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PERSPECTIVE

Visions for digital integrated cardiovascular care: HRS Digital Health Committee perspectives

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Introduction

Few innovations have the potential to reconfigure clinical care as thoroughly as digital medicine. One likely future of continuous physiological monitoring by novel devices—analyzed by artificial intelligence (AI)-guided algorithms and stored in secure repositories—to develop personal biometrics to guide care, improve risk stratifiers, and predict future events is both exciting and daunting. It is unclear how practitioners and patients will transition to that possible future, yet all stakeholders can at the present time directly influence how these technologies will develop and paths evolve.

Cardiovascular medicine is particularly well suited to digital integration because several key physiological indices are readily measured, devices exist to track them, and such data can directly guide care. Digital tools are already central to the detection and monitoring of patients with heart failure, cardiac arrhythmias, and ischemic heart disease, and their use is increasing elsewhere in cardiovascular medicine.[1] Remote monitoring of devices has long been part of cardiovascular practice. Nevertheless, it is less clear how to leverage existing and emerging tools to realize the most effective future models of care and, importantly, how to design the studies needed to test new care pathways and potentially change guidelines.

The Digital Health Committee of the Heart Rhythm Society set out in this document to articulate a near-term vision for how the integration of digital devices with existing care models could improve patient outcomes and clinical workflows for cardiovascular care into the next decade.[2] Herein, we review the literature, discuss emerging technologies, and illustrate potential use cases. We also discuss the use of digital technology for the purpose of training health care providers. The document is intended to cover existing promise, challenges, and limitations, yet also be aspirational and provocative.

My clinic tomorrow: Powered by digital health

In our daily lives we have become accustomed to instant gratification, with orders and purchases at the touch of a button. It is not surprising that our patients may already have expectations and requests that health care should be as easily accessed. With big consumer-facing companies like Amazon and Google entering the health care arena, patients will soon be able to satisfy their desire to receive instantaneous access to their

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diagnosis, chat with a physician, view and print their results, update their records, or refill medications at the touch of a button, anywhere, anytime. It is thus imperative for us to envision the future clinic to anticipate how the advent of digital health tools can help us achieve a fluid and uninterrupted dialogue with our patients to achieve better prevention, diagnosis, and management. The future clinic will be interdisciplinary and will incorporate data from remote monitoring of weight, body mass index, blood pressure, temperature, heart rate, glucose, oxygenation, activity, sleep, socialization, and pain based on sensors and wearables,[3,4] with potential monitoring of consumption such as the groceries our patients are buying. Smart wearables are consumer-grade electronics that can be worn on the body as accessories such as watches, rings, and wristbands or even be embedded in clothing. Machine learning will be able to assist in highlighting data that may be clinically concerning. Health care providers should be able to access these day-to-day data to make recommendations for changes in diet, lifestyle, medications, and potentially even grocery purchases. If a patient has a medical question or is experiencing stress, anxiety, or depression requiring urgent care, they should be able to access a health care provider immediately, virtually.[5]

Clinics of the future may use medical extended realities to create immersive experiences with a "sense of embodiment."[6] Extended reality encompasses virtual reality (VR), augmented reality (AR), and mixed reality (MXR). VR refers to the substitution of the avatar, a virtual body, for the user's own first-person perspective and creates a sense of physical presence in the virtual space for the user. AR, by contrast, refers to an interactive experience in which computer-generated information is used to enhance real-world data, such as glasses in which digital content or labels are overlaid upon viewed objects. MXR integrates real-world and digital elements, such as using sophisticated sensors and imaging technologies for procedural simulations.

In the case of the VR clinic, embodiment is perhaps most important for the patient. One can imagine a VR clinic where the patient and physician each use a VR system from their respective locations, meet in a virtual office space, and obtain a real-time history. For the physical examination, digital health tools could be used to perform a focused cardiac clinical examination; for instance, an electronic stethoscope could be used for cardiac and pulmonary auscultation and then transmit data in real time.[5] In a hybrid model, vital signs and other examination findings could be performed in a rapid-response clinic. Routine cardiovascular testing, such as electrocardiograms (ECGs), device interrogations, and echocardiograms, could also be performed using digital health and remote monitoring technology. The future VR clinic must be patient-centric and add value over traditional clinic visits or telehealth visits and will likely be limited by our own imaginations.

In parallel with such possible near-term realities, health care personnel must be prepared to cope with both a vast increase in the amount of data to be processed and the expectation that this be done rapidly. When envisioning a future clinic, the need for the following should also be considered: personnel for the roles of data checking, curation, and filtering; new data systems; and AI agents to handle these new data flows.[7]

Digital tools to reduce health care disparities

Digital tools cannot move the needle on overall health outcomes unless they also serve to reduce health care disparities. Such disparities reflect social, economic, and environmental disadvantages. The challenges for digital health are interconnected and include awareness of and access to technological advancements, as unequal access and implementation of technology can result in a "digital divide." Although advancements in digital health have the potential to improve health equity across disadvantaged populations, they may have unintended consequences, such as leaving the same vulnerable populations behind by exacerbating exclusion and further widening the digital divide.

