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HEALTH POLICY STATEMENT

2017 Roadmap for Innovation—ACC Health Policy Statement on Healthcare Transformation in the Era of Digital Health, Big Data, and Precision Health

A Report of the American College of Cardiology Task Force on Health Policy Statements and Systems of Care

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The Innovation Summit, a multidisciplinary stakeholder meeting to generate ideas for a roadmap to innovation, was convened with support by The Aetna Foundation, a national foundation based in Hartford, Connecticut, that promotes wellness, health, and access to high-quality health care for everyone. Following the meeting, an independent writing group drafted the content for this roadmap document informed by the discussions at the meeting.

This document was approved by the American College of Cardiology Clinical Policy Approval Committee in September 2017.

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TABLE OF CONTENTS

EXECUTIVE SUMMARY

Healthcare transformation is the product of a shared vision between a broad range of stakeholders to establish the future of care delivery and to develop new patient-centered, evidence-driven models in which value is rewarded over volume. Important within this transformation are newly developed and rapidly evolving technology-based innovations. These include: *digital health* with wearable, smartphone, and sensor-based technologies; *big data* that comprises the aggregation of large quantities of structured and unstructured health information and sophisticated analyses with artificial intelligence, machine learning, and natural language processing techniques; and *precision-health* approaches to identify individual-level risk and the determinants of wellness and pathogenicity. Although there is promise in the development of such innovations to shift traditional healthcare delivery to virtual and real-time methods and to empower the healthcare enterprise to utilize new technologies and data analytics, there remains a lack of true evaluation of whether these innovations actually improve outcomes and the quality of care. There are major integration challenges across the spectrum of health care for the effective use of new devices, data, and precision-health approaches within existing health information technology systems. Furthermore, early adoption of new innovations that are not evidence-based or those that have yet to demonstrate effective integration into patient care may risk unintended consequences, such as breaches of privacy or inadvertently increasing the costs of care. Achieving meaningful transformation requires organizational governance to guide the development of clinical programs and the next phase of research methodologies, and to align the objectives from a cooperative network of partners and stakeholders.

To better understand the scope of the challenges in implementing new healthcare innovations, and to identify solutions, the American College of Cardiology (ACC) convened a Healthcare Innovation Summit to understand the needs and perspectives of various stakeholders across health care, including patient advocacy groups, clinicians, investigators, policy, entrepreneurship, and industry. The aggregated perspectives informed a resultant ACC Health Policy Statement that intends to advocate, inform, and guide healthcare policies and programs related to new healthcare innovations.

Through stakeholder engagement and evidence-based review, the priority objectives for the ACC outlined in this Health Policy Statement are to:

- Continuously engage a multidisciplinary group of stakeholders in an "Innovation Collaborative" to foster an understanding of how patient care guides the development and integration of new technologies;
- Drive patient-centric innovation by broadening patient access to health information, consumer empowerment, and clinician activation;
- Support research into new innovations, including academic pursuits with members in the U.S. and international chapters, and incorporate rural and underserved populations in the next phase of device and precision-based clinical trials;
- Develop a "Compact for Human-Centered Design" and a commitment to measuring the impact of new innovations on health, access, equity, costs, and outcomes through evidence generation and development of best practice models;
- Harness the principles of evaluation, integration, patient and clinician engagement, and measures of care efficiency as "Innovation Platforms" in an inclusive and iterative model to advance new technology development centered around the factors important to patients, clinicians, and healthcare institutions; and
- Identify mile markers for success for innovation activities, including the creation of new ACC innovation groups to guide activities that represent all member types, including fellows-in training.

Transformation is likely to result from a confluence of approaches that brings together those seeking to improve care delivery. Organizing the advances in digital health, big data, and precision health pertinent to research and patient care, and sharing resources through stakeholder engagement and partnerships should be used to demonstrate value, and to be an opportunity to assess the impact of new innovations on the quality of care within the ACC and for the healthcare community at large.

PREAMBLE

This document has been developed as a health policy statement by the ACC. Health policy statements are intended to promote or advocate a position, be informational in nature, and offer guidance to the stakeholder community regarding the stance of the ACC and other contributing organizations on healthcare policies and programs. They are overseen by the ACC Task Force on Health Policy Statements and Systems of Care. The topic of healthcare innovation was identified by the Science and Quality Committee (SQC), the parent committee of the Task Force, as an area of interest for a health policy statement based on the first Healthcare Innovation Summit held in September 2016. A roadmap for innovation was drafted to summarize the information presented at the summit and to aggregate the perspectives related to the advances in digital health, big data, and precision health from a multidisciplinary group of stakeholders. The resulting position is reflected in this statement.

To avoid actual, potential, or perceived conflicts of interest that may arise as a result of industry relationships or personal interests among the writing committee, all members of the writing committee, as well as peer reviewers of the document, are asked to disclose all current digital health-related relationships, including those existing 12 months before initiation of the writing effort. These disclosures are reviewed to determine which companies make products (on market or in development) that pertain to the document under development. Based on this information, a writing committee is formed to include a majority of members with no *relevant* relationships with industry (RWI) and other entities, led by a chair with no *relevant* RWI. Authors with *relevant* RWI are not permitted to vote on recommendations pertaining to their RWI. On all conference calls, RWI is reviewed and updated as changes occur. Author and peer reviewer RWI pertinent to this document are disclosed in Appendixes 1 and 2, respectively. In addition, to ensure complete transparency, authors' comprehensive disclosure information—including RWI not pertinent to this document—is available as an online supplement to this document. The ACC disclosure policy for document development is available online. The work of the writing committee was supported exclusively by the ACC without commercial support. Writing committee members volunteered their time to this effort. Conference calls of the writing committee were confidential

and attended only by committee members and appropriate ACC staff.

Dharam J. Kumbhani, MD, SM, FACC
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1. INTRODUCTION

1.1. American College of Cardiology Healthcare Innovation Summit

The ACC convened an inaugural Innovation Summit in September 2016 to provide a framework for determining how the advances in 3 evolving healthcare arenas—digital health, big data, and precision health—can meaningfully transform the delivery of healthcare. This summit was specifically designed to understand the needs and perspectives of stakeholders across health care, including patients/patient advocacy groups, clinicians, academia, government, healthcare administration, business, entrepreneurship, and industry. Principal areas of discussion included:

1) identifying the challenges of implementing digital health, big data, and precision health into new models of patient care and research;
2) outlining the highest-priority goals for healthcare transformation;
3) defining the regulatory and evaluative pathways pertinent to emerging innovations and consumer-oriented technologies; and
4) creating new patient-clinician-industry collaborations that accelerate the adoption of new technologies within clinical practice.

The primary purposes of this Health Policy Statement are to identify the necessary actions for the ACC and our members to support advances in these arenas, and to create new multidisciplinary strategies for clinical practice, patient engagement, and industry partnerships across the spectrum of healthcare stakeholders. The actions within this document are based on summit participant input, literature review, and the available evidence, and aim to incorporate the key principles of evaluation, integration, and engagement relevant to each stakeholder. Ultimately, the objective for the ACC is to execute these actions, which collectively constitute an innovation strategy to help advance our mission to transform cardiovascular care and improve health outcomes.

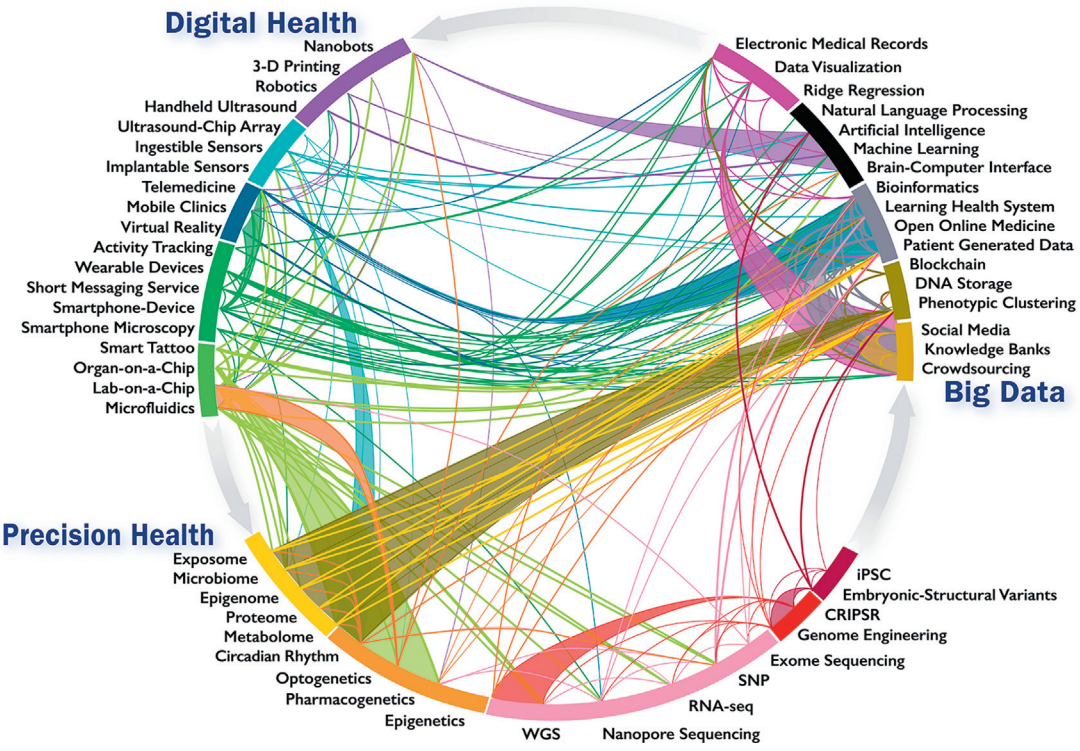
1.2. New and Evolving Healthcare Innovations

Stakeholders across health care have largely supported the concept that new and emerging innovations and technologies can transform health care into a model that is increasingly patient-centered and transparent, and that will thereby improve outcomes and reduce costs (1-4). Fueled by social and mobility trends, smartphone technologies and cloud computing are creating an expansive ecosystem of digitized diagnostic tests, electronic health records (EHRs), and portable health devices. The combination of these is catalyzing a transition in the methods of healthcare delivery from traditional hospital- or office-based visitations, to technology-based encounters that are virtual, on-demand, and patient-generated (5). The recently approved 21st Century Cures Act is one step toward a streamlined process for new technology approvals. This legislation increases capacity building for data sharing as new public health initiatives are developed, includes provisions to further empower patients and improve their access to health information, and promotes designs to improve the efficiency of technology-based clinical trials through both precision- and population-based approaches (6). In the aggregate, the development of new innovations, their application to health care, and the ease and ability to share information are positioning patient care to become increasingly value-based, and are driving practice patterns to become more proactive, engaging, and participatory.

