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STATE-OF-THE-ART PAPER

# The Worldwide Environment of Cardiovascular Disease: Prevalence, Diagnosis, Therapy, and Policy Issues

## A Report From the American College of Cardiology

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**The environment in which the field of cardiology finds itself has been rapidly changing. This supplement, an expansion of a report created for the Board of Trustees, is intended to provide a timely snapshot of the socioeconomic, political, and scientific aspects of this environment as it applies to practice both in the United States and internationally. This publication should assist healthcare professionals looking for the most recent statistics on cardiovascular disease and the risk factors that contribute to it, drug and device trends affecting the industry, and how the practice of cardiology is changing in the United States. (J Am Coll Cardiol 2012;60 Suppl S: S1–S49) © 2012 by the American College of Cardiology Foundation**

The environment in which the field of cardiology finds itself has been rapidly changing. This supplement, an expansion of a report created for the Board of Trustees, is intended to provide a timely snapshot of the socioeconomic, political, and scientific aspects of this environment as it applies to practice both in the United States and internationally. This publication should assist healthcare professionals looking for the most recent statistics on cardiovascular disease and the risk factors that contribute to it, drug and device trends affecting the industry, and how the practice of cardiology is changing in the United States.

### Global Burden of Cardiovascular Disease

Cardiovascular disease (CVD) currently accounts for nearly half of noncommunicable diseases (NCDs). NCDs have overtaken communicable diseases as the world's major disease burden, with CVD remaining the leading global cause of death, accounting for 17.3 million deaths per year, a number that is expected to grow to >23.6 million by 2030 (1,2).

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Increasingly, the populations affected are those in low- and middle-income countries (LIMC) (Fig. 1), where 80% of these deaths occur, usually at younger ages than in higher income countries, and where the human and financial resources to address them are most limited (2,3).

From 2011 to 2025, the projected cumulative economic losses from all NCD is $7.28 trillion in LIMC. As displayed in Figure 2, CVD accounts for nearly 50% of this projected loss (4). Within LIMC, it is projected that reducing CVD mortality by 10% would result in a $377 billion reduction in economic losses from 2011 to 2025 (5).

Economists project that the cost of not investing in CVD prevention and treatment could amount to as much as $47 trillion worldwide in the next 25 years. This loss is potentially avoidable because the prescribed World Health Organization (WHO) "best buy" interventions only cost $11 billion to $13 billion annually (6). The consequences will be more severe in developing countries, given that 80% of cardiovascular deaths occur in LMIC countries (7).

Cardiovascular disease is responsible for 10% of the disability-adjusted life years (DALYs) lost in LMIC, and for 18% of DALYs lost in high-income countries (8). The cost of CVD to both families and society is related to both a loss of productivity and income of the person who has CVD and of their caregiver, who may have to stop working to care for them. This economic loss is exacerbated in the developing world where CVD affects a high proportion of working-age adults (9).

**Abbreviations and Acronyms**

**ACA** = Affordable Care Act
**ACC** = American College of Cardiology
**ACO** = Accountable Care Organization
**AHA** = American Heart Association
**BMI** = body mass index
**CMS** = Centers for Medicare and Medicaid Services
**COI** = conflict of interest
**CVD** = cardiovascular disease
**CVRN** = Cardiovascular Research Network
**DALY** = disability-adjusted life year
**DES** = drug-eluting stent
**EHR** = electronic health record
**FDA** = Food and Drug Administration
**FTE** = full-time equivalent
**HDL** = high-density lipoprotein
**LDL** = low-density lipoprotein
**LMIC** = low- to middle-income country
**NCD** = noncommunicable disease
**NIH** = National Institutes of Health
**PCMH** = patient-centered medical home
**PGPD** = physician group practice demonstration
**TAVR** = transcatheter aortic valve replacement
**YLL** = years of lives lost

**Heart disease and stroke by country.** The SHARE (Survey of Health, Ageing, and Retirement) in 11 European countries, the HRS (Health Retirement Survey) in the United States, and the ELSA (English Longitudinal Study of Aging) survey and collect information regarding the health of the aging population. Table 1 synthesizes the studies and displays comparisons of age-adjusted self-reported prevalence of heart disease and stroke by country. It indicates that the United States has the highest prevalence of heart disease and stroke in both males and females Table 1 (10).

**CVD risk factors.** OBESITY. Globally, the prevalence of obesity (body mass index [BMI] ≥30 kg/m$^2$) doubled between 1980 and 2008, and it is estimated that 2.8 million deaths annually are caused by being overweight (BMI ≥25 kg/m$^2$) or obese. In 2008, 10% of men and 14% of women globally were obese compared with 5% of men and 8% of women in 1980. The Americas had the highest prevalence of overweight (62%) and obese (26%) persons (1,11). Figure 3 and Table 2 display the mean BMI change by WHO region and globally.

HYPERTENSION. Globally, some 40% of people over the age of 25 years have high blood pressure, and the number of people with elevated blood pressure (systolic blood pressure ≥140 mm Hg or diastolic blood pressure ≥90 mm Hg) has increased from 600 million in 1980 to a billion in 2008. The global hypertensive percentage has improved over this period; however, some regions have worsened in this respect. A decrease in the proportion of populations with high blood pressure was seen in the Western Pacific, Europe, and the Americas, as shown in Figure 4 and Table 2 (12). Systolic blood pressure is highest in LMIC. Globally, elevated blood pressure is reported to cause 51% of stroke deaths and 45% of coronary heart disease deaths (Table 2) (11).

