



*A Tradition of  
Leadership and Service*

**Cardiovascular Diseases  
Cardiovascular Surgery  
Pediatric Cardiology**





*Inspired by our Past...*  
*Innovating for the Future*





Dear Colleague,

Since the development of cardiology as a subspecialty, members of the divisions of cardiovascular diseases at Mayo Clinic have provided leadership, expertise, and innovation to the field. In 1922, Fredrick A. Willius, MD, was appointed the first chair of the newly organized Section of Cardiology at Mayo Clinic. The vision of Dr Willius set the standard for the future of the division through the integration of clinical practice, education, and scientific research. He embraced new technology as an important adjunct to clinical practice and introduced many innovations. From its inception, cardiology at Mayo Clinic has involved collaboration with colleagues in surgery, pathology, and physiology and other specialties.



Beyond providing clinical, scientific, and educational leadership, members of our divisions of cardiovascular diseases have provided stewardship and leadership to the profession through participation in numerous national societies. Prominent among these have been the American Heart Association and the American College of Cardiology. As subspecialty societies have grown, members of the divisions have continued to serve as participants, committee chairs, and leaders. These individuals combine the unique expertise of the busy clinician, the medical scholar, and the national leader. We are pleased to bring these perspectives to you from members of the divisions of cardiovascular diseases.



It is evident that the pace of change in recent years has accelerated, and while the specialty of cardiology continues to grow and innovate, it now struggles with the new challenges of health care reform and hospital-based practice. As we enter this next era of medicine, we are confident that members of the divisions will continue to serve the profession in the best interests of our patients.

**Charanjit S. Rihal, MD, MBA**

Chair, Division of Cardiovascular Diseases, Mayo Clinic in Rochester

**Win-Kuang Shen, MD**

Chair, Division of Cardiovascular Diseases, Mayo Clinic in Arizona

**Issam D. Moussa, MD**

Chair, Division of Cardiovascular Diseases, Mayo Clinic in Florida



Dear Colleague,

Members of our divisions of cardiovascular surgery at Mayo Clinic take this opportunity to provide you with an update of our divisional activities. Our members have comprehensive and varied areas of expertise, and each is a leader in his or her respective field. Subspecialty areas include aortic and endovascular, pediatric and adult congenital, minimally invasive/robotic, valve repair, arrhythmia, assist device, and transplant surgery as well as hybrid procedures. Our goal is to provide the highest quality care and safety to each and every one of our patients. Our practice style is a multidisciplinary team approach coordinating efforts from medical and surgical specialties and allied health staff. To that end, the cardiovascular surgery practice integrates clinical care, education, and research in order to provide state-of-the-art care and to develop data-driven, evidence-based best clinical practices.

The future holds many challenges and promises for our specialty. Minimally invasive surgery has become the standard of care for some procedures, placement of assist devices is an everyday operation for end-stage heart failure, reoperations are surpassing primary operations for many disease entities, and collaboration with our medical colleagues with a combined hybrid approach addresses complex cardiovascular problems at lower risk. We aim to provide the highest quality cardiac surgery care at reduced costs as we move forward. We at Mayo Clinic are committed to providing leadership and innovation to our profession as we navigate these challenges, always remembering that “the best interest of the patient is the only interest to be considered.”



Joseph A. Dearani, MD

Chair, Division of Cardiovascular Surgery, Mayo Clinic in Rochester

Francisco A. Arabia, MD

Chair, Division of Cardiovascular and Thoracic Surgery, Mayo Clinic in Arizona

Kevin P. Landolfo, MD

Chair, Section of Cardiothoracic Surgery, Mayo Clinic in Florida





Dear Colleague,

The Division of Pediatric Cardiology at Mayo Clinic was established under the leadership of James DuShane, MD, in the late 1950s. Over the intervening years, members of the division have provided the highest quality care for children with heart disease. Members of our division have diverse backgrounds and are experts in the many aspects of care for patients with congenital heart disease. The congenital echocardiography group has been a national and international leader. Our division publishes cutting-edge research in this area and recently published a seminal textbook on echocardiography for children and adults with congenital heart disease.

Mayo Clinic in Rochester provides comprehensive care for patients with congenital heart disease. This care begins before birth with the use of state-of-the-art prenatal diagnosis. Neonatal surgical results at Mayo are comparable to those of the best centers in the world. Comprehensive care is provided at Mayo for patients with congenital heart disease from before birth through old age. The great successes in congenital cardiac surgery over the last several decades have improved longevity and provided meaningful quality to the lives of patients with congenital heart disease. Currently in the United States, there are more adults than children with congenital heart disease. One of the most exciting aspects of the Mayo Clinic program in pediatric cardiology is the regenerative medicine collaborative project, in which pluripotent stem cells are being inserted into congenitally malformed hearts in an attempt to improve ventricular function.

The Division of Pediatric Cardiology has for over 60 years placed the needs of the patient first. Our paramedical staff, trainees, and consulting staff strive on a daily basis to fulfill this time-honored goal.

**Frank Cetta, MD**

Chair, Division of Pediatric Cardiology, Mayo Clinic in Rochester



## **NATIONAL SOCIETY LEADERSHIP**

Current and former Mayo Clinic physicians continue to provide national and international leadership to their professional organizations.

### **American Association of Cardiovascular and Pulmonary Rehabilitation**

Randal J. Thomas, MD (President, 2009-2010)

### **American Association for the History of Medicine**

W. Bruce Fye, MD, MA (President, 2008-2010)

### **American Association for Thoracic Surgery**

Samuel Robinson, MD (President, 1921-1922)

Stuart W. Harrington, MD (President, 1937-1938)

O. Theron Clagett, MD (President, 1961-1962)

John W. Kirklin, MD (President, 1978-1979)

Dwight C. McGoon, MD (President, 1983-1984)

Robert B. Wallace, MD (President, 1994-1995)

Hartzell V. Schaff, MD (President, 2011-2012)

Fredrick A. Willius, MD

First chair, Division of Cardiovascular Diseases, Mayo Clinic

### **American College of Cardiology**

Robert O. Brandenburg, MD (President, 1980-1981)

Robert L. Frye, MD (President, 1991-1992)

W. Bruce Fye, MD, MA (President, 2002-2003)

David R. Holmes Jr, MD (President, 2011-2012)

### **American Heart Association**

Arlie R. Barnes, MD (President, 1947-1948)

Edgar V. N. Allen, MD (President, 1956-1957)

Jesse E. Edwards, MD (President, 1967-1968)

John T. Shepherd, MD (President, 1976-1977)

Valetin Fuster, MD, PhD (President, 1998-1999)

Raymond J. Gibbons, MD (President, 2006-2007)

### **American Society for Clinical Pharmacology and Therapeutics**

Andre Terzic, MD, PhD (President, 2004-2005)

### **American Society of Echocardiography**

Bijoy K. Khandheria, MD (President, 2005-2006)

Patricia A. Pellikka, MD (President, 2011-2012)

### **American Osler Society**

W. Bruce Fye, MD, MA (President, 1988-1989)

### **Heart Rhythm Society**

David L. Hayes, MD (President, 1998-1999)

Stephen C. Hammill, MD (President, 2004-2005)

Douglas L. Packer, MD (President, 2010-2011)

### **NHLBI Cardiovascular Cell Therapy Research Network**

Robert D. Simari, MD (National Chair, 2010-present)

### **Pulmonary Hypertension Association**

Michael D. McGoon, MD (Chair,  
Board of Trustees, 2006-2008)

### **Society for Cardiovascular Angiography and Interventions**

David R. Holmes Jr, MD (President, 1995-1996)



W. Bruce Fye, MD, MA

Past President,  
American College of Cardiology

Past President,  
American Association for the  
History of Medicine

Past President,  
American Osler Society


## Mayo Clinic Cardiovascular Specialists as Presidents of National Professional Organizations

Several Mayo Clinic cardiovascular specialists have held leadership positions in national organizations. Since 1947, ten staff members have served as president of the two largest organizations, the American Heart Association (AHA) and the American College of Cardiology (ACC). Other Mayo cardiologists have led national societies representing special fields such as interventional cardiology, electrophysiology, and echocardiography. In the addresses published in the official journals of these organizations, the AHA and ACC presidents discussed a range of scientific, social, and economic issues that continue to attract the attention of physicians and others interested in medical practice, biomedical research, and health care delivery. The following excerpts reveal both the timeliness and timelessness of some of their concerns.

### The National Heart Act and Institute—1948

Arlie R. Barnes, Mayo Clinic's second heart specialist, was midway through his residency when the Cardiovascular Division was created in 1922. The AHA was founded two years later in New York City. Barnes was the organization's 13th president (1947-1948). He led the AHA during one of the seminal events in its history—its transformation from a professional society into a voluntary health organization that raised money for research. Immediately after World War II, there was broad public support for increasing the nation's investment in biomedical research. A *New York Times* article entitled "Doctors Advocate U.S. Heart Institute" reported Barnes's remarks at the 1947 AHA meeting.

Professor Arlie R. Barnes of the Mayo Foundation for Medical Education and Research, who was elected president of the American Heart Association, urged Congress to take favorable action on the Javits bill which, he said, 'was urgently needed to provide the resources to defend the nation against diseases of the heart and circulation which are taking the greatest toll of American lives.' More than 587,000 men, women and children, Dr. Barnes said, died of diseases of the heart and blood



vessels during 1945. ‘This figure,’ he continued, ‘represents almost twice the number of Americans who lost their lives in battle during World War II. Deaths from these diseases are three times as high as cancer... eleven times as high as tuberculosis, and at least 500 times as high as infantile paralysis.... Despite these appalling facts, the campaign against heart disease has been the last to receive public recognition and financial support,’ he added.

In the spring of 1948, congressional lawmakers debated a bill termed the National Heart Act that was designed to “provide for research and control relating to diseases of the heart and circulation.” Barnes told members of a senate subcommittee that a major investment in research would result in a steady stream of discoveries and innovations that, in turn, would improve the diagnosis, treatment, and prevention of heart disease.

### **The Public’s Role in Funding Research—1956**

Edgar V. N. Allen became AHA president in 1956. In his presidential address, the Mayo vascular specialist said that the association would spend \$6 million for research that year. He complained, however, that this represented a “per-capita investment in health of only a trifle more than 3 cents.” Hoping to animate AHA members, Allen argued,

The program of medical research represents rebellion against physical deterioration, but the rebellion is still so small that it seems to be hardly more than an insurrection. More scientific minds, more buildings, and more equipment are urgently needed. Almost everyone has had some sorrowful experience with the disease of the heart or blood vessels, or both. Almost everyone we know—a member of his family, a close personal friend, a neighbor or an associate—almost certainly will have or does have heart trouble, or he suffers from the effects of a stroke, of

failure of the kidneys to work properly or of poor circulation to the legs. When we consider such all-pervasive facts, we see clearly that there is actually no need to defend a nation-wide, cohesive, planned attack on diseases of the heart and blood vessels.

### **National Research Policy—1973**

John T. Shepherd, an Irish-American cardiovascular physiologist, became president of the AHA in 1976. Three years earlier, he delivered the Lewis A. Conner Memorial Lecture at the association's annual meeting. He noted that this was the 25th anniversary of the AHA's transformation into a voluntary health organization. Shepherd told his audience that since that time the association's primary focus was on "the support of acquisition of new knowledge through research." He decried recent cuts in the federal funding of research and training grants as well as a new emphasis on applied research.

These are troubled times for the biomedical scientist, who is confused by the lack of a consistent national policy for research. I hope that the American Heart Association will continue, as in the past, to demonstrate how much can be achieved by supporting the man of ideas and especially the young and promising scientist through the critical years of his training. By this example we may help to counter the erroneous concept, so popular today, that the scientist who is corralled by bureaucracy and made 'relevant to society' can find the cause and cure of disease more quickly than can the unfettered man of ideas.

### **The Appropriate Use of Technology—1980**

An avalanche of new diagnostic technologies in the 1960s and 1970s completely transformed the care of heart patients and the practice of cardiology. Robert O. Brandenburg (ACC president 1980-1981) wrote about challenges faced by clinical cardiologists who tried to decide which technologies to use to help understand a patient's history and physical findings, make a diagnosis, and develop a treatment strategy.

