The Year in Epidemiology, Health Services, and Outcomes Research

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The field of outcomes research continues to grow in its sophistication, scope, and importance. Our ability to track patterns of disease and health care and patient outcomes continues to build on stronger methodological approaches, advances in computing technology, and the coordination of talented investigators. Breakthroughs in the diagnosis and treatment of cardiovascular disease are applying pressure on the field to assess and enhance the translation of best practice into actual practice. Spiraling health care costs, as a result of expanding clinical capabilities and the aging of the population, challenge clinicians and policymakers to develop a system that is effective and affordable. Practical research that can provide insight regarding clinical care and population policies is needed now more than ever. Keeping pace with this research requires a survey of a broad range of publication venues in this truly multidisciplinary field.

This overview highlights information from prominent epidemiology, health services, and outcomes research publications from April 2004 through March 2005. Because it is not possible to include all the high-quality publications in this topic area, I sought to feature those I consider to have been particularly high-impact. Similar to last year's review, the studies included here are organized within categories consistent with the core goals for the future of American health care, as articulated by the National Academy of Sciences Institute of Medicine (IOM)—safety, effectiveness, equity, efficiency, timeliness, and patient-centeredness. A new category is included this year for policy-relevant studies of population trends and epidemiology.

SAFETY

Safety was a prominent topic in cardiovascular care this year. Several studies revealed risks associated with common medications, highlighting the need for the careful collection of information about adverse events. Interest in safety and safety-promotion strategies is likely to play an increasingly strong role in the future of clinical care.

Studies of the risks associated with cyclooxygenase (COX)-2 inhibitors had tremendous impact. In a nested case-control study using data from Kaiser Permanente in California, Graham et al. (1) found that rofecoxib was associated with higher risk of acute myocardial infarction (AMI) or sudden death compared with celecoxib. Juni et al. (2) published a cumulative meta-analysis in December 2004, reporting that, even by the end of 2000, there was evidence that rofecoxib, compared with placebo, more than doubled a patient's risk of an AMI. These observational studies were then supported by results from randomized trials. In March 2005, Brasalier et al. (3) reported from the Adenomatous Polyp Prevention on Vioxx (APPROVe) Trial that patients randomized to rofecoxib had nearly twice the risk of a thrombotic event. Nussmeier et al. (4), in a trial of valdecoxib and its intravenous prodrug parecoxib for pain relief after bypass surgery, found that these drugs doubled the risk of an important adverse event. Solomon et al. (5) used data from the Adenoma Prevention with Celecoxib (APC) trial and reported that celecoxib, compared with placebo, doubled the risk of cardiovascular events.

The growing use of statins drew several investigators to examine associated safety issues. Graham et al. (6) from the Food and Drug Administration (FDA) made use of claims data from 11 U.S. managed care health plans to estimate the incidence of rhabdomyolysis in 252,460 patients treated with different statins and fibrates. With 225,640 person-years of monotherapy and 7,300 person-years of combined therapy, the authors found 24 cases of incident rhabdomyolysis (16 with monotherapy and 8 with combined). This study was able to put in perspective the absolute risk for patients. The number-needed-to-treat for one year with monotherapy to observe one case of rhabdomyolysis was 22,727 patients receiving atorvastatin, pravastatin, or simvastatin, and 3,546 patients for those receiving a fibrate. Strandberg et al. (7) addressed concerns that statins might be linked to a cancer risk by examining the experience of the Scandinavian Simvastatin Survival Study (4S). This randomized trial included more than 4,000 patients age 35 to 70 years with previous AMI or angina pectoris, serum total cholesterol 5.5 to 8.0 mmol/l, and serum triglycerides 2.5 mmol/l or lower (8). The investigators found that the benefit of simvastatin persisted in a five-year post-trial period. In addition, over 10 years of follow-up, simvastatin was associated with a non-significant reduction in the risk of cancer, allaying concerns.

Nesiritide, a potent vasodilator, attracted additional safety concerns. Sackner-Bernstein et al. (9), in a meta-analysis of randomized, double-blind, controlled trials of...
nesiritide in patients with acutely decompensated heart failure, reported that nesiritide increased the risk of worsening renal function compared with non-inotrope and inotrope controls. In a separate systematic review, Sackner-Bernstein et al. (10) reported that nesiritide might be associated with an increased risk of death, although a similar analysis by the FDA (11), using more data, failed to identify the danger.