Examining the key trends in new innovations and their applications for research and clinical practice brings these healthcare transformations into focus (**Figure 1**). The first is "digital health," which encompasses the emergence of wireless mobile health (mHealth), wearable and smartphone-connected devices that are increasingly available to measure health in real time. Leveraging nearly ubiquitous Internet connectivity, such programs are providing real-time data transfer of biophysical measurements and patient-generated data to practitioners for clinical decisions and are providing a digital mechanism to facilitate shared-decision making (7). The second trend is "big data" that is enabled by the continuous acquisition of diverse datasets and aggregation of large amounts of information. These acquisition processes allow for the application of newly developed and sophisticated data analyses that are providing robust and highly specific information for biomedical, clinical, and operational decision making (8). The third trend is "precision health," a development initially viewed solely as genomic medicine but that now encompasses a broader field. This field includes the individual-level risk derived from clinical measures, familial inheritance, and social and environmental factors, as well as the application of various new "-omic" sequencing tools (metabolome, microbiome, epigenome, and proteome) to enhance our knowledge of systems biology, human physiology, and pathogenicity (9,10).

Integrating real-time, patient-generated data through wearable and implantable sensor-based technologies with a wide range of existing health information and data sources can provide a highly granular view of the determinants of health, and specifically, a means of

FIGURE 1 New Innovations in Healthcare



Infographic of emerging innovations and developments in digital health (14–32), big data (33–51), and precision health (52–78) and their intraconnections and interconnections. 3d indicates 3-dimensional; CRISPR, clustered regularly interspaced short palindromic repeats; DNA, deoxyrybonucleic acid; iPSC, induced pluripotent stem cells; RNA, ribonucleic acid; SNP, single nucleotide polymorphism; WGS, whole genome sequencing.

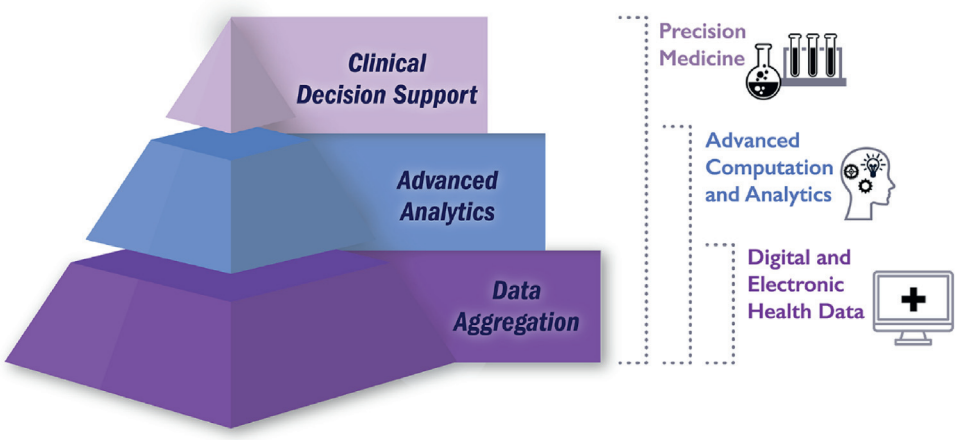
characterizing the factors that drive progression from subclinical disease to pathological phenotypes (11–13). Paralleling these developments, high-fidelity sequencing and deep clinical profiling are forming the basis to more accurately determine genome-phenome associations and for understanding the intraindividual and interindividual variations in response to lifestyle modifications, medications, and device-based interventions.

Taken together, digital-sensing devices and multiomic information form a large-scale collection of biological, radiological, and translational bioinformatics datasets with research and clinical-decision support applications. Making full use of these multidimensional data streams necessitates the development of standardized methods of data aggregation and analysis and cross-disciplinary translation of emerging computational techniques, such as machine learning, natural-language processing, and artificial intelligence. The application of these new analytical methods to health care can enable us to define the dynamic patterns of health and disease and to create more efficient and sustainable models of care that are driven by data and technology (79,80).

1.3. Unintended Consequences of Technological Transformation

Technological advances commonly occur too quickly for existing healthcare practice to keep up, thus creating a mismatch between the rate of development of new technologies and preparedness of the system for effective integration and utilization of new technology-based initiatives. The slow adoption is due to a multitude of factors. These range from a lack of scientific rigor to ensure the effectiveness and safety of newly-developed technologies, to an assumption that practitioners will alter their practice patterns and workflows to accommodate new devices, data analytics, or precision-based approaches for patient care (81). Over the past decade, the transition to EHRs in the United States has produced a shift from fragmented, paper-based care coordination to digitally-enabled data capture for both e-prescribing and quality reporting (82). Although the transition to electronic media constitutes a major effort to improve healthcare service delivery, the mandate for digital documentation and communication has resulted in significant integration and interoperability challenges.

FIGURE 2 Digital Data and Analytics Continuum



These challenges, in part, have led to deep clinician dissatisfaction and workflow constraints stemming from additional documentation requirements that add time to already complex workflows, a lack of harmonization leading to nonstandardized practices, and poor incentive structures to drive economic benefit resulting from the adoption of EHR systems (83,84).

Given that complex challenges exist as new technologies are applied to patient care, to ensure success, several fundamental steps are necessary as new innovations are vetted by research and, when appropriate, adopted into clinical practice. These include (**Figure 2**): developing new systems of practice that incorporate emerging digital, genomic, and personalized datasets (85,86); streamlining regulatory and research frameworks; creating effective methods of collecting, analyzing, and communicating digital data for clinical-decision support; identifying the factors that drive care efficiency and outcomes; and stimulating both physician interest and active patient participation (87).

These requirements notwithstanding, the implementation of new data- and technology-based initiatives can be used in 2 healthcare delivery model examples. The first is within established health systems that are based on existing and constrained information technology and data infrastructures. The second is within the design of next-generation "learning health systems." Such systems are based on a socio-technical transformation that harnesses continuous data collection and analytics to generate new knowledge, optimize resource allocation, and improve organizational processes (88–91). Within both (**Figure 3**), new data- and technology-based innovations involve an iterative process of design, implementation, evaluation, and adjustment and provide a bidirectional flow of information between research and patient care to solve key clinical problems, eliminate common healthcare inefficiencies, and demonstrate economically viable health care for an ever aging and growing chronic-disease population (92–94).

2. VITAL DIRECTIONS FOR THE AMERICAN COLLEGE OF CARDIOLOGY

To align these developments with the ACC's core principles and priorities for patients and clinicians and to demonstrate value for various stakeholders, the ACC must position itself with several priority measures and "Vital Directions" (95) that accelerate new innovations for positive care transformation (79,96–100). In order to scale, new healthcare innovations require:

1. Partnerships across healthcare stakeholders;
2. Direction on patient and clinician engagement and the adoption of new technologies in clinical practice;
3. Environments that support research and development of new innovations; and
4. Generation of clinically meaningful findings that lead to the development of best-practice methods.

2.1. Innovation Collaborative Across Healthcare Stakeholders

The ACC will strive to lead meaningful innovation in cardiovascular care by facilitating the creation of an "Innovation Collaborative." This will bring together patients, caregivers, clinicians, industry partners, technology entrepreneurs, payers, and administrators to better understand the opportunities and problems to be prioritized, and to engage in multidirectional collaborations. Such collaborations foster an understanding for how patient care guides the development, evaluation, and integration of new technologies. Key roles for the ACC are to facilitate

FIGURE 3 Developmental Cycle for New Innovations in Research and Clinical Practice

new stakeholder partnerships, promote collaborative efforts to identify unmet clinical needs, and to implement new ideas. Important factors relevant to care efficiency may emerge during the facilitation of an innovation collaborative. Promoting collaboration and forging new partnerships will enable various stakeholders to assess available products more rapidly and to mitigate the risks and impediments associated with the development and curation of new innovations specific for patient care.

2.2. Provide Directions on Patient and Clinician Engagement

The healthcare sector at large is committed to further understanding what patients and clinicians require from new innovations and to identify those measures aimed at solving key clinical problems (1–4). Identifying these priority measures will allow the ACC to seek the necessary resources and partnerships to drive new innovations that improve access to healthcare services, and to facilitate more personalized and patient-centered models of care. Implementing these new innovations in a patient- and clinician-centric manner will capture the advantages of user-generated data, thus leading to enhanced patient-caregiver-clinician communication and making it possible to leverage guidance from patient advocacy groups and practitioners within new technology development and evaluation. These changes will, in turn, improve the ability to characterize the effectiveness of new technologies in clinical practice.

2.3. Support Research Into and Development of New Innovations

The ACC is committed to strengthening the biomedical research enterprise and seeks to support research methodologies and academic pursuits in digital health, big data, and precision health. In addition, we will support and encourage our members in U.S. and international chapters to become involved in these arenas that include research into the development, evaluation, and safety of new technologies; interoperability; user interface; data analytics and processing; as well as research to assess the impact of technology-enabled initiatives on healthcare quality, costs, and outcomes. In parallel, the ACC will assist researchers by providing awareness of specific funding relevant to new innovations and a framework on how best to evaluate the outcomes of such innovations. The involvement of fellows-in-training will need to be prioritized as new research infrastructures and educational curricula are developed and as new multidisciplinary research teams are formed.

2.4. Generate Evidence-Based Best Practices for Guideline Consensus and Patient Care

It is unclear how the healthcare community should develop the resources necessary for administering digital health, big data, or precision-health services within fields that do not have established regulatory frameworks (101). Therefore, priority objectives for the ACC are to:

- Review the evidence that supports the generation of guideline-based consensus;
- Create working groups specific to the development and evaluation of new innovations;
- Solicit input from key opinion leaders;
- Devise and disseminate best-practice models focused on workflow integration, costs of care, and outcomes; and
- Define the clinical, technological, and financial priorities for federal advocacy.

To identify best practices, the ACC is currently pursuing, and will continue to request, input from those practitioners and administrators who have successfully utilized new technologies within value-based practice environments. Continuous dissemination of information and the emerging evidence of best practices will enable the ACC to engage our members in ongoing needs assessments and to promote policy dialogues relevant to stakeholders and payers. Through partnerships and the ACC's objectives to facilitate collaborations (see Section 2.1), such policy and advocacy activities include: promoting methods for data sharing across healthcare stakeholders; sharing pre- and post-market evidence and efficacy evaluations; and advancing an agenda centered around a commitment to patient-centered innovation to the U.S. Food and Drug Administration, the Center for Device and Radiological Health, the National Institutes of Health, and other federal agencies involved in the development and evaluation of new healthcare innovations.