Solutions to tackle these disparities can be complex and must be multifaceted, targeting not only affordability, accessibility, and connectivity but also specific technologies. Such solutions should include not only allied professionals (APs) but the entire health care team, per societal guidelines.[8] While funding agencies and technology developers are allocating more resources to tackle these structural problems, more must be done. In particular, efforts from both industry and health care payors must focus on increasing affordability of digital health tools and access to infrastructure, since cost is a major driver of disparities. Concerted efforts are required to ensure that digital medicine is best able to fulfill its potential to increase health care access, measure outcome gaps for vulnerable populations, provide tools to fill such gaps, and personalize care for diverse communities.

Improving access to health care

Digital health could dramatically reduce barriers to access. By reducing the need to travel to a brick-and-mortar facility, or to take travel time at all, digital health has been shown to reduce challenges of access to care.[9] This was demonstrated during the COVID-19 pandemic, which rapidly accelerated the adoption of digital health in every aspect of our health care delivery—from acute triage to emergency care to comprehensive outpatient telemedicine visits. Tools must be developed across medical specialties to seamlessly integrate with in-person and procedural encounters.

Identifying and closing gaps in clinical guidelines for all populations

While cardiovascular medicine is evidence based, it is increasingly clear that disadvantaged and vulnerable populations have been excluded from evidence gathering.[10,11] It thus remains unclear if guideline-directed management should be tailored for different communities for blood pressure control, atrial fibrillation (AF) management, stroke prevention, or other needs. Digital health provides a unique opportunity to reframe data collection toward communities of interest without bias.[12] However, new digital health care pathways

must be designed, tested in trials, and then implemented to address these challenges.

While digital health tools can close some existing disparities,[13] the complexity and sheer number of health-related apps is confusing and may contribute to new disparities,[14] especially for older patients, those with poor literacy, and non-English speakers. Digital health models that are accessible for all communities are needed. APs can help address these digital health disparities by seeking out opportunities to assist with developing digital health solutions, whether within their clinic or institution or by providing consulting services to third-party entities developing such solutions. A key strength of APs in this regard is the experience many bring in developing patient education resources that are both culturally relevant for the populations they serve and developed with consideration of the patient's health literacy. APs can also assist patients in navigating and understanding the data deluge they may experience accessing medical records via electronic health record (EHR) portals.

Digital health tools for monitoring and diagnosis

Technologies are advancing rapidly for the diagnosis of cardiac disease, including hypertension, coronary artery disease, and congestive heart failure, and wearables for monitoring health and disease have introduced digital health widely to consumers.[15–17] A variety of wearables already exist, and many more are emerging. Care pathways are urgently needed in order to select and prioritize applications that best address critical unmet needs, from which it should be possible to identify the strengths and limitations of devices in each space. For detecting cardiac rhythm, photoplethysmography and single- or multiple-lead ECGs have been integrated into smartphones, rings, wristbands, and chest straps for screening and diagnosis, particularly for AF.[1] Recent studies, such as the Apple Heart Study,[18] demonstrated that in optical sensors used to detect an irregular heartbeat, 84% of notifications were consistent with AF, and the probability of being notified for an irregular pulse was low. These results, together with those from the Huawei Heart Study and ongoing initiatives, were promising, but they also highlight the challenges of screening low-risk, young populations with a low disease prevalence. Studies have now demonstrated the ability of such devices and infrastructure to accurately monitor other arrhythmias.[19] Future studies must be tailored to consider the pretest probability of disease in various populations, how the data will be used, and hence how each device will integrate into clinical screening and management efforts.

Emerging devices will likely not only provide information on rhythm but also allow for detection and management of conditions including congestive heart failure, coronary artery disease, and diabetes and improvement of preventative care by monitoring blood pressure, blood glucose, physical activity,[20] and sleep.[7] Results from studies using sensors to measure intracardiac pulmonary arterial pressure or thoracic impedance, activity, heart rate, respiration, and heart sounds in cardiac implantable electronic devices for cardiac resynchronization therapy[16] show that these devices can enable physicians to use algorithms to monitor and predict heart failure events, thus reducing hospitalization and heart failure events. Similarly, these sensors may be applied to patients for preventative care by quantifying activity including heart rate, heart rate variability, and daytime and nighttime heart rate and also by quantifying hours of sleep or rest. ECG data obtained from the wearables can also help in assessing the QT interval and premature atrial or ventricular complex burden and potentially can be used as a continuous ambulatory monitor.