The wise, mature, and skillful cardiovascular clinician usually...learns to give proper emphasis and de-emphasis to the huge amount of data now potentially available and attainable. The important characteristics

of selectivity have become well developed in this clinician. He or she does not need an echocardiogram, treadmill test, nuclear studies and cardiac catheterization for every patient with a significant cardiac lesion.... The clinician gains stimulation and is challenged to develop a management scheme for the patient with a thoughtfully chosen, limited number of special studies. The patient's course is likely to be enhanced and much less expensive with this course of action.... As consultants and teachers we must make wise and intelligent use of these new tools to avoid both overuse and underuse.

### **The Medicare Fee Schedule—1991**

Robert L. Frye (ACC president 1991-1992) published a President's Page on the Medicare Fee Schedule in November 1991, six weeks before the Resource-Based Relative Value Scale (RBRVS) was implemented. This new system would be used to establish payments to physicians for care provided to Medicare beneficiaries. The ACC staff (assisted by outside consultants) had just completed a detailed analysis of the plan and its potential consequences for doctors, patients, and medical centers. Frye wrote, "As I struggle to grasp some of the technical aspects of the proposed changes, I cannot avoid wondering, what in the world is happening? Conversion factor (CF), technical component, relative value unit (RVU)—all are part of the new jargon." After reproducing a complex mathematical equation used to determine physician payments, he explained, "This bureaucratic maze causes me to reflect on the degree of central control and manipulation of economic forces in America at a time when most societies that have tried such experiments are rejecting them with a vengeance. While Eastern Europe and the Soviet Union are reeling from decades of such central fine tuning, America is establishing direct central control of pricing in medical markets."

Frye acknowledged the problem but expressed concern about the proposed solution: "Although it is easy to criticize the current approach, it is more difficult to propose obvious and easily implemented solutions to the problem. The experience with efforts to change the Medicare fee schedule emphasizes the importance of consensus development, trust and utilization of accurate data in making decisions." Frye thought it was especially important to address the question, "What are the precise components of the continuing rise in the cost of health care? An answer...seems essential to a successful

strategy for controlling health care costs and avoiding the targeting of single components that may be particularly attractive politically, for example, physician reimbursement.” Writing two decades ago, he explained, “The ACC remains committed to working with all parties to help solve this major societal problem, while improving access for those without insurance.”

### **The Challenge of Conflicts of Interest—2003**

W. Bruce Fye (ACC president 2002-2003) addressed challenges accompanying the recent explosion of clinical trials that yielded evidence used to produce practice guidelines.

Powerful scientific and socioeconomic forces continue to transform medical practice and research, especially in this country. In the past fifteen years the parallel clinical trial, practice guideline, and continuing education movements combined to create one of the greatest paradigm shifts in the history of medicine. What I will call the ‘trial-guideline-education process’ is having profound effects on cardiology research and practice—effects almost as significant as the invention of the stethoscope in France in 1816 and the electrocardiograph in Holland in 1902.... Conflicts of interest are unavoidable in the trial-guideline-education process that evolved during the past half-century. But their impact can be minimized if we reach consensus on thresholds beyond which real conflicts are more likely to occur, set reasonable dollar limits for specific services, and require detailed disclosures. Academic medicine, corporate bioscience, organizations, our government, and other interested parties should develop common standards that reflect a shared commitment to ensuring the integrity of the trial-guideline-education process. Disclosure statements should be required not only for obvious end product activities, such as publications and presentations, but also for other functions, like committee and editorial work, where conflicts might influence outcomes. To be effective, these statements must be explicit, accessible, and they must be used when appropriate.... We can’t treat conflicts of interest like some family secret no one talks about. We must become more comfortable asking and answering pertinent questions about the sources and substance of industry funding that might potentially influence individuals, institutions, and organizations. Meanwhile, we

must continue to invent and implement more effective ways to protect and promote productive partnerships between industry, academia, and practitioners—because these relationships are vital to medical progress and optimal health care.

### **The Future of Health Care—2007**

Raymond J. Gibbons (AHA president 2006-2007) explained at the opening of his presidential speech, “I will break with tradition and address a topic that is more political and social than scientific—the future of health care.” In addition to encouraging greater emphasis on disease prevention, research, and the use of allied health personnel, Gibbons advocated incentives to reward efficiency and quality.

In the face of this escalating crisis, there has been remarkably little public discussion of the need for fundamental change in the healthcare system. It is the ‘elephant in the corner’ that everyone tries to politely ignore. Although we can debate the multiple reasons for this silence, there is no question that further delays will only increase the changes required in the healthcare system. I believe that the time is long overdue for responsible members of the healthcare community to begin the public discussion that must take place before the public, our patients, our political leaders, and we ourselves are willing to make the necessary difficult decisions.... One of the factors that has inhibited adequate public discussion is the widespread inertia favoring the status quo for the short term rather than recognizing the necessity of long-term change and accepting its potentially adverse short-term consequences.

These and other comments by former leaders of the nation’s largest cardiovascular organizations were heard and read by tens of thousands of health care professionals. They both reflected and influenced contemporary opinions and concerns with an array of issues that continue to generate discussion and debate.



## Perspectives on the Evolution of Treatment of Coronary Artery Disease and Acute Myocardial Infarction

As a house officer in the 1950s, all that I could offer patients with acute myocardial infarction was six weeks of bed rest. No  $\beta$ -blockers, no anticoagulation, no aspirin. In retrospect, it is not surprising that mortality from myocardial infarction was then so high and increasing due to the increasing incidence and prevalence of coronary artery disease.

Samuel A. Levine of Harvard Medical School pioneered the concept of arm-chair recuperation rather than bed rest as treatment for acute myocardial infarction, a revolutionary idea at the time. The prevailing wisdom among pathologists and cardiologists was that any thrombus in epicardial coronary arteries represented a postmortem event and was not the primary mechanism of myocardial infarction. The development of coronary angiography by Sones and Judkins was critical to our understanding of the pathophysiology of coronary artery disease and helped demonstrate the role of thrombus as the primary event in acute infarction. The critical early work of these investigators ultimately led to the remarkable advances with thrombolysis, percutaneous interventions, and coronary artery bypass grafting, which are now the standards of care.

There was likewise little to offer patients with stable angina in the 1950s other than nitroglycerin. Charles H. Mayo, one of the founders of Mayo Clinic, had performed cervical sympathectomies for relief of angina many years earlier; dramatic relief of chest pain with this procedure was reported even before coronary angiography was available to establish the presence and severity of coronary disease. Nevertheless, the early surgical approach to coronary artery disease was controversial. Unusual operative approaches, including placing talcum powder in the pericardial space and aortocoronary sinus grafts, did not produce clinical improvement. A small, randomized Canadian trial involving a sham operative procedural arm utilizing the internal mammary artery did not demonstrate any objective benefit.

The most popular surgical approach to coronary artery disease was the Vineberg procedure, which involved implantation of the left internal mammary

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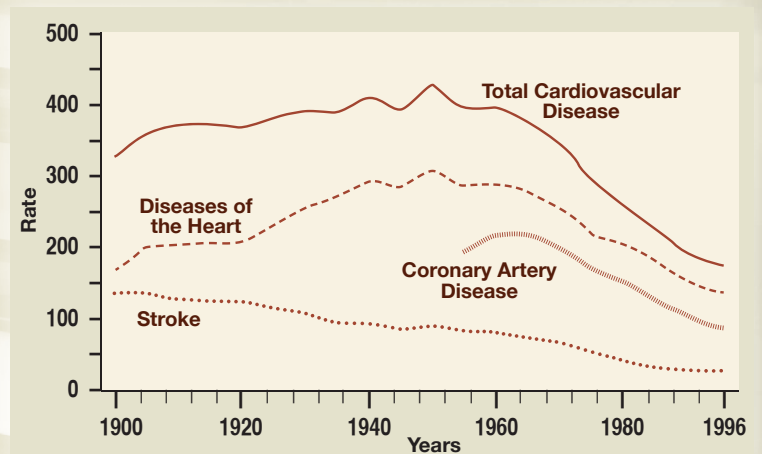
Past Chair,  
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Past President,  
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artery directly into the myocardium. At Mayo Clinic, it was first performed by Robert Wallace in 1965 and was facilitated by the work of Ben D. McCallister who performed the first coronary angiogram at Mayo Clinic. Exercise hemodynamic studies were done in the catheterization laboratory before angiography to have an objective performance assessment before and after the Vineberg procedure (and later, coronary artery bypass grafting). Studies at Mayo Clinic suggested that the effectiveness of the Vineberg procedure was secondary to the development of extensive myocardial collaterals, presaging current attempts at cardiac neoangiogenesis.

The focus on primary prevention became more prominent, with identification of hypertension, hyperlipidemia, smoking, and diabetes mellitus as risk factors. Lifestyle changes, pharmacologic management, and interventional therapies have been important components in efforts to reduce the incidence of and mortality from vascular disease. It is noteworthy that the major decline in cardiac mortality began well before invasive high-tech interventions.

Thus, the story of progress in treating patients with coronary artery disease is evident from the dramatic reduction in mortality over the past six decades, the result of a more fundamental understanding of the mechanisms of atherosclerosis, major advances in medical, invasive, and operative interventions, and primary prevention strategies.



Age-adjusted death rates (per 100,000 population, standardized to the 1940 US population) for total cardiovascular disease, diseases of the heart, coronary artery disease, and stroke, in the United States, 1900-1996. Diseases were classified according to the International Classification of Diseases codes in use when the deaths were reported. Data adapted from Centers for Disease Control and Prevention.



David R. Holmes Jr, MD

Past Director,  
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## Cardiology— Past, Present, and Global Future

Over the past 80 years, monumental advances in our understanding and treatment of cardiovascular diseases have occurred. The first recorded human cardiac catheterization was performed in 1929 by Werner Forssmann, who at the time was training in surgery in Germany. Ignoring the advice of his department chief and an operating room nurse, he anesthetized his own arm and passed a urology catheter 65 cm through his antecubital vein. Then he walked to a radiology laboratory and documented that the catheter tip was in his right atrium. Subsequent to that pioneering adventure he was relieved of his duties; he went on to a successful career in urology. Documentation of this early work was advanced by André Cournand and Dickinson Richards; the three of them shared the Nobel Prize in 1956. Subsequent seminal advances have included

- Selective coronary angiography, discovered accidentally in 1958 by F. Mason Sones Jr.
- Peripheral arterial interventions by Charles Dotter.
- Performance of the first percutaneous coronary balloon angioplasty in 1977 by Andreas Gruentzig.
- Placement of the first coronary stent in 1986 by Jacques Puel and Ulrich Sigwart.
- Development, testing, and widespread use of drug-eluting stents.

The intervening decades have seen other major advances in the field, including our understanding of the pathophysiology of heart disease, the development of coronary artery bypass grafting, percutaneous and operative repair of complex congenital heart disease, percutaneous and operative valvular repair and replacement, device therapy, and cardiac transplantation. These and other beneficial developments occurred as a result of the contributions of many individuals and are in part due to the following:

- Research demonstrating the role of risk factors in the pathogenesis of cardiovascular disease and the benefits of risk factor modification through diet, exercise, blood pressure control, and discontinuation of tobacco use.
- Recognition of acute coronary syndromes.
- Development of coronary care units and systems of care to optimize reperfusion therapy.
- Translation of findings in the laboratory into clinically applicable testing and treatment through close collaboration between clinicians and researchers.
- Partnerships between industry and clinicians to acquire technology that facilitated the development of sophisticated imaging systems, catheters, stents, valves, conduits, pacemakers, defibrillators, and left ventricular assist devices.
- Multicenter clinical trials and registries that allowed clinicians to evaluate prospectively and retrospectively the effectiveness of screening programs and therapeutic drugs and procedures.
- Performance, analysis, and implementation of the results of multicenter randomized trials with devices and with adjunctive medical therapy in large subsets of patients with acute and chronic cardiovascular disease.
- Collaborations between cardiologists, cardiovascular surgeons, radiologists, and pathologists to share findings and integrate patient care, including nursing and paramedical personnel, essential as new technology is developed and applied to an aging population with multiple comorbid conditions.
- Application of catheter-based technology to treat peripheral, carotid, and intracranial disease, including stroke.

