;100759.
109. Adler-Milstein J, Nong P. Early experiences with patient generated health data: health system and patient perspectives. *J Am Med Inform Assoc*. 2019;26:952–959. doi: 10.1093/jamia/ocz045
110. Radanliev P, De Roure D. Epistemological and bibliometric analysis of ethics and shared responsibility: health policy and IoT systems. *Sustainability*. 2021;13:8355. doi: 10.3390/su13158355
111. Canali S, Schiaffonati V, Aliverti A. Challenges and recommendations for wearable devices in digital health: data quality, interoperability, health equity, fairness. *PLoS Digital Health*. 2022;1:e0000104. doi: 10.1371/journal.pdig.0000104
112. Liddell K, Simon DA, Lucassen A. Patient data ownership: who owns your health? *J Law Biosci*. 2021;8:lsab023. doi: 10.1093/jlb/lsab023