3. STAKEHOLDER PERSPECTIVES AND IDENTIFYING THE KEY ACCELERANTS FOR HEALTHCARE TRANSFORMATION

By soliciting input from a broad variety of healthcare stakeholders (See Online Supplementary Table), the ACC can develop an ongoing and thorough needs assessment to understand how the pace of consumer and patient expectations are changing, as well as the factors leading to cultural transformation with new technologies, data, and precision-health approaches. Obtaining input from a diverse range of stakeholders will also help the ACC adapt to the challenges associated with conducting technology-based clinical trials and for evidence generation. Finally, these stakeholders' perspectives will identify the functions that the ACC can facilitate to address these challenges and to incorporate the key accelerants for organizational governance as new programs are designed.

3.1. Patients as Partners

In contrast to viewing the position of patients as "end-users" of healthcare delivery and services, engaging patients as "partners," with a role that is facilitated by increased access, can provide a key accelerant for healthcare transformation. New technology-based programs can be designed and focused on patient-centric models of care to allow patients to access their data and contribute to shared decision-making (102,103). Data from information and communication technologies, mHealth, and point-of-care devices can approach patient-centeredness from different directions to better understand how disease burden influences the way patients engage in self-care. Such initiatives can also provide information on how new devices are utilized in real-world settings and can provide a digital method to collect and track important patient-reported outcomes for more accurate and real-time assessments of health and disease (104,105). Patient-centered innovation within the early stages of research and technology development can enable rapid identification of high-priority clinical problems and gaps in care delivery, and may guide post-market approval including decisions for payment coverage as new innovations are translated into patient care (106). Inclusion of diverse patient populations and those located in international, rural, and underserved communities will advance our knowledge of the effectiveness of new innovations (107). Greater inclusivity will also enhance community participation for the development of pragmatic device- and genomic-based initiatives.

3.2. Augmenting Clinical Workflows

A primary function of new innovations is to improve the efficiency and effectiveness of care delivery (98). Key accelerants of such improvements include identifying those technologies that replace common workflow tasks within episodic care, particularly for chronic diseases, and the enhancement of patient and caregiver participation. Integration of new technologies into clinical practice may introduce new models of care such as telehealth and virtual care, with such models providing a method for ongoing chronic care management, patient participation, and workflow augmentation. An essential requirement for modifying workflow is the translation of digitally-derived data into clinically useful information. These data can include information to facilitate medication adherence, to monitor the trajectory of health status, and for quality improvement initiatives. An additional accelerant for optimization of clinical workflow is matching the use of resource and care management on the one hand, to the intensity of care and follow-up, on the other. Improving workflow in this manner requires aligning clinician and administrator objectives for how new innovations integrate to patient-care, and the various requirements including technical, financial, and personnel-related factors that determine new technology functionality and usability. Moving data such as that derived from genomic sequencing technologies, point-of-care laboratory testing, and handheld imaging to the patient-physician interface

can harness this data to quantify individual patient risk for precision-health approaches to diagnosis and treatment. Developing such models of personalized care requires that data derived from new technologies be incorporated into both EHRs and existing patient-related data sources (98). This practice would render data available for analysis, thereby facilitating findings that drive efficient patient care and streamline clinical workflows.

3.3. Open Data and Data Transparency

Several present-day data initiatives are accelerating the development of new methods to execute clinical trials, disseminate their results, and provide free access to research datasets. These include: 1) proposals to provide open access to publicly and privately funded clinical trial databases and research results (41,108); 2) sharing of detailed genotypic, clinical, radiographic, and outcomes information from population-based biomedical data repositories to generate new insights into disease prediction and prevention (109); and 3) public and patient participation to collect health data and vital statistics in new online citizen-science and crowdsourcing platforms for research and public-industry-academic collaborations (110). Key factors to increase data transparency are for patients and consumers to access their health records and related health information both electronically and freely. Greater inclusivity and patient access requires simple, longitudinal formats that are easy to understand, secure, and are automatically updated. As patient care and research migrate into digital and cloud-based platforms, it becomes easier to share research results and practice-based observations relating the efficacy, safety, and outcomes of new medical innovations, thereby also promoting transparency of research methodologies (111,112). Paralleling these open-data efforts, leveraging existing databases—such as the ACC's National Cardiovascular Data Registry (NCDR) programs—may provide a means of enhancing public and industry collaborations. These databases may also function as an integrated and robust medium via which to incorporate data from new technologies for the next phase of quality improvement and population health initiatives.

4. A COMPACT FOR HUMAN-CENTERED DESIGN

Because new healthcare initiatives typically have multiple broad objectives, practical considerations constrain the design of large effective programs, and for how new innovations are identified, deployed, and scaled across various health systems and practice settings (113). Herein, we propose a "Compact for Human-Centered Design" that is focused on the key principles of clinical practice and patient engagement. A model for healthcare innovation that is focused on human-centered design is not only critical, but is also an opportunity to develop new competencies that align with a rapidly changing healthcare environment. This compact (**Table 1**) is structured to include the design factors for implementation of new innovations and to identify the elements important to each healthcare stakeholder within 5 principal categories:

1. Identification of the priority problems to solve;
2. Facilitation of meaningful communication and information exchange;
3. User (patient, caregiver, and physician) activation;
4. Dedicated infrastructure and resources; and
5. Cultural empowerment and best practice models.

It is crucial to understand a number of factors within this compact as new innovations are developed and translated to patient care. For instance, when considering healthcare transformation with digital health, big data, or precision health, the first steps comprise understanding several factors including: 1) identification of high-priority clinical problems; 2) user-related factors specific to patients, caregivers, and practitioners; and 3) factors pertinent to clinical workflows, outcomes, and cost containment. This strategy is fundamentally different from a "technology-leading" strategy, which is pursued in search of a clinical problem and where new innovations are designed to disrupt healthcare processes by introducing new devices and data for consumer engagement and discovery (114). The design principles of each strategy hinge on different focal points: one is health and patient-centric innovation, and the other is a technology-driven focus. The differential effect resulting from a lack of synergy between both often leads to variability in outcomes and in the type of value derived for patients and healthcare stakeholders. Such variability may be mitigated, if not avoided, when employing human-centered principles prior to the adoption of new innovations in clinical practice.

Structured design principles are beneficial for the challenges of dynamic practice patterns, chronic disease management, and rising costs of care, and to identify the technical requirements, resources, and people necessary prior to implementing new innovations for patient care (115). For example, in contrast to usual practice patterns and physician prescription for diagnostic tests and therapeutics, health care is seeing direct-to-patient marketing of an increasing number of new innovations such as personalized genomic-technologies and mobile health devices. In this regard, consumerization represents a major shift in the manner that patients acquire and engage with healthcare services (116). In 2014 to 2015, over 20 million individuals in the United States sought a virtual healthcare encounter outside of a traditional clinic visitation—through smartphone applications, Internet video-based programs, or retail channels and pharmacy-based clinics (117). On the basis of the increasing availability of

TABLE 1 Compact for Human-Centered Designs and the Principal Components for the Implementation of New Healthcare Innovations

Compact for Human-Centered Design	Specific Elements	Principal Components for the Implementation of New Healthcare Innovations
Identification of the priority problems to solve.	Utilize new digital health, data analytics, and personalized medicine to: ■ Improve outcomes, ■ Enhance patient engagement, and ■ Reduce healthcare costs.	■ Identify the high-cost, high-burden clinical conditions (e.g., diabetes, hypertension, obesity, coronary disease, adult congenital heart disease, heart failure) and those processes of care that can be augmented with new technologies. ■ Determine how technology-enabled care improves healthcare access for consumers and patients. ■ Identify methods for the implementation of new innovations for rural and underserved communities.
Facilitating meaningful communication and information exchange.	Match clinic-based needs with technology solutions.	■ Identify the clinical and patient use cases that support new technologies. ■ Determine the use-case scenarios for next-generation genome sequencing and personalized-medicine techniques in patient care. ■ Match digital retention with new technologies and patient expectations for long-term care.
	Data exchange: ■ Enable integration of data from multiple sources. ■ Translate data analytics into useful clinical information.	■ Leverage existing datasets and clinical registries (e.g., the ACC's NCDR programs) for new predictive analytics. ■ Merge personal health, patient-reported outcomes, and mHealth device data within clinical registries. ■ Improve data extraction from EHRs for quality improvement reporting. ■ Improve big-data validity, accessibility, and reliability.
	Effective communication of information at transitions of care.	■ Utilize new technologies to enhance communications between patients, caregivers, and physicians (e.g., telehealth, virtual health, app-based care coordination). ■ Enable patients to view, download, and transmit their health information.
User (patient, caregiver, physician) activation.	Drive innovations aimed at the patient-clinician interface.	■ Provide continuous information exchange and communications between clinical visitations. ■ Improve data transparency and patient access to medical information. ■ Augment clinical workflows and streamline information exchange between clinicians. ■ Incorporate structured patient-reported outcomes within clinical documentation.
	Determine the outcomes of technology-based solutions.	■ Improve patient and caregiver health and digital literacy. ■ Determine the cost of care that includes technology development and implementation costs. ■ Enhance technology-enabled care for secondary prevention vis-à-vis outcomes in areas such as readmissions, morbidity, and mortality. ■ Reduce the redundancy of tests, procedures, and documentation across the care continuum.
Dedicated infrastructure and resources.	Overcome the technological barriers to meaningful care transformation.	■ Determine the technological impediments to improving clinical workflow. ■ Automate data analytics for point-of-care clinical-decision support. ■ Standardize the methods for the integration and interoperability of digital health technologies.
	Determine the interoperability and data standards specific to healthcare innovations.	Develop the integration and interoperability specifications to support the following: ■ Incorporation of digital health device and genomic sequencing data into health information warehouses and EHRs; ■ Creating standards for the analyses of unstructured electronic and patient health data; ■ Quality reporting of big data analyses used for clinical-decision support; and ■ Open-source, free, licensing solution for digital-health devices that can be implemented at any facility.
Cultural empowerment and best practice models.	Determine the business cases to adopt new technologies.	Develop the financial/payment models for new technologies that are specific to patients, clinicians, and health systems within the following: ■ Value-based payment models that will provide incentives to leverage digital health and other emerging technologies; ■ Chronic care management programs for elderly patient populations and those with high-risk conditions; ■ Determination of the financial incentives for using and exchanging data; and ■ Stabilization of cross-organizational collaborations and private/public partnerships.
	Determine the best practice models to support the implementation of new innovations.	■ Utilize new innovations to identify high and low-risk patient populations. ■ Provide robust and safer methods for patient self-care and caregiver support. ■ Shift the emphasis toward prevention with goal-directed care (e.g., lifestyle changes and medication compliance). ■ Provide governance for data-sharing and privacy.