Unintended consequences of practice change after the publication of a randomized trial was the subject of a study by Canadian investigators (12) who examined rates of hospital stays for hyperkalemia after the release of the Randomized Aldactone Evaluation Study (RALES) (13), which showed that spironolactone, an aldosterone antagonist, was associated with a reduction in mortality and morbidity for patients with severe heart failure. After the RALES trial was published, the prescription rate for spironolactone increased markedly, but so did the hospital-stay rate for hyperkalemia. Interestingly, the increased use of spironolactone prescription after the RALES trial was not associated with a population-based improvement in heart failure outcomes.

Masoudi et al. (14) had previously reported that thiazolidinediones and metformin were prescribed commonly for patients with heart failure and diabetes despite strong warnings by the FDA against this practice. In a retrospective observational study of 16,417 Medicare beneficiaries hospitalized with heart failure, they found that these medications were actually associated with a lower risk of death at one year, but a slightly higher risk of readmission with thiazolidinedione treatment (hazard ratio 1.06; 95% confidence interval 1.00 to 1.09) (15). This finding leaves some doubt about whether these drugs should be considered contraindicated for patients with heart failure.

Safety concerns surround not only the effects of the medications but how they are prescribed. Growing enthusiasm for electronic health records can obscure the potential risks inherent in computer systems. Investigators from the University of Pennsylvania used qualitative and quantitative methods to investigate the possible role of computerized physician order entry systems in medical errors (16). They determined that this system facilitated 22 types of medication error risks, which were reportedly observed by a high percentage of house staff on an at-least-weekly basis.

**EFFECTIVENESS**

Several studies addressed the effectiveness of interventions to improve cardiovascular care and outcomes. Effectiveness particularly implies the impact of strategies in real-world settings and includes efforts to assess and improve quality of care.

Studies of the effectiveness of guideline-based strategies are useful in testing whether their application in actual practice matches the results achieved in a clinical trial. In a national Medicare study, Masoudi et al. (17) investigated patterns of angiotensin-converting enzyme (ACE) inhibitor use and its effectiveness, particularly in populations that were generally not represented in the trials. They found that ACE inhibitors were associated with a lower risk of mortality, a benefit that was slightly less than that reported in previously published trials. Moreover, even though creatinine levels were the strongest predictors of use, the benefit of ACE inhibitors appeared consistent across various strata of renal function. That ACE inhibitors prescribed at discharge did not replicate the trial result might be explained in a study by Butler et al. (18), who found that only about two-thirds of patients who were prescribed ACE inhibitors at discharge were current users one year later.

Several studies sought to characterize the nature of the relationship between volume and outcomes. This topic is particularly important as organizations increasingly push for volume standards. Epstein et al. used a large national claims database to examine institutional volume standards for percutaneous coronary intervention that were promulgated in the American College of Cardiology/American Heart Association (ACC/AHA) guidelines (19,20). They found that, compared with institutions with ≥400 cases, those with <200 had worse outcomes; however, the group with 200 to 399 cases annually was indistinguishable from the highest volume hospitals. In contrast, Wu et al. (21) studied bypass surgery in New York and reported that hospital and surgeon volume were related to outcome over a broad range of volume.

Many institutions are developing the capacity for percutaneous coronary intervention without onsite bypass surgery facilities. Wennberg et al. (22) used Medicare claims data to compare outcomes at sites with and without bypass surgery capability. After adjustment for case mix, there was no significant difference in the short-term risk of mortality for primary/rescue intervention. For patients undergoing a non-primary/non-rescue procedure, however, the mortality rate at hospitals without bypass surgery capability was significantly higher, a finding that was primarily the result of the experience of hospitals that performed ≤50 Medicare procedures annually. A randomized trial by Wharton et al. (23) also provided evidence that primary angioplasty at a site without bypass surgery capability can achieve results that are similar to those achieved by hospitals with such capacity.

The importance of the organizational factors in quality of care was highlighted by a study in which Bradley et al. (24) reported remarkable national hospital-level variation in the use of beta-blockers after AMI. In investigating the relationship between quality improvement efforts and beta-blocker rates, they found that administrative support and physician leadership, rather than particular tools, were the most important factors associated with higher beta-blocker rates. They conclude that a positive organizational environment is an essential factor for excellent clinical performance.