- Development of specialized care centers dealing with acute cardiovascular symptoms.
- The recent documentation of the benefits of treatment of structural heart disease with catheter-based technology such as percutaneous aortic valve replacement, treatment of mitral regurgitation, and left atrial appendage ligation for stroke prevention.

As we look forward to the next 80 years, our challenges are different and numerous. The cumulative effects of years of chronic heart disease take their toll. Patients are older and living longer, frequently have additional comorbid conditions, and may require specialized care for decades. The costs of many patients' requiring many years of specialized care are presenting enormous challenges to the US health care system. Given the prevalence of cardiac disease in the population, developing and supporting practice models that provide quality care that is also cost-efficient is the most immediate challenge. No proposed practice paradigm is obviously superior. Cardiologists will continue to apply the same skills used in clinical practice: develop and test practice models, evaluate the results, and apply findings and modify practice as appropriate. In parallel, it will be necessary to

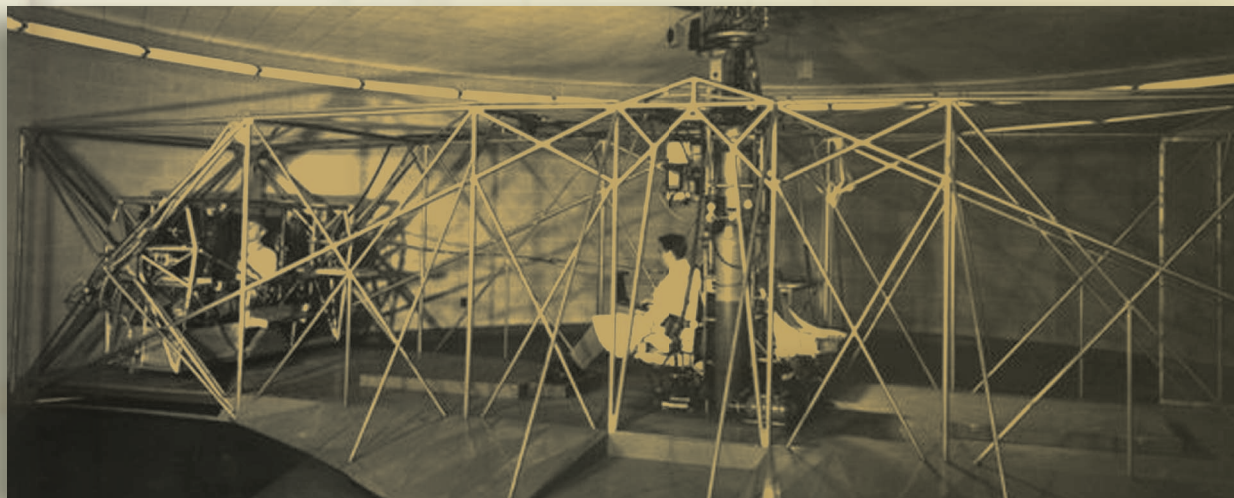
- Continue to develop evidence-based guidelines that direct clinical care.
- Emphasize lifestyle modifications and preventive cardiology to address the increasing prevalence of obesity and diabetes mellitus in the United States. While providers can provide multidisciplinary encouragement and program support, there is a need for individuals to take the initiative to adopt healthier lifestyles.
- Eliminate financial incentives for marginal or unnecessary testing and treatment, including understanding by providers and patients that the most expensive test or treatment is not necessarily the most effective.
- Ensure adequate funding streams to support cardiovascular research and train researchers.
- Support medical education and training, including a commitment to a continuing medical education and recertification program that provides objective, nonpunitive evaluation.

- Develop new modalities to train and credential physicians in new procedures such as percutaneous valve placement.

Finally, it is necessary that we not lose sight of the fact that cardiovascular disease is a global health problem. As more countries adopt Western lifestyles, its prevalence is increasing worldwide, and we have a professional responsibility to work collaboratively with our colleagues, sharing experience and effective strategies to prevent and treat cardiovascular disease.



Earl H. Wood, MD, PhD, made many seminal contributions to the understanding of cardiovascular physiology between his arrival at Mayo Clinic in 1942 and his death in 2009. At left, Dr Wood is shown testing an early gravity suit (the G suit), and below is the human centrifuge he designed in 1946 to simulate the forces of gravity on the human body.





Raymond J. Gibbons, MD

Past Director,  
Nuclear Cardiology Laboratory,  
Mayo Clinic in Rochester

Past President,  
American Heart Association

## Health Care Reform

The need for health care reform received considerable attention during the 2008 presidential campaign; during that time, the *Sunday New York Times* carried a two-page advertisement signed by 10 past political leaders, including a former chairman of the Federal Reserve Board, which summarized the need:

Mounting healthcare costs...threaten American competitiveness, and, if they remain unchecked, could even bankrupt the country.... The prognosis for our nation's health is beyond unacceptable—it is inconsistent with America's long-standing tradition of stewardship.

Since 1970, the annual growth in both public and private health care spending has exceeded the annual growth in the economy (Figure 1). As a result of this growth, health care continues to take a larger proportion of US economic activity, thus limiting the possibility that economic growth in general will exceed continued increases in health care spending.

The problem facing employers is summarized in Figure 2, which shows the cumulative increase in health insurance premiums since 1991, compared with changes in the US consumer price index and Medicare reimbursement per relative value unit. Health insurance premiums are now 340% what they were in 1991. In contrast, inflation has risen only 160% over that same period. In other words, health insurance premiums have risen at more than twice the rate of the increase in inflation. This trend was fairly modest until 2000 and 2001, when it accelerated; this acceleration coincided with the failure of Medicare reimbursement rates to keep up with inflation. The gap between Medicare reimbursement and inflation has grown steadily over the past decade.

Private health insurance premiums have also continued to rise rapidly over the past decade. Many factors have contributed to this increase, including insurance company profits, dividends to shareholders, cost shifting from Medicare to non-Medicare patients, and increasing use of health care technology. Regardless of the precise mix of these factors, employers face

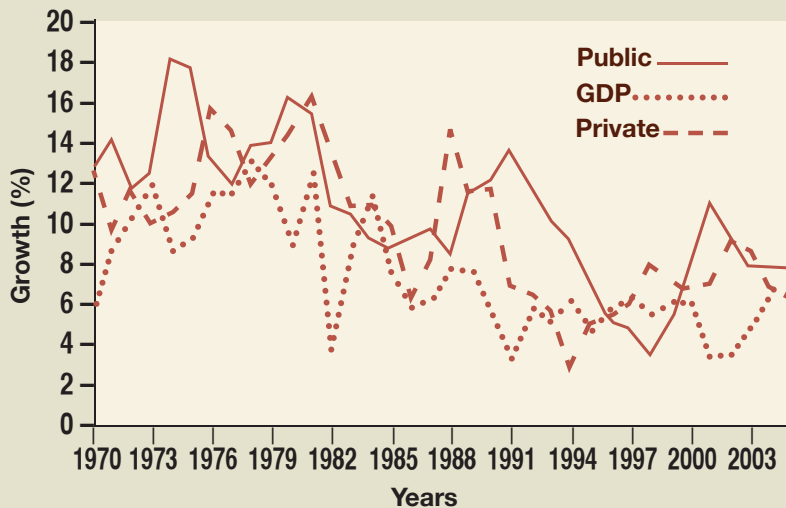


Figure 1. Annual growth in health care spending (Congressional Budget Office data). GDP indicates gross domestic product.

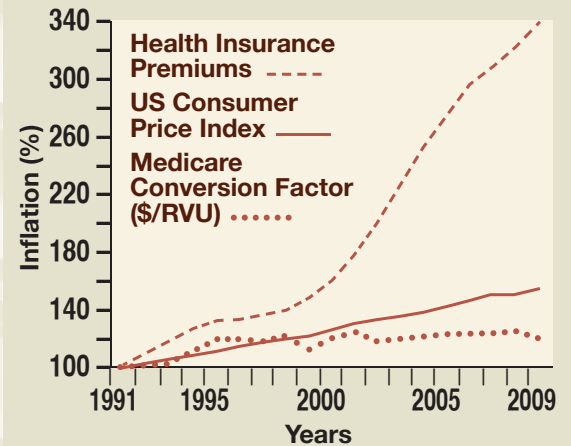


Figure 2. Cumulative inflation in health care insurance premiums, 1991-2009, with 1991 data used as the baseline value of 100 (American Medical Association and Kaiser Family Foundation data).

a stark economic reality that has forced many of them to reduce or eliminate health care coverage for their employees.

Many people, both within and outside the health care delivery system, believe that the aging of the population has been a major reason health care costs have risen. The extensive literature in the health care economics field shows that age has been only a modest factor until now; however, in 2011, it will become a much greater factor when the first wave of baby boomers begins to retire. Compared with the middle of 2010, when approximately 6,000 Americans turned 65 every day, in 2011, 10,000 Americans will turn 65 every day, and that trend will continue for the next 20 years. The increase in the elderly population in the United States between 2000 and 2010 was approximately 5.1 million Americans (Figure 3). In contrast, the increase in elderly Americans between 2010 and 2020 will be over almost three times that number at 14.4 million Americans. The increase will be even greater between 2020 and 2030, when 16.8 million more Americans will be over the age of 65. This baby boomer effect is not

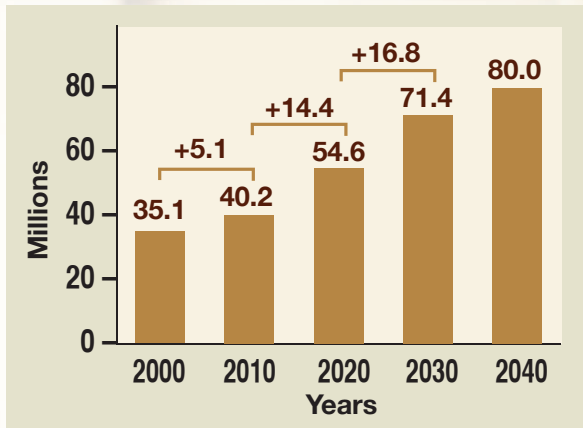


Figure 3. Increase in the US elderly population (≥65 years), 2000-2040 (US Census Bureau data).

unique to the United States; virtually every country involved in World War II has a large proportion of their population reaching retirement age.

The implications of this fundamental demographic trend for future health care spending are astounding. Shown in Figure 4 is an estimate from the Congressional Budget Office of future federal health care spending for Medicare and Medicaid, expressed as a percentage of the gross domestic product. By 2047, federal spending on health care will exceed 21% of GDP. This is a noteworthy landmark, because total federal revenue (shown in the dark band of Figure 3) has ranged between 17% and 20.9% of GDP ever since World War II. Thus, unless there is a major expansion of the federal government, by 2047, all federal revenue will go to fund health care, and no money will be left for any other federal spending. It is worth pointing out that these projections do not include state spending on Medicaid or private health care spending.

Each year the Medicare trustees produce an annual report, although it receives little public attention. The 2008 report noted that the Hospital Insurance Trust Fund can be brought into balance with

- an immediate 122% increase in the Medicare payroll tax (from 1.45% to 3.22%), or
- an immediate 51% reduction in spending, or
- some combination of the two.

Unfortunately, these projections are based on two optimistic assumptions:

- By 2032, the trustees assume that the growth in Medicare Part A will be only 1.3% greater than GDP (unfortunately, as shown in Figure 1, it has been 2.5% greater for the past 20 years).