The growing use of wearables for diagnostic evaluation offers an exciting opportunity to develop their role for therapeutic interventions. Several peripheral biosignals and anatomical targets can be leveraged, with multiple near-term possibilities. As one example for cardiac arrhythmias, the vagus nerve can be measured noninvasively from the tragus of the ear and then modulated by electrical stimulation; this approach has been shown to potentially reduce electrical and structural remodeling in an animal model of pacing-induced AF.[21,22] Several wearables are being tested to assess the impact of low-level vagus nerve stimulation, and, in early reports, chronic intermittent tragus stimulation resulted in a lower AF burden than sham control stimulation, supporting its use for treatment of paroxysmal AF in selected patients.[23] It has been reported that median nerve stimulation can prevent the shortening of the atrial refractory period and increase AF inducibility during rapid atrial pacing.[24] An ongoing clinical trial (NCT04529941) is evaluating chronic subcutaneous nerve stimulation and its impact on AF burden in individuals unresponsive to conventional therapies for AF.

For coronary disease, initial reports using optical-based transdermal sensors show that they correlate well with cardiac troponin I,[25] and development of sensors to measure hepatic, renal, metabolic, and coagulation profiles[26] is underway. Wearables are also used for risk factor screening. For instance, a semi-supervised learning algorithm, developed from >57,000 person-weeks of data (data acquisition from Fitbit, Apple Watch, and Wear OS), classified high cholesterol levels and hypertension with reasonable accuracy (area under the curve 0.7441 and 0.8086, respectively) using heart rate and step count data.[27]

For glucose monitoring, moving away from our familiar era of frequent skin punctures, noninvasive biosensors have the potential to greatly simplify monitoring of patients with diabetes mellitus.[28] Glucose levels in fluids such as perspiration or tears may be monitored by wearable patch or contact lens.[29] Enzymatic sensors use glucose oxidation for assessment of glucose levels, while nonenzymatic sensors use electrochemical and electromechanical properties using fluorescence principles and nanofiber technology.[30] The glucose levels are assessed in real time and on demand and are transmissible to smartphones for self-assessment and optimization of therapy. Compared with conventional glucose monitors, continuous glucose monitoring has shown

improvements in glycemic control and reduction in episodes of hypoglycemia.[31,32]

Digital health technology is also being explored in secondary prevention for cardiac rehabilitation. It has potential to improve access to care and enhance participation, and such telehealth is being tested in ongoing clinical outcome studies.[33,34] Other areas of digital monitoring include hypertension. Photoplethysmography signals may be used to estimate blood pressure from wristbands, toilet seats, sensors in T-shirts, or even devices such as a computer mouse.[15] Emerging bedside technologies also include the tele-stethoscope, which can convert audio signals from conventional stethoscopes to digital signals transmissible to smartphones; novel devices to monitor glucose levels in readily accessible fluids such as perspiration or tears;[29] and monitors for sleep.[7] There is also potential real-time wireless technology where audio and video signals can be transmitted via a data network. Such devices will provide access to patients in remote areas.[35]

Since formally testing each of this plethora of devices will be impossible, it is critical to design and implement frameworks to enable future comparisons. Such frameworks could embody categories based on biomarker type or sensor and be further subdivided for specific device or software versions. Such frameworks should be developed with input from clinicians drawn from the entire health care team, clinical trialists, members of regulatory agencies, and industry. Such frameworks should be able to prioritize digital tool types and then articulate best practices and expected data types and study designs in each space.

Patient views on how we should shape digital health

From fitness trackers to mobile apps, digital health tools have revolutionized care for patients with cardiovascular disease by empowering patients to take control of their health by monitoring themselves in real time and enabling access to information and support. However, patients may have concerns regarding the use of these devices, and taking these concerns into consideration should be central to future technological and care pathway development.

Which major patient issues can be addressed by digital medicine?

Conceptually, technology can enhance patient engagement and enable more personalized and data-driven care, with the end goal of improving health outcomes across the spectrum of care. Moreover, digital health tools can facilitate support networks and enable patients to build a community with others sharing in the journey. While relevant for all, digital health tools are particularly helpful for connecting patients who suffer from rare diseases. Medication adherence and persistence remain a significant concern in the case of chronic disease management and can be enhanced by the use of personalized reminders and real-time tracking with alerts in the case of missed medication doses, as well as automated transmission for prescription renewal. Digital health tools can help patients better understand their health conditions, provided historically by asynchronous educational resources, eg, websites and videos, which can enable patients to better engage with medical systems to make better-informed decisions regarding their health choices and subsequent care.

Wearable and smart devices empower patients to monitor their vital signs (eg, heart rate and rhythm, blood pressure, and pulse oximetry), biometrics (eg, weight and thoracic impedance), and symptoms, providing real-time feedback on health status. This enables patients to take an active role in their care by reporting symptoms, increasing their sense of control, and possibly reducing stress and anxiety. The ability to transmit data to health care providers means that the patient's condition can be remotely monitored, facilitating prompt medical attention in the case of clinical deterioration and enabling health care providers to address issues before they become serious (eg, averting the need for hospitalization).

