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The Benefits of Moving Quality to a National Level

Robert M. Califf, MD, MACC

Editor-in-Chief, American Heart Journal, Vice Chancellor for Clinical Research, Director, Duke Translational Medicine Institute, Duke University Medical Center, Durham, NC 27710, robert.califf@duke.edu

This issue of the *American Heart Journal* contains major updates on the accomplishments of the U.S. cardiovascular community over the past several decades, as we have struggled to reduce the impact of acute coronary syndromes (ACS), the leading cause of death in economically developed regions. Considered broadly, these three articles^{1–3} validate a construct that in retrospect seems obvious. Its practical implementation, however, was technologically impossible two decades ago, and the necessary social organization was imagined by only a few visionaries. Careful evaluation of this successful paradigm may point the way for organized medical care to approach most illnesses and illuminate issues that must be addressed in order to achieve the next level of wide application of effective therapies.

An increasing number of experts have concluded that individual clinics, hospitals, and practices can use continuous quality improvement principles to provide better health care. The concepts of prevention of medical errors⁴ and the multiple dimensions of quality,⁵ as articulated by the Institute of Medicine (IOM), include safety, efficacy, timeliness, patient-centered care, efficiency, and equity. More recently, the IOM has emphasized that the best opportunity for conquering these significant challenges will arise from a transformation of our systems of healthcare delivery into “learning health systems.”⁶ These three manuscripts describe how a community of practitioners and researchers can create a learning system on a national basis, yielding substantial benefits for our patients, as well as helping to clearly define a mission that requires the joint efforts of cardiovascular professionals, the medical products industry, regulators, administrators, and eventually, patients, as this model is extrapolated to the outpatient arena.

The construct of the “cycle of quality⁷” (Figure) evolved from the work of thousands of dedicated investigators, clinicians, and administrators, who helped orchestrate therapeutic elements that heretofore had been disjointed and chaotic. Fueled by the National Institutes of Health (NIH) in the United States, by publicly funded science agencies in other countries, and by research and development efforts in the biomedical products industry, our understanding of the biology of ACS has continued to unfold in amazing ways. Distilling rarified scientific knowledge into useful diagnostic and therapeutic technologies has proven to be a major challenge, however. Once a technology is “packaged,” it is examined in preclinical and early-phase proof-of-concept studies prior to definitive phase III clinical trials, which must be completed before the product is allowed on the market. After a product is marketed, or a procedure or technology begins to be used in practice in a variety of additional observational studies, clinical trials and registries accrue new data on that

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product's applicability to clinical practice. Professional organizations are then charged with developing clinical practice guidelines⁸ to sort through disparate sources of data and translate this information into knowledge that can be used to guide clinical decisions. The most definitive therapeutic principles are distilled into performance measures that provide an estimate of the quality of practice. Central to the entire effort is an emphasis on data acquisition and education related to empirical findings within the community of practice.

The first manuscript¹ in this trilogy, by Peterson and colleagues, demonstrates that the use of effective therapies has continuously improved across the spectrum of treatment for myocardial infarction (MI) in an enormous national sample. Further, these improvements account for an estimated 37% of the overall improvement in mortality among this population; indeed, the overall reduction in ST-segment elevation myocardial infarction (STEMI) mortality is saving an additional 35 patients per 1000 treated, while the corresponding life saving for non-ST-segment elevation myocardial infarction (NSTEMI) is 19 per 1000. Or, to put it another way: in 1990, 115 of every 1000 STEMI patients reaching hospital died, while only 80 of 1000 died in 2006; the corresponding numbers for NSTEMI patients are 71 per thousand in 1990 versus only 52 in 2006.

The second manuscript,² by Gibson and colleagues, focuses on acute reperfusion therapy and confirms an improvement in the speed of care delivery for both fibrinolytic treatment and direct percutaneous intervention (PCI). The decline in mortality for direct PCI was spectacular: a reduction from 8.6% to 3.1%, a significant portion of which was due to implementation of more rapid treatment protocols.

Finally, Rogers and colleagues³ document an overall reduction of 23% in the mortality of the spectrum of STEMI and NSTEMI patients with acute ischemic symptoms upon arrival at the emergency department.

While the cardiovascular community deserves to celebrate these successes, there remains much work to do, both within the community and beyond. Looking to the future, elements of the quality cycle deserve serious consideration at each step along the path to improved healthcare outcomes.

First, the fundamental nature of discovery science is changing as mechanistic biology merges with systems biology, yielding a much more comprehensive view of molecular and physiological targets of therapy. To date, cardiovascular therapeutics have been dominated by a combination of broad therapies proven to work "across the board" in relevant populations, coupled with the use of specific procedures and devices in selected patients. The coming wave of biological science will focus on the complex molecular signatures and pathways that undergird the development and progression of long-term diseases.⁹ This is likely to lead to a new view of such diseases, a view based on characterization of individuals and populations using integrated biomarkers consisting of molecular imaging "signatures," together with assessments of how these signatures change over time. Dealing with this more insightful (but correspondingly more complex) conception of biology will require major adjustments in our systems of translational research; this adjustment must include the reconfiguration of our academic medical center training programs. This transformation will serve a twofold purpose: it will prepare new generations of researchers to further advance this science; and it will educate practitioners to help them assimilate and effectively deploy tools that will transfigure clinical medicine.