ACC indicates American College of Cardiology; EHR, electronic health record; mHealth, mobile health; NCDR, National Cardiovascular Data Registry.

these digital services, actuarial trends predict a growing consumer base that is expected to eclipse 200 million virtual visitations by 2020 (7). Although this shift represents new opportunities for health promotion centered around convenience and readily available healthcare practitioners (integral factors for patient and consumer engagement), it also presents challenges for how clinical practices derive benefit through noncoordinated and virtual care, and how such innovations drive improved care quality and lower healthcare costs (118–120).

5. INNOVATION PLATFORMS

In general, individual hospitals and clinical practices lack the necessary infrastructure and expertise to develop and test new innovations. For new innovations to succeed in improving healthcare delivery, several regulatory and implementation principles that align with key scientific questions and clinical endpoints must be observed. These include:

- defining the foundational principles of evaluation;
- systems implementation and integration;
- stakeholder engagement, and;
- monitoring the efficiency of technology-enabled care and outcomes.

The ACC plans to facilitate (i.e., through partnerships) the creation of "innovation platforms" that support the efficient development, evaluation, and implementation of emerging digital health, big data, and precision-health solutions. Moreover, the ACC will support the dissemination of knowledge and best practices stemming from innovation platform evaluations. Such platforms are important vehicles to generate greater clinician-patient-industry interaction and collaboration for the development, evaluation, and implementation of new technologies. Ideally, such platforms will work inclusively, incorporating ongoing stakeholder feedback and the key accelerants of healthcare transformation (**Figure 4**). Last, innovation platforms can support the development of new technologies by addressing the principal factors that can impede a product's progress, and can streamline clinical translation of those innovations that are safe and effective for patient care.

5.1. Principles of Evaluation

As new technologies emerge, it becomes vital to strengthen the research enterprise by providing the scientific community with the guidance and assets required to design and adapt new methodologies to evaluate the clinical usefulness of new innovations. Although new clinical trial designs and analytical plans are important, their methodological sophistication must be viewed in the context of the quality of the data collected (structured versus unstructured), type of trial (clinical trial versus real world), type of data (quantitative versus qualitative), and the population (consumer or patient) in which innovations are studied (121). To the extent that is feasible, flexible clinical trial protocols are required that accommodate the various stages of technology development (discovery, prototype, preclinical, clinical, and postmarket testing and surveillance) and evolving analytical methods (e.g., artificial intelligence, machine learning, and natural-language processing) while still fulfilling the evidentiary requirements that inform quality of care, safety, and outcomes (122).

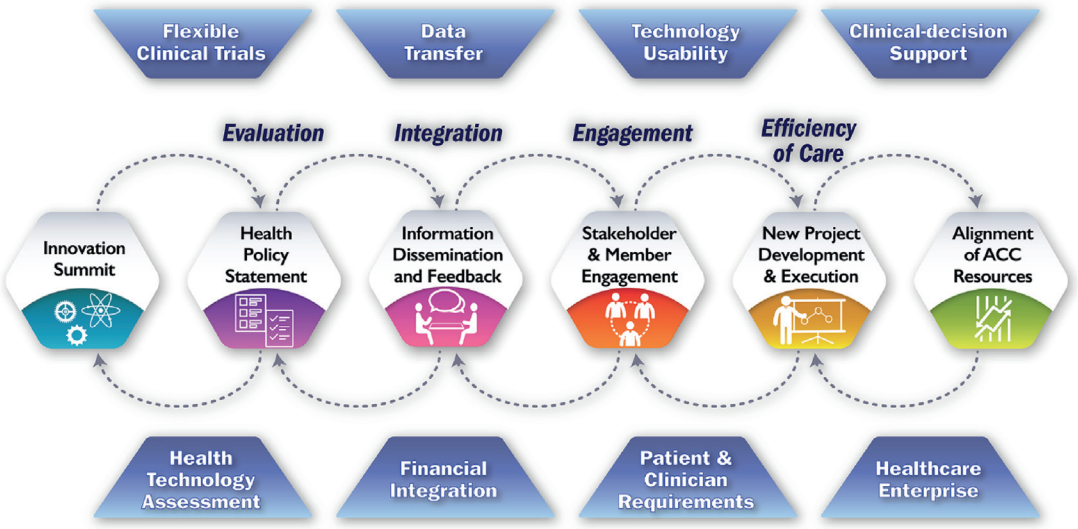
Although randomized study designs remain the standard for assessing the effectiveness of new therapies, several new methodologies have emerged that are designed to accommodate the rapid and iterative nature of technology development and to reduce the time and costs associated with trial organization and throughput. These new designs include N-of-1 clinical trials (123), genome-wide association studies using EHR to further understand phenotypic classifications (124), community engagement and participatory research models (125), technology-based cluster randomized trials (126,127), and digital and paperless trial coordination (128). Leveraging data captured on smartphone applications or online programs will accelerate trial enrollment, improve trial efficiency, and provide big datasets to quantify individual and population-related changes during follow-up (128).

Concurrently, standardized health technology assessments are required to provide objective measures of functionality as new devices are field tested in various clinical settings (129). Real-world evidence and healthcare information that are derived from observational studies and clinical practice provide additional evaluative mechanisms. Combining data aggregated from EHRs, claims data, and registries with patient-generated data gathered from new devices such as mHealth and genomic-sequencing technologies may provide information on the effectiveness of new innovations for clinical practice and public health. Combining these forms of data may also facilitate the generation of hypotheses for subsequent diagnostic or interventional trials with next-generation technologies (130). Although further study is needed to validate these methodologies, they hold promise for gathering data on the safety, cost, and efficacy of new innovations.

5.2. Principles of Integration

Achieving integration and interoperability—the ability of different information technology systems and software applications to communicate and exchange data with each other—requires identification of precisely how new innovations merge into systems of care, and how integration and data transfer are applied to various practice settings. A top-down approach to integration is determined by how new innovations align with institutional objectives for patient care,

FIGURE 4 Innovation Platforms and the Foundational Principles of Evaluation, Integration, Engagement, and Efficiency of Care



ACC indicates American College of Cardiology.

and by business cases and return-on-investment that incorporate payment models such as fee-for-service, performance-based reimbursement, bundle payments, and value-based payment models (131). Specific integration methods such as Health Level 7 (HL7) and Clinical Document Architecture (CDA) provide for the exchange and retrieval of electronic health information (132). New computational infrastructure platforms and APIs (application programming interfaces), FHIR (Fast Healthcare Interoperability Resource), and SMART (Substitutable Medical Applications and Reusable Technologies) collectively and individually provide an open, modular, and standards-based platform for the interface between information communication technologies and EHRs (133,134). Merging genetic information into EHRs and analyzing this information in combination with patient-health data can allow for the identification of new and important phenotypic and pharmacogenetic associations. This particular use of genetic information constitutes one technique currently emerging for integrating genomic sequencing with clinical-decision support that may be used for personalized health initiatives and predictive modeling (135,136).

Bottom-up approaches require execution within the governance of privacy and security, and in accordance with healthcare-accepted standards. Ensuring confidentiality and integrity of health data from mHealth devices, genomic sequencing technologies, and patient information in EHRs is a responsibility shared among institutions, practitioners, researchers, and industry. A thorough understanding of patient and public views about privacy and security is essential for designing integration channels for new innovations. Such an understanding is particularly important when integrating direct-to-consumer technologies, where commercial and proprietary devices are often dominant, and those innovations that leverage digitally derived health data on mobile devices for patient care and research (137,138).

Top-down and bottom-up approaches to integration are complex and highlight the ongoing need to provide a framework as practices consider a shift to technology-enabled care (139). The ACC recognizes the importance of informatics, software development, and technology transfer, as well as the efforts undertaken by federal agencies (e.g., Office of the National Coordinator, White House Office of Science and Technology, Food and Drug Administration), academic organizations, and other professional societies (e.g., Healthcare Information and Management Systems Society, and the American Medical Informatics Association) to achieve progress toward advancing the healthcare applications of emerging innovations. Extending the ACC's member base to include those with expanded skillsets will garner the expertise needed for a deeper understanding of ongoing developments in data integration and to include ACC members and stakeholders within these activities.

5.3. Principles of Engagement

The evaluation of new scientific discoveries, whether technology- or data-related, commonly occurs in a diverse ecosystem of stakeholders. However, as new innovations are developed and tested, the preferences and views of patients, caregivers, and practitioners are often overlooked. Recent studies have demonstrated discordance

between patient expectations of new technologies and requests for access to health data on the one hand, and clinicians' willingness to adopt technology-enabled care and share health data on the other, with patients more open and willing to data sharing than their clinical counterparts (140,141). In an evolving landscape of healthcare transparency in which new technologies are becoming increasingly available, these data reveal an important inflection point in users' bidirectional participation in collaborative care. Engagement also includes maintaining privacy and protecting data, especially as health information moves across entities and into nonclinical locations.

A vital determinant of engagement is who bears the costs of acquisition of new devices and technologies. Assuming that this responsibility falls on health systems, clinicians, or patients may not be sustainable, especially because few new innovations have coverage or a third-party payer, and many are associated with high out-of-pocket expense (142). This question of who bears the cost of acquisition is particularly germane to how new personal health devices and genomic-sequencing technologies reach underserved communities, especially when socioeconomic disparities may discourage the implementation of new technology-assisted models of care. Driven by a high disease burden, these communities may derive benefit from new innovations, and therefore, efforts to include these patients and practices are of high priority. Incentivized approaches that link technology-enabled care with guideline-based measures of clinical performance and value-based reimbursement are potentially practical methods of enhancing user engagement. Such approaches may simultaneously reduce disparities and variations in new technology dissemination and application (143).

The ACC can provide oversight for new technology development and evaluation through the involvement of our quality improvement and health policy committees, informatics and information technology task force, and member innovation groups. These groups can help to determine and develop the engagement strategies important to each stakeholder. They can also monitor ongoing efforts to understand contemporary trends that drive user perceptions of new technologies, and to identify models of engagement that are effective and economical. Concomitantly, harnessing user participation and input within technology development and evaluation will serve as an ongoing engagement mechanism and will allow for regular assessment of device and user performance over time.

5.4. Principles of Care Efficiency

Introducing new innovations in clinical and academic programs involves a myriad of factors related to organizational governance that improve the state of medical technology development and the application within patient care. These include measures to identify the appropriate information technology, personnel, and financial resources for clinical program development, and to translate high-value demonstration projects for patient care across clinical practices and for long-term care delivery (144). Aligning the principles within the innovation platforms with these factors will provide a basis to understand how data from new devices and sequencing technologies mitigate risk and improve efficiency of care. Providing the right content to the right stakeholder at the right time, or purposeful education and support, is an overarching strategic theme for the ACC and means leveraging our strengths for organizing research and aggregating and reporting data that inform the quality of care.

