Transparent sharing of digital health data: A call to action

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Preamble

This HRS Needs Assessment is in the category of the Heart Rhythm Society (HRS) documents delineating a future direction of research, technology development, or health care policy and adheres to the following requirements set forth by the HRS:

1. There are no clinical practice recommendations.
2. The Chair (and Vice-Chair) of the document is free of any relationships with industry and other entities (RWIs).
3. The remainder of the writing committee may have RWIs, with no dollar limit, but may not have relevant stock, stock options, equity, or royalties or be employed by industry.
4. The writing committee is encouraged to gain information from advisors. Advisors must be physicians or health care

providers who are not able to serve as writing committee members because they have relevant stock, stock options, equity, royalties, or other relationships that may be determined to create conflict of interest. Advisors cannot be employed by industry and do not participate in writing.

5. The writing committee uses industry forums to engage representatives of industry, the U.S. Food and Drug Administration, or other third-party organizations in a dialogue to provide an exchange of information.

6. A full disclosure of RWIs for each writing committee member and each advisor is provided in Appendix 1.

The landscape

Tools of digital health are empowering individuals to assume a central role both in maintaining health and in detecting and managing chronic diseases. Patients, the public at large, health care providers, and other stakeholders are using digital health to reduce inefficiencies, improve access, reduce cost, increase quality, and make medicine more personalized for patients.[1] As a result, there is a growing awareness and increasing expectation by patients and the public for access to transparent and secure health care data. The U.S. Department of Veterans Affairs recently announced that veterans will soon be able to access an aggregated view of their allergies, conditions, immunizations, lab results, medications, procedures, and vitals in the Health application on their iPhone (Apple, Inc, Cupertino, CA).[2] It is inevitable that this trend will accelerate and that patients will soon have transparent access to all their medical data, possibly in real time. Heart rhythm care professionals and patients routinely depend upon digital health data obtained by cardiovascular implantable electronic devices (CIEDs), medical-grade ambulatory cardiac monitors, and, most recently, consumer personal biometric monitoring devices. Yet the data typically reside either exclusively with the health care team, or, in the case of consumer devices, with the patient. If we are to realize the transformative opportunity of digital health, it will be necessary to ensure that all stakeholders, particularly patients, have complete, transparent, and secure access to their data. This document focuses on digital health and cardiac electrophysiology, outlining the present state and future vision of key stakeholder groups. It also is meant to serve as a call to action to heart rhythm professionals to join in leading this transformation.

The document is organized into sections representing the constituents involved in the digital health transformation: patients and caregivers, clinicians, research, industry, and regulatory agencies. Additionally, we present our thoughts on adoption of digital health tools by clinical providers. In order to inform the writing group, a 1-day Think Tank was held in August 2018 to convene patients, clinicians, and industry leadership from Abbott, Biosense Webster, BIOTRONIK, Boston Scientific, iRhythm, Janssen, Medtronic, and Preventice Solutions. Representatives from the U.S. Food and Drug

Administration (FDA) did not attend the Think Tank but participated in discussions with the writing group and were able to provide a global regulatory perspective through the FDA division that studies global regulatory policy.

Digital health

Digital health can be defined as the convergence between health care and emerging digital technologies that acquire, collect, manipulate, and share health data.[1,3,4] Many terms have been employed to refer to the various aspects of the digital health revolution, such as mHealth (mobile health), wireless health, big data, quantified self and self-tracking, wearable computing, telehealth, body computing, precision medicine, and personalized medicine.

Digital health may be divided into technologies that are physician-facing (ie, electronic medical records, medical websites, CIEDs, medical-grade wearable heart monitors), patient/consumer-facing (ie, self-monitoring with consumer wearable devices, Internet searches), or centered on patient-physician communication (ie, telehealth, patient portals).[5] The data generated by physician-facing technology, such as CIEDs and medical-grade wearable cardiac monitors, reside within the traditional closed-loop medical establishment infrastructure, whereas data generated from patient/consumer-facing technologies reside primarily with the individual, to be shared as needed with health care providers to assist in interpreting and developing treatment plans. Therefore, the challenges of sharing digital health data from CIEDs and medical-grade wearable cardiac monitors vs patient/consumer-facing devices are fundamentally different. Cardiac electrophysiology, by nature of the technology central to arrhythmia diagnosis and management, is among the first domains of medicine to face both the opportunity and the challenges of sharing and managing patient data under this new paradigm.

Many important questions related to the new consumer wearable technology, such as privacy, security, and reimbursement, are beyond the scope of this document's charge and will need to be addressed in subsequent forums.

