Priorities for Cardiovascular Outcomes Research

A Report of the National Heart, Lung, and Blood Institute’s Centers for Cardiovascular Outcomes Research Working Group

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Abstract—The Centers for Cardiovascular Outcomes Research (CCORs) held a meeting to review how cardiovascular outcomes research had evolved in the decade since the National Heart, Lung, and Blood Institute 2004 working group report and to consider future directions. The conference involved representatives from governmental agencies, outcomes research thought leaders, and public and private healthcare partners. The main purposes of this meeting were to (1) advance collaborative high-yield, high-impact outcomes research; (2) identify priorities and barriers to important cardiovascular outcomes research; and (3) define future needs for the field. This report highlights the key topics covered during the meeting, including an examination of the recent history of outcomes research, an evaluation of the current academic climate, and a vision for the future of cardiovascular outcomes research. (Circ Cardiovasc Qual Outcomes. 2017;10:e001967. DOI: 10.1161/CIRCOUTCOMES.115.001967.)

Key Words: delivery of health care □ health services research □ heart □ outcome assessment (health care) □ United States

In 1999, the American Heart Association (AHA) held its first cardiovascular outcomes meeting. Five years later, the National Heart, Lung, and Blood Institute (NHBLI) formed a working group to define a road map for cardiovascular outcomes research, specifying key research priorities and training needs for the young discipline.1 That group also provided a succinct description of outcomes research: the study of the delivery and consequences of health care on outcomes from the perspective of patients, practitioners, and the healthcare system whose focus is on providing evidence to assess and promote the effectiveness of therapeutic interventions, enhancing the migration of best practice to clinical practice, improving decision making, elevating the quality of care, and supporting the optimal allocation of resources for all patients.1

Since then, the field has rapidly evolved and matured. The AHA created an interdisciplinary working group on cardiovascular outcomes and in 2008, recognized the group as a formal AHA Council. There are now several journals dedicated to cardiovascular outcomes, 2 supported by the AHA and the European Society of Cardiology. In 2009, the NHBLI further supported growth in the field when it solicited specific centers for cardiovascular outcomes research (CCORs).2 After a competitive call, 3 centers (University of Massachusetts Medical School, Yale University, and Boston Medical Center) and a research coordinating unit (Duke Clinical Research Institute) were selected to form a cardiovascular outcomes research network to support independent outcomes research projects, cross-institution methodological collaborations, and career development for early-stage investigators.3,4

As a capstone of the effort, the CCORs held a meeting from June 1, 2014, to June 2, 2014, to review how cardiovascular outcomes research had evolved in the decade since the NHBLI 2004 working group report and to consider future directions (Table). Beyond network participants, the conference involved representatives from NHBLI, other governmental agencies, including Centers for Medicare and Medicaid Services, Agency for Healthcare Research and Quality, Department of Veterans Affairs, and the Patient-Centered Outcomes Research Initiative (PCORI), outcome research thought leaders, and other public (eg, the Society for Participatory Medicine, United States).
PatientsLikeMe) and private healthcare partners (BlueCross/BlueShield, Kaiser, and Optum Laboratories; Table I in the Data Supplement). The main purposes of this meeting were to (1) advance collaborative high-yield, high-impact outcomes research; (2) identify priorities and barriers to important cardiovascular outcomes research; and (3) define future needs for the field.

This report highlights the key topics covered during the meeting, including an examination of the recent history of outcomes research, an evaluation of the current academic climate, and a vision for the future of cardiovascular outcomes research.

**A Look Back and a Look Forward**

The first NHLBI cardiovascular outcomes report outlined 4 top priorities, including (1) initiation of national disease surveillance programs, (2) promotion of patient-centered care, (3) translation of science into clinical practice, and (4) conduct of cost-effectiveness studies. A decade later, we reviewed the progress made.

**Surveillance Efforts**

In the last decade, the nation has seen substantial growth in national disease-based registries, including the AHA and the American Stroke Association Get With The Guidelines programs in heart failure, stroke, atrial fibrillation, and ambulatory care; the American College of Cardiology (ACC) National Cardiovascular Disease Registries programs, including acute myocardial infarction, sudden cardiac death and implantable cardioverter-defibrillators, coronary disease and percutaneous coronary disease intervention, valvular and vascular care, and ambulatory care; and the Society for Thoracic Surgeons National Cardiac Surgery Database, focusing on coronary artery bypass, valve, congenital heart, and thoracic surgeries and several others. In addition to the creation of these data warehouses, several of these cross-sectional registries have linked their clinical data with Medicare claims and other data sources to permit long-term outcomes assessment. Additionally, the evolution of safety surveillance networks and distributive research networks, such as the Mini-Sentinel developed by the food and drug administration, have led to many important outcomes studies that have moved the field forward and improved our understanding of how health care is delivered in the United States.