While relevant for all patients, these benefits are particularly important for those in remote or underserved areas (ie, without local access to primary and specialty care). In effect, digital health tools can ensure and maintain equitable access to health services. As technology evolves, we expect that more advanced tools will further improve patient empowerment and enable more personalized care.

What do patients like the least about digital medicine?

It is important to recognize the limitations of digital health tools. Digital tools have variable diagnostic accuracy and may not work equally well for all patients. A central issue is the concept of digital equity, which is a condition in which all individuals and communities have the information technology capacity needed for full participation in our society, democracy, and economy (National Digital Inclusion Alliance).[36] Conversely, digital inequity typically manifests as problems with infrastructure access (eg, patients in underserved or remote areas may not have access to the necessary technology infrastructure) or financial barriers (eg, commercially available digital health tools often require an up-front "purchase" cost or require subscription fees). Less clear is how digital inequity may result from technological unfamiliarity, as patients less exposed to digital devices may struggle with them or even resist using them for their health in place of a traditional medical encounter.

Moreover, the growth in digital health tools has led to concerns regarding privacy and data security. Many digital health tools are commercially available yet not regulated in the same manner as traditional devices. In the United States, commercial-use digital health data are not covered by the Health Insurance Portability and Accountability Act, leading to concerns that the lack of regulation and oversight may compromise the security and privacy of personal health information. While this concern may focus on data security, such as leakage across unsecured networks or sharing with third-

party vendors, in exceptional cases patient data (which is often not "owned" by the patient) has been misused.

Lastly, for some patients, the exclusive use of digital health tools may feel "soulless," lacking the personal connection associated with a face-to-face interaction. As such, it is critical that patients and providers work together to maintain the human touch while removing barriers to access and personalizing care, by striking an appropriate balance between digital and in-person care.

How can patients avoid getting lost in the digital divide?

The term "digital divide" loosely encompasses many of the challenges and limitations mentioned above. A key to solutions is to focus on education and empower patients in the use of these tools, thus enabling them to make an informed decision on when to use or not use them. This introduces the notion of patient advocates trained for specific digital tools, which differ greatly in cardiovascular medicine for electrophysiology, heart failure, and hypertension tracking or for other disease entities. It is important that patients and providers actively engage in such conversations. Patients need to stay informed on the practical developments in digital medicine, express their preferences, and advocate for platforms best suited to their needs. Patients lacking technological familiarity may require assistance from family and friends to access digital tools or may consider access through community resources such as public libraries or community centers. Ultimately, digital health, like other aspects of health care, benefits greatly from shared decision-making and patient self-advocacy.

Digital dashboards to coordinate care

The widespread adoption of digital tools has been hindered by lack of integration with clinical workflows and the EHR.

Digital dashboards represent one immediate and practical solution for clinical integration. Their key goal is to make data actionable at the point of care and to prioritize the care of patients with emergent or urgent issues.[37] Figure 1 indicates some elements of a dashboard; many others could be envisioned. The role for a digital dashboard was recently shown in a study of alert-based remote monitoring of patients with implantable cardiac defibrillators: when transmissions were filtered for actionability, the number of evaluations required to detect a clinically actionable event was reduced by 75%.[38] One main challenge for digital health companies is to present data in an intuitive and actionable fashion for patients and clinicians. Data from monitoring devices may not alter practice unless key outputs have been shown to be meaningful in clinical studies.[39] SafeHeart is an example of a study that leveraged multiple sources of data to provide real-time clinical decision support in patients at risk for an implantable cardiac defibrillator shock[40] via a clinical dashboard. Investigators at the Mayo Clinic developed a dashboard to display AI-based ECG algorithm outputs and Apple Watch tracings within the EHR, accessible by a single sign-on, to detect heart failure.[41] This dashboard illustrates how digital tools can be deployed and made available at the point of care. However, to be most valuable, they should ultimately include a "universal data ingest engine" capable of pulling data from many other digital tools, and further work is needed to build systems for annotation of results, to enable prioritization alerts for time-sensitive critical findings, to provide timely notification of patients of their results, and to streamline the documentation and billing processes (Figure 1). By collating and organizing various patient care activities in one central venue, digital dashboards could simplify and support billing procedures, and future billing frameworks should be developed with such portals in mind.

In general, few streamlined methods exist to ingest, filter, annotate, or archive data, as they are generated from several novel technologies currently outside of the clinical ecosystem, particularly the EHR. Since most devices, monitors, or applications have their own user interfaces (often requiring a unique login), it is at best cumbersome to expect providers to work across systems. A multitude of interoperability and technical constraints challenge both short- and long-term deployment, and few health systems have demonstrated success in integrating digital health tools into health care systems. For instance, the Brigham and Women's Hospital Digital Health Innovation Group recently reported that only 4 of 23 efforts to integrate such digital tools progressed to a pilot study.[39] These considerations underscore the need to integrate tools in digital dashboards. Such dashboards would include and prioritize different elements across disease states and across settings of different acuity, such as the operating room suite, emergency room, and doctor's office.