The data

Digital health tools generate many types of data; therefore, it is necessary to specify which types of data this document is referring to as we advocate for transparent and secure access by patients and their health care providers. We define these to be clinically relevant data that are patient-specific and could be useful to either the patient or their health care provider for the purposes of evaluating and managing an individual patient's health. This may include, for example, physiologic data recorded by the patient, battery status of an implantable CIED, or recordings from a wearable medical-grade heart monitor. This would not include proprietary data used by the manufacturer to assess product performance or other proprietary algorithms that are not available to the health care team.

Sharing and organizing digital health data, whether obtained from CIEDs or from medical-grade or consumer wearable devices, is a subject of critical importance to patients and the health care team. The data categories, regardless of device manufacturer, are often identical. However, for CIEDs and now for the emerging consumer wearable devices, each manufacturer develops proprietary terminology and communication protocols, isolating the granular data in digital silos, thereby limiting the findings to be communicated as an image file. Patients and health care providers expect the data to be securely and readily available and interoperable with electronic health records (EHRs), smart phones, and other digital platforms for research, cataloging, and sharing. There are numerous potential solutions to this challenge, beginning with the creation of a single nomenclature or data standard developed in partnership with the appropriate standards development organization, such as the Regenstrief Institute's Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT),[6] Logical Observation Identifiers Names and Codes (LOINC),[7] Health Level Seven International (HL7),[8] the Institute of Electrical and Electronics Engineers (IEEE),[9] and Integrating the Healthcare Enterprise (IHE).[10] Achieving interoperability or liquidity of the data requires a coalition and cooperation of industry, clinicians, informaticians, EHRs, and health information technology vendors.

Patient perspective

The writing committee sought to understand what types of data patients want to access, as well as how and when. The patient perspective was sought through 3 avenues: (1) the Digital Health Think Tank, which was held in August 2018 and included 2 patient representatives, 1 with implantable CIED and 1 with extensive experience using a consumer wearable device; (2) the participation of an arrhythmia patient, who we will refer to as DM, on the document writing group who is also an experienced patient advocate with a large social media following of arrhythmia patients who have CIEDs and/or experience with consumer wearable digital health products; (3) a survey of DM's online social media followers (of which a small number responded) with CIEDs, inquiring if they wished to have access to data from their device and, if so, what type of data.

CIED patient perspective

What type of data and how much?

> *In 2007, I learned that my implantable defibrillator could and would be monitored remotely. I was very excited and I asked the doctor, what is the URL for the patient website? He said, there is no patient website. The sad reality is that to date, some things really haven't changed.*
> *∼ Hugo Campos[11]*

This quote from a patient with an implantable defibrillator represents the perspective of a small and vocal group of patients with CIEDs who have been advocating for full

and unrestricted access to all clinically relevant data from their implantable device. This aligns with the request of 1 of the participants of the Think Tank, Dr Ira Nash.[12] As a patient and cardiologist, Dr Nash was surprised to learn he could not have direct access to data from his implantable loop recorder. This is not the view expressed by the majority of patients with CIEDs when asked either informally, at the Think Tank, or through the survey conducted to inform this writing group. The survey conducted by DM of her social media followers asked the following 5 questions: age, gender, type of CIED, what information does your doctor share with you about your device, and what information would you like your doctor to share with you about your device. Fifty-two respondents completed the informal survey. Average age was 62 years (range 26–89 years), 65% were female. Six patients reported having an implantable defibrillator, 23 an implantable pacemaker, and 21 an implantable loop recorder. Recognizing the limitations of this self-selected population, who are already engaged in social media and therefore not representative of most CIED patients, the responses are still valuable and align with the experience of the writing group when inquiring from their patients what type of information they presently receive and what they would like to receive.

Most patients reported receiving very little information about their CIED, with data limited to battery longevity, and only receiving it at in-office follow-up appointments. A few stated that they received monthly reports from their health care team through their patient portal that included arrhythmias recorded, other physiologic trends such as heart rate, and information about the device, including battery status.

In response to the question "What information would you like your doctor to share with you?" the responses were remarkably consistent: a log of arrhythmia episodes, information that they could use to determine if their condition was changing, and an expressed desire to receive reports on the status of their device at regular predefined intervals. Additionally, the contents of the report should be expressed in nontechnical language that they could understand, and should include battery status, a summary of any arrhythmias detected, and any physiologic data recorded, such as heart rate trends. Patients explained that they want this information in order to better understand their chronic disease and to determine if their symptoms corresponded to any abnormal heart rhythms recorded by their device. Some indicated that they had become frustrated with an inability to access these data, which led them to purchase consumer wearable devices such as the Kardia device or Apple Watch in order to attempt to record on their own and have access to their arrhythmia data.

