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***JACC* FOCUS SEMINAR: FUTURE TECHNOLOGY OF CARDIOVASCULAR CARE**

***JACC* REVIEW TOPIC OF THE WEEK**

Using Digital Health Technology to Better Generate Evidence and Deliver Evidence-Based Care

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ABSTRACT

As we enter the information age of health care, digital health technologies offer significant opportunities to optimize both clinical care delivery and clinical research. Despite their potential, the use of such information technologies in clinical care and research faces major data quality, privacy, and regulatory concerns. In hopes of addressing both the promise and challenges facing digital health technologies in the transformation of health care, we convened a think tank meeting with academic, industry, and regulatory representatives in December 2016 in Washington, DC. In this paper, we summarize the proceedings of the think tank meeting and aim to delineate a framework for appropriately using digital health technologies in healthcare delivery and research. (J Am Coll Cardiol 2018;71:2680–90)
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Broadly defined, digital health describes using digital information, data, and communication technologies to collect, share, and analyze health information for purposes of improving patient health and health care delivery (1–10). More than 20 years ago, health care's industrial age (characterized by physicians ruling over tertiary care centers) was predicted to shift to an information age (characterized by patients being at the center of health care delivery) (1,2,11). Until recently, health care has remained relatively isolated from the digital and mobile technology revolution. In parallel with the creation of more powerful, versatile, and low-cost digital health technologies, titanic shifts in U.S. health care have been stimulated by the $27 billion federal investment under the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009. Venture capital and private

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investments in digital health have also risen significantly, exceeding $3.5 billion dollars in 2017 (**Figure 1**) (2).

Digital health technologies also have the potential to accelerate, streamline, and optimize clinical research operations while reducing costs. These technologies could facilitate and advance more conventional randomized clinical trials (RCTs), which is particularly necessary because RCTs are becoming increasingly expensive and complex, are slow to complete, and take an extensive amount of time to implement results into practice (12). Integration of digital technologies into clinical trials remains to be explored, but there is a critical need to evaluate these technologies in order to conduct more streamlined and pragmatic trials. Perhaps the benefits of digital health technologies for both clinical care and research will be appreciated when certain challenges have been resolved regarding data quality, safety, accessibility, privacy, and the need for regulation. Furthermore, the negative consequences of integrating digital technologies into clinical workflows, such as a paradoxical decrease in productivity, the decline of patient-physician interaction, and the creation of silos within health care teams, require further study (13).

To establish an understanding of digital health technologies in health care delivery and clinical research, cross-sector stakeholders from academia, industry, professional organizations, regulatory bodies, and government agencies convened for a think tank meeting in December 2016 in Washington, DC (for a complete list of meeting attendees, please refer to Online Table 1). The aims of this meeting were as follows: 1) to understand the current landscape of digital health technology use in health care delivery and clinical trials; 2) to identify issues and barriers to the development and adoption of these technologies; and 3) to identify potential solutions using perspectives from providers, industry, regulatory agencies, payers, and professional societies.

ABBREVIATIONS AND ACRONYMS

CTTI = Clinical Trials Transformation Initiative

EHR = electronic health records

FDA = U.S. Food and Drug Administration

FD&C = Federal Food, Drug, and Cosmetics Act

HITECH = Health Information Technology for Economic and Clinical Health Act

RCT = randomized clinical trial

CURRENT DIGITAL LANDSCAPE IN HEALTH CARE DELIVERY AND CLINICAL RESEARCH CONDUCT

USE OF DIGITAL HEALTH TECHNOLOGIES AS A DIAGNOSTIC TOOL. The rapid growth in computing power of digital technologies has enabled the development of machine-learning algorithms that are used by companies such as Facebook, Amazon, and Google to optimize search queries and advertisement placements. These algorithms arose from the development of artificial neural networks in the 1940s and 1950s (4), which attempted to simulate the human brain's neuronal response to external stimuli in order to perform learning and pattern recognition (4). One example of the utility of these neural networks arises from a convolutional neural network analysis conducted by Gulshan et al. to aid in the detection of diabetic retinopathy (5,6). In the field of cancer, the use of deep learning has expanded into detection of lymph node metastases after the diagnosis of breast cancer using whole-slide pathology (14). A number of studies are under way that are attempting to leverage consumer wearable sensing technologies to aid in clinical diagnosis of common diseases. As an example, the Apple Heart Study is

received consulting fees from Amgen, Bayer, Gilead, Merck, MyoKardia, and The Medicines Company; has received fees for consulting and educational programs from WebMD; has received grant funding from AstraZeneca, Bristol-Myers Squibb, CSL Limited, GlaxoSmithKline, Janssen, Merck, Novartis, Portola, Sanofi, and The Medicines Company; holds equity in Element Science and Scanadu; and holds an unpaid seat on the board of directors of the AHA. Dr. McClellan has received personal fees from Johnson & Johnson. Dr. Turakhia has received research support from Amazon, AstraZeneca, Bristol-Myers Squibb, Medtronic, the AHA, Apple, Janssen, Cardiva Medical, and Boehringer Ingelheim; and holds equity in iBeat, AliveCor, Metrica Health, Zipline Medical, and CyberHeart; has received consulting fees from Abbott, Medtronic, iRhythm, Precision Health and Boehringer Ingelheim; and has received honoraria for presentations from Medscape. Dr. Steinhubl has received grant support from the National Institutes of Health/National Center for Advancing Translational Sciences grant UL1TR001114 and a grant from the Qualcomm Foundation; and has served as a medical advisor for DynoSense, EasyG, Spry Health, and FocusMotion. Dr. Mault is an employee of Qualcomm Life. Dr. Majmudar has received consulting fees from AliveCor, HUINNO, MC10, and Nokia; holds ownership in BioFourmis, Cardiogram, and HiLabs; and has conducted personal research with Echosense. Dr. Majmudar has received research grants from GE Healthcare. Dr. Roessig is a full-time employee of Bayer AG, Wuppertal, Germany. Dr. Chandross is a full-time employee of Sanofi. Dr. Green has an equity stake in MyoKardia. Mr. Patel owns shares in Boston Scientific. Dr. Hamer is an employee of Amgen Inc.; and owns Amgen shares. Dr. Olgin has received research support from ZOLL and the National Institutes of Health. Dr. Roe has received research grants from AstraZeneca, Eli Lilly & Co., Janssen Pharmaceuticals, Sanofi, Daiichi-Sankyo, Ferring Pharmaceuticals, and The Familial Hypercholesterolemia Foundation; speaker honoraria from Amgen and Bristol-Myers Squibb; and consultant/advisory board fees from AstraZeneca, Eli Lilly & Co., Daiichi-Sankyo, Amgen, PriMed, Myokardia, Boehringer Ingelheim, and Merck & Co. Dr. Peterson has received grants from Amgen Inc.; grants and personal fees from AstraZeneca, Merck & Co., and Sanofi; and has served as a consultant for SignalPath. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

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