TOPIC IN REVIEW

Digital health in electrophysiology and the COVID-19 global pandemic

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The tools of digital health are facilitating a much-needed paradigm shift to a more patient-centric health care delivery system, yet our health care infrastructure is firmly rooted in a 20th-century model that was not designed to receive medical data from outside the traditional medical environment. COVID-19 has accelerated this adoption and illustrated the challenges that lie ahead as we make this shift. The diverse ecosystem of digital health tools share 1 feature in common: they generate data that must be processed, triaged, acted upon, and incorporated into the longitudinal electronic health record. Critical abnormal findings must be identified and acted upon rapidly, while semi-urgent and noncritical data and trends may be reviewed within a less urgent timeline. Clinically irrelevant findings, which presently comprise a significant percentage of the alerts, ideally would be removed to optimize the high-cost, high-value resource (ie, the clinicians' attention and time). We need to transform our established health care infrastructure, technologies, and workflows to be able to safely, effectively, and efficiently manage the vast quantities of data that these tools will generate. This must include new technologies from industry as well as expert consensus documents from medical specialty societies, including the Heart Rhythm Society. Ultimately, research will be fundamental to inform effective development and implementation of these tools.

KEYWORDS Cardiac monitor; Clinical pathway; Digital health; COVID-19 pandemic; Implantable defibrillators; Pacemakers; Remote monitoring

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As the medical community addresses the complexities associated with the coronavirus disease 2019 (COVID-19) pandemic, digital health tools, by communicating physiologic data recorded outside the traditional boundaries of the health care environment, are providing solutions to many of the challenges. The pandemic has accelerated the adoption of digital health, yet our health care system infrastructures are firmly rooted in a 20th-century closed-loop delivery model: systems have been designed to enable clinicians to place an order for diagnostic and therapeutic interventions, which are then performed within the traditional boundaries of the clinician's office, hospital, or other clinical care settings. For the most part, current health care systems are suited for these tasks: the test is performed, a report is generated, and the results neatly arrive in the clinicians' in-box. The results are reviewed with patients either by phone, via the patient portal, or at the next clinic encounter. This health care clinician–centric model was ripe for disruption, and the era of digital health and the global COVID-19 pandemic has indeed forever changed care delivery.

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Physiologic data captured outside the traditional medical environment by digital health tools are fundamentally changing the way patients and clinicians communicate, manage diseases, and maintain health. The extensive recording and transmitting of physiologic data and engaging patients in the data collection and review process have caused a paradigm shift. Despite the paucity of data, many have postulated that this new model of health care delivery will result in significant improvements in patient outcomes.[1–3] Yet the traditional medical establishment, structured around office encounters and periodic testing, is not well suited to evaluate and manage the incessant stream and vast quantity of data and alerts generated by these near-continuous monitoring devices. Additionally, little attention has been devoted to addressing how such data will enter the medical establishment or how it will be incorporated into the electronic medical record. It is not fully understood how patients and their clinicians should most effectively communicate between scheduled office encounters. In this article, we describe the present state of heart rhythm digital health tools, highlighting some of the effects of the COVID-19 pandemic, and propose ways to develop innovative workflows and technological solutions that will make it possible for practices to efficiently process and manage information. In addition, we highlight some of the research gaps that should be addressed to push this field forward.

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KEY FINDINGS

- The tools of digital health are facilitating a paradigm shift to a more patient-centric health care delivery system.
- Our present health care infrastructure was not designed to process, triage, and incorporate digital health data generated outside the traditional medical environment.
- We must transform our established health care infrastructures, technologies, and workflows to be able to safely and efficiently manage the vast quantities of data these tools generate.
- Research is needed to inform the effective development and implementation of these tools and to identify which have the potential to improve patient-centered outcomes.

Present state

Heart rhythm digital health tools fall into 3 broad categories: medical-grade implantable devices such as cardiac implantable electronic devices (CIEDs), medical-grade wearable monitors such as mobile cardiac telemetry monitors, and consumer devices that record physiologic data such as heart rate, activity, and single-lead electrocardiograms (ECGs). There is a diverse ecosystem of digital health tools that generate many different types of data. However, there are similarities between the underlying data, the need for triaging and responding to the data, and the importance of incorporating the data into the electronic medical record. Critical abnormal findings must be identified and acted upon rapidly, while semi-urgent and noncritical data and trends may be reviewed within a less urgent timeline. Clinically irrelevant findings, which presently comprise a significant percentage of the alerts, ideally would be removed to optimize the high-cost, high-value resource (ie, the clinicians' attention and time).