The patients we engaged recognized that they are a self-selected group with greater interest in receiving data than the majority of patients. Therefore, they advised that given the wide range of patients' desires for more or less information from their CIED, the best approach at the present time is for the health care team to have a conversation with the

patient to understand how much and what type of information the individual would like to know.

How patients wish to access CIED data

The vocal minority of patients who want access to all of the clinical data from their CIED also would like to be able to access their data at the same time they become available to their health care team and through the same servers.[11,12] However, most patients accept the paradigm of the existing health care infrastructure, which appoints the patient's health care team as the sole group to have direct access to their data, which can then be shared via the electronic medical record patient portal once the clinician has reviewed and interpreted the information. Both patient groups agree that having direct access to basic data about their CIED, such as battery status, estimated longevity, and overall status of the device function, is important. A practical approach for the immediate future suggested by patients at the Digital Health Think Tank is for teams to post basic data at a minimum on the patient portal as soon as the clinical team has reviewed it.

Consumer wearable devices patient perspective

Consumer wearable devices capable of recording heart rate trends, beat-to-beat intervals, and single-lead electrocardiograms are rapidly being employed by patients with known or suspected arrhythmias. Two types of population using such devices are individuals at high risk or those who use them for early detection and prevention purposes and patients already diagnosed or suspected to have an arrhythmia. A common scenario is to employ these devices for patients with known or suspected arrhythmias, either to make an initial diagnosis or to assist in managing the arrhythmia after it has been detected. Individual patient interest in employing these tools varies dramatically, often based upon their comfort with digital technology. Once patients use this technology, they often find themselves forced to figure out how to share the data with their clinical provider. Providers must make accommodations for these patients, such as providing e-mail access, since EHR portals typically do not accommodate attachment of digital health data. The patient perspective of these tools will need to be assessed as these technologies mature.

Perspective of the cardiac electrophysiology clinical team

The perspective of the cardiac electrophysiology clinical team was assessed through discussions with the Heart Rhythm Society's Digital Health Working Group, which includes clinical cardiac electrophysiologists and allied professionals, a subset of whom comprise the writing group for this document. There was unanimous agreement among the clinicians of the working group that both patients and health care team beyond the electrophysiology service should have full access to data obtained from CIEDs, medical-grade ambulatory cardiac monitors, and consumer wearable devices in a timely and secure manner. Although the electrophysiology team manages abnormal findings detected by CIEDs and medical-grade ambulatory cardiac monitors, many of the findings are also of significance to general cardiologists and primary care physicians managing those patients. Ensuring clear and timely sharing of this information with these individuals is important. Equally important is sharing this information with the patient. Clinicians recognize that patients have the right to access their health records, and data from CIEDs and medical-grade ambulatory cardiac monitors are not different. However, how much data from devices should be shared with patients is an important consideration. Many believe that all data that clinicians have access to should be made accessible to patients. However, even these advocates acknowledge that patients have considerable variance in their desire of how much data they would like to access.

Clinicians advocate that in an ideal scenario patients should have access to all of their data, but that the data should be organized in layers in a format that is comprehensible to the lay public. A quick-view summary should be available to patients, with appropriate explanations. Full disclosure of the entire data should also be available, permitting the patient to share the information with other health care providers if they choose. Patients, health care providers, and industry should collaborate to determine the most effective patient-facing format for presenting the data. The writing group recommends that stakeholders develop a consensus regarding which data elements should be included in the high-level summary presentation and implement consistent reporting of these in the summary for all patients with a particular type of device (ie, pacemaker, defibrillator, event monitor, etc), regardless of manufacturer.

Data from CIEDs and medical-grade wearable cardiac monitors

While CIEDs have been in clinical use for decades, their follow-up was only recently revolutionized through the advent of remote monitoring.[13,14] Remote monitoring has been shown to improve patient outcomes through the prompt detection and management of arrhythmias and device-related issues.[15–20] It also has enabled a reduction in the frequency of office encounters for routine device checks. While this is convenient for patients and improves efficiency for the office practice, it leaves a potential gap in communication of information between the patient and clinician. Based upon the Digital Health Working Group's experience as well as the findings from DM's survey of CIED patients, we know that most practices do not share data received through remote transmission with patients. Therefore, there is a need to ensure that remote transmission reports are made available through patient portals in a format that is comprehensible to patients. This can be accomplished by creating timely patient-centric and user-friendly brief reports for patients that include the basic

information that most, if not all, patients are interested in. Such information, according to patients who participated in the Think Tank and DM's survey, includes an acknowledgement that the transmission was received, battery status, the overall function of the device and leads, whether arrhythmias were detected, and if the transmission has been reviewed and verified by a clinician. Because developing and implementing a template for such reports at a given site may take time, an initial step is for clinicians to make the data available to patients through the EHR patient portals. However, this should not be considered an acceptable long-term solution.