Standardization and regulation: Software as a medical device

With the proliferation of consumer-facing applications, the line between tools that can be used without US Food and Drug Administration (FDA) regulation and those that are more prescriptive about care decisions and that may warrant regulatory oversight is sometimes challenging to define. The International Medical Device Regulators Forum defines clinical software in 3 categories: (1) software that is intended for 1 or more medical purposes and performs those purposes without being part of a hardware medical device (software as a medical device [SaMD]), (2) software that is integral to a product (software in a medical device), and (3) software used in the manufacturing or maintenance of a medical device.[42] SaMDs have a wide range of applications, including diagnosis, mitigation, treatment, and prevention of diseases.

In the United States, the regulatory framework for SaMDs primarily utilizes pathways applied to low-risk medical devices, such as the de novo and 510(k) pathways.[42] The de novo process is commonly used for the clearance of novel low-risk devices (eg, class I and II) and requires "reasonable assurance of safety and effectiveness for the intended use" of the device in question.[3] The regulatory pathway of 510(k) requires demonstration of substantial equivalence to 1 or more already marketed devices and does not require the submission

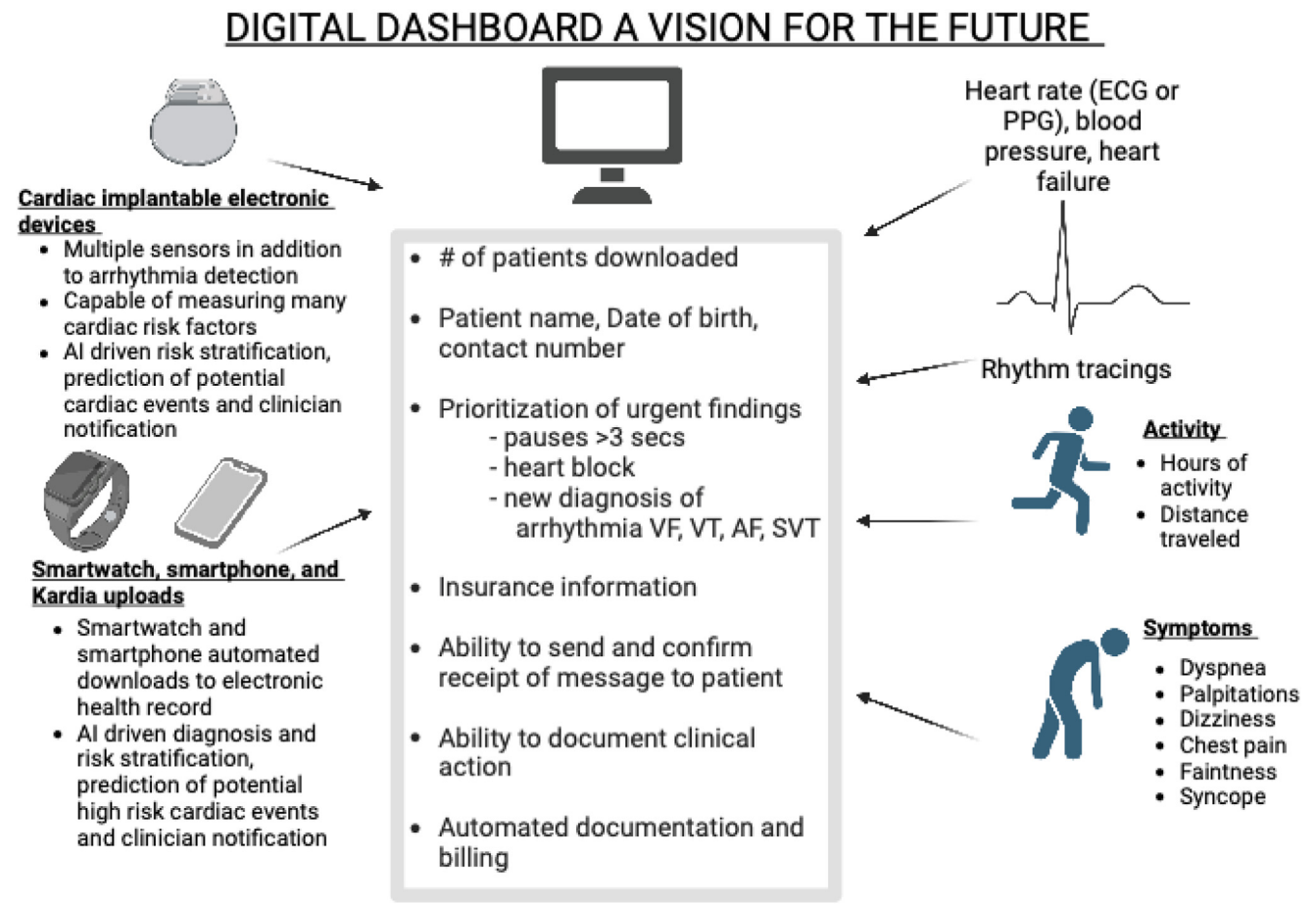

Figure 1 Proposed elements of a digital dashboard for cardiovascular care. The dashboard could be personalized by the clinic or patient and expanded to integrate management of other disease entities. AF = atrial fibrillation; AI = artificial intelligence; ECG = electrocardiogram; PPG = photoplethysmogram; SVT = supraventricular tachycardia; VF = ventricular fibrillation; VT = ventricular tachycardia.

of additional data on safety or efficacy.[42] There have been several examples of these devices that have been cleared for treatment of insomnia and psychological disorders.[43,44]