**Promotion of Patient-Centered Care**

The Institute of Medicine first emphasized the importance of patient-centered care and shared decision making in 2001 in their report Crossing the Quality Chasm. Participants in the 2004 NHLBI working group also highlighted the need for more patient-centered care and related research in 2004. Having patients, end users of scientific evidence, involved in the process of developing, conducting, and disseminating research continues to be a top priority for our field. The past 10 years have also seen the birth of both the national institutes of health (NIH)-led patient-reported outcomes measurement information system and PCORI. Patient-reported outcomes measurement information system’s goal is to support the development and proliferation of standardized tools for objectively measuring patient-reported outcomes. Since its inception, patient-reported outcomes measurement information system has facilitated the development and evaluation of >50 calibrated instruments and >300 publications. PCORI is an independent agency established by congressional legislation in 2010 with a mission to produce and promote high-quality evidence that comes from research guided by patients, caregivers, and the broader healthcare community. PCORI has placed a strong emphasis on the inclusion of patients throughout the research process and supports evaluating outcomes and interventions that are important to patients and families.

**Translation of Science into Clinical Practice**

National registry data have been leveraged for use in quality-improvement initiatives and to improve outcomes. The first of all major nationwide quality-improvement projects was the Cooperative Cardiovascular Project, sponsored in the 1990s by the federal agency that is now the Centers for Medicare and Medicaid. Cooperative Cardiovascular Project focused on the evidence-based management of acute myocardial infarction across all (≈6000 at the time) acute-care US hospitals. From then on, a series of large quality-improvement projects has demonstrated the potential to speed the adoption of evidence-based care on a national level. For example, the multi-sponsored CRUSADE (can rapid risk stratification of unstable angina patients suppress adverse outcomes with early implementation of the ACC/AHA guidelines) quality-improvement initiative has provided timely feedback and educational interventions to ≈400 US hospitals and has been able to demonstrate more rapid adoption of evidence-based guidelines for non-ST-elevation acute coronary syndromes. Similarly, the ACC has performed multiple successful national quality-improvement initiatives to improve door-to-balloon times and reduce readmissions, leveraging National Cardiovascular Disease Registries data to demonstrate baseline gaps and monitor improvement in practice. The industry-sponsored Get With The Guidelines Stroke initiative has reported that door-to-needle times for fibrinolytic therapy for stroke patients could be significantly improved with a national campaign designed to improve this using 10 simple strategies including better first-responder training and faster delivery of tPA (tissue-type plasminogen activator). Other examples include the industry-sponsored registry to improve the use of evidence-based heart failure therapies in the outpatient setting and the outcomes registry for better informed treatment of atrial
fibrillation. These national quality-improvement initiatives have been successful in demonstrating treatment gaps and disparities, improving adherence to treatment guidelines, and supporting the translation of evidence into practice.

Cost-Effectiveness Studies

Although some clinical trials have performed cost-effectiveness analyses, to date, most large multicenter clinical data registries have not assessed detailed cost information. The appropriations bill for PCORI stated that it would focus on comparative effectiveness research and prohibited it from making cost a primary focus of its funds. The bill stated that PCORI should not develop or use a dollars-per-quality adjusted life-year (or similar measure that discounts the value of a life because of an individual’s disability) as a threshold to establish what type of health care is cost effective or recommended and that it cannot use such an adjusted life-year (or such a similar measure) as a threshold to determine coverage, reimbursement, or incentive programs. Still, the reality of cost becoming a consideration in shaping authoritative recommendations for healthcare delivery is illustrated by the Choosing Wisely campaign and the ACC’s appropriate use criteria; these demonstrate that clinical societies are committed to providing appropriate and value-based care. In addition, the AHA/ACC now are considering cost-effectiveness analyses in the formation of their national clinical guidelines and performance measures. These efforts are in line with the growing national focus on value-based care, providing the best care possible, efficiently using resources, and achieving optimal results for every patient.