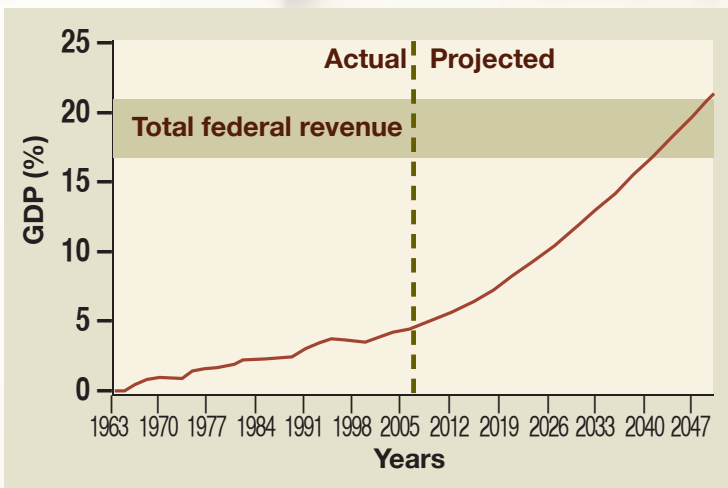


Figure 4. Medicare and Medicaid spending estimated to 2047 and depicted as a percentage of the gross domestic product (GDP) (Congressional Budget Office data).

- Medicare Part B, Medicaid, and other federal programs for the uninsured will be financed in other ways.

The second assumption has already been violated by the Affordable Care Act of 2010, which mandates only a 0.9% increase in the payroll tax in 2013 and only for taxpayers with annual incomes higher than \$250,000.

The issue of health care costs is even worse at the state level. Many states and cities have promised health care benefits to their employees and teachers after retirement. The magnitude of these commitments is huge. The Pew Charitable Trust noted in a 2010 report that the total liability for the 50 states for retiree health care benefits exceeded \$400 billion. The Pew Trust estimated that only 7% of this enormous liability is currently funded. Twenty states have not funded any of their future liability.

Health care policy experts have also long been aware of local and regional variation in the delivery of health care services. An analysis of the 2005 total Medicare reimbursements per enrollee in 200 health care markets in the United States reveals enormous regional variations ranging from approximately \$5,000 per Medicare beneficiary to more than \$15,000. There is considerable variability between markets dominated by nationally prominent cardiovascular practices.

Many patient factors probably contribute to some of these differences. However, careful research has been done on this issue in several separate studies by the Medicare Payment Advisory Commission (MedPAC), which has reported that patient variation and fee differences probably account for less than 50% of this cost disparity. At least 50% of the cost difference is attributable to differences in utilization rates for high-cost procedures, which reflect individual physician behavior. For example, the utilization rates for percutaneous coronary intervention (expressed as a number per 1,000 Medicare enrollees) in 2005 across the same 200 markets varied from 4 to 27, nearly a sevenfold range. Thus, it would appear that differences in clinical practice are major factors in the differences in health care expense across the country.

In summary, continued health care reform is urgently needed, as the current system is not sustainable. Health care reforms must increase value and eliminate overuse. The required major fix of the health care system will be painful to everyone. Patients, insurers, employers, and health care providers will all have to make continued efforts to secure the health care system of the future.



## Cardiovascular Cell Therapy Research Network Facilitating Clinical Trials of Cell-Based Therapeutics

In 2005, the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health concluded that federal funding for research into the use of cell therapy for cardiovascular diseases needed to be advanced. Although the NHLBI had funded basic science studies of stem and progenitor cell biology in the hope of developing novel treatments, many of the early clinical studies in cardiovascular cell therapy had been performed in Europe. The NHLBI decided to apply an approach that had been used previously with success in the field of pulmonary disease, the clinical trial network model. In 2007, the NHLBI initiated the Cardiovascular Cell Therapy Research Network (CCTRN), with a goal of performing early-stage clinical trials in heart disease using cell-based therapeutics.

This clinical trial network was set up with a national view to perform studies in a cooperative manner. The CCTRN includes five major regional centers throughout the United States—University of Minnesota/Minneapolis Heart Institute, Cleveland Clinic, Vanderbilt University, University of Florida, and Texas Heart Institute—with eight satellite treatment sites of which Mayo Clinic in Rochester is one. Currently three clinical studies in the field of cell delivery for left ventricular dysfunction are under way. These clinical trials—TIME (Transplantation in Myocardial Infarction Evaluation), LateTIME, and FOCUS—all use autologous bone marrow mononuclear cells that are delivered into the hearts of patients with acute, subacute, or chronic myocardial infarction. This unique clinical trial network has features that differentiate it from ongoing efforts internationally. The CCTRN follows rigorous cell isolation and delivery procedures that were developed by the network. In addition, a central biorepository allows for analysis of patient samples throughout the study. All three studies should be completed by the end of the initial funding cycle in 2011. It is anticipated that the CCTRN will be re-funded following its completion.

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The field of cell therapy for the treatment of cardiovascular diseases is in its infancy. The current trials being performed by the CCTRN involve bone marrow mononuclear cells with the thought that these cells have direct and indirect effects on ventricular remodeling and function. Taken with the ongoing efforts at Mayo Clinic and elsewhere to develop cells that have a higher likelihood of therapeutic potential in cardiac differentiation, these early studies will provide a basis for further studies that may have greater clinical impact. The CCTRN plans to expand beyond studies of left ventricular dysfunction to clinical trials intended to address other unmet needs of cardiovascular medicine, including the treatment of critical ischemia, nonischemic cardiomyopathy, and stroke.





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## The Growing Role of Prevention in Cardiology Today

After decades of important research and clinical application, principles of cardiovascular disease prevention have moved in recent years to the mainstream of cardiovascular research and clinical practice. This evolution reflects an important shift in focus in cardiology today that includes what was once thought to be unlikely or even impossible—preventing the onset and mitigating the impact of cardiovascular disease.

Several trends explain this evolution toward preventive cardiology in recent years. First, important research has unraveled important steps in the pathophysiology of atherosclerosis, making it more feasible to identify and target important pathophysiologic steps with lifestyle and medical therapies. Second, basic and clinical research studies have been successful in finding key components to optimal preventive therapies that can arrest and even reverse the process of atherosclerosis, thereby reducing its associated morbidity and mortality. Finally, system-based care models have been developed that help apply preventive strategies in successful and cost-effective ways.

Despite these positive trends, however, two negative trends have also helped propel preventive cardiology into the spotlight. First, there has been growing evidence and consensus that adverse lifestyle habits, including tobacco use, sedentary lifestyle, and diets high in saturated fats, salt, and calories, are responsible for a large percentage of atherosclerotic cardiovascular disease. Second, there has been a growing realization that current lifestyle trends are increasingly unhealthy. In fact, in recent years, the percentage of the population that is considered to be at low risk for cardiovascular disease (normal blood pressure, normal lipid levels, normal blood glucose, and healthy lifestyle habits) has been decreasing at an alarming rate. This paradox—that we more clearly understand the power of lifestyle, yet are less and less likely to apply that power—has led to a realization that something must change. This realization is a key factor that has raised the importance of preventive cardiology today. Effective therapies and strategies exist, but they must be applied to be truly effective.

As long as current trends persist, it is likely that preventive cardiology will continue to play an important role in the science and practice of cardiology in the future. Important future trends will likely include the following:

- While new medical and device-oriented treatment options will become available in the future, the power and importance of lifestyle therapies will continue to be clear—probably even clearer.
- The keys to adoption of and adherence to healthy lifestyle therapies will be further identified and applied.
- Cardiovascular clinicians will be held accountable for delivering preventive services appropriately and effectively to their patients.
- Clinical services that deliver preventive care alone will not be sufficient.
- Population-based efforts will be essential in order for communities to reduce the incidence of cardiovascular disease.
- Effective delivery of preventive services will depend more and more on effective delivery systems—many of which will be outside the traditional face-to-face patient-physician encounter.
- The success that we, as a society, will have in limiting the burden of cardiovascular disease will depend directly on a coordinated, multidisciplinary, and cost-effective approach that involves traditional and nontraditional partnerships at the population, hospital, and clinic levels in our communities.

Mayo Clinic is poised to contribute significantly to efforts to prevent cardiovascular disease. New scientific discoveries and effective methods to implement those new developments are important areas of focus at Mayo Clinic. In addition, important partnerships throughout our community, region, and nation have been forged involving medical and nonmedical groups. These partnerships will help promote the environments and health delivery systems of tomorrow to meet and overcome the challenges that we face in reducing the incidence and prevalence of cardiovascular disease.





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## Using Registries to Assess Clinical Practice and Improve Patient Care

An article published recently in *JAMA*, “Non–Evidence-Based ICD Implantations in the United States,” stirred widespread comment. The research assessed patients receiving an implantable cardioverter-defibrillator (ICD) for primary prevention of sudden cardiac death who were entered in the National Cardiovascular Data Registry (NCDR) ICD Registry between January 1, 2006, and June 30, 2009, to determine if they received the ICD on the basis of practice guidelines established by the professional societies. The study reported that 22.5% of patients did not meet evidence-based criteria for implantation. The development of this registry highlights the emerging practice of measurement and public reporting of physician and hospital outcomes with a goal of improving the quality of medical care.

### Developing the National ICD Registry

The registry was developed through a partnership of the Heart Rhythm Society (HRS) and the American College of Cardiology Foundation (ACCF) using the expertise of the NCDR. The registry was mandated by the Center for Medicare & Medicaid Services (CMS) in the National Medicare Coverage Decision to expand ICD coverage on the basis of the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT) results. The National Medicare Coverage Decision described a policy termed Coverage With Evidence Development that allowed expanded coverage as long as patients were entered into a registry to track outcomes. The registry began collecting data in April 2006 and now includes all 1,489 hospitals in the United States performing ICD procedures and has collected data on more than 750,000 ICD placements. The CMS directive is to enter data on Medicare beneficiaries receiving an ICD for the primary prevention of sudden cardiac death, but to their credit, 84% of hospitals have chosen to submit data on all device recipients, regardless of age or device indication. Approximately 95% of all ICD procedures in the United States are entered into the ICD Registry. This extensive reporting provides

the most comprehensive characterization of contemporary ICD practice and permits meaningful comparison with published randomized controlled trials. Comparison of characteristics of patients enrolled in SCD-HeFT and the Multicenter Automatic Defibrillator Implantation Trial II (MADIT-II) with those of patients in the ICD Registry indicated that the registry patients are older, with a greater proportion of women and patients with atrial fibrillation, hypertension, and diabetes.

The ICD Registry better depicts the types of patients receiving ICDs in the real world, in contrast to randomized controlled trials where patient entry was restricted. The registry has made substantial progress toward several predefined goals:

- Reveal the degree to which clinicians are managing ICD therapy in accordance with evidence-based medicine.
- Enable clinicians to compare their in-hospital outcomes with those of other physicians.
- Provide insights for clinical investigation.
- Highlight ICD performance outside clinical trial constraints.
- Provide a detailed view of the morbidity, mortality, and resource utilization associated with ICD therapy.
- Assess local hospital needs for quality assurance and quality improvement.
- Serve as a hospital and physician response to “performance measures” initiatives.

A key aspect of the registry is to improve quality performance at hospitals implanting ICDs, which is achieved, in part, through benchmarking reports provided to hospitals on a quarterly basis, detailing the outcome for all data elements and summarizing performance metrics. Each hospital is compared with hospitals of similar procedure volume and the national aggregate. Reviews of the annual data reports published by the ICD Registry Steering

Committee since 2007 have demonstrated a gradual trend in improvement of outcomes during the first four years of registry activity. The total procedure-related adverse events have decreased from 3.77% in 2006 to 2.87% in 2009. The ICD Registry is part of the NCDR program developed by the ACCF, which assesses outcomes in multiple different areas of cardiovascular disease, including cardiac catheterization and percutaneous intervention, carotid artery stenting, and outpatient cardiovascular practice. Data from the ICD Registry have been used in several important publications, providing information on patients receiving ICDs that was not available through the randomized controlled trials including

- Understanding the application of ICD therapy in the general population, gender differences, and procedure-related adverse events.
- Association of physician certification to outcomes and appropriate use of cardiac resynchronization therapy with defibrillator (CRT-D).
- Racial and ethnic differences in CRT-D use.
- ICD outcomes in patients with end-stage renal disease.
- The relationship between hospital procedure volume and complications of ICD procedures.
- The prevalence and predictors of off-label use of CRT-D therapy.