The promise of health information technology and electronic alerts was reinforced by a study of venous thrombosis prophylaxis conducted at the Brigham and Women’s Hos-
hospital in Boston (25). The investigators randomized patients to usual care or an intervention group in which the responsible physician was alerted to the patient’s risk of a venous thrombosis. The alert increased the appropriate use of prophylaxis and was associated with a significant reduction in the risk of deep vein thrombosis or pulmonary embolism. The study was remarkable because it showed both a process and outcome improvement from a relatively simple intervention.

The relationship of continuing medical education (CME) to quality of care was undermined by the findings of Patel et al. (26) at Duke. Using a large Medicare database, their study found no indication that states with CME requirements had better use of evidence-based therapies. Moreover, there was no association between CME requirements and one-year mortality.

Quality of cardiopulmonary resuscitation efforts were the focus of a few high-impact studies this year. Abella et al. (27), in a prospective, observational study of 67 patients, identified a number of commonly occurring defects. Within the first 5 min of each resuscitation effort, chest compressions were too slow in 28% of the 30-s time segments and too shallow for 37%. In 61% of the segments, ventilation rates were too high. Swedish investigators also examined the quality of out-of-hospital resuscitation efforts in a prospective study of 176 patients (28). They too found problems in the frequency and depth of compressions and substantial deviance from the advanced cardiac life support guidelines. These troubling findings were in contrast to the report of an Emory program that tested a strategy to improve in-hospital resuscitation outcomes. They employed education and replacement of monophasic defibrillators with a combination of manual biphasic defibrillators used in automatic external defibrillator (AED) mode and AEDs in all outpatient clinics and chronic care units (29). After initiation of this program, patients with an arrest from ventricular tachycardia or fibrillation had their chances of surviving to hospital discharge increased 14-fold.

Several notable studies focused on improving the organization of care. Koren et al. (30) demonstrated that a lipid-lowering disease management clinic in managed care and Veterans Administration settings was much more successful than usual care in helping patients reach National Cholesterol Education Program (NCEP) goals. Ho et al. (31) found that cardiology involvement with Veterans Administration patients with coronary artery disease was associated with better cholesterol and blood pressure management.

Disease management for patients with heart failure also emerged as a potentially important intervention. Galbreath et al. (32) randomized 1,069 patients to a telephonic disease management system conducted by CorSolutions Inc. (Rosemont, Illinois). The intervention group had a survival benefit but no change in health care use. In assessing a disease management program provided for 90 days to high-risk heart failure patients, Kimmelstein et al. (33) found that the intervention reduced hospital days related to heart failure. Koelling (34) specifically studied the impact of discharge education for heart failure patients and reported that a one-hour teaching session reduced the risk of repeat hospital stay or death. The costs in the intervention group during the subsequent six months were nearly $3,000 lower.

What we are likely to see in the future is an even greater emphasis on programs of care that seek to optimize the impact of the best medical science. Insights generated by medical research are insufficient without practical application, and the science of application has lagged behind the advances in more basic medical disciplines. There is a realization that there needs to be a strong effort to appropriately apply what we know.

**EQUITY**

Many studies focusing on cardiovascular disease have addressed the issue of equity in our health care system. These studies are beginning to clarify where and how race/ethnicity, gender, and socioeconomic status might disadvantage specific populations in the care they receive and the outcomes they experience.

Several studies have advanced our understanding of how disparities are mediated. Bradley et al. (35) showed that racial differences in time to reperfusion of ST-segment elevation myocardial infarction (STEMI) patients, which were almost 20 min longer for black patients undergoing primary angioplasty, could be accounted for by the hospital to which the patients were admitted. Bach et al. (36) showed that black patients predominately receive care from a small number of doctors who, on average, have less training and certification than those who care for white patients. Barnato et al. (37) examined evidence-based care for AMI and found that observed racial differences were, in large part, explained by a hospital effect. Koneyt et al. (38) demonstrated that black patients were more likely than white patients to undergo bypass surgery at hospitals with the highest mortality rates. Voigt et al. (39), in a California study, showed that black patients with a strong indication for an implantable cardioverter-defibrillator were much less likely than white patients to receive one (odds ratio 0.19).

Groeneveld et al. (40) reported that racial differences in implantable cardioverter-defibrillator use can, in part, be attributable to geographic variation. These articles suggest that racial differences in care might be importantly related to where black patients receive care. Remedies must address potential deficiencies in care at such institutions and ensure that these populations have access to high-quality providers.