Cardiac implantable electronic devices

CIEDs, the most sophisticated of our digital health tools, have the highest-resolution recordings and highly refined software algorithms capable of accurately identifying most arrhythmias and virtually eliminating artifacts, except in clinically important scenarios of device or lead malfunction. Yet remote monitoring of these devices poses a massive data burden on clinical practices because practices still must interpret and triage data according to clinical relevance for an individual patient. For example, the clinical significance of nonsustained ventricular tachycardia or atrial fibrillation varies tremendously across patients, yet when these alerts are received by a technician at a given practice, each alert must be reviewed and processed by an experienced clinician with equal diligence to ensure that clinically important events are acted upon (Figure 1a). A patient with known atrial fibrillation, on appropriate thromboembolic prophylaxis, may have many alerts for atrial fibrillation even after attempts to optimize alert triggers. At a minimum, this requires that a clinician process each alert and confirm in the medical record that the patient is known to have atrial fibrillation and is receiving thromboembolic prophylaxis.

Subcutaneous cardiac rhythm monitors, which are prone to detecting artifacts and are at times unreliable at accurately interpreting the heart rhythm, add an additional level of burden to a practice. An experienced clinician must review the electrogram recordings to assess if an event is due to an artifact or a true arrhythmia. Then, the clinician must manage the arrhythmia.

An often overlooked but critical burden for practices is the need to have a rigorous quality assessment process in place to ensure that each patient's remote transmitter is communicating. The present CIED remote monitoring technology is designed to communicate a complete data download every 90 days (for pacemakers and implantable defibrillators) or every 30 days (for implantable subcutaneous cardiac rhythm monitors). Between these intervals, many vendors have designed their systems to transmit data only if a new event or abnormality is detected. Therefore, either practices must have robust processes in place to identify if an individual patient reaches the end of their monitoring interval and their transmitter has not communicated appropriately, or the practice must monitor each of the CIED vendor's web portals, carefully culling any inactive patients from the list and noting when an alert is triggered indicating that a remote transceiver has stopped communicating. Once a practice identifies that a remote transmitter is no longer communicating, the tedious and lengthy process of tracking down the patient and addressing the specific problem may take hours.

Medical-grade wearable monitors

Holter monitors, extended ECG monitors, event recorders, and mobile cardiac telemetry monitors record varying degrees of data, but unlike CIEDs or consumer wearable devices, a well-established workflow that includes trained telemetry technicians, nurses, or other skilled allied professionals is an essential component of the initial data-screening process. As a result, most of the artifact and noncritical findings are presented to the interpreting clinician in a single review session, making the burden of data review and interpretation more manageable.

Consumer-grade wearable monitors

Data generated from digital health tools utilizing photoplethysmography to record heart rate or devices capable of recording a single-lead ECG pose a different challenge for established medical practices. Primary concerns surrounding these devices are fundamental: identifying how data will physically or electronically enter the medical establishment, the quality of the data, the patient and clinician expectations regarding review and communication about the data, and a mechanism for incorporating the data into the patient's longitudinal electronic medical record. Many clinicians