Data from medical-grade wearable cardiac monitors should be available to patients in a similar format: a high-level summary with explanations understandable to the patient, with the ability to access the full data set if the patient wishes.

Data from consumer wearable devices

Consumer products are typically initiated by individual patients and the flow of data are now reversed: from patient to their clinical team. Therefore, expectations should be set between the clinician and the patient or consumer regarding how to communicate and transmit the data into the clinical practice, how frequently they will transmit, and over what period of time. Generally, clinicians are unable to review tens or hundreds of tracings generated by consumer products a week, and reimbursement structures are not fully implemented. Clinicians can help educate patients about what features/data of the wearables will be useful. For example, knowing a patient's heart rate every minute of the day has not been shown to provide any benefit. Instead, patients should pay attention to measures that are likely to impact outcomes, such as documenting their heart rhythm at times when they are experiencing symptoms such as palpitations. Also, educating patients about the inaccuracies of rate and rhythm determinations by wearables is critically important.[21] For example, fast heart rates detected by a wearable device may be due to an arrhythmia, but they could also be due to artifact or double counting of heart beats. Finally, patients will need assistance learning about the features of the different consumer products available and guidance identifying which device might be most appropriate for their individual use.

Consumer wearable devices remain relatively untested and the regulatory paradigm (covered later in this document) is unfamiliar to most clinicians. Physicians are accustomed to receiving data from rigorously tested medical-grade diagnostic equipment, typically after prescribing or ordering the test for a specific indication. Clinical studies will be needed to assess and validate the data and to guide both the public and clinicians in utilizing the technologies effectively.

Research perspective
Consumer wearable digital health data

There will be numerous opportunities for research in relation to digital health. Many of these opportunities involve how patients use and interact with their data and whether their interaction with these data informs self-management and impacts outcomes. Such outcomes may include time to diagnosis and treatment of identifiable issues, overdiagnosis and/or treatment that may have adverse consequences, or patient satisfaction and quality of life. Related research areas include how patients' use of their data affects practice workflows and whether it burdens or unburdens health care providers. Data obtained by digital health tools, which enable more continuous measures of patient status, may lead to new clinical trial endpoints that could accelerate discovery. Important issues of patient privacy, ethical use of data, and the question of bias in digital health studies will need to be considered as these studies are designed and the data acquired.

Digital health tools will challenge the traditional care models by providing the opportunity for data to be communicated from the patient to the provider between routine office visits. This will facilitate a more collaborative relationship between the patient and provider and will likely require frequent but brief interactions rather than the intermittent and lengthy encounters during which much of the time is devoted to administrative tasks of little value to the patient.

The greatest research opportunity, however, relates to how digital health can be embedded in multicenter clinical trials and other types of prospective research studies to monitor patients for certain outcomes or to interact with patients. This is particularly pertinent to clinical trials that are patient-centric, where patient involvement could extend to patient-reported outcomes and handling of digital health data. Not only will this be innovative and paradigm changing, but the embedding of digital health in research will likely enhance efficiencies and reduce burden and need for resources.

Regulatory perspective
Implantable CIEDs and consumer wearable devices

Most clinicians recognize that regulatory approval of a CIED in the United States indicates that a device has been demonstrated to be safe and effective for its labeled indication by rigorous clinical trials and bench testing data. But regulatory oversight of digital health products such as consumer wearable devices is less well understood. As clinicians begin to use data acquired by these devices to make clinical decisions, it becomes important to understand the regulatory model for this emerging group of devices.

The FDA's regulatory paradigm for medical devices is based on the degree of control necessary to assure that a device is safe and effective. This generally correlates with how critical the device function is for sustaining or supporting life. Devices with higher risk have more regulatory controls placed on them while devices with lower risk have fewer controls. Devices that fall into the highest category of risk (class III) typically are essential for sustaining or supporting life and require a Premarket Approval Application; examples include devices such as implantable cardioverter-defibrillators and pacemakers. This typically involves data from a randomized controlled clinical trial and performance testing of the device

in the intended population. Moderate-risk devices (class II) require a Premarket Notification 510(k) application, which requires that a device demonstrate that it is substantially equivalent to a legally marketed device. This may or may not involve clinical evaluation as well as performance testing. Examples of class II devices include implantable and wearable loop recorders and intracardiac mapping catheters. Most medical devices are considered class II devices. The lowest-risk devices (class I) typically do not require a regulatory review prior to marketing the device. Examples include elastic bandages and tongue depressors.