Other studies examined outcomes by race. Using the Society for Thoracic Surgeons (STS) national cardiac database, Taylor et al. (41) compared the rate of in-hospital adverse outcomes after valve replacement surgery in 3,137 black patients and 46,249 white patients. The STS database contains detailed information about the patient and the surgery that has been abstracted from the medical record.
Although black patients did not have a higher adjusted risk of in-hospital mortality compared with white patients, there was an association with a higher risk of complications.

From a population perspective, evidence remains that race is strongly associated with mortality risk. Satcher et al. (42) reported that the black/white standardized mortality ratios show a disadvantage for blacks that has not changed substantially since 1960. They project that 83,570 excess deaths each year could be averted through elimination of the racial mortality gap.

Disparities by education were brought to the forefront by a Lancet article in which Huisman et al. (43) analyzed mortality data that were representative for Western Europe. They focused on the period from January 1, 1990, through December 31, 1997, including 304,410 deaths and 11,030,032 person-years at risk. They classified low educational level as lower secondary education (9th grade) or lower, and high educational level as higher secondary education (10th grade) or above. Low educational level was common, exceeding 70% in the population. For every 100,000 person-years at risk, there were 796 excess deaths in the low educational group compared with the high group. The total number of excess deaths was highest for cardiovascular deaths, with a difference of 315/100,000 person-years at risk, representing almost 40% of the difference in total mortality between the educational groups in men and 60% in women. The authors conclude that reduction of cardiovascular mortality among groups at low educational levels should be a particular priority for Western Europe; it is likely that these finding are generalizable to other regions.

A number of studies of disparities focused on differences in procedure rates. Cromwell et al. (44) added to this literature in a study using Medicare claims. They reported that white and Asian patients have higher rates of cardiac catheterization and revascularization procedures after an admission for ischemic heart disease. Rathore and Krumholz (45), in an opinion piece, emphasized the importance in such studies of understanding whether differences in rates are associated with disparities in outcomes; that is, do the described differences have consequence. These types of inferences are difficult to discern without information about the indications for the procedures. Without information about the appropriateness of the intervention, it is not possible to equate higher use with better care.

Interest in interventions to modify risk profiles in vulnerable populations has led to alternative models of care. Becker et al. (46) compared community-based care with “enhanced” primary care to reduce heart disease risk in high-risk black families in Baltimore. They randomized siblings of black patients <60 years of age who were hospitalized for heart disease. The community-based care was designed by a community advisory panel and provided in a non-clinical site. In visits to these sites, a physical assessment, including blood pressure, was performed by a nurse practitioner, and education was provided by a community health worker. Enhanced primary care included usual health care and education. Risk-reduction medications were covered for both groups. The 196 patients in the community-based group were twice as likely to reach blood pressure and low-density lipoprotein goals than the 168 patients in the primary care group. The community group was also much more likely to quit smoking. This rigorous study shows remarkable improvement in risk reduction in a very high-risk population, and should open the possibility of expanding this model.

The bottom line of these studies is that disparities persist, and the goal of real equity in health care, although possible, remains currently beyond our reach. The root causes might be structural and societal, and the necessary remedies will likely take the form of system reform and quality improvement—as well as addressing societal problems that lead to poor health and health outcomes.

EFFICIENCY

Health care costs remain a focus of many studies. Figures tend to lag, and the information for 2003 has just recently become available. In a Health Affairs article, Smith et al. (47) reported that the growth in health care slowed in 2003 for the first time in seven years; however, slow growth is growth nevertheless, and the national health spending still increased 7.7% to reach $1.7 trillion, or $5,670/person. In 2003, the U.S. devoted 15.3% of its gross domestic product to health care, an increase of 0.4% from 2002. Of note, prescription drug sales rose 10.7% to $179.2 billion.

Cost issues have naturally raised interest in regional variation in the intensity of treatment and its relationship to outcomes. Stukel et al. (48) investigated whether AMI patients living in areas with more intensive invasive treatment options had better outcomes. Cardiac catheterization rates ranged from 29% to 93% across the 566 coronary angiography service areas. Among the regions with high use of appropriate medical management, invasive management was not associated with better survival. The authors concluded that routine use of more invasive treatment strategies might not be associated with an overall population benefit beyond that seen with excellent medical management.