Second, numerous recent findings underscore the inescapable fact that the balance of benefit and risk for a given therapy cannot be understood unless it is tested in a series of adequate clinical trials, in the appropriate setting, for the appropriate duration, in the population in whom the treatment is intended to be used. Several key adjustments in the current system by

which evidence is generated through clinical trials must be made in order to produce the knowledge needed to guide practice. We need an enhanced research environment in which early-phase human studies can accurately measure the integrated biology of proposed therapies in individuals, including effects both related and unrelated to the intended therapeutic target; the outcome of this effort will depend in large part on the successful transformation of our academic medical centers by the NIH through its Clinical and Translational Sciences Awards (CTSA) (www.ctsaweb.org).

Third, while the academic, practice, and regulatory communities for ACS have been relentless in demanding appropriate evidence, our present system of later-phase clinical trials is threatened by escalating bureaucracy and costs.¹⁰ Public-private partnerships will be needed to develop new, streamlined systems of clinical research (www.trialstransformation.org). Finally, in the United States and elsewhere, we must continue to forge approaches that enable practitioners to conduct clinical trials within the context of their practices, despite the many other demands on their time.

Fourth, the power of the findings in this issue of the *Journal* emphasizes the critical importance of maintaining a system in which clinical practice guidelines and quality measures reside in a trusted professional environment. High-profile concerns about conflicts of interest in this arena serve as a warning that continued empirical study and policy analysis of the constitution and functioning of guidelines committees is required if a societal consensus is to be reached.¹¹ In addition to safeguarding public trust in guidelines, renewed efforts should be directed toward developing an efficient system of updating guidelines in a balanced fashion, so that relevant professional consensus is readily available to practitioners.

Fifth, the issue of pay-for-performance will continue to evolve, and it is imperative that we continue to evaluate both the intended and unintended consequences of such systems.¹² A recent report from the United Kingdom¹³ has documented that the national system of pay for quality has had a significant effect, reducing inequalities in care related to the economic statuses of the practices and their patients.

Sixth, by continuously measuring quality in its multiple dimensions, we will be able to detect gaps in knowledge and its appropriate application. A recent review of the American College of Cardiology/American Heart Association (ACC/AHA) Clinical Practice Guidelines found that the proportion of recommendations based on Level of Evidence A continues to hover at less than 15%.¹⁴ In general, although our approaches to evidence generation are improving, they do so slowly, while ignoring some fields (such as valvular heart disease) almost entirely. We must develop systematic approaches to defining gaps in our knowledge, so that the evidence-generating endeavors within the healthcare system can be directed toward the most important questions.

Finally, the central role of education and data assessment must be supported and reinvigorated. Communications and information technologies and the capacity to aggregate data continue to improve at remarkable rates. Most recently, the entry of technology giants Microsoft® and Google™ into the spheres of electronic health records (EHRs) and medical data repository technology signals that further major improvements in the retrieval and storage of medical data are on the horizon.¹⁵ The countervailing force to improved use of aggregated data to inform practice is increasing time pressure on practitioners. There is reason to believe, however, that over time we can develop interdigitating systems of data collection that will include EHRs (providing longitudinal information on individual patients from single practices or health systems), personal health records (providing continuous information across health systems, which the patient controls) and disease registries (providing detailed data on particular medical problems across practices and health

systems). The development of sophisticated disease registries should be a primary professional activity of organizations such as the ACC, the AHA, and the European Society of Cardiology (ESC). As approaches to building data repositories improve, more and more of these data will be available to practitioners and researchers, leading to a better understanding of the effect of therapies and systems of care on clinical outcomes, as well as how best to apply therapies to individual patients in a more refined manner. Preparing practitioners for this future, however, will require continuous educational efforts, and serious consideration must be given to enabling practitioners to take adequate time to learn to deal with the potent new approaches to decision support made possible by this powerful information technology.

Another important lesson contained in these manuscripts is that effective public-private partnerships can engender major improvements in public health. The effort described here began with a disease registry initiated and funded by Genentech in order to track the treatment of STEMI; a similar registry for non-ST-elevation ACS was initially funded by Cor Therapeutics, Millennium Pharmaceuticals, and Schering Corporation.¹⁶ Both efforts were characterized by the formation of independent steering committees comprising leaders in academia and practice, who were given access to raw data and were able to publish their findings without preconditions or interference.

The motivation for the formation of these registries doubtless was not purely in the interest of public health; each of these companies had a stake in therapies used for these clinical scenarios. Due to the implementation of appropriate rules and operational methods, however, the partnership fostered quality improvement initiatives that have led to remarkable improvements in outcomes, broad improvements in knowledge through hundreds of publications, and eventually to an enduring disease registry housed among professional societies (the ACC and the AHA), with analytic centers at several major academic institutions (Duke University, St. Luke's Mid America Heart Institute, and Yale University).¹⁷ While inappropriate conflicts of interest must be eschewed, methods for defining and encouraging proper arrangements for shared activity between industry and practice must replace the current trend towards discouraging any relationships among industry, practice, and academia.

These spectacular accomplishments by the cardiovascular community and its many constituents should be recognized and lauded. But we cannot afford to rest on our laurels, given the massive increase in the population at risk for cardiovascular disease and the corresponding waves of obesity, diabetes, and sedentary lifestyles. This issue of the *American Heart Journal* offers a model for quality improvement at a national level capable of improving the plight of the population at risk, while providing a common ground for the combined efforts of all sectors of the healthcare system, and perhaps even serving as a platform to support global efforts aimed at curbing the impact of cardiovascular disease.

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Figure.