The Changing Landscape of Medicine in America

The past decade has seen major changes in health care in the United States. Emerging fiscal pressures have shifted historical methods of reimbursement based on fee-for-service payment to new systems, such as value-based reimbursement, accountable care organizations with shared savings, episode-based payments, and care management fees. The health care industry is moving from a producer-centered model to a patient-centered approach. Rather than focusing on clinical volumes, there is now greater emphasis on outcomes-driven care where patients, clinicians, administrators, and other stakeholders are focusing on use of best practices to improve outcomes. There is a transition from a reliance on surrogate outcomes to a realization of the use of outcomes. Stakeholders are better positioned to leverage health systems data from electronic health records (EHRs) using team-based care.

Funding for clinical and population-based research has also shifted rapidly. The growth in the NIH budget slowed down dramatically after 2003. Federal budget cuts, rising research costs, an increasing number of investigators, and continued growth of institutions have strained funding agencies. Federal funding slowdowns from the 2008 recession and 2013 budget sequestration have continued to worsen the funding crisis. The percentage of NIH grants that are funded has dropped from 30% to 10%, whereas there was a 37% drop in the number of new R01 awards between 2003 and 2012. Of note, whereas NIH’s annual budget has been hovering at 30 billion dollars for years, most of it going to bench research, the combined annual budget for outcomes or population-based research by other entities (Centers for Disease Control and Prevention, Veterans Affairs, PCORI, Agency for Healthcare Research and Quality, Centers for Medicare and Medicaid Services, and some foundations) has been in the 2- to 3-billion dollar range.

Future Priorities for Outcomes Research

During the CCOR meeting, several themes emerged on future research priorities for the coming decade.

1. Translation and Dissemination of Evidence into Practice (Implementation Science)

Despite progress during the past decade, most scientific discoveries have not been rapidly, fully, and appropriately translated into clinical practice. Evidence is often outdated by the time it permeates into real-world settings. The 4 steps (T1–T4) in the translation of laboratory discovery science into clinical settings need to be optimized, ranging from the translation of bench to humans (T1), to clinical trials (T2), to practice (T3), and to community health (T4). Regarding the latter steps, the NHLBI has organized internal retreats to discuss the dilemmas of doing more timely and meaningful research and has made a commitment to support T3/T4 translation research, focusing specifically on dissemination and implementation science. Their strategic vision is to sustain investigator-initiated portfolios; establish collaborative, iterative processes with our communities; identify critical knowledge gaps and compelling questions; and outline strategies for future investment of research dollars.

Outcomes research has made great strides in the past decade with the establishment of large national data registries. However, dissemination of information, rapid evaluation of best practices, and the incorporation of evidence into clinical practice remain crucial areas for improvement. Lessons learned through scientific investigation should penetrate to clinical care and population health. With the push toward participatory medicine—a model of care where the patients are actively engaged in their health care—comes a need to disseminate information not only to clinicians but also to patients. Key priorities for the future include implementation science resulting in greater dissemination and adoption of evidence in real-world settings, as well as a continued move toward precision medicine by delivering more personalized care to patients based on their individual genetics, environment, and behaviors.

2. Harnessing Big Data for Practical Research

At the CCOR meeting, Dr Richard Platt commented: “We have islands of data with seas of unanswered questions.” Although the number of clinical registries and data warehouses has grown, these centers of data continue to have few linkages across them. Engaged clinical organizations, patients, and collaborative frameworks are working to bridge these gaps. Early examples of distributed research networks, like Mini-Sentinel, have built a data-sharing infrastructure where multiple organizations can participate in multiple networks but still control their own governance and coordination. Such efforts have demonstrated that distributed research networks can provide valuable insight into disease surveillance and comparative effectiveness research. The Patient-Centered Outcomes Research Institute (PCORI) is a United States organization created to improve healthcare through the translation of evidence into practice. 3

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Research Network and the NIH Distributed Research Network have invested almost $300,000,000 and are now building networks that are designed to share infrastructure, data management, analytics, security, and software development to create new frameworks and methods for answering many key questions. The long-term hope is that these research frameworks will become self-sustaining.

In the coming years, EHRs and data from insurers and integrated health plans could be used to assist both clinicians and patients in shared decision making at the point-of-care. EHRs will allow the automatic population of data elements of registries. Instead of studies testing hypotheses in specific groups of people, data could be used from the point-of-care to help assess risks of complications at the time of admission, identify patients who may be at risk for adverse events, identify participants who may be eligible for clinical trials, and decrease readmissions to the hospital. Tempering this vision is the reality that current EHR data are highly variable in quality, and their use in research needs to account for this. The use of electronic clinical data for research may depend on health-care system maturity with EHRs and their resources to provide information technology infrastructure to support research efforts.