### **Public Reporting of Outcomes**

CMS and other payers are increasingly interested in reporting valid measures of patient outcomes, and this reporting requirement has been put into law by the US Congress. Unfortunately, administrative databases developed by payers to assess provider outcomes have several limitations:

- Data definitions are often imprecise.
- Final coding may not be supported by the clinical record in a substantial proportion of cases.
- It is difficult to distinguish comorbid conditions from complications.
- Important clinical risk data, such as ejection fraction and New York Heart Association symptom classification, are not available.

Prospective clinical registries maintained by professional societies, such as the ICD Registry, eliminate these inherent deficiencies of administrative data. While the clinical NCDR registries are more detailed and accurate than administrative data, they are limited by the lack of long-term follow-up. Obtaining reliable follow-up information using chart level data or subsequent patient contact is too costly and resource intensive to collect in a representative national sample as large as that included in the ICD Registry. A hybrid approach being used to develop reliable performance measures combines NCDR clinical data with Medicare Claims Data for follow-up, thus capitalizing on the strengths of both data resources. CMS is working through the National Quality Forum (NQF) and professional societies, including HRS and ACCF, to develop hospital and physician performance measures that will be publicly reported. One such performance measure to assess outcomes following ICD placement using data from the ICD Registry and Medicare Claims Data has been approved by the NQF. The initial analysis using this performance measure identified the median complication rate for a hospital as 7%, with the lowest decile being 4% and the highest decile 13%. This wide range of complications provides an opportunity for improvement by moving hospitals with the highest rate of complications closer to the median and moving the median closer to the lowest decile group. Variation was also observed with non-evidence-based implants reported in the *JAMA* paper ranging from 5% to 60% in ICD Registry hospitals, highlighting an area for improvement. Approximately 50% of patients who meet guideline indications for an ICD do not receive the device, suggesting that physicians are not following practice guidelines and failing to refer many patients who would benefit from this life-saving therapy. Ralph Brindis, MD, president of the ACCF, stated “when we see that level of variation, there is no way even a skeptic could say that we don’t have room for improvement in the way that we apply ICD technology.”

Cardiology has led the medical profession in developing practice guidelines based on well-designed randomized controlled trials; these guidelines are used to aid clinicians in practicing evidence-based medicine. Registries then demonstrate to physicians how the guidelines are being applied and how evidence-based medicine is being practiced in the community. The continued active involvement of physicians and professional organizations in developing and supporting registries that are clinically relevant and using the collected data to optimize cost-effective patient care is critically important.



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## Impact of Health Care Reform on Imaging: How Will We Respond?

The growth of health care expenditures in the United States is an issue of great concern to members of the American Society of Echocardiography (ASE). The Medicare system is now projected to run out of money as early as 2018. Government reimbursement for services for the Medicare population has not kept up with the cost of these services, with consequent cost shifting to non-Medicare patients. Health insurance premiums have escalated, and fewer employers can provide insurance. The percentage of US residents without health insurance has increased, and this has culminated in the ongoing overhaul of the US health care system. Imaging has gained attention as the fastest growing expense for Medicare.

Dramatic improvements in cardiac imaging are among the remarkable advances in treatment and technology that have impacted the practice of medicine and have contributed to the escalation of health care expenditures. Echocardiographic imaging is currently the most versatile, portable, and widely applied imaging modality. Improvements in echocardiographic instrumentation and technology and the addition of echo contrast now result in more than 99% diagnostic-quality images. Developments in three- and four-dimensional echocardiographic imaging, new means of evaluating myocardial mechanics with strain, strain rate, and speckle tracking, hand-held echocardiographic instruments, and noninvasive vascular ultrasound continue to advance understanding and improve detection of cardiac disease, including subclinical disease. Nuclear perfusion imaging has also continued to advance, with improvements in image quality and reduction in scanning times. Positron emission tomography has had an increasing application not only for assessment of myocardial viability but also for stress testing of patients with large body habitus. Advances in cardiac computed tomography and CT angiography have included an increase in slices with improved resolution, decreased scanning times, and a reduction in the amount of contrast required; coronary plaque can be monitored three-dimensionally. Magnetic resonance imaging now permits comprehensive assessment of myocardial perfusion and

anatomy, including extracardiac structures, but remains relatively expensive and is less widely available. Digital coronary angiography has evolved so that three-dimensional images are possible; these images may have advantages for navigation and anatomic reference. Thus, the many options for evaluation of a patient with known or suspected cardiac disease pose challenges for the practitioner attempting to incorporate these advances into optimal clinical care, while striving to practice cost-effectively.

The ASE has taken a lead in providing education to the practitioner as well as to the public. The ASE includes 14,000 professionals committed to excellence in cardiovascular ultrasound and its application to patient care through education, advocacy, research, innovation, and service to its members and the public. Members are dedicated to improving their patients' health and quality of life. With its SeeMyHeart products, the ASE has helped to inform the public about echocardiography and its applications. The ASE has established guidelines for quality in performing and interpreting echocardiography, and the Mayo Clinic Echocardiography Laboratory, in close collaboration with the Society, has embraced the highest level of these standards, with comprehensive examinations using state-of-the-art methods and equipment. Along with the American Heart Association and American College of Cardiology, the ASE has also contributed to the writing of many published guidelines regarding optimal practices in various disease conditions and the appropriateness of use of echocardiography and other imaging modalities. The ASE and other cardiology and imaging organizations are opposed to restrictions to limit the physician's choice regarding the most appropriate test for the patient and believe that the well-informed physician, rather than the payer, should make this decision. The ASE recommends that those who perform and interpret echocardiograms are certified by the National Board of Echocardiography, which requires documentation of training and satisfactory completion of an examination. In 1996, the ASE founded the Intersocietal Commission for the Accreditation of Echocardiography Laboratories (ICAEL) to improve quality



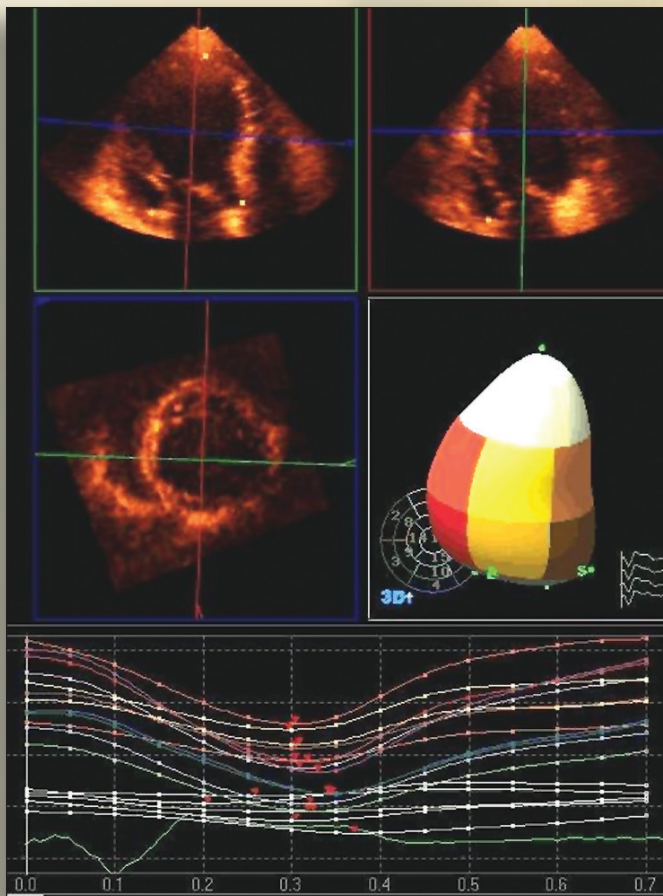
and standardization of echocardiography laboratories. The organization now operates independently and provides specific standards, including training and competency of the physician and allied health staff, and ongoing quality assurance, by which a laboratory may be accredited. The ASE provides numerous educational programs for physician and sonographer competency to assist them with successful completion of the board examinations, continuing medical education, and laboratory accreditation. The ASE recommends that quality requirements for imaging should not be dictated by any single specialty and is working with other imaging organizations regarding issues of licensure and coding. The organization continues to emphasize implementation of standards of quality and is urging Medicare carriers to adopt quality standards as a condition of Medicare payment.

The Society supports efforts to develop a national database whereby images can be viewed from any site. This will reduce the redundant testing that is frequently performed, as images obtained will be viewable from any site and will also inspire all centers to adopt high standards of quality.

Importantly, the ASE annually provides several research grants to support innovative research by new investigators, established investigators, and sonographer investigators to demonstrate the key role that cardiovascular ultrasound plays in the diagnosis and management of patients with heart and vascular disease. Over the past several years, demonstration that patient outcomes are positively impacted by echocardiography has been the major emphasis of several research grants awarded by the ASE.

Experts in cardiac imaging must work closely together to determine the best test in a given clinical circumstance. Collaborative research on comparative effectiveness will involve experts from various disciplines of cardiac imaging. We will need to train more physicians with broad understanding and expertise regarding the relative strengths and limitations of various imaging modalities. Imaging strategies that keep radiation exposure to a minimum require further development. As third-party payers are increasingly likely to impose increased pressure to restrict utilization of imaging and reduce payment rates, experts in imaging must work together to define the best approach to utilization of our imaging tests. We must avoid overutilization of services and be integrated in our efforts to solve clinical problems and explore solutions using cardiovascular imaging. The imager must seek to truly understand

the clinical question being posed so that the imaging test can be tailored to provide optimal and maximal information. Further evidence that our tests and imaging are not only identifying patients at increased risk, but truly improving patients' outcomes will be crucial as we go forward. Centers with broad expertise in all forms of cardiovascular imaging, such as Mayo Clinic, will play a key role in these important endeavors.



Three-dimensional echocardiography for global and regional left ventricular systolic function.



# The Future of Cardiovascular Education

## The Transformation of Traditional Continuing Medical Education

Medical education is undergoing a paradigm shift, and this is particularly true for cardiovascular education. Traditional continuing medical education (CME) meetings are declining in number for many reasons. It has become increasingly difficult for the busy cardiovascular physician to take time away from work, programs are expensive to put on, industry support is diminishing, and whether the educational content is retained by the physician and applied to practice is a subject of debate. Additionally, it is recognized that traditional CME focused more on what faculty members wanted to teach, rather than identifying knowledge gaps of the learner and providing content to fill those gaps. Programs should be interactive and intellectually engaging for the audience, and it is necessary to demonstrate that learning has taken place to comply with regulatory requirements. Interactive teaching with case-based discussions and audience interaction is more effective than simple didactic teaching. It is no longer sufficient to demonstrate that the learner attended an educational program, but outcomes evaluations must also be performed. The challenges to meet all the learners' needs will not be addressed with traditional face-to-face programs, however carefully planned and well designed.


These changes are happening at a time of "information overload." In 2009, an estimated 1.5 million articles were published in science, technology, and medicine. When we are bombarded with an increasing number of new publications and new cardiovascular journals, it is increasingly challenging to stay current, and yet it is clear that optimal patient care requires continued learning. Cardiovascular medicine is such a dynamic field that each month new trials are published with different treatment strategies to assimilate and implement. Thus, other education delivery models are becoming increasingly important.

These new information technologies are focused on "just in time" learning, whereby technologies deliver online learning to provide answers to important questions while the cardiologist is in the office and has a patient

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question that needs to be resolved promptly. This immediate need requires concise information that can be accessed quickly and efficiently, rather than large chapters, textbooks, or guidelines to search. Currently a vast array of information is available on the Internet, but much of it is outdated and unreliable.

The ultimate goal of educational success will involve quick and efficient access to reliable, evidence-based, vetted information from electronic knowledge repositories. Medical informatics will play a vital role in customizing the acquisition and retrieval of relevant information. Use of smartphones, tablets, and similar electronic devices may facilitate rapid access to these knowledge repositories while the clinician is at the patient bedside. Learning modules can be provided online, and the points achieved used toward maintenance of certification. Physician decision support tools linked to the electronic medical record can apprise physicians of urgent alerts, care process models, and appropriate utilization of medical tests. Electronic registries and scorecards can facilitate feedback regarding patient treatment strategies.