With increasing concerns about escalating health care costs, choices about the allocation of scarce resources are under scrutiny. Several studies addressed the cost-effectiveness of specific strategies. Many reported that the more expensive strategies were a reasonable investment by the usual standard of being below $50,000/year of life saved. Whether we can afford to implement all the strategies in this range requires debate at the national level. For now, several of the studies described in the following section provide some perspective on the relationship of cost to clinical benefit.

Many studies specifically estimated cost-effectiveness ratios for medical strategies. Weintraub et al. (49), in a study sponsored by Pfizer, used data from the Eplerenone Post-Acute Myocardial Infarction Heart Failure Efficacy and
Survival Study (EPHESUS) to investigate the cost-effectiveness of eplerenone compared with placebo in patients with left ventricular systolic dysfunction and heart failure after AMI. Using a daily cost of $3.60 for eplerenone, they estimated that the cost-effectiveness ratio was <22,000/life-year gained, a ratio that would be considered an economically attractive investment. Unfortunately, the authors did not model how eplerenone would compare with spironolactone, a much less expensive aldosterone antagonist. If the favorable results in the EPHESUS trial represent a class effect, it might be a more efficient strategy to start with the less expensive option.

Weintraub et al. (50), in another industry-sponsored study, employed data from the Clopidogrel in Unstable angina to prevent Recurrent Events (CURE) trial to determine the cost-effectiveness of clopidogrel, compared with placebo, up to one year after an acute coronary syndrome without ST-segment elevation. The cost-effectiveness ratios were estimated to be <$6,500/life-year gained. The authors demonstrated that the strategy remained economically attractive even if the life expectancy gain was just 20% of that projected from the trial or if the consequence of bleeding was higher than their best estimates.

Clopidogrel was also the subject of a study that examined the economic consequences of extending therapy after percutaneous coronary intervention from one month to one year (51). On the basis of randomized trial results, investigators estimated that this additional therapy cost $879/patient and reduced the risk of AMI by 2.6%. On the basis of their projections, it was estimated that extending therapy had a cost-effectiveness ratio of $15,696/year of life saved.

Debate also continues about the role of bivalirudin versus heparin. The Randomized Evaluation in PCI Linking Angioplasty to Reduced Clinical Events (REPLACE-2) study found that bivalirudin with provisional glycoprotein IIb/IIa inhibition was not inferior to heparin with routine glycoprotein IIb/IIa inhibition. In an industry-sponsored study, Cohen et al. (52) found that the bivalirudin strategy saved about $400/patient, owing mostly to a reduction in bleeding and thrombocytopenia.

Particular clinical strategies are also commonly the subject of these types of studies. For example, debates are ongoing about whether STEMI patients should be diverted to centers with primary angioplasty capabilities. The Comparison of Angioplasty and Pre-hospital Thrombolysis in Acute Myocardial Infarction (CAPTIM) trial, a European study, showed that primary angioplasty and pre-hospital fibrinolytic therapy with rescue angioplasty, as needed, had similar results at 30 days (53). The study included STEMI patients who were within an hour of a percutaneous coronary intervention center. Machecourt et al. (54) compared the costs of these strategies, finding the fibrinolytic group to be disadvantaged in that, even though they received medical therapy first, 83% had coronary angiography during the initial hospital stay and 35% had rescue angioplasty. At one year, costs were slightly more than $1,000 lower in the group randomized to primary angioplasty. It is currently unknown if these results can be replicated in other settings.

Many cardiologists have adopted a transeosophageal echocardiography-guided strategy instead of a conventional anticoagulation strategy for patients with atrial fibrillation of >2-days duration who are scheduled to undergo electrical cardioversion. The best study of this approach was the Assessment of Cardioversion Using Transesophageal Echocardiography (ACUTE) trial that found, at eight weeks, the two strategies had comparable rates of death, maintenance of sinus rhythm, and functional status (55). Klein et al. (56) also examined the relative costs of the strategies, because conventional therapy was associated with longer time to cardioversion and a higher risk of bleeding complications; however, considering the cost of the transeosophageal echocardiogram, total costs were not significantly different between the groups.

The costs of devices and procedures are also attracting a share of attention. Studies have shown that there is embolic protection for patients undergoing percutaneous intervention of saphenous vein bypass grafts. On the basis of data from the Saphenous Vein Graft Angioplasty Free of Emboli Randomized (SAFER) trial (57), investigators conducted an industry-sponsored economic analysis of the GuideWire balloon occlusion device. Cohen et al. (58) estimated that the lifetime cost-effectiveness ratio for the protection device was $3,718/year of life gained.