A significant number of consumer medical applications fall outside the purview of regulatory oversight by the FDA, as they are intended to promote general fitness, health, and wellness and do not fulfill the regulatory definition of a medical device.[5] Along these lines, many patient-facing applications have been developed that seek to provide feedback to patients as they make lifestyle intervention changes such as weight loss, setting and tracking physical activity goals, or smoking cessation.

The distinction between consumer-facing applications requiring FDA regulation and those that do not can be challenging to determine. While current regulatory frameworks serve as a solid foundation, it is essential to adapt and innovate these approaches to keep pace with the rapid growth of digital devices in the medical field. By refining the regulatory strategies for software-based medical devices and applications, we can ensure the safe and effective integration of these emerging technologies while maximizing their potential benefits in health care and patient well-being.

Allied professionals and digital health

APs are uniquely positioned to innovate digital health solutions across the entire spectrum of clinical interaction and design new technologies. For instance, in electrophysiology clinics, APs are often the first point of contact for routine patient calls and incoming data, such as remote transmissions from cardiac implanted electronic devices (CIEDs) or wearable data communicated by patients via an EHR portal (Figure 2). APs can help develop workflows for integration of digital data into clinical use, which can be models for clinical and data flow across the entire team. APs are also integral to patient education at the initial clinic visit and throughout the entire clinical journey. APs are already responsible for developing patient-facing resources that introduce patients to digital health, such as education materials that review and summarize various options for consumer wearables. An example is “Best Use” guidelines, which assist clinicians and patients in matching wearable devices to diagnoses or symptoms. As information for wearables is received, APs are in a prime position to triage data and escalate issues to other members of the team as appropriate.