Patients have expectations that they and their clinicians will have access to sufficient health data related to their care, and practitioners expect that data will be available, be analyzable, and provide clinical-decision support. Although these expectations exist across new technologies, data, and precision health, their translation to patient care remains largely incomplete. The operational characteristics of a learning health system and data-driven models of care involve organizing biomedical datasets derived from patient care, EHRs, and new technologies, and analyzing them to improve quality of care through enhanced clinical prediction, resource optimization, and therapeutic personalization (145,146). This system is designed to work cyclically, incorporating the adoption of new technologies and data analytics as well as providing a digital medium that monitors performance and outcomes over time.

The objective behind collecting digital data is to improve the various factors of care efficiency expected by each participant in the care delivery cycle. At the hospital level, efficiency can be demonstrated by improving clinical throughput and providing rapid referral of patients to needed services; improving disease management and care coordination; containing costs; and implementing evidence-based practices (147). Collecting and analyzing patient-reported outcomes, risk profiling that matches patients' risk with technology-based risk (diagnostic and therapeutic devices versus communication and monitoring technologies), and improving health and digital literacy are measures of efficiency important at the level of the patient and caregiver. Educational and support systems modeled within these efficiency metrics will provide methods to identify and close the gaps in care, and to identify strategies for meaningful engagement, develop new parameters for technology surveillance, and monitor quality improvement and outcomes.

6. ACC IMPLEMENTATION STEPS FOR HEALTHCARE INNOVATION

To re-envision health care with the objective of creating a competency- and success-based system for evolving

FIGURE 5 Mile Markers of Success

ACC indicates American College of Cardiology.

healthcare innovations, the ACC is committed to a process of: 1) continuous identification, evaluation, and dissemination of stakeholders' top priorities; 2) collation and synthesis of the evidence in digital health, big data, and precision health; and 3) providing support for fellows-in-training, early-career investigators, and fellows of the ACC through a connected community network for all members with shared interest in innovation. The Innovation Collaborative provides a framework for how new innovations can be effectively translated to patient care. From beginning to end, several "mile makers" of success will guide project development and align the necessary resources to identify high-yield, technology-based solutions for research and patient care (**Figure 5**).

6.1. Evidence-Based Recommendations and "Horizon Scanning"

The ACC will take a leadership role in evidence synthesis and making recommendations in relation to digital health, big data, and precision health, just as we have in all areas of cardiovascular medicine via evidence-based guidelines, consensus documents, and appropriate use criteria. For example, the ACC plans to participate in the development of an evaluation system and a priority evidence-based review program, which are necessary to provide strategic support to our stakeholders, as well as participate in device and data standards development. This process will encourage the development and reporting of new research methodologies, updating of human protection and institutional-review board requirements for the design of technology-based investigations (148,149), monitoring of experiences with devices and data collected outside of the United States (150), and identification of new engagement methods for the inclusion of diverse populations in device and precision-health studies (151). The ACC will participate in ongoing efforts to create a standard methodology for reporting research investigations (proof-of-concept, explanatory, and effectiveness studies) using digital technologies, big data, and precision-health interventions (152), and will encourage organizing the literature from peer-review and new open-access and prepublication journals within the evidence synthesis process (153).

The ACC seeks to enhance our "horizon scanning" via a structured approach that reviews important scientific literature (published and unpublished) and provides a systematic process for identifying and assessing future trends and uncertainties. Developing a network to gather and share information will assist in the creation of an inventory of emerging devices, data analytics, and precision-health approaches that have the greatest applicability for research and patient care. This approach will consider technologies and data analytics funded by federal agencies and those developed by the medical device and startup industries, with the purpose of aligning these developments with the relevant healthcare context. Additionally, interval horizon scanning will aid the ACC to anticipate and prepare for emerging innovations by focusing our clinical and research efforts in these areas, and to regularly disseminate findings via webinars, workshops, and publications to better inform our stakeholders.

6.2. New ACC Healthcare Innovation Member Workgroup

The ACC has created an interdisciplinary Healthcare Innovation Member Workgroup to serve as a professional resource for those members and affiliates with an interest in healthcare innovation. Currently a part of the Academic Section, the Innovation Workgroup will be evaluated to determine its potential as a unique and separate ACC member section in 2017. The priorities of this workgroup include:

- Working with the ACC Chief Innovation Officer and Innovations Advisory Group to provide input on the ACC's strategy and on the preparation of clinical policy documents;
- Integrating and working synergistically with various sections at the ACC and collaborating with the task forces on data standards, guidelines and performance measures, and registries such as the NCDR;
- Identifying key domains of healthcare innovation and the "state-of-the-science," which will provide key input for ACC leadership;
- Providing subject matter expertise to education/lifelong learning resources on relevant education programming related to key healthcare innovation topics (ACC Scientific Sessions, Cardiovascular Summit, ACC.org, online education);
- Seeking opportunities to evaluate key gaps and variations in healthcare delivery, for example, via NCDR manuscripts, to highlight key areas of need for healthcare innovation;
- Creating an interactive community within the ACC (e.g., using social media, publications, webinars, and conference planning) around healthcare innovation with a focus on career development and promoting the ACC as an innovative organization to external stakeholders.

Optimally equipping cardiovascular fellows for the future delivery of medicine will require a grassroots change in how trainees are exposed to new innovations and how fellowship programs are structured (154–156). The factors outlined within the innovation platforms—evaluation, integration, engagement, and care efficiency—and fundamental knowledge in informatics, data analytics, and genome sequencing should be incorporated as core competencies in the next phase of research training and clinical curricula (Core Cardiology Training Statement) (157,158). The Innovation Member Workgroup will serve as a mentorship resource and will include those fellows-in-training interested in academic or clinical project development involving new technologies, data science, and precision-health techniques. As innovation activities continue to mature, the development of new multidisciplinary skills in engineering, data analytics, clinical informatics, technology transfer, entrepreneurship, research, and policy will complement clinical and procedural skills for the design of blended fellowship programs and for the evolution of new career development pathways (159–161).

The Healthcare Innovation Summit participants and the Innovation Member Workgroup will provide new content specific to new healthcare innovations for inclusion in the annual scientific sessions and to include research, clinical, and policy developments within the program charter. This content will include abstracts, presentations, expert panels from best-practice clinics and hospitals, as well as design-thinking workshops. The ACC can host and promote innovation challenges that will allow its members to collaborate and become involved in generating new ideas. Examples include: 1) leveraging NCDR data to identify high-need clinical problems; 2) requesting participation from the public, academic organizations, and industry partners to identify the innovations that advance our understanding of these problems; and 3) defining the implementation pathways of new solutions. By developing a needs-based innovation program centered on key problems in cardiovascular medicine, the ACC can incubate these ideas and oversee their development. The emergence of cocreated solutions important to patient care and quality improvement initiatives may provide higher value as new technologies are considered within the contexts of research and patient care.

7. CONCLUSIONS

The roles of digital technologies, big data, and precision health in healthcare are rapidly shifting from drivers of marginal efficiency to enablers of fundamental innovation, offering paradigm-shifting opportunities to change the way that patients and clinicians engage in mutual progress and success. It is important for the healthcare enterprise to embrace these changes and to organize its efforts to provide meaningful knowledge translation to meet its stakeholders' objectives. The agenda proposed herein identifies the multitude of factors that drive new technology development, and provides a roadmap that focuses on organizational strengths for building strategic partnerships. It also includes an inclusive and iterative process of evaluation, integration, engagement, and care efficiency that supports the research ecosystem, strengthens the clinical workforce, and trains the next generation of innovators.

This agenda is meant to be a starting point and assumes a level of flexibility required in dynamic and evolving fields. At the heart of the ACC's ongoing innovation efforts will remain continuous stakeholder engagement and feedback to better understand the high-impact accelerators that promote healthcare transformation and transparency, the drivers of patient and consumer

expectations, and those accelerants that enable the creation of new multidimensional datasets that provide rich insights for the next phase of research and patient care. By organizing new developments in digital health, big data, and precision health, and by creating learning methods that lead to continuous performance improvement and optimal practice management, the ACC will be well positioned to bring value to patients, clinicians, and stakeholders, and to play a key role in the future delivery of healthcare.

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REFERENCES

1. Daniel H, Sulmasy LS. Policy recommendations to guide the use of telemedicine in primary care settings: an American College of Physicians position paper. Ann Intern Med. 2015;163:787–9.

2. Cowie MR, Bax J, Bruining N, et al. e-Health: a position statement of the European Society of Cardiology. Eur Heart J. 2016;37:63–6.

3. Eapen ZJ, Turakhia MP, McConnell MV, et al. Defining a mobile health roadmap for cardiovascular health and disease. J Am Heart Assoc. 2016;5:e003119.

4. Califf RM, Robb MA, Bindman AB, et al. Transforming evidence generation to support health and health care decisions. N Engl J Med. 2016;375:2395–400.

5. Bhavnani SP, Narula J, Sengupta PP. Mobile technology and the digitization of healthcare. Eur Heart J. 2016;37:1428–38.

6. Hudson KL, Collins FS. The 21st Century Cures Act - a view from the NIH. N Engl J Med. 2017;376:111–3.

7. Dorsey ER, Topol EJ. State of telehealth. N Engl J Med. 2016;375:154–61.

8. Rumsfeld JS, Joynt KE, Maddox TM. Big data analytics to improve cardiovascular care: promise and challenges. Nat Rev Cardiol. 2016;13:350–9.

9. Topol EJ. Individualized medicine from prewomb to tomb. Cell. 2014;157:241–53.

10. Parikh VN, Ashley EA. Next-generation sequencing in cardiovascular disease. Circulation. 2017;135:406–9.

11. Shameer K, Badgeley MA, Miotto R, et al. Translational bioinformatics in the era of real-time biomedical, health care and wellness data streams. Brief Bioinform. 2017;18:105–24.

12. Miotto R, Li L, Kidd BA, et al. Deep patient: an unsupervised representation to predict the future of patients from the electronic health records. Sci Rep. 2016;6:26094.

13. Torkamani A, Andersen KG, Steinhubl SR, et al. High-definition medicine. Cell. 2017;170:828–43.

14. Neubeck L, Lowres N, Benjamin EJ, et al. The mobile revolution—using smartphone apps to prevent cardiovascular disease. Nat Rev Cardiol. 2015;12:350–60.

15. Topol EJ, Steinhubl SR, Torkamani A. Digital medical tools and sensors. JAMA. 2015;313:353–4.

16. Chan PH, Wong CK, Poh YC, et al. Diagnostic performance of a smartphone-based photoplethysmographic application for atrial fibrillation screening in a primary care setting. J Am Heart Assoc. 2016;5:e003428.