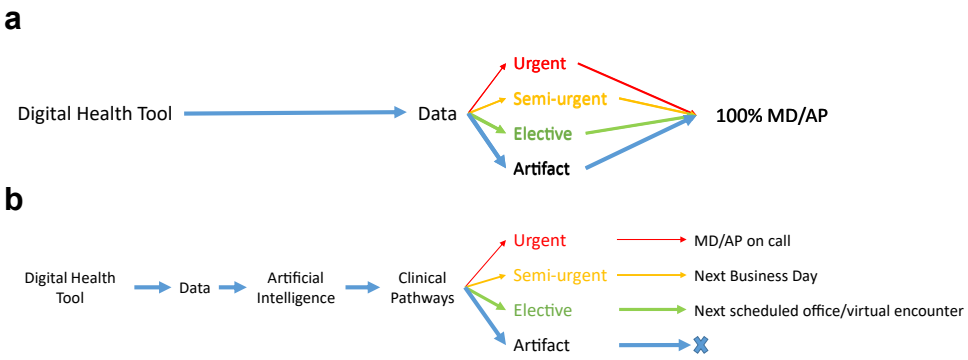

Figure 1 **a:** Present state: All data generated by digital health tool must be evaluated with equal urgency and attention from the physician (MD) or allied professional (AP). **b:** Future state: Data would be sorted by urgency utilizing artificial intelligence tools and clinical pathways to guide staff. Only urgent data would be forwarded to the MD/AP on call. Semi-urgent and elective data would be scheduled for review by MD/AP the next business day or the next scheduled encounter, respectively. Artifact, a significant data burden particularly from subcutaneous cardiac rhythm monitors, would be eliminated from the review process. (Width of arrows corresponds with typical volume of data.)

avoid recommending the use of these tools owing to these uncertainties as well as concern that they will be inundated with data of uncertain significance. Patients may become unnecessarily concerned by artifact, inaccurate data, and/or overreliance on a device's ability (or inability) to correctly categorize the data as normal or abnormal.

Pandemic

The COVID-19 pandemic highlighted both the potential of digital health tools to enable delivery of health care beyond the traditional boundaries of medical facilities and the inadequacies of our present health care infrastructure to make this switch. The abrupt shuttering of all but essential hospital-based medical services forced patients and clinicians to turn to alternative methods of both acquiring health data and communicating the results. Telehealth services, which previously had struggled to gain traction among both patients and clinicians, suddenly became routine, with both parties quickly learning to appreciate the advantages of telehealth while also recognizing its limitations. Patients with CIEDs already on remote monitoring were at a distinct advantage, as clinicians could rapidly and efficiently identify and triage patients with significant arrhythmias or device malfunctions and reassure the remaining patients to avoid medical environments that could pose risk of COVID-19 infection. Medical practices that had not implemented CIED remote monitoring were forced either to outsource the technical aspects of initiating and maintaining patients on remote monitoring or to identify resources, educate patients, and redeploy staff to figure out the complex process of managing data remotely. Identifying well-trained technicians and nurses to help manage these data is challenging even in normal times. Similarly, patients who had adopted digital health tools such as automatic blood pressure cuffs, pulse oximeters, glucose monitors, and consumer single-lead ECG recorders were at a distinct advantage, as they could provide their clinician with potentially important data that would otherwise require them to risk exposure to the medical environment to obtain. Yet even the early adopters of digital health tools were left to struggle with sharing the data and how best to communicate with their clinicians. It is likely that changes brought forward by the pandemic will remain and continue to grow even after the pandemic is over.

What is needed

The first critical step to managing the deluge of data from consumer devices is to develop the infrastructure that will make it possible for data recorded by these devices to be securely and reliably communicated and incorporated into a patient's electronic health record. This basic requirement does not yet even exist for CIEDs, let alone wearable devices. The result is a patchwork of unsatisfactory workflows, often requiring copious amounts of staff time to scan image files into the electronic health record. Data from consumer wearable devices—if communicated by patients at all—come as an image file sent by e-mail or the patient portal directly to the clinician with no triaging.

The second step is to develop a mechanism to triage incoming digital health data so that it can be efficiently and effectively managed by a practice (Figure 1b). Triage should be possible by a combination of artificial intelligence tools and clinical pathways that make it possible for staff with varying levels of clinical expertise to stratify incoming data into 4 buckets: (1) urgent data that must be reviewed and acted upon as soon as possible by a clinician; (2) semi-urgent data that can be sent to a clinician's in-box for review within the next business day; (3) elective findings that the clinician will want to review with the patient at their next routinely scheduled encounter; and (4) artifact that is incorrectly detected as an arrhythmia. Expert consensus documents should guide these clinical pathways, while industry engineers will be called upon to develop artificial intelligence tools.