Mayo Clinic and subspecialty societies such as the American College of Cardiology and the American Heart Association are vigorously pursuing and developing these online modalities to help the busy clinician keep up to date and provide optimal patient care.

### **The Trend Toward Continuous Professional Development**

CME traditionally has been geared toward medical and clinical knowledge, and an examination every 10 years has been necessary for certification. Governing professional bodies are now considering CME more as a continuum and are moving away from the concept of a single examination; instead, they are favoring maintenance of competencies as defined by the Accreditation Council for Graduate Medical Education. These competencies include not only medical knowledge, but also patient care, interpersonal

and communication skills, practice-based learning and improvement, professionalism, and systems-based practice. The concept of continuous professional development (CPD) has been defined as what the physician does to remain current, to expand awareness, knowledge, and skills, and to provide quality care, while CME represents the educational and practice improvement tools and resources used in support of CPD. There has been renewed interest in competency-based medical education along a continuum. Participation in quality improvement projects, demonstration of patient satisfaction, and compliance with professionalism requirements will become part of the lexicon of practice for the cardiovascular physician to remain board certified and licensed. For cardiovascular fellows in training, there will be less emphasis on acquiring knowledge, the amount of time required for training, and the number of procedures performed. Instead, greater emphasis will be placed on abilities and skills and a synthesis of knowledge into observable competencies. This shift in emphasis will necessitate changes to curriculum development and a shift away from a “timetable” of rotations toward a collection of observable and measurable competencies that must be achieved. Both the public and the medical boards expect cardiovascular physicians to be competent, and this will need to be measured and assessed in an ongoing way.

These requirements and changes for both the trainee and for the practicing cardiologist will be helped by the development of an individualized electronic portfolio. The portfolio will provide a central location for a lifelong chronicle, not only of scholarly medical education modules, but also of career, research, and leadership accomplishments. It also documents the achievement and maintenance of licensure and certification and accreditation as well as practice improvement modules and performance metrics. All these measures will be important components of maintenance of certification and could serve as a link to the national boards. In addition, a personalized portfolio could enable the cardiologist to identify both knowledge and competence gaps and could provide opportunities and resources for improvement. The portfolio could potentially begin in medical school and continue until retirement.

A “multitier” approach to education and new technologies will play a major role in these innovations. Mayo Clinic is currently pursuing all these new approaches to education to help not only Mayo Clinic staff, but other health care providers around the world.



Rick A. Nishimura, MD, speaking at the Mayo Clinic Cardiovascular Board Review. This course is the premier board review course, drawing nearly 1,000 attendees each year. In conjunction with the board review course, parallel review courses in interventional cardiology, echocardiography, and electrophysiology are held.



The Mayo Multidisciplinary Simulation Center allows students to practice vascular access and invasive procedures before encountering live patients.



## Cardiac Implantable Electronic Devices: Past and Future

### Where We Have Been

Although many medical disciplines have seen marked advances in past decades, few, if any, rival the technology-driven area of cardiac implantable electronic devices (CIEDs), ie, pacemakers, implantable cardioverter-defibrillators (ICDs), and cardiac resynchronization therapy (CRT).

Cardiac pacing was introduced in the late 1950s. The evolution of cardiac pacing has permitted even faster development of ICD therapy and CRT. As pacemakers evolved from single-chamber to dual-chamber devices with sensors for rate adaptation, more reliable battery sources, and miniaturization, it was thought that a point would be reached when no additional improvements were possible. However, these devices continue to evolve, with more advanced diagnostic and treatment algorithms, new mechanisms of monitoring, and much greater capacity for storage of retrievable information.

When work began on the ICD, many felt that a safe and reliable device would never be commercially available. The first human implant was performed in 1980, and the device was approved for use later in that decade. Since then, randomized clinical trials have led to a broad array of indications for ICD therapy, and it is now widely embraced around the world as an important therapeutic tool.

Combining the pacemaker and ICD knowledge bases, the use of device therapy for refractory congestive heart failure (CHF) was first attempted in the 1990s. The first CRT devices were released in approximately 2000, and high-voltage CRT (CRT with defibrillator [CRT-D]) is gaining increasing use around the world. (CRT with pacing only, CRT-P, is also widely available but tends to be used less often than CRT-D.)


Randomized clinical trials have demonstrated improvement in more than 70% of patients who undergo CRT. Initially approved only for patients with

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New York Heart Association class III and ambulatory class IV CHF, additional clinical trials have resulted in an expansion of inclusion criteria for use of CRT.

In the past decade, implantable devices have also been used for diagnostic purposes only. The implantable ambulatory monitor, although not used in large numbers compared with pacemakers or ICDs, has been embraced as a diagnostic tool that may provide a clinical answer when all other diagnostic tools fail. For the patient with continued “spells” or unexplained syncope, an implantable monitor may allow correlation of the symptoms with the rhythm that has otherwise eluded the caregiver.

Stand-alone implantable hemodynamic monitors have also been introduced. A number of devices have been tried or are currently under clinical investigation that are capable of various measurements, such as pulmonary artery pressure, right ventricular pressure (allowing for estimates of pulmonary artery and left ventricular end-diastolic pressures), and left atrial pressure. Only recently have such hemodynamic sensors been incorporated into therapeutic devices, namely, ICD and CRT devices.

Device follow-up has changed dramatically in recent years. In the earliest years of cardiac pacemakers, all follow-up required a visit to the pacemaker clinic for a face-to-face encounter with the caregivers managing the pacemaker. Decades ago transtelephonic monitoring was introduced to allow remote monitoring of the pacemaker battery status and some degree of certainty that the device was functioning normally.

In the early portion of the current millennium, remote home monitoring was introduced for the follow-up of high-voltage devices, ie, ICDs. This practice has rapidly expanded to all the major device manufacturers. Patients with ICDs and CRT devices are often, if not routinely, enrolled in a home-monitoring program at most US implant facilities. The advent of wireless transmission of data provides the potential for seamless follow-up of CIEDs

and allows patients the convenience of home follow-up as well as the reassurance that their device is continuously under surveillance. Low-voltage CIEDs, ie, pacemakers, are now being enrolled in certain remote home-monitoring systems, and this monitoring will undoubtedly become the norm in the future.

### **Where We Are Going**

There has been considerable interest in leadless devices. An ICD system that incorporates a subcutaneous lead, where no endocardial or intravascular hardware is required, is available in some parts of the world and under investigation in the United States. Leadless pacing systems that operate via delivery of a receiver electrode in the heart with ultrasound-mediated pacing have also been under investigation. To date, no such device has been approved for clinical use but the technology seems promising.

The marriage of therapeutic CIEDs with hemodynamic sensors expands device use into the broader arena of disease management. Most CHF patients have a number of comorbid conditions, including diabetes mellitus, chronic renal insufficiency, hypertension, chronic obstructive pulmonary disease, sleep-disordered breathing, coronary artery disease, and atrial fibrillation. CIEDs currently monitor a number of parameters that may be used to predict early development of CHF (preclinical CHF), and a number of other predictive parameters are under investigation.

Specific monitoring considerations for disease management include the following:

- ST-segment monitoring for early-onset myocardial ischemia.
- Oxygen saturation monitoring for management of any pulmonary process where oxygen saturation may be compromised.
- Pressure measurements that directly or indirectly derive pulmonary artery pressure, left atrial pressure, left ventricular pressure,  $dP/dt$  to manage systemic hypertension, pulmonary hypertension, or any disease state in which hemodynamics may be altered and require manipulation of medications to optimize hemodynamics.
- Respiration monitoring for apnea/hypopnea for the diagnosis and management of sleep-disordered breathing.

- Online measurement of specific blood analytes, eg, blood glucose for management of diabetes mellitus.

Coupling the CIED with selected hemodynamic or laboratory monitoring with remote home-monitoring capability, specific diseases could be managed remotely 24/7, with the device directing some specific interventions or medication changes on the basis of preset criteria or surveillance at a remote monitoring system that could direct patients to change their regimen without having to make a visit to their health care provider or emergency department. The ultimate outcome of such a system is improved patient care, with earlier intervention and sparing of more expensive hospital-based health care resources.

As the discipline moves forward with growing numbers of patients, expanding indications, and closer attention to costs and benefits of device therapy, the need for high-quality performance and outcomes data will increase. Despite multiple attempts, a comprehensive CIED registry has not been developed. As a result of government mandates, the American College of Cardiology National Cardiovascular Data Registry maintains a registry of all Medicare patients receiving a high-voltage device, and many institutions submit registry data on non-Medicare high-voltage device recipients as well. Literature is emerging from this registry that will remain a rich source for performance and outcomes data for high-voltage devices.

These data repositories, as well as product performance monitoring that is accomplished by each CIED manufacturer, will potentially allow earlier recognition of suboptimal product performance. Overall CIED performance is excellent, as well as performance of the associated permanently implanted leads; however, intermittent design and manufacturing problems lead to a higher than acceptable rate of failure. Although no absolute number has been agreed to identify an unacceptable failure rate and different types of failure may be more or less clinically significant, ongoing and early recognition of a problem is critical. Due to a number of advisories and recalls in the past decade, the importance of this surveillance is recognized by caregivers, regulatory agencies, payers, and patients and their families.



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## The Future Role of Professional Societies in Cardiovascular Disease

The cardiovascular community is undergoing tumultuous change in the 21st century. “Health care reform” will result in significant changes both for cardiologists in private practice and for those in academic medical centers. Reimbursement for patient care has been dramatically affected, and as a result, the majority of private practices are being incorporated into hospital systems. Cardiologists in academic practices are now asked to increase patient care activities, detracting from their commitment to education and research. Support for research has become even more competitive, and industry funding for educational activities is decreasing because of increased scrutiny and limited resources.

At the same time, tremendous advances have occurred in the science and technology of cardiovascular diseases. Although these developments have favorably impacted care of the patient with cardiovascular diseases, they have resulted in an information overload on the cardiologist. Finally, there is now a public demand that physicians demonstrate continual competence in all aspects of patient care and professionalism. With all practices and medical centers struggling to keep up with these changes in the health care environment, the national societies must be able to provide the information and tools for cardiologists to accommodate to this rapidly changing landscape.

Professional societies must play a number of changing roles. The role of the national cardiovascular societies at their inception was to educate the cardiologist and support the science. Although these important aspects must continue, the societies now need to become involved in other areas, including support and creation of national guidelines, establishment and maintenance of national databases, transformation of “the new education,” and assurance to the public and certifying bodies that their members are truly highly competent physicians.

Members of professional societies expect their leadership to represent them during key legislative decisions, especially in this new era of health care

reform. It is beneficial for groups to speak to lawmakers with one voice, and the collective efforts of all the national societies are required. However, societies should not be viewed as trade unions that only protect the financial interest of their members. Instead, the major message from our national societies should be to promote quality of care, with payment based on quality, not quantity. Thus, it is essential that our professional societies provide the resources and tools for all of us to practice the highest quality medicine with the ability to seamlessly document that this is accomplished.

It is first necessary for the profession to define high-quality care. The American College of Cardiology and the American Heart Association have been leaders in the development of national guidelines for diseases and procedures. The development of these guidelines has included input from the appropriate subspecialty societies, as well as collaboration with societies outside the field of cardiovascular medicine. These guidelines are formulated when possible from evidence-based medicine, providing practical recommendations as well as data that support the recommendations. Although guidelines do not offer a perfect solution, the collective knowledge of a group of experts and users who synthesize the evidence and arrive at consensus does provide cardiologists with the best available approach to care of the patient. Consensus documents and Bethesda conferences are extremely useful in vetting information on topics that do not necessarily have an underlying evidence base of formal guidelines, but nevertheless are important for the practicing cardiologist. The development of appropriateness criteria summates the opinion of colleagues as to what tests or procedures are and are not appropriate for a specific clinical scenario.