The Mode Selection in Sinus Node Dysfunction Trial (MOST) showed that dual-chamber pacing was associated with a lower rate of atrial fibrillation and subsequent hospital stay for heart failure than single chamber pacing (59). Rinret et al. (60) sought to determine whether the quality-of-life advantage of dual-chamber pacing was economically attractive. The mean age of the patients in the trial was 74 years. They estimated that, during the course of a patient’s lifetime, the dual chamber pacemaker increased quality-adjusted life expectancy by 0.14 years, with a cost-effectiveness ratio of $6,800/quality-adjusted year of life gained.

The Bypass Angioplasty Revascularization Investigation (BARI) showed that bypass surgery and angioplasty achieved similar results (61). Long-term follow-up information is now available, and the BARI study investigators have examined costs and quality-of-life outcomes at 10 to 12 years after randomization (62). Initially, patients in the bypass surgery arm had greater improvement in physical function, but that advantage narrowed over time and was not significant by four years. Bypass surgery was initially more expensive, but by 12 years the costs were virtually identical. Over 12 years, percutaneous transluminal coronary angioplasty patients accrued a mean of 8.42 life-years of survival compared with 8.58 life-years for bypass surgery patients. At 12 years, the cost-effectiveness of bypass surgery was $14,300/life-year.

Overall, these studies help quantify the resources required to produce a benefit. Very few studies reveal strategies that
can save money, and almost all require an investment for a benefit to the patient. How we will afford all of the strategies with favorable cost-effectiveness ratios is yet to be determined.

TIMELINESS

An important goal of the health care system is timeliness and appropriate access to care. This issue has recently received substantial emphasis with respect to time to reperfusion for STEMI. The ACC/AHA STEMI guidelines emphasized the importance of timely treatment and set targets of 30 min after hospital presentation for the provision of fibrinolytic therapy and 90 min for primary angioplasty (63). These targets were informed by the work of Nallamothu et al. (64), who examined the results of trials of fibrinolytic therapy and angioplasty and found that the difference between the therapies was related to the difference in time to provision of therapy. When the time to reperfusion was similar between the two strategies, then primary angioplasty was clearly superior; however, when primary angioplasty required about an hour longer to provide than fibrinolytic therapy, the two strategies yielded similar results.

Nallamothu et al. (65) also looked at the total time to reperfusion, for STEMI patients transferred from one hospital to another to undergo primary angioplasty, a neglected time interval. The authors examined 4,278 transfer patients with STEMI who underwent primary percutaneous coronary intervention at 419 hospitals included in the National Registry of Myocardial Infarction database. The median time from the initial hospital arrival to the first balloon inflation at the receiving hospital was 180 min. Only 16% of the patients had a total door to balloon time <2 h, and <5% had a door to balloon time of 90 min, the guideline standard.

PATIENT-CENTEREDNESS

There continues to be strong interest in assessing a wide range of outcomes from the patient’s perspective, with particular interest in health status and quality of life. Many studies are incorporating these outcomes into their patient assessments.

One such example is the third Randomized Intervention Trial of unstable Angina (RITA-3), which compared an early interventional strategy (IS) with a conservative strategy (CS) in the treatment of patients with unstable angina or non-STEMI (66). After one year, the treatment groups had similar rates of the combined end point of death or nonfatal AMI. The investigators added to the trial results by comparing quality-of-life outcomes and reported IS to be associated with greater improvements in quality of life, principally because of its effect on angina burden (67).

Another contribution by Spertus et al. (68) addressed the symptom outcomes of patients undergoing percutaneous coronary intervention. Their observational study demonstrated that although many patients experienced a quality-of-life benefit, 13% of the patients with no angina at the time of the procedure had worse quality of life one year later. The strongest predictors of quality-of-life improvement at one year were baseline functional status and angina burden.

POPULATION TRENDS AND EPIDEMIOLOGY

Many studies have focused on recent trends in cardiovascular risk factors and disease. In a notable publication, Framingham Heart Study investigators examined heart disease mortality and sudden death from 1950 to 1999 (69). In this period, overall coronary heart disease deaths decreased by 59%, and sudden death decreased by 49%, consistent in men and women. These estimates should be considered fairly reliable and better than studies based on death certificates because, in Framingham, each event is adjudicated.