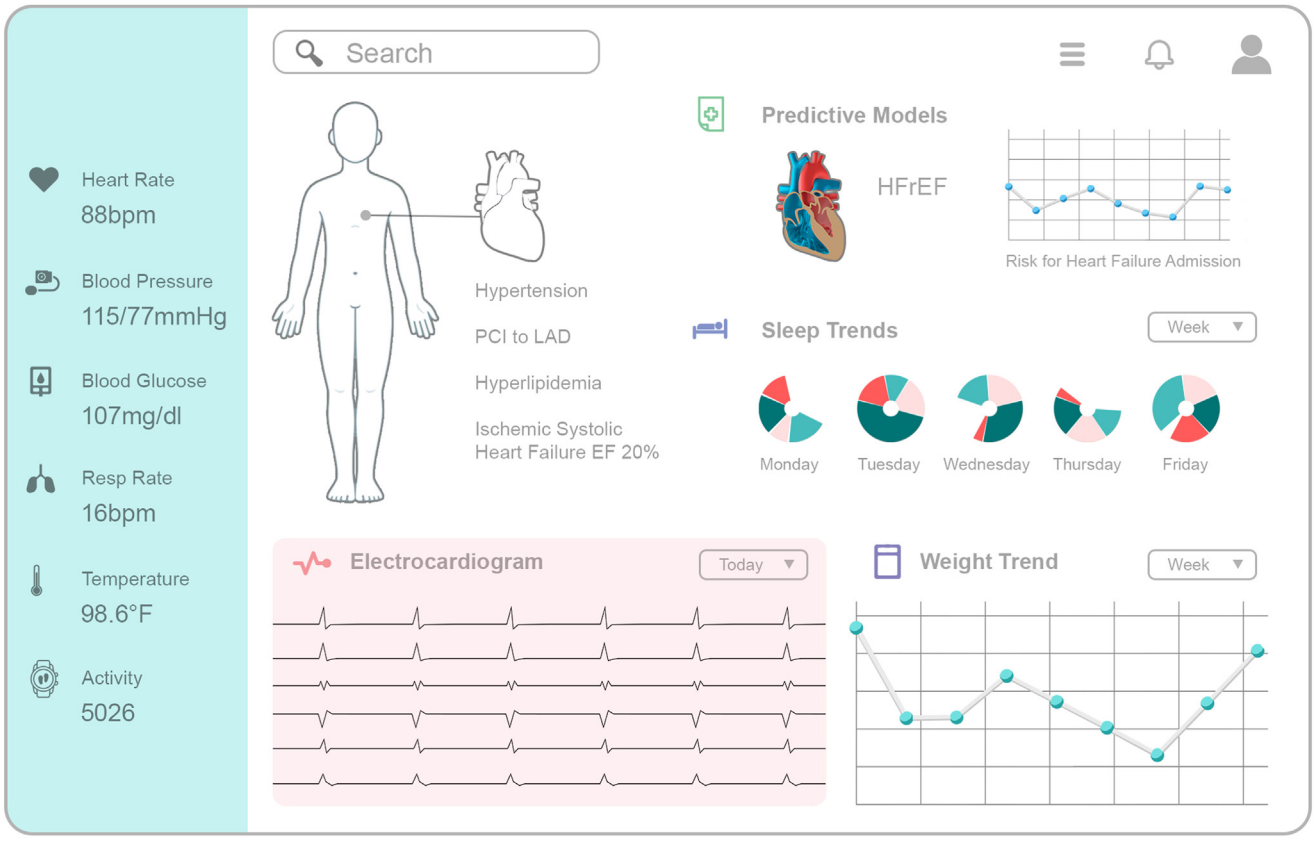

Figure 2 Granular clinical and physiological metrics on a current digital dashboard. Such metrics could be prioritized to highlight abnormal values or to suggest predicted near-term issues for which additional data should be collected. Several other disease states could be integrated in this way. EF = ejection fraction; HFrEF = heart failure with reduced ejection fraction; LAD = left anterior descending artery; PCI = percutaneous coronary intervention; Resp = respiration.

A key role for APs is in promoting a proactive approach to digital health interventions. At the simplest levels, APs can leverage EHR portals to communicate proactively with patients, but there are other higher-level interventions to consider. A recent meta-analysis on digital health interventions for modifiable cardiovascular risk factors showed significant effects on patient behaviors including alcohol intake, smoking, and medication adherence, as well as objective physiologic measures such as HDL and LDL cholesterol and systolic and diastolic blood pressures.[17] Population-level dashboards have been suggested as an adjunct to conventional management of anticoagulation,[45] a concept that could be expanded to antiarrhythmic medications. A prospective study has been proposed to investigate the use of a mobile phone application to capture lifestyle for integration into an individualized digital dashboard to enable health coaching for patients with pulmonary arterial hypertension.[46] Such methodologies could be adapted for the care of patients with AF or other chronic disease processes.

The advantages of digital health are not limited to patient-facing technologies. Indeed, APs can utilize digital technologies for their own training. The most common implementation of digital training is via online education platforms that can provide in-depth instruction on skills such as ECG analysis and CIED management. There is also a growing role for simulation technologies in health care training,[47,48] which offer many advantages to supplement to traditional training. Chief among these is the opportunity to practice low-frequency/high-intensity scenarios in a controlled environment, allowing complex situations to be broken down into smaller components, which can then be practiced individually and reassembled into the complete skill. Furthermore, simulation allows individual clinicians to identify opportunities for improvement in specific technical skills and in background skills that facilitate teamwork, such as leadership, communication, and problem solving. As educational digital health technologies continue to evolve, becoming more sophisticated and interactive, they will grow to touch all aspects of AP training and education.

Aspirational use cases

The remarkable pace of innovation in digital health means that many tools that were considered science fiction only a few years ago are already in practice. This section highlights a selection of emerging technologies that fill an important unmet need at the current time and could form part of our digital clinic a decade from now.

Remote device reprogramming

Remote monitoring of CIEDs has long enabled routine assessment and early notification of system problems, and its use was

accelerated by the COVID-19 pandemic.[49] However, communication has been 1 way: to access device-based data. Cybersecurity concerns have delayed remote reprogramming, such as that to change output voltages, to reprogram around inappropriate shocks, or to alter bradycardia pacing parameters. Nevertheless, the COVID-19 pandemic saw a limited form of "remote control," allowing remote operation of a bedside programmer in accordance with physician's orders, without device-trained personnel, to program devices in real time.[50] This method has been shown to be safe, effective, and expeditious for CIED management in the magnetic resonance imaging setting.[51] Initial reports with an industry-specific system have been followed recently by a simple multivendor custom-built solution for multiple platforms.[52] Early collective experience shows minimal perceptible delays, programming errors, or connectivity or programming issues. Since direct reprogramming has become available for implantable loop recorders, guidelines for safe use cases for general reprogramming should be developed, with appropriate backup and manual verification as necessary.