The national societies need to help cardiologists implement guidelines in practice. As well-trained cardiologists, we all believe we are practicing high-quality medicine. However, many gaps in practice can be identified when analyzing data from our own practices. One of the major roles of the national

societies is to construct national databases, so that practice-specific data can be collected and reviewed by individual cardiologists and their practices. Only by knowing one's own data can one take the steps needed to truly improve the quality of practice.

There needs to be a paradigm shift in cardiovascular education. In the past, education primarily consisted of didactic lectures given by professors of medicine, who spoke about topics that they themselves considered important. However, the new paradigm of education needs to focus on the needs of practicing cardiologists. These needs can be identified by assessment of either knowledge gaps (through self-assessment questions) or practice gaps (through databases). Only by understanding the knowledge and practice gaps can optimal education be offered. In addition, the traditional courses with didactic lectures have never demonstrated improvement of a cardiologist's knowledge, much less a beneficial change in patient outcomes. Newer education modalities such as case presentations, self-assessment of knowledge, and simulation will be important in the future.

Ultimately, optimal learning occurs at the point of care. Physicians will certainly retain specific knowledge provided to them regarding their own patients. Thus, the professional societies need to be responsible for providing vetted information at the point of care, perhaps imbedded with the electronic health record to optimize workflow. This will require unique and novel search mechanisms through all the well-vetted sources that the national societies have.

Finally, maintenance of certification is with us. The American Board of Internal Medicine is responsible to the public for assuring that all cardiovascular diplomates are competent physicians. The current mechanisms for demonstrating competence to the certifying boards are time-consuming and may not necessarily be applicable to all practice. The national societies can collaborate with the American Board of Internal Medicine to define mechanisms by which these competencies can be assessed and documented during daily practice.

Overall, the field of cardiovascular diseases is dramatically changing, with new responsibilities on both practicing and academic cardiologists. Professional societies will need to adapt their roles to provide the knowledge and tools for all cardiologists to achieve optimal patient care.



James W. DuShane, MD, first chair of pediatric cardiology at Mayo Clinic in Rochester.



John W. Kirklin, MD, first chair of cardiovascular surgery at Mayo Clinic in Rochester.



Giancarlo Rastelli, MD, developed the Rastelli procedure for complex congenital heart disease.



## Cardiovascular Surgery in the 21st Century

In 1952, John W. Kirklin led a group of clinicians at Mayo Clinic in Rochester to develop a cardiac surgical program using a mechanical pump oxygenator. The group included Jesse E. Edwards in pathology, Earl H. Wood and H. Jeremy Swan in physiology, Howard B. Burchell in cardiology, James W. DuShane in pediatric cardiology, Robert T. Patrick in anesthesiology, David E. Donald in research, and E. Richard Jones in mechanical engineering. After evaluating a number of potential devices, Kirklin obtained the blueprints of the Gibbon-IBM pump oxygenator, and based on this design, a pump oxygenator was developed by the biomedical engineers at Mayo Clinic. After a two-year laboratory program of research and development, the investigators were ready to proceed with clinical application.


In 1955, Kirklin and his team at Mayo Clinic in Rochester performed a series of cases using a heart-lung machine, which allowed direct visualization of the inside of the opened human heart to repair otherwise-fatal intracardiac defects. These early operations pioneered the new era of open heart surgery, and surgical treatment of heart disease became widely available with dissemination of the heart-lung machine. Dwight C. McGoon joined the cardiac surgery staff in 1957, and the surgical suites were moved to Saint Marys Hospital to accommodate the rapidly increasing volume of cardiac surgery at Mayo Clinic.

Cardiopulmonary bypass has been used to perform more than 70,000 cardiac operations at Mayo Clinic, and more than 2,800 such procedures are currently performed annually. More than 125 cardiothoracic and cardiovascular surgeons have been trained at Mayo Clinic in the intervening years; subspecialty training in cardiac anesthesia is also offered. Thousands of journal articles describing surgical technique, optimal timing of operation, pre- and postoperative physiology, pathology, anesthesia technique, and imaging modalities have been published by Mayo Clinic clinicians. This knowledge,

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coupled with technologic innovation, has permitted increasingly complex procedures to be performed.

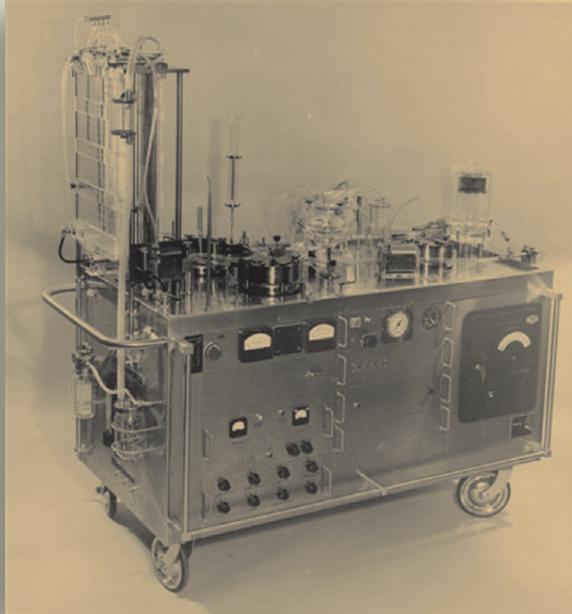
The success of the original series of open heart operations at Mayo Clinic required the multidisciplinary effort of a group of talented and dedicated individuals. That same integrated team approach will be key to successfully meeting the challenges of patient care in the future.

- Current cardiac patients are older and usually have comorbid conditions that require multispecialty management.
- Carefully planned hybrid procedures performed in conjunction with interventional cardiologists are becoming more common.
- Many valves can be repaired rather than replaced, obviating the need for long-term anticoagulation. Precise imaging is required in selection of these patients and for intraoperative assessment of repair.
- Percutaneous valve replacement offers patients who are not good operative candidates the opportunity for valve replacement. This patient population will likely expand to include those traditionally considered for open surgical repair or replacement. Cardiac surgeons in partnership with interventional cardiologists will develop optimal patient selection and treatment plans.
- The demand for left ventricular assist devices, both as bridge-to-transplant and as destination therapy, is increasing as a result of technological advances in the device, a continued organ shortage, and an increasing number of patients who do not qualify for transplant listing and fail medical therapy. These patients require close monitoring by cardiac surgeons, transplant cardiologists, and arrhythmia specialists for optimal outcomes.

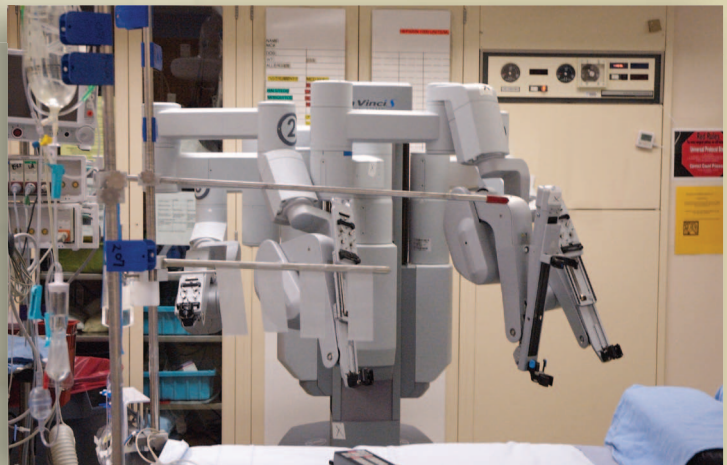
- Success with initial operative repair of complex congenital cardiac abnormalities has created a population of adults who need collaborative management with adult congenital cardiology specialists. Some of these patients need specialized operative revision of earlier repairs.
- Minimally invasive procedures, especially with robotic assistance, are becoming more common. Colleagues in biomedical engineering and industry have facilitated increasingly sophisticated robotic technology. Minimally invasive procedures offer patients less pain and discomfort as well as shorter recovery times.

An additional area of change is in education of cardiac surgeons. Manpower studies suggest there may be a critical shortage of cardiothoracic surgeons in the next 20 years due to declining interest among medical students in training programs and career paths that require long hours and intense effort. Many residencies, including that at Mayo Clinic, have modified and shortened their programs by offering a “4+3” option and a pathway to certification in six years for medical students who wish to omit general surgical training.

As new practice models with an emphasis on cost-effectiveness are implemented, it will be important to continue to collect outcomes data into standardized databases, both for individual institutional quality improvement efforts and as part of national registries. For example, data collected by the International Registry of Acute Aortic Dissection (IRAD), with participation by 24 major centers in 12 countries, have provided new insights to management of acute dissection. New technology has provided welcome diagnostic and treatment options for patients, but it is important that these innovations be tested in well-designed clinical trials to demonstrate efficacy and identify patients best served by each approach.



First heart-lung machine developed at Mayo Clinic in Rochester.



Robotic technology allows minimally invasive cardiac surgery.



Douglas L. Packer, MD

Director,  
Heart Rhythm Service, Mayo Clinic  
in Rochester

Past President,  
Heart Rhythm Society

## Continuing Evolution of Therapy for Atrial Fibrillation

The origins of the field of cardiac electrophysiology might be attributed to Wilhelm Einthoven, who developed the modern electrocardiogram in 1903, for which he subsequently received the Nobel Prize for Physiology or Medicine in 1924. In subsequent decades, abnormalities of the cardiac conduction system were recognized and described. Effective treatment for these disorders awaited the development of invasive diagnostic systems and implantable devices. Today, many complex arrhythmias can be diagnosed and treated with catheter-based approaches. Computerized three-dimensional mapping systems, variously configured catheters, intracardiac ultrasound, and epicardial ablation techniques provide therapeutic options for arrhythmias, which, in the past, would not have been considered for percutaneous ablative treatment. Ongoing research has provided valuable insights into genetic syndromes and the cellular mechanism of arrhythmias. The accomplishments of the past three decades are remarkable; nevertheless, extraordinary challenges remain.

Atrial fibrillation (AF) is the most prevalent arrhythmia in North America and presents the most immediate challenge. The numbers continue to rise; currently 2.5 million Americans have AF, but as the population ages and survival improves, this number will at least double by 2050. AF is problematic in part because of the thromboembolic risk. It is estimated that 15% to 30% of patients with acute stroke have underlying AF. Patients with AF have an increase in mortality, although Framingham data suggest that AF is a risk factor rather than a direct cause of this increase.

Patients with AF are frequently symptomatic, with exercise intolerance, syncope or presyncope, dyspnea on exertion, and uncomfortable palpitations. Clinical trials have provided some insight into the optimal management of AF. The AFFIRM (Atrial Fibrillation Follow-up Investigation of Rhythm Management), RACE (Rate Control Versus Electrical Cardioversion for Persistent Atrial Fibrillation), PIAF (Pharmacologic Intervention in Atrial Fibrillation), and STAF (Strategies of Treatment of Atrial Fibrillation) trials

demonstrated no difference in overall mortality over the course of long-term follow-up with either rate or rhythm control. The Atrial Fibrillation and Congestive Heart Failure (AF-CHF) trial also failed to demonstrate a difference in multiple endpoints; additionally, bradycardia and rehospitalization rates were higher in patients treated with antiarrhythmic drugs. In ATHENA (A placebo-controlled, double-blind, parallel-arm Trial to assess the efficacy of dronedarone 400 mg BID for the prevention of cardiovascular Hospitalization or death from any cause in patiENTs with Atrial fibrillation/atrial flutter), the class III antiarrhythmic agent dronedarone was compared with placebo and demonstrated a reduction in cardiovascular mortality and hospitalization. One drawback of this study was that dronedarone was compared against placebo and not against a rate control strategy.

Ablative procedures have become an option for patients with symptomatic AF. A number of observational studies have demonstrated reduced frequency or elimination of AF. In patients with paroxysmal AF, pulmonary vein isolation may be sufficient, while those with persistent or chronic AF are likely to need more extensive ablation procedures.

