Accepted Manuscript

Digital Health: Present Conundrum, Future Hope Or Hype?

Thomas F. Deering, Gerhard Hindricks, Nassir F. Marrouche

PII: S1547-5271(19)30430-8

DOI: https://doi.org/10.1016/j.hrthm.2019.04.047

Reference: HRTHM 8011

To appear in: *Heart Rhythm*

Received Date: 23 April 2019

Please cite this article as: Deering TF, Hindricks G, Marrouche NF, Digital Health: Present Conundrum, Future Hope Or Hype?, *Heart Rhythm* (2019), doi: https://doi.org/10.1016/j.hrthm.2019.04.047.

DIGITAL HEALTH: PRESENT CONUNDRUM, FUTURE HOPE OR HYPE?

Thomas F. Deering[1], Gerhard Hindricks[2], Nassir F. Marrouche[3]
from the [1]Arrhythmia Center, Piedmont Heart Institute, Medical College of Georgia, Atlanta, Georgia, [2]Department of Electrophysiology, Heart Center Leipzig, University of Leipzig, Leipzig, Germany, [3]The CARMA Center, University of Utah Health Science Center, Salt Lake City, Utah

Dr. Hindricks reports research institutional grants from Abbott and Biosense without personal financial benefits. Dr. Marrouche report research grants and consulting fees from Biosense Webster, Medtronic, Abbott, Boston Scientific and Siemens. Dr. Deering reports no conflicts of interest

Address reprint requests and correspondence: Dr Thomas F. Deering, Piedmont Heart Institute, Medical College of Georgia, 95 Collier Rd, Suite 2045, Atlanta, GA 30309. E-mail address: thomas.deering@piedmont.org

Coming together is a beginning.
Keeping together is progress.
Working together is success.
Henry Ford

In this issue of *Heart Rhythm* the newly formed Digital Health Working Group clarifies the existing state of the art concerning digital health and addresses the significant opportunities and challenges associated with integrating the advanced diagnostic improvements incorporated in cardiovascular implantable electronic devices (CIEDs) and wearable cardiac devices into existing healthcare systems.[1] In the foreseeable future health-based digital applications will become routine at multiple levels within the healthcare system, guiding individuals through novel pathways while bridging the outpatient and inpatient treatment sectors.[2] These monitors will generate and transmit automatically data obtained from many biological signals. This information will be incorporated into advanced data management algorithms that will then be used to detect the onset of disease; assess disease progression and identify opportunities for improved treatment.

Unfortunately, the rapid technical advances in monitoring incorporated into CIEDs and wearable devices has exceeded the ability of most existing healthcare systems to incorporate the available information into their organizational systems in a clinically advantageous manner. Therefore, actualization of the potential inherent in these technological improvements to improve health care outcomes at a lower cost will necessitate collaborative efforts among the five major affected stakeholder groups (patients, providers, industry, regulators and payers). Because many of the early digital health initiatives have taken place in the arrhythmia world, the specialty of cardiac electrophysiology is poised to lead the charge by establishing high foundational standards of excellence in this new arena.

Maximizing patient outcomes and assuaging patient concerns about the clinical implications associated with information derived from these devices constitute the most important patient goal. The concerns relevant for CIED patients typically differ from those of patients with wearable devices. While some CIED patients want timely access to all of their device data, others only want their providers to craft effective care plans based upon that data. Accordingly, as the authors note, clinicians and healthcare systems should lead the effort to 'democratize' data and institute full transparency by providing patients with regular, 'non-technical' summaries of device functionality and routine clinical observations via an electronic health record (EHR) patient portal.[3] In addition, they should put into place robust patient communication processes about important digitally identified items, which might impact health outcomes (e.g. new onset atrial fibrillation, an excessively rapid ventricular response to AF, VT therapies, data suggesting worsening heart failure, etc.). Wearable devices, available in the retail marketplace without a physician prescription or recommendation, afford patients a great opportunity to take a more active role in managing their medical conditions. However, the exclusion of the

traditional heath care system from the information generated by these devices carries significant risk for individuals with critical health observations. This concern might result in deleterious outcomes if patients respond incorrectly to clinically insignificant or erroneous device data or if untrained clinicians misinterpret the data. Accordingly, qualified clinicians should be included as integral members of digital data management programs to optimize health outcomes and minimize health risks.[4]

As the only liaison between the manufacturer and the patient, the provider is faced with three major challenges - satisfying patient needs; dealing with the vast amount of generated data and constructing effective care plans. Clinicians must demonstrate a commitment to the maintenance of robust physician-patient relationships by working with both CIED patients and patients using wearable devices to determine the specific components that will be shared and the timelines and methods by which that information will be made available. While progress in deep machine learning and artificial intelligence has significant potential to improve efficiency and augment accuracy, the role of the clinician in orchestrating patient-focused care delivery will remain paramount.

Industry, regulatory bodies and payers all play important roles in furthering the innovation trajectory and encouraging the development of the requisite support systems. Device and EHR manufacturers must coordinate efforts to overcome in a cost-effective manner the existing technical and operational hurdles that limit interoperability. Device manufactures must continue to develop innovations to augment arrhythmia detection accuracy and make false positive transmissions a distant memory. Regulatory bodies will need to work with clinicians and industry engineers minimize the risk of cyber-security breaches and maximize device function and safety. Governmental and private payers must adopt effective reimbursement schemas for both existing and evolving healthcare delivery systems.

The availability of rapidly evolving, digitally enhanced monitoring options place patients, scientists, clinicians, industry, healthcare executives, regulators and payers on the threshold of a paradigm shift in healthcare delivery with significant potential to enhance patient outcomes and involve patients more constructively and proactively in their care. In proposing a potential roadmap for the future, the Digital Health Working Group has thrown down the gauntlet, challenging electrophysiologists everywhere and the Heart Rhythm Society to lead the way. To meet this challenge we must encourage researchers and industry partners to seek continuous improvement so that previously unimagined potentialities become routine; convince providers and patients of the importance of embracing digital health technology while establishing realistic expectations; engage clinician and institutional leaders to maximize operational structures by developing best practice models that will consistently put patients in touch with clinically relevant data and recommendations in a timely manner; work with device manufacturers, EHR vendors and regulatory officials to protect patient privacy, safeguard their security and maximize interoperability; and push payers to establish globally effective

reimbursement schemas. If we pick up this gauntlet and provide effective leadership, engaging proactively and collaboratively all of the stakeholders, we will be taking small but significant steps toward creating this 'brave new world' and advancing the Heart Rhythm Society vision of working 'to end death and suffering due to heart rhythm disorders.'

1. Slotwiner DJ, Tarakji KG, Al-Khatib SM. Transparent sharing of digital health data: A call to action. Heart Rhythm 2019.
2. Ganeshan R, Enriquez AD, Freeman JV. Remote monitoring of implantable cardiac devices: current state and future directions. Curr Opin Cardiol. 2018;30:20-30.
3. Slotwiner D, Varma N, Akar JG, et al. HRS expert consensus statement on remote interrogation and monitoring for cardiovascular implantable electronic devices. Heart Rhythm. 2015. doi:10.1016/j.hrthm.2015.05.008.
4. Agarwal S, LeFevre AE, Lee J, L'Engle K, Mehl G, Sinha C, Labrique A; WHO mHealth Technical Evidence Review Group. Guidelines for reporting of health interventions using mobile phones: mobile health (mHealth) evidence reporting and assessment (mERA) checklist. BMJ. 2016. doi: 10.1136/bmj.i1174.