For example, an artificial intelligence tool could provide a first-pass screening to triage data. A CIED may communicate an event that it labels as nonsustained ventricular tachycardia with 97% certainty. If the CIED is an implantable cardioverter-defibrillator, if the episode lasted 3 beats, and if this was the first event in 18 months, the significance of the event is very different from a 3-beat run of nonsustained

ventricular tachycardia detected by a mobile cardiac telemetry monitor placed on a patient with coronary artery disease and a left ventricular ejection fraction of 40% who is being evaluated for recurrent syncope. The electronic medical record should be able to provide an artificial intelligence tool with sufficient clinical data to enable the tool to determine if the patient has an implantable cardioverter-defibrillator and whether this is a new arrhythmia, thereby providing a first-pass screen. If the event does not meet this criterion, it is labeled as potentially clinically significant and is triaged accordingly. Technology should allow patients to know if an event has been detected, transmitted, and reviewed. Once reviewed, it should be possible for the clinician to easily communicate with the patient—and vice versa.

An Achilles heel of the present CIED wireless remote monitoring systems is the absence of a robust, streamlined method for both medical practices and patients to quickly and reliably be notified if their transceiver stops communicating. It is not uncommon for patients to learn that their remote monitor stopped communicating months after the fact. Although each CIED manufacturer has made some progress in alerting practices when communication stops, the systems are poorly designed and inconsistent, even within a manufacturer's product line. This basic quality concern requires a higher-priority status from industry and may be best addressed by developing an industry standard approach, such as has been taken to consistently and uniformly message the clinical community the definition of the CIED elective replacement indicator.

Managing the patient needs and the data generated by digital health tools requires well-trained technicians and nurses, and appropriate staffing numbers have yet to be defined. Despite the robust training resources available through the International Board of Heart Rhythm Examiners and educational programs offered by private organizations, these remain out of reach from a financial as well as time commitment perspective for most allied professionals. Difficulty identifying and training staff is the reason some practices are outsourcing the technical components of managing the acquisition and collation of digital health data to independent remote monitoring organizations.

What research is needed?

The tools of digital health bring several new categories of unanswered questions that require scientific study. The first questions pertain to implementation of these tools. Patients and the broader public at large are essential partners in acquiring the data; therefore it is imperative that the design and interfaces of these tools be intuitive to individuals who span a broad range of ages and educational and cultural backgrounds. Next, it will be important to assess the quality and reliability of data that clinicians receive from these tools. This will be an ongoing question as new tools are developed. We then need to identify which tools and what data will form a basis for improving patient-centered outcomes. Lastly, we need to understand the best tools and strategies for communication to occur between patients and clinicians to maximize patient engagement and optimize the potential benefits of digital health.

Reimbursement

Economics is fundamental to driving change, and to date this has limited the impact of telehealth and digital health. There was perhaps no greater acknowledgment of this than the Centers for Medicare and Medicaid Services (CMS) sudden announcement at the onset of the COVID-19 pandemic that it would immediately change course and offer reimbursement for a wide range of telehealth services.[4] Prior to this, CMS would only reimburse clinicians for very limited telehealth services, such as a routine visit, and only if the patient lived in a rural area.

Digital health tools and the data they generate present new challenges for reimbursement. To date, the public has not expected insurance carriers to pay for consumer devices, but with home blood pressure monitors and heart rate and rhythm monitors, patient expectations are changing. Clinician time and effort vary widely based upon the frequency and volume of data received. In the United States, CMS has implemented base billing codes with additional add-on codes designated for use when the clinician time exceeds a base value within a 30-day window. It remains unclear if private insurance carriers will follow Medicare's example. If compelling evidence indicates that these tools improve clinical outcomes, patients and the public will expect their clinician to be adequately reimbursed for reviewing and interpreting such data.

Conclusions

The tools of digital health are facilitating a much-needed paradigm shift to a patient-centric health care delivery system. COVID-19, with its attendant need to minimize patient exposure to the health care environment, has accelerated the adoption of these tools and illustrated the challenges that lie ahead as we make this shift. We now need to focus attention on adapting our established health care systems, technologies, and workflows to be able to safely, effectively, and efficiently manage the vast quantities of data that these tools generate. This will require new technologies to be developed by industry as well as expert consensus documents from medical specialty societies, including the Heart Rhythm Society. Ultimately, research will be fundamental to inform effective development and implementation of these tools and to understand how they can be used to achieve clinically meaningful improvements in health care outcomes for patients.

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