17. Abraham WT, Adamson PB, Bourge RC, et al. Wireless pulmonary artery haemodynamic monitoring in chronic heart failure: a randomised controlled trial. Lancet. 2011;377:658–66.

18. McManus RJ, Mant J, Haque MS, et al. Effect of self-monitoring and medication self-titration on systolic blood pressure in hypertensive patients at high risk of cardiovascular disease: the TASMIN-SR randomized clinical trial. JAMA. 2014;312:799–808.

19. Singh S, Bansal M, Maheshwari P, et al. American Society of Echocardiography: remote echocardiography with web-based assessments for referrals at a distance (ASE-REWARD) study. J Am Soc Echocardiogr. 2013;26:221–33.

20. Ramachandran A, Snehalatha C, Ram J, et al. Effectiveness of mobile phone messaging in prevention of type 2 diabetes by lifestyle modification in men in India: a prospective, parallel-group, randomised controlled trial. Lancet Diabetes Endocrinol. 2013;1:191–8.

21. Koehler F, Winkler S, Schieber M, et al. Impact of remote telemedical management on mortality and hospitalizations in ambulatory patients with chronic heart failure: the telemedical interventional monitoring in heart failure study. Circulation. 2011;123:1873–80.

22. Chow CK, Redfern J, Hillis GS, et al. Effect of lifestyle-focused text messaging on risk factor modification in patients with coronary heart disease: a randomized clinical trial. JAMA. 2015;314:1255–63.

23. Arora S, Kalishman S, Thornton K, et al. Project ECHO (Project Extension for Community Healthcare Outcomes): a national and global model for continuing professional development. J Contin Educ Health Prof. 2016;36 Suppl 1:S48–9.

24. Sengupta PP, Narula N, Modesto K, et al. Feasibility of intercity and trans-Atlantic telerobotic remote ultrasound: assessment facilitated by a nondedicated bandwidth connection. J Am Coll Cardiol Img. 2014;7:804–9.

25. Maragiannis D, Jackson MS, Igo SR, et al. Replicating patient-specific severe aortic valve stenosis with functional 3D modeling. Circ Cardiovasc Imaging. 2015;8:e003626.

26. Bhatia SN, Ingber DE. Microfluidic organs-on-chips. Nat Biotechnol. 2014;32:760–72.

27. Gurun G, Tekes C, Zahorian J, et al. Single-chip CMUT-on-CMOS front-end system for real-time volumetric IVUS and ICE imaging. IEEE Trans Ultrason Ferroelectr Freq Control. 2014;61:239–50.

28. Ndieyira JW, Kappeler N, Logan S, et al. Surface-stress sensors for rapid and ultrasensitive detection of active free drugs in human serum. Nat Nanotechnol. 2014;9:225–32.

29. Li J, de Ávila BE-F, Gao W, et al. Micro/nanorobots for biomedicine: delivery, surgery, sensing, and detoxification. Science Robotics. 2017;2:eaam6431.

30. Xu S, Zhang Y, Jia L, et al. Soft microfluidic assemblies of sensors, circuits, and radios for the skin. Science. 2014;344:70–4.

31. Dasgupta K, Rosenberg E, Joseph L, et al. Physician step prescription and monitoring to improve ARTERial health (SMARTER): a randomized controlled trial in patients with type 2 diabetes and hypertension. Diabetes Obes Metab. 2017;19:695–704.

32. Halcox JPJ, Wareham K, Cardew A, et al. Assessment of remote heart rhythm sampling using the AliveCor heart monitor to screen for atrial fibrillation: the REHEARSE-AF study. Circulation. 2017 Aug 28 [E-pub ahead of print]; http://circ.ahajournals.org/content/early/2017/08/28/CIRCULATIONAHA.117.030583.

33. Dehmer GJ, Jennings J, Madden RA, et al. The National Cardiovascular Data Registry Voluntary Public Reporting Program: an interim report from the NCDR Public Reporting Advisory Group. J Am Coll Cardiol. 2016;67:205–15.

34. Kumar S, Abowd GD, Abraham WT, et al. Center of excellence for mobile sensor data-to-knowledge (MD2K). J Am Med Inform Assoc. 2015;22:1137–42.

35. Gollamudi SS, Topol EJ, Wineinger NE. A framework for smartphone-enabled, patient-generated health data analysis. PeerJ. 2016;4:e2284.

36. Rumsfeld JS, Brooks SC, Aufderheide TP, et al. Use of mobile devices, social media, and crowdsourcing as digital strategies to improve emergency cardiovascular care. Circulation. 2016;134:e87–108.

37. Gouda P, Das D, Clark A, et al. The impact and implications of twitter for cardiovascular medicine. J Card Fail. 2017;23:266–7.

38. Sinnenberg L, Buttenheim AM, Padrez K, et al. Twitter as a tool for health research: a systematic review. Am J Public Health. 2017;107:e1–8.

39. Singer M, Bulled N, Ostrach B, et al. Syndemics and the biosocial conception of health. Lancet. 2017;389:941–50.

40. Pilling LC, Atkins JL, Bowman K, et al. Human longevity is influenced by many genetic variants: evidence from 75,000 UK Biobank participants. Aging (Albany NY). 2016;8:547.

41. Krumholz HM, Waldstreicher J. The Yale Open Data Access (YODA) Project—a mechanism for data sharing. N Engl J Med. 2016;375:403–5.

42. Huang H, Zhang P, Qu XA, et al. Systematic prediction of drug combinations based on clinical side-effects. Sci Rep. 2014;4:7160.

43. Angraal S, Krumholz HM, Schulz WL. Blockchain technology: applications in health care. Circ Cardiovasc Qual Outcomes. 2017;10:e003800.

44. Narula S, Shameer K, Omar AMS, et al. Machine-learning algorithms to automate morphological and functional assessments in 2D echocardiography. J Am Coll Cardiol. 2016;68:2287–95.

45. Mortazavi BJ, Downing NS, Bucholz EM, et al. Analysis of machine learning techniques for heart failure readmissions. Circ Cardiovasc Qual Outcomes. 2016;9:629–40.

46. Evans RS, Benuzillo J, Horne BD, et al. Automated identification and predictive tools to help identify high-risk heart failure patients: pilot evaluation. J Am Med Inform Assoc. 2016;23:872–8.

47. Scruggs SB, Watson K, Su AI, et al. Harnessing the heart of big data. Circ Res. 2015;116:1115–9.

48. Church GM, Gao Y, Kosuri S. Next-generation digital information storage in DNA. Science. 2012;337:1628.

49. Omar AMS, Narula S, Rahman MAA, et al. Precision phenotyping in heart failure and pattern clustering of ultrasound data for the assessment of diastolic dysfunction. J Am Coll Cardiol Img. 2017;10:1291–303.

50. Buggenthin F, Buettner F, Hoppe PS, et al. Prospective identification of hematopoietic lineage choice by deep learning. Nat Methods. 2017;14:403–6.

51. Shah RV, Yeri AS, Murthy VL, et al. Association of multiorgan computed tomographic phenomap with adverse cardiovascular health outcomes: the Framingham Heart Study. JAMA Cardiology. 2017 Sep 20 [E-pub ahead of print]; https://doi.org/10.1001/jamacardio.2017.3145.

52. McPherson R, Tybjaerg-Hansen A. Genetics of coronary artery disease. Circ Res. 2016;118:564–78.

53. Ehret GB, Ferreira T, Chasman DI, et al. The genetics of blood pressure regulation and its target organs from association studies in 342,415 individuals. Nat Genet. 2016;48:1171–84.

54. Fuchsberger C, Flannick J, Teslovich TM, et al. The genetic architecture of type 2 diabetes. Nature. 2016;536:41–7.

55. Santovito D, Egea V, Weber C. Small but smart: MicroRNAs orchestrate atherosclerosis development and progression. Biochim Biophys Acta. 2016;1861:2075–86.

56. Tang WW, Wang Z, Li XS, et al. Increased trimethylamine n-oxide portends high mortality risk independent of glycemic control in patients with type 2 diabetes mellitus. Clin Chem. 2017;63:297–306.

57. Tang WW, Wang Z, Fan Y, et al. Prognostic value of elevated levels of intestinal microbe-generated metabolite trimethylamine-N-oxide in patients with heart failure. J Am Coll Cardiol. 2014;64:1908–14.

58. Tang WW, Wang Z, Levison BS, et al. Intestinal microbial metabolism of phosphatidylcholine and cardiovascular risk. N Engl J Med. 2013;368:1575–84.

59. Ussher JR, Elmariah S, Gerszten RE, et al. The emerging role of metabolomics in the diagnosis and prognosis of cardiovascular disease. J Am Coll Cardiol. 2016;68:2850–70.

60. Wahl S, Drong A, Lehne B, et al. Epigenome-wide association study of body mass index, and the adverse outcomes of adiposity. Nature. 2017;541:81–6.

61. van der Harst P, van Setten J, Verweij N, et al. 52 genetic loci influencing myocardial mass. J Am Coll Cardiol. 2016;68:1435–48.

62. Burke MA, Cook SA, Seidman JG, et al. Clinical and mechanistic insights into the genetics of cardiomyopathy. J Am Coll Cardiol. 2016;68:2871–86.

63. Lubitz SA, Ozcan C, Magnani JW, et al. Genetics of atrial fibrillation: implications for future research directions and personalized medicine. Circ Arrhythm Electrophysiol. 2010;3:291–9.

64. Locke AE, Kahali B, Berndt SI, et al. Genetic studies of body mass index yield new insights for obesity biology. Nature. 2015;518:197–206.

65. Harper AR, Nayee S, Topol EJ. Protective alleles and modifier variants in human health and disease. Nat Rev Genet. 2015;16:689–701.

66. Doll JA, Neely ML, Roe MT, et al. Impact of CYP2C19 metabolizer status on patients with ACS treated with prasugrel versus clopidogrel. J Am Coll Cardiol. 2016;67:936–47.

67. Huang H, Darbar D. Genotype influence in responses to therapy for atrial fibrillation. Expert Rev Cardiovasc Ther. 2016;14:1119–31.

68. Zhang J, Xu S, Xu Y, et al. Relation of mitochondrial DNA copy number in peripheral blood to postoperative atrial fibrillation after isolated off-pump coronary artery bypass grafting. Am J Cardiol. 2017;119:473–7.

69. Assimes TL, Roberts R. Genetics: implications for prevention and management of coronary artery disease. J Am Coll Cardiol. 2016;68:2797–818.

70. Mega JL, Walker JR, Ruff CT, et al. Genetics and the clinical response to warfarin and edoxaban: findings from the randomised, double-blind ENGAGE AF-TIMI 48 trial. Lancet. 2015;385:2280–7.