The rise of big data or large amounts of data that are collected on multiple fronts (healthcare, social media, and surveys) gives promise of future investigation to answer the key questions. Harnessing EHR and big data and making them available to improve public health will be a challenge in the years ahead, and analyzing the data so that they meaningfully contribute to the knowledge base will be particularly difficult. Many professional organizations are addressing these issues and attempting to define standards, educate professionals and the public, and build digital infrastructure for harnessing these data. There are many potential sources of error and bias, including data inaccuracy and incompleteness, and much work is needed to ensure that big data fulfill their promise and lead to statistically valid insights. In addition, enhanced biostatistical methods and advanced analytic methods like machine learning are critical to analyze data that exist along the continuum of research and in the middle ground between a priori stated hypotheses and data mining. To help mitigate bias and ensure data quality, the process of gathering and analyzing data should be transparent and include a complete and accurate description of the approaches, assumptions, and methods.

The use of point-of-care medical data in the delivery of health care in the United States is bolstered by the increasing number of pragmatic clinical trials using cluster randomization and EHR data. This is changing the research landscape by including data from patients in real-world clinical practice. Additionally, the push to merge genomic data and biobanks with EHR can help understand the variability in diseases and responses to treatment. Traditionally, randomized clinical trials have been plagued by strict inclusion and exclusion criteria, slow pace, and expenses, whereas observational outcomes research has been burdened by difficulty in accessing data, its descriptive nature, and barriers to moving beyond hypothesis generation. Pragmatic trials have the potential to unite these 2 worlds and create relevant evidence from readily available sources. Michael Lauer—the former director of the Division of Cardiovascular Sciences at the NHLBI and current NIH deputy director for extramural research—recommends the LEVIS (large/leveraged, embedded, valuable, inexpensive/innovative, and based in sound science) approach to pragmatic clinical trials. Forward-thinking national initiatives, like Patient-Centered Outcomes Research Network, are laying the groundwork for future pragmatic trials.

Although EHRs and big data offer great promise to the outcomes community for research and quality improvement, there are major challenges to overcome. Our current regulatory system has multiple roadblocks that will need modification or clarification to enable these initiatives and others to be successful in providing answers to clinical questions in a timely manner. Decades ago, the Department of Health and Human Services adopted the common rule for the protection of human subjects, outlining the basic requirements for informed consent, institutional review board consideration, and data monitoring. This framework has recently been updated to include more stringent rules for informed consent. Many have suggested possible new frameworks, such as calibrating the level of review with the level of risk and re-engineering to facilitate the development of a basic set of principles that protects patients while allowing researches to expand the knowledge base. For example, instead of traditional informed consent, the use of electronic health data will require researchers to use methods such as notification, opting out, and shortened consent forms. Institutional review boards may need to adopt more centralized methods used in multicenter trials, such as shared review or central review boards. Many multicenter trials include cluster randomization, where the unit of randomization is the hospital, clinic, or provider and not the individual patient, but the outcomes may be measured at the patient level. These types of trials raise ethical issues about identifying the research subject and nature of consent that will be required, as well as methodological issues of imbalance of characteristics at the patient level, statistical lack of independence of observations at the patient level, and challenge of estimating intracluster correlation coefficients.

3. Bringing Forth the Promise of Patient-Centered Care

The hopes of Patient-Reported Outcomes Measurement Information System, PCORI, and health research networks focusing on precision medicine include generating questions and new methods that are relevant to patients, to conduct studies in real-world settings with better patient participation and at lower cost, and to disseminate findings into practice more quickly through patients and stakeholders. Unlike other clinical studies that often have strict exclusion criteria and are only relevant to small subsets of the population, these groups aim to answer questions for broader groups of patients in real-world settings and also for patients with rare diseases who have historically struggled to get answers because of inadequate sample sizes. This orientation provides an opportunity to address health disparities in racial and ethnic minorities, older people, people living in poverty, and other vulnerable populations.