Although there have been updates to the device regulations since they were first published in 1976, the technological advances to devices have outpaced these updates. Consumer electronics have enabled new paradigms for health care. Software applications themselves now can be considered devices that run on commercial platforms such as smart phones and enable patients to be actively involved in their own care. Such is the case with the Apple Watch (Apple Inc, Cupertino, CA), for which the software (but not the hardware) of the device is considered a class II medical device and has been granted clearance by the FDA.[22] By assessing the software as the medical device, updates to the product become less burdensome. The FDA has developed a number of guidance documents that describe the policies for digital health technologies.[1,23] These include, but are not limited to, guidance on mobile apps, products intended for general wellness, software modifications, and cybersecurity.

Regulatory agencies around the globe recognize the need for consistent approaches to oversight for all aspects of health care. This is particularly important for consumer products that cross international boundaries. Regulatory agencies have therefore formed the International Medical Device Regulators Forum (IMDRF), accessible at http://www.imdrf.org. Members to date include Australia, Brazil, Canada, China, European Union, Japan, Russia, Singapore, South Korea, and the United States. The IMDRF brings together medical device regulators from around the world for the purpose of harmonizing device regulations policies, guidance documents, and standards. The work products of the organization are guidance documents, written by individual working groups, which are then used by member countries as the basis for writing regulatory policy.

International work in the digital health space has been focused on developing guidance policies for regulating software intended to be used for medical purposes. The IMDRF defines this as Software as a Medical Device.[24] Consistent international regulatory policy for such products is widely seen as essential for promoting innovation and adoption of digital health products by consumers. Recognizing that health care decisions will increasingly rely on information provided by the output of Software as a Medical Device, global regulators developed tools to categorize software based upon its intended medical purpose and targeted health care condition. The intended purpose and targeted health condition are used to determine the degree of regulatory oversight necessary. For example, software that stores noncritical data would have a low risk of causing harm and therefore be exempt from regulatory oversight. In contrast, if the software is intended to drive clinical management of a serious or critical condition, regulatory oversight might be warranted.

The FDA has recently initiated an additional change to the overall regulatory paradigm for digital health through the Pre-Cert Pilot Program to promote innovation. Under this pilot program the FDA is determining how to identify organizations that have demonstrated a culture of quality and organizational excellence based upon objective criteria.[25] These precertified developers would then be qualified to either market their lower-risk devices without additional FDA review or with a streamlined approach such as a reduced content submission, faster review by the FDA Center for Devices and Radiologic Health, or both. They would also be permitted to take advantage of the real-world evidence generated by their device over the product life cycle in order to demonstrate safety and effectiveness.

Industry perspective
Medical device industry perspective

As the tools of the digital health era make it possible for patients to assume a greater role in managing their health, the relationship of the medical device industry to both patients and the health care team will necessarily evolve. Historically, data sharing has been limited to the exchange of information between industry and health care team, who in turn communicate the results to their patients. Clinicians have traditionally been the gatekeepers of patients' data. As most patients now are connected online and have expectations that they should be able to access their personal health data, the concept of industry sharing data directly with patients has become potentially feasible, at least from a technical standpoint, and vocally requested by a small group of patients[26,27] (Figure 1).

Cardiac rhythm management industry leaders shared their perspective on this evolution during the Think Tank meeting in Chicago in August 2018. Industry leaders expressed recognition that sharing digital health data with patients and caregivers has the potential to be a powerful tool in improving health care outcomes, an endpoint by which many of their new products will be measured. Furthermore, they believe it will be essential for industry to partner with patients, caregivers, health care providers, and regulatory bodies to explore the optimal methods for sharing digital health data to meet the needs of all stakeholders. One obstacle noted by industry is the fact that some health care providers view their role as gatekeepers of the information. The balance between patient satisfaction and physician satisfaction represents a challenge for the medical device industry. Other challenges include logistical, regulatory, and financial considerations of sharing data directly with patients.