71. Lubitz SA, Lunetta KL, Lin H, et al. Novel genetic markers associate with atrial fibrillation risk in Europeans and Japanese. J Am Coll Cardiol. 2014;63:1200–10.

72. Pasipoularides A. Genomic translational research: paving the way to individualized cardiac functional analyses and personalized cardiology. Int J Cardiol. 2017;230:384–401.

73. Karakikes I, Termglinchan V, Cepeda DA, et al. A comprehensive TALEN-based knockout library for generating human induced pluripotent stem cell-based models for cardiovascular diseases. Circ Res. 2017;120:1561–71.

74. Kehr B, Helgadottir A, Melsted P, et al. Diversity in non-repetitive human sequences not found in the reference genome. Nat Genet. 2017;49:588–93.

75. Liu P, Yuan B, Carvalho CM, et al. An organismal CNV mutator phenotype restricted to early human development. Cell. 2017;168:830–42.e7.

76. Hughey JJ. Machine learning identifies a compact gene set for monitoring the circadian clock in human blood. Genome Med. 2017;9:19.

77. Rand AC, Jain M, Eizenga JM, et al. Mapping DNA methylation with high-throughput nanopore sequencing. Nat Methods. 2017;14:411–3.

78. Shah SJ, Katz DH, Selvaraj S, et al. Phenomapping for novel classification of heart failure with preserved ejection fraction. Circulation. 2015;131:269–79.

79. Collins FS, Varmus H. A new initiative on precision medicine. N Engl J Med. 2015;372:793–5.

80. Shah SH, Arnett D, Houser SR, et al. Opportunities for the cardiovascular community in the precision medicine initiative. Circulation. 2016;133:226–31.

81. Joyner MJ, Paneth N, Ioannidis JP. What happens when underperforming big ideas in research become entrenched? JAMA. 2016;316:1355–6.

82. Washington V, DeSalvo K, Mostashari F, et al. The HITECH era and the path forward. N Engl J Med. 2017;377:904–6.

83. Sinsky C, Colligan L, Li L, et al. Allocation of physician time in ambulatory practice: a time and motion study in 4 specialties. Ann Intern Med. 2016;165:753–60.

84. Halamka JD, Tripathi M. The HITECH era in retrospect. N Engl J Med. 2017;377:907–9.

85. Khoury MJ, Galea S. Will precision medicine improve population health? JAMA. 2016;316:1357–8.

86. Mann DL, Newby LK. Will the precision medicine initiative transform cardiovascular translational research? J Am Coll Cardiol Basic Trans Science. 2016;1:298–9.

87. Kumar S, Nilsen WJ, Abernethy A, et al. Mobile health technology evaluation: the mHealth evidence workshop. Am J Prev Med. 2013;45:228–36.

88. Smoyer WE, Embi PJ, Moffatt-Bruce S. Creating local learning health systems: think globally, act locally. JAMA. 2016;316:2481–2.

89. English M, Irimu G, Agweyu A, et al. Building learning health systems to accelerate research and improve outcomes of clinical care in low- and middle-income countries. PLoS Med. 2016;13:e1001991.

90. Klann JG, Abend A, Raghavan VA, et al. Data interchange using i2b2. J Am Med Inform Assoc. 2016;23:909–15.

91. Lu CY, Williams MS, Ginsburg GS, et al. A proposed approach to accelerate evidence generation for genomic-based technologies in the context of a learning health system. Genet Med. 2017 Aug 10 [E-pub ahead of print].

92. Vasan RS, Benjamin EJ. The future of cardiovascular epidemiology. Circulation. 2016;133:2626–33.

93. Yusuf S, Rangarajan S, Teo K, et al. Cardiovascular risk and events in 17 low-, middle-, and high-income countries. N Engl J Med. 2014;371:818–27.

94. Dieleman JL, Baral R, Birger M, et al. US spending on personal health care and public health, 1996-2013. JAMA. 2016;316:2627–46.

95. National Academy of Medicine. Vital directions for health & health care: priorities from a National Academy of Medicine initiative. Available at: https://nam.edu/vital-directions-for-health-health-care-priorities-from-a-national-academy-of-medicine-initiative/. Accessed June 8, 2017.

96. American College of Cardiology. The ACC's strategic plan. Available at: http://www.acc.org/latest-in-cardiology/articles/2014/02/27/13/18/the-accs-strategic-plan. Accessed January 10, 2017.

97. Windle JR, Katz AS, Dow JP Jr., et al. 2016 ACC/ASE/ASNC/HRS/SCAI health policy statement on integrating the healthcare enterprise. J Am Coll Cardiol. 2016;68:1348–64.

98. Lloyd-Jones DM, Hong Y, Labarthe D, et al. Defining and setting national goals for cardiovascular health promotion and disease reduction: the American Heart Association's strategic Impact Goal through 2020 and beyond. Circulation. 2010;121:586–613.

99. O'Gara PT, Parakh K, Rumsfeld JS. The ACC and Google: engaging patients to promote guideline-based care. J Am Coll Cardiol. 2016;68:868–70.

100. Pasquali SK, Jacobs JP, Farber GK, et al. Report of the National Heart, Lung, and Blood Institute Working Group: an integrated network for congenital heart disease research. Circulation. 2016;133:1410–8.

101. Shuren J, Califf RM. Need for a national evaluation system for health technology. JAMA. 2016;316:1153–4.

102. Kish LJ, Topol EJ. Unpatients-why patients should own their medical data. Nat Biotechnol. 2015;33:921–4.

103. Jouni H, Haddad RA, Marroush TS, et al. Shared decision-making following disclosure of coronary heart disease genetic risk: results from a randomized clinical trial. J Investig Med. 2017;65:681–8.

104. von Thiele Schwarz U. Co-care: producing better health outcome through interactions between patients, care providers and information and communication technology. Health Serv Manage Res. 2016;29:10–5.

105. Okunrintemi V, Spatz ES, Di Capua P, et al. Patient-provider communication and health outcomes among individuals with atherosclerotic cardiovascular disease in the United States. Medical Expenditure Panel Survey 2010 to 2013. Circ Cardiovasc Qual Outcomes. 2017;10:e003635.

106. Mackay EA. Patients, consumers, and caregivers: the original data stewards. EGEMS (Wash DC). 2015;3:1173.

107. Bhavnani SP, Sola S, Adams D, et al. A randomized trial of pocket-echocardiography integrated mobile health device assessments in modern structural heart disease clinics. J Am Coll Cardiol Img. 2017 Sep 9 [E-pub ahead of print].

108. Taichman DB, Backus J, Baethge C, et al. Sharing clinical trial data—a proposal from the International Committee of Medical Journal Editors. N Engl J Med. 2016;374:384–6.

109. Sudlow C, Gallacher J, Allen N, et al. UK biobank: an open access resource for identifying the causes of a wide range of complex diseases of middle and old age. PLoS Med. 2015;12:e1001779.

110. Kostkova P, Brewer H, de Lusignan S, et al. Who owns the data? Open data for healthcare. Front Public Health. 2016;4:7.

111. Margolis R, Derr L, Dunn M, et al. The National Institutes of Health's Big Data to Knowledge (BD2K) initiative: capitalizing on biomedical big data. J Am Med Inform Assoc. 2014;21:957–8.

112. Krumholz HM, Kim J. Data escrow and clinical trial transparency. Ann Intern Med. 2017;166:893–4.

113. Devlin AM, McGee-Lennon M, O'Donnell CA, et al. Delivering digital health and well-being at scale: lessons learned during the implementation of the Dallas program in the United Kingdom. J Am Med Inform Assoc. 2016;23:48–59.

114. Ioannidis JP. Stealth research: is biomedical innovation happening outside the peer-reviewed literature? JAMA. 2015;313:663–4.

115. McGrath S, Ghersi D. Building towards precision medicine: empowering medical professionals for the next revolution. BMC Med Genomics. 2016;9:23.

116. Kvedar JC, Fogel AL, Elenko E, et al. Digital medicine's march on chronic disease. Nat Biotechnol. 2016;34:239–46.

117. Daniel H, Erickson S. Retail health clinics: a policy position paper from the American College of Physicians. Ann Intern Med. 2015;163:869–70.

118. Uscher-Pines L, Mulcahy A, Cowling D, et al. Antibiotic prescribing for acute respiratory infections in direct-to-consumer telemedicine visits. JAMA Intern Med. 2015;175:1234–5.

119. Ashwood JS, Gaynor M, Setodji CM, et al. Retail clinic visits for low-acuity conditions increase utilization and spending. Health Aff. 2016;35:449–55.

120. Martsolf G, Fingar KR, Coffey R, et al. Association between the opening of retail clinics and low-acuity emergency department visits. Ann Emerg Med. 2017;69:397–403.e5.

121. Annas GJ, Elias S. 23andMe and the FDA. N Engl J Med. 2014;370:985–8.

122. King K, Grazette LP, Paltoo DN, et al. Point-of-care technologies for precision cardiovascular care and clinical research: National Heart, Lung, and Blood Institute Working Group. J Am Coll Cardiol Basic Trans Science. 2016;1:73–86.

123. Lillie EO, Patay B, Diamant J, et al. The n-of-1 clinical trial: the ultimate strategy for individualizing medicine? Per Med. 2011;8:161–73.

124. Hoffmann TJ, Ehret GB, Nandakumar P, et al. Genome-wide association analyses using electronic health records identify new loci influencing blood pressure variation. Nat Genet. 2017;49:54–64.

125. Yingling LR, Mitchell V, Ayers CR, et al. Adherence with physical activity monitoring wearable devices in a community-based population: observations from the Washington, D.C., Cardiovascular Health and Needs Assessment. Transl Behav Med. 2017 Jan 17 [E-pub ahead of print].

126. Tian M, Ajay VS, Dunzhu D, et al. A cluster-randomized, controlled trial of a simplified multifaceted management program for individuals at high cardiovascular risk (SimCard Trial) in rural Tibet, China, and Haryana, India. Circulation. 2015;132:815–24.

127. Steventon A, Bardsley M, Billings J, et al. Effect of telehealth on use of secondary care and mortality: findings from the Whole System Demonstrator cluster randomised trial. BMJ. 2012;344:e3874.

128. McConnell MV, Shcherbina A, Pavlovic A, et al. Feasibility of obtaining measures of lifestyle from a smartphone app: The MyHeart Counts Cardiovascular Health Study. JAMA Cardiol. 2017;2:67–76.

129. World Health Organization. 2015 global survey on health technology assessment by national authorities. Available at: http://www.who.int/health-technology-assessment/MD_HTA_oct2015_final_web2.pdf?ua=1. Accessed January 10, 2017.

130. Sherman RE, Anderson SA, Dal Pan GJ, et al. Real-world evidence—what is it and what can it tell us? N Engl J Med. 2016;375:2293–7.