Currently, patient-centered outcomes research is still in its infancy with large gaps in assessing longitudinal outcomes, implementation, and integration of different health systems. Thus, a key priority should be to bridge these gaps and create...
a more integrated research framework. PCORI has aimed to address this issue by building a national network of 13 clinical data and 20 patient-powered research networks called Patient-Centered Outcomes Research Network.\textsuperscript{58,66} This initiative will facilitate studies that have traditionally not been done because of limitations of sample size, methodology, funding, and time constraints and will engage health social networks, crowdsourcing techniques, smartphone health applications, and EHRs.\textsuperscript{62} The first Patient-Centered Outcomes Research Network study, Aspirin Dosing: A Patient-Centric Trial Assessing Benefits and Long-Term Effectiveness (ADAPTABLE), has been initiated and will examine which aspirin dose is best to protect patients from heart disease.\textsuperscript{67}

Similar groups and efforts are also promoting community-based research. The Million Hearts campaign, a public–private partnership led by the Centers for Disease Control and Prevention and the Centers for Medicare and Medicaid Services aims to prevent 1 million heart attacks and strokes by 2017.\textsuperscript{72,73} It is focusing on population health through community-based interventions, including sodium restriction, tobacco cessation, and artificial transfat reduction.\textsuperscript{71} Also, the rise of mobile technology through medical devices, sensors, mobile health applications, and remote patient monitoring is allowing patients to collect their own data. By embracing a more grassroots approach to research, it is hoped that such strategies will better align payment incentives and allow for better care at lower cost.

4. Quality-Measurement/Improvement Collaboratives and Learning Networks

Provider-led clinical registries have consistently demonstrated that feedback and quality-improvement measures can create better care through motivated advocates, timely feedback, simple tools, and collaborative teams. Even though there have been dramatic advances in cardiovascular quality in the past decade,\textsuperscript{74} the question remains on exactly how to keep quality-improvement efforts consistent with the least amount of burden to providers. The movement toward increased use of technology in health care, including EHRs and clinical decision support tools, may help move the field in this direction.

The Institute of Medicine has articulated a vision of a learning healthcare system wherein data collected at the point-of-care are used for continuous learning, quality improvement, and research.\textsuperscript{75} In this context, a goal for outcomes research is to ensure that scientific investigation, quality improvement, and clinical care are iterative and complementary, thereby creating a sustainable healthcare system.\textsuperscript{75} Although this vision remains largely aspirational, the culmination of the work being done by all these agencies and the recent work with pragmatic trials and distributed networks helps get the systems incrementally closer to the envisioned learning healthcare system. Innovative methods for collecting, analyzing, and distributing data will be necessary, and this may require different incentives for researchers and perhaps an expansion into the realms of entrepreneurialism. However, rules on conflicts of interest may conflict with this expansion.

5. Training the Next Generation

Training in outcomes research has been more structured and readily available during the past decade through programs like the NHLBI’s CCOR and AHA’s Pharmaceutical Roundtable Outcomes Research program.\textsuperscript{5,76} Moving forward, there needs to be more group mentorship and training in both academic and nonacademic settings. Trainees and researchers will need to collaborate more than ever, working in interdisciplinary teams and across different systems. They will need new data skills in areas like informatics, demographics, economics, and marketing. The coming decade has multiple healthcare forces at play—greater accountability for outcomes through bundling, public reporting, and accountable care organizations with a focus on improving quality while also maintaining cost neutrality. Outcomes researchers will need to develop an armamentarium of diverse skills and expertise, and they will need to be trained not only as researchers but as true leaders.

To translate research into practice and to disseminate and implement important findings, future outcomes researchers will need expertise not only in policy and innovation but also in management and entrepreneurship. They will need to embrace new technology like smartphone apps and will need to conduct research using new methodologies like crowdsourcing.\textsuperscript{77} Also, there will need to be shifts in the type of positions new graduates are looking for after training, including both traditional academic paths and private settings. Government funds are diminishing, but the researchers present were optimistic about pursuing outcomes future research, despite the changing fiscal climate and the pressure to acquire funding through private groups and pharmaceutical companies.

Conclusions

The field of outcomes research has evolved during the past decade with the development of large data registries and silos of data, but, unlike a decade ago, much outcomes research is now conducted with nontraditional tools and partners. With the growth of the learning health system, it is imperative that we keep research, quality improvement, and clinical care complementary and iterative. We will need to enhance the incorporation of patient-reported outcomes into routine care delivery and create integrated data systems that inform not just health systems but also community health. By improving the sustainability of novel research methods and infrastructure, we hope to foster innovation and discovery, optimism in trainees, promote cross collaboration, and transform the way health care is delivered.

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**Supplemental Table. NHLBI CCOR Think Tank Meeting Directory, June 2014**

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