Industry leaders recognize that different health care providers have different levels of interest in engaging in new paradigms of patient care and have different comfort levels
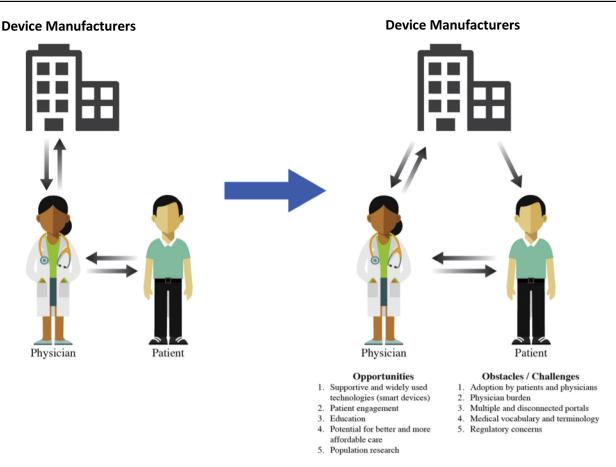
Device Manufacturers

Device Manufacturers

Physician   Patient

Physician   Patient

Opportunities	Obstacles / Challenges
1. Supportive and widely used technologies (smart devices)	1. Adoption by patients and physicians
2. Patient engagement	2. Physician burden
3. Education	3. Multiple and disconnected portals
4. Potential for better and more affordable care	4. Medical vocabulary and terminology
5. Population research	5. Regulatory concerns

Figure 1   The contemporary flow of data is illustrated on the left side of the figure. Digital health data from implantable and medical-grade wearable cardiac monitors is communicated to patients exclusively via a health care provider. The right side illustrates a future state in which patients receive data both directly from a device manufacturer and from a health care provider. The opportunities as well as potential obstacles and challenges of this future state are listed in the figure.

in dealing with and adopting new technologies. These differences exist even on institutional levels. For example, while the ability to provide access to patient data via EHR portals already exists, many institutions still do not participate in these work flows.[26] Additionally, business agreements between cardiac device companies and providers sometimes limit industry's ability to provide data directly to patients. Industry members recognize that if they provide patients open access to data from their CIED or mobile cardiac rhythm monitor, many clinicians are concerned that they might be deluged with phone calls from anxious patients and that this might lead a physician to select an alternative vendor.

From a regulatory point of view, industry leaders expressed concern that sharing data directly with patients before official review and interpretation by health care providers could be viewed as providing a diagnosis to patients. They fear that this might change the regulatory category of the remote monitoring services of CIEDs from class II to class III.[27] Any such change in this regulatory category could drastically increase the regulatory requirements for remote monitoring equipment, resulting in increased costs and slower innovation.

Achieving the goal of making data directly available to patients will require significant efforts at creating and maintaining patient-facing data portals that provide the data in a way that is meaningful and helpful to patients. This, in turn, will require the development of new, sustainable business models to support the necessary investment of time and resources.

Short- and long-term proposed solutions from industry perspective

For the short term, device industry leaders advocated that the health care team utilize the electronic record's patient portal to share data once the team has reviewed it. In the long run, industry recognizes the widespread use of smart devices by patients is an opportunity for industry to move toward a model of remote monitoring that makes use of patients' own smart devices and provides the patient with access to at least some of the clinically relevant data acquired by their device.[28] Industry also recognizes the importance of making data available directly to patients in a manner that will be meaningful and constructive to patients. The development of these tools should be done in conjunction with, and with guidance from, patients and providers.

Medical team adoption of digital health tools

Health care professionals as a group recognize that changes in practice should be guided by research-based evidence. With stakes so high in health care, this is often a laudatory quality: wait to adopt new therapies or techniques until enough evidence has accumulated to assure a reasonable likelihood of safety and efficacy. These familiar characteristics of the profession can be seen once again as practitioners are thrust into the era of digital health. Patients, however, are increasingly seeking providers who accommodate their interest in exchanging digital health data and incorporating these tools into the diagnostic and/or therapeutic process. It is therefore incumbent upon the clinicians to be supportive of this transition and facilitate patients' interests in proactively participating in their care.

Data from CIEDs and medical-grade wearable cardiac monitors

Activist patients have challenged both the medical community and the device manufacturers to support their requests for direct access to their own data on the remote monitoring servers. As noted earlier, most patients accept the existing paradigm, which requires the data to first be reviewed by the health care team and then be shared with the patient.

The possibility of giving patients direct access to their data creates great anxiety among many arrhythmia team professionals. The most common initial concern expressed by colleagues to members of the writing committee is that the health care team will be inundated with inquiries from patients requesting interpretations and explanations of the data, particularly if the data have not previously been interpreted and verified by the health care team. Concerns regarding liability and expectations of duty arise: will patients presume their implantable loop recorder has accurately detected atrial fibrillation and seek medical care from a physician not experienced in interpreting these recordings? This could result in a patient receiving anticoagulation inappropriately if the rhythm turns out not to be atrial fibrillation.