131. Schneider EC, Hall CJ. Improve quality, control spending, maintain access—can the Merit-Based Incentive Payment System deliver? N Engl J Med. 2017;376:708–10.

132. Office of the National Coordinator for Health Information Technology. Connecting health care for the nation: a shared nationwide interoperability map. Available at: https://www.healthit.gov/sites/default/files/nationwide-interoperability-roadmap-draft-version-1.0.pdf. Accessed January 10, 2017.

133. Wagholikar KB, Mandel JC, Klann JG, et al. SMART-on-FHIR implemented over i2b2. J Am Med Inform Assoc. 2017;24:398–402.

134. Mandel JC, Kreda DA, Mandl KD, et al. SMART on FHIR: a standards-based, interoperable apps platform for electronic health records. J Am Med Inform Assoc. 2016;23:899–908.

135. Rasmussen-Torvik LJ, Stallings SC, Gordon AS, et al. Design and anticipated outcomes of the eMERGE-PGx project: a multicenter pilot for preemptive pharmacogenomics in electronic health record systems. Clin Pharmacol Ther. 2014;96:482–9.

136. Johnson KW, Shameer K, Glicksberg BS, et al. Enabling precision cardiology through multiscale biology and systems medicine. J Am Coll Cardiol Basic Trans Science. 2017;2:311–27.

137. Papoutsi C, Reed JE, Marston C, et al. Patient and public views about the security and privacy of Electronic Health Records (EHRs) in the UK: results from a mixed methods study. BMC Med Inform Decis Mak. 2015;15:86.

138. Filkins BL, Kim JY, Roberts B, et al. Privacy and security in the era of digital health: what should translational researchers know and do about it? Am J Transl Res. 2016;8:1560–80.

139. Krumholz HM, Terry SF, Waldstreicher J. Data acquisition, curation, and use for a continuously learning health system. JAMA. 2016;316:1669–70.

140. Boeldt DL, Wineinger NE, Waalen J, et al. How consumers and physicians view new medical technology: Comparative survey. J Med Internet Res. 2015;17:e215.

141. Mafi JN, Mejilla R, Feldman H, et al. Patients learning to read their doctors' notes: the importance of reminders. J Am Med Inform Assoc. 2016;23:951–5.

142. Delaney SK, Hultner ML, Jacob HJ, et al. Toward clinical genomics in everyday medicine: perspectives and recommendations. Expert Rev Mol Diagn. 2016;16:521–32.

143. Cheung C, Bietz MJ, Patrick K, et al. Privacy attitudes among early adopters of emerging health technologies. PloS One. 2016;11:e0166389.

144. Harris C, Garrubba M, Allen K, et al. Development, implementation and evaluation of an evidence-based program for introduction of new health technologies

and clinical practices in a local healthcare setting. BMC Health Serv Res. 2015;15:575.

145. Krumholz HM. Big data and new knowledge in medicine: the thinking, training, and tools needed for a learning health system. Health Aff (Millwood). 2014; 33:1163–70.

146. Maddox TM, Albert NM, Borden WB, et al. The learning healthcare system and cardiovascular care: a scientific statement from the American Heart Association. Circulation. 2017;135:e826–57.

147. Chambers DA, Feero WG, Khoury MJ. Convergence of implementation science, precision medicine, and the learning health care system: a new model for biomedical research. JAMA. 2016;315: 1941–2.

148. Grady C, Cummings SR, Rowbotham MC, et al. Informed consent. N Engl J Med. 2017;376:856–67.

149. Bloss C, Nebeker C, Bietz M, et al. Reimagining human research protections for 21st century science. J Med Internet Res. 2016;18:e329.

150. Drain PK, Hyle EP, Noubary F, et al. Diagnostic point-of-care tests in resource-limited settings. Lancet Infect Dis. 2014;14:239–49.

151. Nebeker C, Lagare T, Takemoto M, et al. Engaging research participants to inform the ethical conduct of mobile imaging, pervasive sensing, and location tracking research. Transl Behav Med. 2016; 6:577–86.

152. Agarwal S, LeFevre AE, Lee J, et al. Guidelines for reporting of health interventions using mobile phones: mobile health (mHealth) evidence reporting and assessment (mERA) checklist. BMJ. 2016;352: i1174.

153. Lauer MS, Krumholz HM, Topol EJ. Time for a prepublication culture in clinical research? Lancet. 2015;386:2447–9.

154. Bhavnani SP, Munoz D, Bagai A. Data science in healthcare: implications for early career investigators. Circ Cardiovasc Qual Outcomes. 2016;9: 683–7.

155. Schwartz JG, Kumar UN, Azagury DE, et al. Needs-based innovation in cardiovascular medicine. J Am Coll Cardiol Basic Trans Science. 2016;1: 541–7.

156. Vaduganathan M, Ginsburg GS, Qamar A, et al. Preparing fellows for precision cardiology. are we ready? J Am Coll Cardiol. 2017;70:1675–9.

157. Sinha SS, Julien HM, Krim SR, et al. COCATS 4: securing the future of cardiovascular medicine. J Am Coll Cardiol. 2015;65:1907–14.

158. Nishimura RA, Warnes CA. Educating cardiovascular fellows in the contemporary era: developing competent cardiologists. JAMA Cardiol. 2017;2:119–20.

159. Majmudar MD, Harrington RA, Brown NJ, et al. Clinician innovator: a novel career path in academic medicine. A presidentially commissioned article from the American Heart Association. J Am Heart Assoc. 2015;4:e001990.

160. Nerbonne JM, Mann DL. Training the next generation of translational cardiovascular investigators : Is the pipeline half-full or half-empty? J Am Coll Cardiol Basic Trans Science. 2016;1:524–6.

161. Gubin TA, Iyer HP, Liew SN, et al. A systems approach to healthcare innovation using the MIT hacking medicine model. Cell Syst. 2017;5:6–10.

KEY WORDS **Health Policy Statement, big data, cardiovascular medicine, digital health, evidence-based medicine, healthcare acceleration, innovation, organization and administration, precision health**

APPENDIX 1. AUTHOR LISTING OF RELATIONSHIPS WITH INDUSTRY AND OTHER ENTITIES (RELEVANT)—2017 ROADMAP FOR INNOVATION—ACC HEALTH POLICY STATEMENT ON HEALTHCARE TRANSFORMATION IN THE ERA OF DIGITAL HEALTH, BIG DATA, AND PRECISION HEALTH

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This table represents the relationships of committee members with industry and other entities that were determined to be relevant to this document. These relationships were reviewed and updated in conjunction with all meetings and/or conference calls of the writing committee during the document development process. The table does not necessarily reflect relationships with industry at the time of publication. A person is deemed to have a significant interest in a business if the interest represents ownership of ≥5% of the voting stock or share of the business entity, or ownership of ≥$5,000 of the fair market value of the business entity; or if funds received by the person from the business entity exceed 5% of the person's gross income for the previous year. Relationships that exist with no financial benefit are also included for the purpose of transparency. Relationships in this table are modest unless otherwise noted.

According to the ACC, a person has a relevant relationship IF: a) the relationship or interest relates to the same or similar subject matter, intellectual property or asset, topic, or issue addressed in the document; or b) the company/entity (with whom the relationship exists) makes a drug, drug class, or device addressed in the document, or makes a competing drug or device addressed in the document; or c) the person or a member of the person's household, has a reasonable potential for financial, professional or other personal gain or loss as a result of the issues/content addressed in the document.

*Significant relationship.

†No financial benefit.

APPENDIX 2. REVIEWER RELATIONSHIPS WITH INDUSTRY AND OTHER ENTITIES (COMPREHENSIVE)—2017 ROADMAP FOR INNOVATION—ACC HEALTH POLICY STATEMENT ON HEALTHCARE TRANSFORMATION IN THE ERA OF DIGITAL HEALTH, BIG DATA, AND PRECISION HEALTH

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Jeff Nosanov	Content Reviewer—Individual	V-Sense Medical Devices—Founder and CEO	None	None	■ V-Sense Medical Devices*	None	None	None
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Bray Patrick-Lake	Content Reviewer—Individual	Duke CTSA—Director of Patient Engagement	None	None	None	None	None	None
Anthony W. Roberts	Content Reviewer—Individual	HCA Physician Services—Chief Information Officer	None	None	None	None	None	None

This table represents all relationships of committee members with industry and other entities that were reported by authors, including those not deemed to be relevant to this document, at the time this document was under development. The table does not necessarily reflect relationships with industry at the time of publication. A person is deemed to have a significant interest in a business if the interest represents ownership of ≥5% of the voting stock or share of the business entity, or ownership of ≥$5,000 of the fair market value of the business entity; or if funds received by the person from the business entity exceed 5% of the person's gross income for the previous year. Relationships that exist with no financial benefit are also included for the purpose of transparency. Relationships in this table are modest unless otherwise noted.
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*Significant relationship.

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Ashish Atreja, MD, MPH	Planning Committee/Speaker	Icahn School of Medicine at Mount Sinai—Chief Technology Innovation and Engagement Officer
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Joseph Hutter, MD, MA	Attendee	Centers for Medicare & Medicaid Services Center for Clinical Standards and Quality—Lieutenant Commander, U.S. Public Health Service
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Adam Landsman, MD, MS, MIS, MHS	Attendee	Brigham and Women's Hospital—Chief Information Officer
David Lansky, PhD	Attendee	Pacific Business Group on Health—Chief Executive Officer
Amir Lerman, MD, FACC	Attendee	Mayo Clinic—Professor of Medicine
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Erin MacKay	Attendee	National Partnership for Women and Families—Associate Director, Health Information Technology Programs
Thomas M. Maddox, MD, MSc, FACC	Attendee	BJC Healthcare/Washington University School of Medicine—Director, Health Systems Innovation Lab Washington University School of Medicine—Professor of Medicine (Cardiology)
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Rich Milani, MD, FACC	Attendee	Ochsner Health System—Chief Clinical Transformation Officer
David K. Nace, MD	Attendee	MarkLogic Corporation—Chief Medical Officer
Ira S. Nash, MD	Attendee	Northwell Health Physician Partners—Senior Vice President and Executive Director
Jeff Nosanov	Attendee	V-Sense Medical Devices—Founder and CEO
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JACC VOL. 70, NO. 21, 2017
NOVEMBER 28, 2017:2696–718

APPENDIX 3. CONTINUED

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Lisa Johnstone	Staff	American College of Cardiology—Associate, Executive Support, Science & Quality
Kim Kaylor	Staff	American College of Cardiology—Associate, Communications
Kathleen Hewitt	Staff	American College of Cardiology—Team Leader, Science & Quality Strategy and Innovation
Brendan Mullan	Staff	American College of Cardiology—Division Vice President, Market Strategy