Although the U.S. has been experiencing a decline in cardiovascular disease, there is evidence that other countries are undergoing an epidemiologic transition. In China, between 1984 and 1999, Critchley et al. (70) reported that coronary heart disease mortality rates increased by 50% in men and 27% in women. They further determined that rising cholesterol levels and the prevalence of obesity and diabetes accounted for 77% of the additional deaths. The potential consequences of an epidemic of vascular disease in China cannot be overestimated.

There are also indications that progress by the U.S. in reducing heart disease could be in jeopardy on the basis of reports of cardiovascular risk factors in young people. Using the Third National Health and Nutrition Examination Survey (NHANES) 1988 to 1994, de Ferranti et al. (71) found that two-thirds of the surveyed adolescents (age 12 to 19 years) had at least one metabolic abnormality and 10% had metabolic syndrome. Ford et al. (72), using data from 1988 to 1994 and 1999 to 2000, found temporal increases in waist circumference (~2 cm) and systolic blood pressure (about 2 mm Hg). Hedley et al. (73) reported that in 2001 to 2002, the prevalence of overweight (85th to 94th percentile) among children age 6 through 19 years was 31.5% and obesity (≥95th percentile) was 16.5%.

Heart failure is also the focus of considerable work. Roger et al. (74) studied trends in Olmsted County, Minnesota, as part of the Rochester Epidemiology Project. They found that the incidence of heart failure in men and women did not change substantially over the periods 1979 to 1984, 1985 to 1990, 1991 to 1995, and 1996 to 2000. Among patients with heart failure, the risk of mortality over five years decreased from 57% in 1979 to 1984 to 48% in 1996 to 2000. Younger men experienced the greatest gain in survival.

Koelling et al. (75), using the National Hospital Discharge Survey, examined trends in heart failure hospital stays. They estimated that by 2000 there were more than 1 million heart failure hospital stays yearly in the U.S., an increase from approximately 800,000 at the beginning of the
decade. They report that rates remained fairly constant for men but increased steadily for women.

Substantial attention has been placed on the epidemic of obesity. Daviglus et al. (76) investigated how body mass index in midlife affects long-term risk and health care resource consumption. They used data from the Chicago Heart Association Detection Project in Industry (CHA) (1967 to 1973) for 9,978 men (mean age, 46.0 years) and 7,623 women (mean age, 48.4 years) and tracked their long-term health care outcomes using Medicare data. They reported that people who are overweight and obese in middle age consume substantially more health care resources in old age.

With attention on obesity, Dansinger et al. (77) compared four popular diets (Atkins, Zone, Weight Watchers, and Ornish) for weight loss and cardiac risk-factor reduction. Participants had lost approximately 3 kg at one year, and no significant differences were found between the diets. The change in cardiovascular risk factors was also similar. Meanwhile, Knoops et al. (78) made use of a 10-year follow-up of the Healthy Ageing: a Longitudinal study in Europe (HALE) population and investigated the effect of adhering to a Mediterranean diet and a healthy lifestyle. The Mediterranean diet was associated with a 23% lower risk of mortality. Moderate alcohol consumption, physical activity, and nonsmoking were also associated with substantially lower risks of mortality, heart disease, and cancer.

One of the most remarkable contributions this year was a case-control study of AMI across 52 countries, in which Yusuf et al. (79) investigated the importance of cardiovascular risk factors. Despite the increased attention that has been focused on new risk factors, they found that standard, traditional risk factors accounted for most of the risk of AMI. These factors included abnormal lipids, smoking, hypertension, diabetes, abdominal obesity, psychosocial factors, consumption of fruits, vegetables, and alcohol, and physical activity. The population-attributable risk for these factors was >90%. The finding suggests that public health efforts should focus on currently known risk factors and that modification of these factors has the potential to prevent most cases of AMI.

CONCLUSIONS

This year was another remarkably productive period for articles relevant to improving health and health care delivery. These studies, which represent only a sample of the highlights of the year, generate knowledge that can immediately be incorporated into practice and policy as we seek to ensure that patients and populations have every opportunity to achieve the best possible outcomes. The field will seek, increasingly, to provide insight about our achievements and shortfalls—and to strive to contribute to the positive evolution of the health care system by providing a scientific basis for clinical practice and system improvement.

REFERENCES