Since 1997, more than 2,500 pulmonary vein isolation procedures for the treatment of AF have been performed at Mayo Clinic in Rochester. In the most recent review, 73% of patients with paroxysmal AF and 66% of patients with persistent AF maintained sinus rhythm for 1 year after the procedure without antiarrhythmic drug therapy. Another 10% of patients with paroxysmal AF and 11% with persistent AF were able to maintain sinus rhythm with previously ineffective antiarrhythmic drug therapy. The procedure was repeated in 13% of patients.

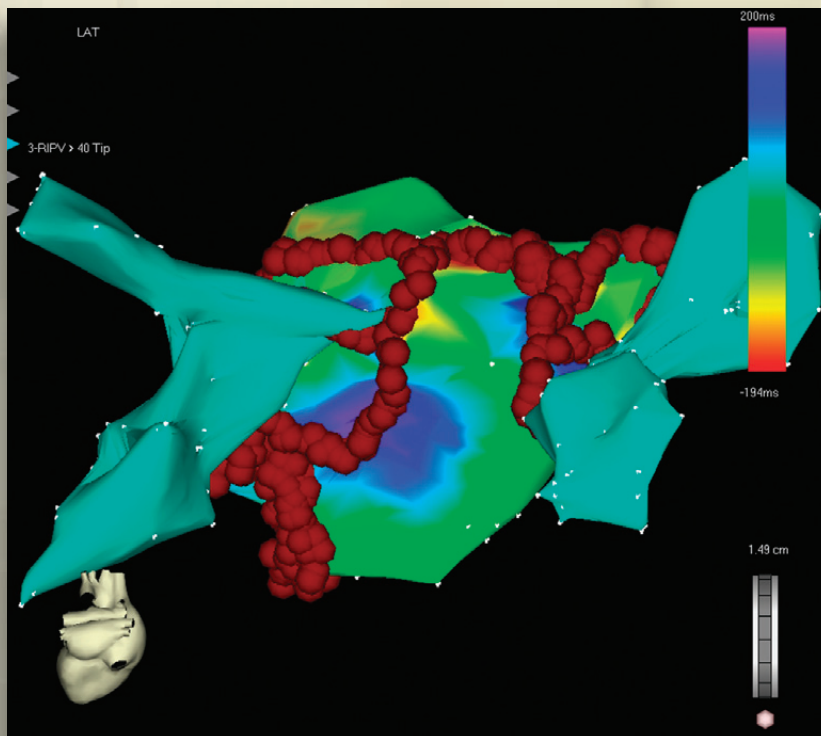
Even in the absence of cost data, there is sufficient information from observational studies, meta-analyses, and comparative studies to support widespread application of AF ablation in patients in whom treatment with a single antiarrhythmic drug failed because of AF recurrence or drug

intolerance. The Guidelines for the Management of Patients With Atrial Fibrillation, endorsed by the American Heart Association (AHA) and the American College of Cardiology (ACC), recommend this nonpharmacologic approach as second-line therapy. Similarly, the Expert Consensus Statement on Catheter and Surgical Ablation of Atrial Fibrillation: Recommendations for Personnel, Policy, Procedures and Follow-up, developed by the Heart Rhythm Society and endorsed by the AHA and ACC, comes to a similar conclusion. A number of centers are moving toward a primary therapy role for ablation, as success rates increase and complication rates decline.

In clinical practice, it is important to be clear on the indication for any intervention in AF patients. Of primary importance is the need to prevent stroke or other peripheral thromboembolic events. Treatment with warfarin and, more recently, dabigatran therapy has been best demonstrated to reduce this risk in most patients. Additional studies will be required to establish a reduction in stroke risk with rhythm control strategies. The role of therapy to establish and maintain sinus rhythm in patients with left ventricular dysfunction is acceptably clear-cut in recent ablation studies. However, of greatest importance is the need to reduce or eliminate AF in symptomatic patients. This remains the primary indication for ablative intervention. Patients who have failed to respond to one drug may be good candidates for intervention, although the anticipated success rate depends on the type of AF and the presence of underlying left ventricular or left atrial dysfunction. Age appears to be a less important factor than previously thought.

While observational studies and limited randomized comparisons demonstrate symptomatic improvement in patients undergoing ablation and early data suggest a cost benefit, larger long-term studies are required to establish a mortality benefit and a reduction in stroke risk. One such trial is CABANA (Catheter Ablation Versus Antiarrhythmic Drug Therapy for Atrial Fibrillation Trial), currently ongoing, which will attempt to address these issues. This study, originating from Mayo Clinic, will examine the benefit of ablation versus drug therapy in 3,000 patients with AF enrolled in 140 centers around the world. The study will also establish long-term complications of AF treatment and their prevention by appropriate ablative or drug therapy. Importantly, this study will also establish the actual impact of the arrhythmia and its treatment on patient quality of life and health care costs of various treatments.

Given the projected numbers of individuals in whom AF will develop, it is imperative that recommendations be evidence-based to the extent possible and include not only immediate risk and benefit, but also long-term outcomes, quality of life with each management approach as perceived by patients, and careful cost-benefit analysis of various treatment options. As we struggle to identify appropriate management of the individual patient with AF, we also need to understand that the burden of AF is a growing public health issue.



Computer-generated biatrial mapping demonstrates sites of radiofrequency ablation performed during pulmonary vein isolation for the treatment of atrial fibrillation.



## International Challenges in Cardiology

Many issues in cardiovascular disease are causes for concern, both nationally and internationally, including the aging of the population, the appropriate use of procedures, the need to extend primary prevention into all sectors of society, and the need to find the means to pay for these efforts.

The greatest international challenge may be the epidemic of cardiovascular disease in the developing world and its global implications. A forthcoming meeting of the United Nations will focus on the global importance of noncommunicable diseases and draws needed attention to major issues facing the cardiovascular disease community, in addition to other noncommunicable diseases, namely, cancer, chronic respiratory tract disease, and diabetes. The leading cause of death in the world is cardiovascular disease, and the death rate is threefold greater than deaths due to HIV/AIDS, tuberculosis, and malaria combined. Moreover, 80% of worldwide cardiovascular deaths occur in developing (low- and middle-income) countries, and in these populations, deaths occur at a younger age, devastating families without a social safety net and having a major impact on the workforce and productivity. Additionally, in 2010, approximately 70% of the elderly were living in the developing world. Moreover, in many low- and middle-income countries, the proliferating epidemic of cardiovascular disease is juxtaposed with an already formidable burden of communicable diseases and other diseases of poverty. In countries with limited economic resources, the burden of multiple diseases adds to overall socioeconomic stress.

Given this background, the case for primary and secondary prevention is unequivocal. It is time for international organizations not only to focus on the ravages of communicable diseases but also to realize the potentially greater threat of a global epidemic of premature cardiovascular disease. Nonetheless, a key component of prevention is to understand the underlying socioeconomic environment that is fueling the epidemic. The concept of the “epidemiologic transition” provides a useful framework for integrating changes in cardiovascular epidemiology into the context of the changing socioeconomic

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and cardiovascular risk factor environment. Stage 1 (The Age of Pestilence and Famine) still exists in parts of sub-Saharan Africa, Southeast Asia, and Latin America, but basically ended in the developed world over 100 years ago. Stage 2 (The Phase of Receding Pandemics) was present in the United States around the first 20 years of the 20th century and was characterized by a predominance of cardiovascular deaths due to rheumatic heart disease and stroke (principally hemorrhagic stroke). Stage 3 (The Phase of Degenerative and Manmade Diseases) was characterized by the rapidly expanding epidemic of ischemic heart disease and ischemic stroke, and this was present in the United States from the 1920s to the mid 1960s and in Western Europe until approximately 10 years later. In this phase, the development of coronary artery disease was noted primarily among the better educated and wealthier members of society. Stage 4 (The Phase of Delayed Degenerative Diseases) is the situation currently prevalent in the developed world and is characterized by a reduction in age-adjusted cardiovascular diseases but an overall increase in cardiovascular deaths due to an aging population. In this phase, premature cardiovascular disease occurs in patients of lower socioeconomic status, whereas more privileged classes experience coronary heart disease at an older age. It is important to emphasize that in many countries in South Asia, China, some regions in Latin America, and South Africa the various phases of the epidemiologic transition coexist and to some extent depend on socioeconomic status.

Whether there is a stage 5 in which the hard-won gains in reducing cardiovascular mortality over the past 5 decades are lost due to the epidemic of obesity and diabetes remains to be seen. The signals, however, are not encouraging and suggest that particularly in younger patients the declines in cardiovascular mortality in the United States have leveled off and are perhaps increasing. One of the major global challenges is the control of obesity and the prevention of diabetes, and in this regard, prevention begins in childhood.

The INTERHEART study has made an important contribution by



demonstrating that the traditional risk factors account for the majority of the attributable risk of premature myocardial infarction. These are obviously the major targets for prevention, and following publication of the initial Framingham report, the United States and other countries in the developed world have witnessed the rewards of standard risk factor modification, and a gratifying if not extraordinary reduction in cardiovascular mortality has been the result. Thus, we know what can be achieved by prevention strategies, but implementation of these strategies is an entirely different issue, particularly in low- and middle-income countries.

In addition, the developing world faces many potentially devastating traditional and nontraditional risk factors. The latter include air pollution, emerging as a powerful risk factor; overcrowded cities not conducive to exercise; tobacco use, including exposure to secondhand smoke; the multiple socioeconomic stressors of rural to urban migration; poor diet; and a clash between traditional cultural values and “modern” society. This “hostile” cardiovascular environment occurs in countries with limited national resources and a lack of infrastructure. The increasing risk factors in low- and middle-income countries pose a formidable global challenge for the developed world. The health of any country is in part reflected in its economic and political stability and, as such, a driver of global trade and prosperity.

The problem is well documented. In South Asia, China, the Middle East, and Eastern Europe, the epidemic of cardiovascular disease is already rampant. In sub-Saharan Africa, however, ischemic heart disease is still rare in the urban and rural indigenous populations, but the prevalence of risk factors, especially diabetes and hypertension, is increasing at a rapid rate. Among the wealthier countries in the world, obesity, tobacco abuse (particularly among women), and socioeconomic disparities in the recognition and treatment of risk factors are all challenges.

Preventive strategies are easy to enunciate but difficult to implement widely, especially in low- and middle-income countries. Population-based strategies include controlling diet and reducing salt intake, smoking cessation and limiting exposure to secondhand smoke (successful in the developed world and gaining ground in parts of Asia and Latin America), and increasing physical activity (which requires facilities, leisure time, and perhaps income). These strategies can be advanced with government intervention, eg, taxation of

tobacco, food labeling standards, agricultural policies, and cultural awareness. Corporate responsibility in regard to sales of tobacco and fast food also may play a major role.

The other approach is to intervene in high-risk populations with a proven therapy such as lipid-lowering drugs, antihypertensives, platelet inhibitors, and perhaps the “polypill,” currently undergoing clinical trials. The problem is that for a patient to receive these treatments, the disorder has to be diagnosed, and this is less likely to be the case in socially disadvantaged populations, and as such, the higher-risk population approach has the potential to widen social inequalities.

The international agenda is lengthy. It has been emphasized that research into prevention cannot be divorced from interactive policies, ie, agriculture and food policies, industrialization, urban design, social and cultural values, and economic and political stabilities. The health of a population is not just an issue for the cardiovascular community, but both the people and their leaders need to realize that their nation’s health is a top priority. The forthcoming United Nations Summit on Noncommunicable Diseases will advance a commitment at the highest level by the world’s leaders to deal with the issues of noncommunicable disease. An encouraging aspect of this unprecedented forum is the mobilization of federations around the world into a global, civil-society movement via an alliance. The NCD Alliance provides for the four leading noncommunicable diseases: cardiovascular disease, cancer, chronic respiratory tract disease, and diabetes.

The global epidemic of cardiovascular disease may be the biggest current challenge to the cardiovascular community. Why should the wealthy countries of the world be concerned about the health of poorer nations? There are three good reasons. First, it is the moral and right thing to do, and second, it is in the political and economic best interest of developed countries to care. Finally, although some problems are specific to low- and middle-income countries, many are not, and so common ground and action are required to stall an epidemic of cardiovascular disease in both the developed and the developing worlds.

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