Patient preprocedural education and procedural consent

Preprocedural education is an important strategy to reduce patient anxiety before a procedure and is mostly still completed in person via patient-physician interactions. VR provides avenues to deliver this information to patients more flexibly, in immersive and safe ways. Chang and colleagues[53] published a case-control study of patients who were randomized to preprocedural education with paper handouts (n = 22) vs VR (n = 11). Patients in the VR group showed higher self-assessed knowledge about AF ablation than the on-paper group and had less periprocedure pain, anxiety, and impatience. The VR group also reported increased effectiveness of education and increased preparedness for the procedure and were willing to recommend this to other patients. Although population studies are pending, there is significant promise for the use of VR for preprocedural education in at least some patient groups.

During the FDA Patient Engagement and Advisory Committee (PEAC) Meeting on Medical Extended Realities in July 2022,[54,55] the topic of using VR and MXR to improve patient education was discussed. Using this educational component to improve the consent process has been identified by PEAC as an important patient initiative.

Digital tools for training in interventional procedures

Physician training

VR simulation training has had an important impact in surgical specialties and minimally invasive procedures.[56–58] Wang and colleagues[59] developed a VR-based surgical skills training simulator for catheter ablation including a beating heart model and tested it in a mixed-user group (n = 34 users) comprising medical students (n = 15), residents (n = 10), attending cardiologists (n = 5), and interventional radiologists (n = 4). While it was rated highly by users for realism, the lack of haptic feedback in the simulator mitigated enthusiasm for the tool, though it was found to be superior to traditional training methods. Ideally, VR simulator experiences that have high levels of realism coupled with haptic feedback will likely find a user base among cardiac electrophysiology fellows and early attendings.

Procedural sedation

Cardiac electrophysiology studies often use procedural sedation, ranging from partial sedation to general anesthesia. Based on data from other medical specialties where VR has successfully been used to aid in procedural analgesia,[60–62] a feasibility and efficacy study was undertaken at the University Hospital of Poitiers in France in 48 patients who underwent AF ablation (cryoablation, using Arctic Front Advance; Medtronic) who were compared to a historical cohort of patients (n = 51).[63] While device setup was straightforward and <10% of patients experienced cybersickness, VR during AF ablation was associated with pain reduction and comfort improvement but did not lead to a reduction in opioid consumption. While the objective endpoint of opioid consumption was not met in this study, the patient benefit endpoint is an equally important one and should be considered for future studies.

Medical extended reality

Extended-reality headsets are wearable devices with embedded sensors. These devices span a broad range of technologies, including VR, AR, and MXR. VR is an entirely immersive experience that excludes engagement with the natural environment in favor of interactions with the virtual, digital environment—an example being the Oculus Rift headset. AR and MXR, however, are transparent platforms, allowing the user to post digital images, sometimes referred to as holograms, in their viewable natural environment. In AR (eg, Google Glass), the images can be posted and viewed; but in MXR (eg, Magic Leap), the user can interact with these digital images to enhance their understanding, such as by rotating, zooming, cutting planes, and so on. FDA-cleared medical applications using these approaches have increased recently, mostly using VR and MXR.[64] Current and emerging applications include heads-up AR display of electrophysiological data on goggles in the electrophysiology laboratory, and several emerging training and simulation applications. Such technologies will very likely grow in scope and availability in the future.

Intraprocedural mixed reality

The ability to display real-time, 3-dimensional patient-specific electroanatomic maps has been realized by Sentiar (Sentiar, Inc, St. Louis, MO) using an MXR headset. In their CommandEP system, physicians can augment cardiac ablation procedures by having a 3-dimensional hologram of the electroanatomic data during the procedure. In small-sample-size patient studies (n = 15), this technology has been shown to improve navigational accuracy[65] and reduce

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(*Continued*)

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Number value: **0** = $0; **1** = =< $10,000; **2** = > $10,000 to =< $25,000; **3** = > $25,000 to =< $50,000; **4** = > $50,000 to =< $100,000; **5** = > $100,000.
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intraprocedural communications.[65] Additionally, Jang and colleagues[66] have demonstrated the ability to import cardiac magnetic resonance imaging data into a MXR headset to display detailed anatomic models of ventricular scar to assist in ventricular tachycardia ablation. Use cases beyond this include the potential for MXR to assist in left atrial appendage occlusion procedures[67] and cardiac rhythm management device implantation.[68]

Conclusion

Digital health tools have enormous potential to improve cardiovascular care by improving diagnosis, enabling predictive analytics, removing obstacles of access to care, and, thus, reducing health care disparities. However, the window to achieve these goals is now, because once infrastructures are in place, they will be very difficult to drastically revise. This document outlines several near-term and some potential science-fiction use cases that are clearly achievable with the current trajectory of technological and clinical innovation.[1] Health care providers, patients, and industry and professional leaders must actively cooperate to achieve the digital medical future that is needed to achieve equitable health outcomes for all.[1]

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