The open chart model for electronic medical records gives patients full and unrestricted access to their EHR in real time. This method is being employed at many leading academic medical centers and serves as the prototype for what the clinical team might expect if patients are given full access to their data. Initial concerns by health care providers regarding a high volume of time-consuming patient inquiries for explanations and interpretation of data have largely not materialized[29]; surveys show that patient portals result in significant improvements in patient self-management of chronic disease, quality of care, and satisfaction. Providers who use the open-chart EHRs are more likely to follow guidelines and have a lower rate of medication errors.[30] Both patients and providers report improved patient-provider communications and support the use of e-mail for messaging, though a minority describe security concerns and deficiencies in user-friendliness. Once educated and familiar with their personally collected data, patients often learn to manage their disease and understand why their data may deviate under certain conditions. This creates a partnership rather than a patriarchal relationship with their health care team, empowering the patient, who then feels more in control. While many in the medical community have feared that the use of patient portals would generate more work and expose the health care team to legal jeopardy, these concerns have not materialized.

Data from consumer wearable devices

Innovative tools of digital health are entering the consumer space rapidly, outpacing our ability to address all the potential health care–related implications. For example, the very basic details of how the data are communicated from the patient to the health care provider and how they can be incorporated into the medical record have not been worked out. Ground rules between the patient and the health care team must be specified at the outset, including the frequency and mode of transmission/communication and what types of biometric data the patient should transmit to their arrhythmia specialist and what is beyond the scope of practice. From the clinical team's perspective, we must operationalize and triage the data and define realistic response times based on evidence. Reimbursement models, which are beyond the scope of this document, need to be established that reflect our level of assumed responsibility and appropriate legal guidelines need to be defined. Lastly, interoperability between new devices and the EHR needs to be established. While many questions and challenges remain and the potential for unintended/unanticipated problems are real, patients will not wait for these to be solved. It is therefore incumbent upon the medical team to facilitate implementation of the tools of digital health as we work out the challenges with other stakeholders.

Conclusions

The writing group recognizes that technology and tools of digital health are evolving rapidly and stakeholders will continue to gain experience over time. Therefore, this document will require updating as the tools of digital health and the experience of all stakeholders evolve. We also recognize that creating the infrastructure to realize an environment in which patients have full access to their digital health data with high-level summaries as well as full disclosure will take time and resources. The document proposes interim solutions, such as using EHR patient portals. These interim steps should not be considered acceptable endpoints. Anything less than full and transparent access to digital health data will not be acceptable to patients or the public, and it will limit the potential for these tools to reduce inefficiencies, improve access, reduce costs, and make medicine more personalized for patients.

Key points

Patient Perspective

- Patients want to receive regular reports about the functions of their cardiovascular implantable electronic device (CIED), including battery status, arrhythmia event types and burden, and assurance that the device is functioning normally.
- Patients are willing to discuss options with their physician about the type and amounts of data to receive from their CIED, recognizing that not everyone will want the same sets of data.
- Most patients prefer to have access to their data through an electronic medical record portal, after the data have been reviewed by their health care provider.

Clinical Team Perspective

- Clinical team members agree that patients should have timely access to their CIED data via the electronic medical record, once the data have been verified by the clinical provider.
- The data should be presented in a way that is comprehensible to the lay public, in layers so individuals may obtain the level of detail that meets their interest and/or needs. Patient-advocacy groups, professional societies, and other stakeholders should determine the optimum format for presenting the data to patients.
- Clinical team members appreciate the value of consumer wearable devices but have concerns that important and fundamental components of how the data are communicated and stored remain unresolved. They are also concerned that some individuals may inundate a practice by overutilizing the technology. Finally, reimbursement must be established commensurate with the burden and risk assumed by the provider.

Medical Team Adoption of Digital Health Tools

- Patients are embracing the tools of digital health; therefore, it is incumbent that members of the medical team help guide and be supportive of this transition.
- For patients with CIEDs, this requires a conversation with the individual patient to understand what data the patient would like to have and then making those data available on the electronic medical record portal at prespecified regular intervals.
- For medical-grade cardiac monitors, data should be accessible to patients in a high-level summary as well as full disclosure, similar to CIED data.
- Medical team members should discuss at the outset expectations for patients who wish to share data from their consumer wearable device with the team. This discussion should include the method by which the data will be communicated, expected frequency, the type of data, and expected response time from a team member.

Medical Device Industry Perspective

- Industry supports the paradigm shift that will give patients access to their CIED data. Doing so successfully will require:
  1. Changing relationships between patients, health care providers, and industry;
  2. Navigating the potential for increased regulatory requirements; and
  3. Developing new, sustainable business models to support the effort required to create and maintain a portal or other mechanism for patients to have direct access to their data in a meaningful way.

Regulatory Perspective

- Regulatory agencies across the world recognize the importance of a unified paradigm for evaluating, approving, and monitoring the safety and effectiveness of medical devices. This is particularly important for consumer devices that will cross international boundaries. The International Medical Device Regulators Forum has been established to meet this need.
- The U.S. Food and Drug Administration is recognized as a leader in regulatory policy of digital health devices and has developed innovative pathways to minimize the regulatory burden for this group of devices in order to promote innovation. Regulation of software as a medical device is an important component of this paradigm.

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Appendix 1   Disclosure table

Name	Employment	Honoraria/Speaking/Consulting	Speakers' bureau	Research*	Fellowship support*	Ownership/Partnership/Principal/Majority stockholder	Stock or stock options	Intellectual property/Royalties	Other
Writing group members									
Sana M. Al-Khatib, MD, MHS, FHRS, CCDS	Duke University	None	None	None	None	None	None	None	None
Debbe McCall, MBA	Lay volunteer/patient representative	None	None	None	None	None	None	None	None
Rod S. Passman, MD, MSCE, FHRS	Northwestern University Feinberg School of Medicine	1: Abbott Laboratories; 1: Janssen Pharmaceuticals; 1: Medtronic	None	1: AliveCor; 1: Bristol-Myers Squibb	None	None	None	2: UpToDate	None
Nicholas S. Peters, MD, FHRS	Imperial College London and NHS Trust	2: Cardialen; 4: Synergix Health; 4: Verily/Google	None	None	None	None	None	None	2: Boston Scientific; 2: Abbott; 3: Regenrys
Leslie A. Saxon, MD, FHRS, CCDS	Center for Body Computing, Keck School of Medicine, University of Southern California	2: Bristol-Myers Squibb; 6: Abbott Laboratories	None	None	None	None	None	None	None
David J. Slotwiner, MD, FHRS (Chair)	NewYork-Presbyterian Queens and Cardiology Division, Weill Cornell Medical College	None	None	None	None	None	None	None	None
Khaldoun G. Tarakji, MD, MPH, FHRS	Cleveland Clinic	2: AliveCor; 1: Medtronic	None	None	None	None	None	None	None
Advisors									
Elizabeth E. Davenport, BA, RN	Atrium Health	1: BIOTRONIK; 1: Boston Scientific; 1: Medtronic	None	None	None	None	None	None	None
Gerhard Hindricks, MD	Heart Center Leipzig at the University of Leipzig	None	None	4: Abbott Vascular	None	None	None	None	None
Nassir F. Marrouche, MD, FHRS	University of Utah	1: Preventice; 3: Biosense Webster; 3: BIOTRONIK; 3: Medtronic	None	5: Abbott Laboratories; 5: Biosense Webster; 5: Boston Scientific	None	None	None	None	None
G. Stuart Mendenhall, MD, FHRS	Scripps Memorial Hospital	1: BIOTRONIK; 1: Medtronic	None	None	None	None	0: Grektek	None	None

(*Continued*)

Name	Employment	Honoraria/ Speaking/ Consulting	Speakers' bureau	Research*	Fellowship support*	Ownership/Partnership/ Principal/Majority stockholder	Stock or stock options	Intellectual property/ Royalties	Other
Sanjiv M. Narayan, MD, PhD, FHRS	Stanford University	1: American College of Cardiology; 1: TDK Inc.; 2: Abbott Laboratories	None	8: National Institutes of Health	None	None	None	1: UpToDate	None
Jill Schaeffer, MSN, CRNP, FHRS, CEPS, CCDS	Penn Medicine – The Heart Group of Lancaster General Health	1: Abbott Laboratories	None	None	None	None	None	None	0: CCI
Mintu P. Turakhia, MD, MAS, FHRS	Center for Digital Health, Stanford University; VA Palo Alto Health Care System	1: Abbott Vascular; 1: AliveCor; 1: BIOTRONIK; 1: iRhythm Technologies; 1: Medtronic	None	4: Boehringer Ingelheim; 5: AstraZeneca Pharmaceuticals; 5: Cardiva Medical; 6: American Heart Association; 8: Apple; 8: Bristol-Myers Squibb; 8: Janssen Pharmaceuticals	None	None	None	None	None

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 to ≤$200,000; **6** = >$200,000 to ≤$300,000; **7** = >$300,000 to ≤$400,000; **8** = >$400,000.

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