DYSLIPIDEMIA. Mean total cholesterol levels around the world are highest in high-income countries and have been dropping since 1980 throughout the world. The most drastic decreases have been in high-income countries (5.62 to 5.19 mmol/l), but modest decreases in low-income countries (4.46 to 4.20 mmol/l) and middle-income countries (4.91 to 4.7 mmol/l) have also been seen. Nevertheless, some 39% of the global population still has elevated cholesterol, as do more than one-half of those in higher income countries (Fig. 5) (3).

SMOKING. Smoking rates among adults in the United States have declined by more than one-half over the past 25 years, from 33.5% in 1980 to 15.1% in 2010—thought to be the fourth lowest rate among OECD countries (countries that signed the convention on Organization for Economic Cooperation and Development) after Iceland, Sweden, and Mexico. In contrast, at least 25% of residents living in Greece, Chile, Ireland, Hungary, Estonia, Spain, and Turkey smoke cigarettes, according to the most recent data (Table 3) (13).

**Drivers of CVD.** AGING AS A GLOBAL PHENOMENON. Populations in the developed world have been aging for decades due to rising life expectancy and falling birth rates. The United Nations has calculated that the proportion of the world's population over the age of 65 years will more than double by 2050, at which point approximately 1 billion people around the world will be over the age of 65 years (Fig. 6).

Problems associated with an aging population are expected to be particularly acute in wealthy, industrialized countries such as Japan, Italy, and Germany, where 20% or more of the population was 65 years of age or older in 2010. In LIMC, the elderly are also expected to become an increasingly large economic burden as they are expected to

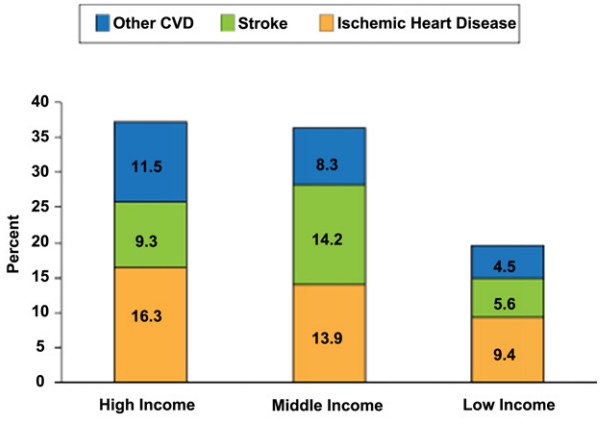


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**Figure 1** Crude Data: Proportion of Deaths Due to CVD by Country Income Level

CVD = cardiovascular disease. Source: Sinclair H. CVD Improvements and Challenges of a Global Epidemic; MD Conference Express, November 2010.

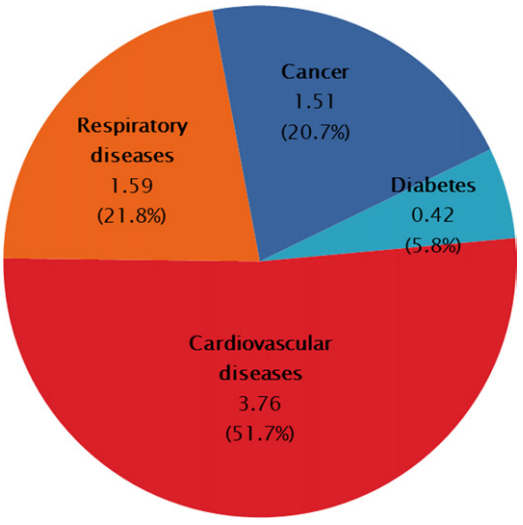


**Figure 2** Economic Loss (Trillions of US$ in 2008) of Noncommunicable Diseases in Low- and Middle-Income Countries, 2011 to 2025

Source: World Economic Forum and World Health Organization (5).

represent at least 15% of the population in countries in which the per capita income was under $10,000 in 2005 (14). In the absence of targeted policy measures, the aging of the population is expected to lead to significant increases in societal expenditures beginning around 2020 onward, the largest proportion of it going to pensions, followed by health and long-term care.

Life expectancy has been progressively increasing for the last 50 years. Figure 7 shows life expectancy at birth in 2009 (or nearest year available), and the years gained since 1960.

**URBANIZATION AND THE CVD RISK FACTOR BURDEN.** Living in a city—often a megacity (>10 million people), of which there are now 21 in the world—brings with it a number of predictable hazards (15). Among those that contribute to CVD are heavy environmental pollution, high traffic, no sidewalks, and even the threat of violence outside the home; these factors are major obstacles to physical activity. Additionally, there are very few "green spaces," or open land for public use, contributing to the lack of exercise and sedentary lifestyle (8).

Globalization and urbanization are key factors driving the worldwide increase in obesity and diabetes mellitus (major CVD risk factors), along with hypertension. With urbanization has come the global nutritional transition. This transition includes an increase in consumption of animal-source foods, edible oils, and sugars that has occurred in high-income countries and is progressively occurring in LMICs. This dietary change is influenced by the increasing numbers of supermarkets in developing countries that tend to serve processed foods higher in salt, fat, and added sugar. In Latin America, for example, supermarkets' share of food sales increased from 15% to 60% over a 10-year period (1990 to 2000). Another factor is the decreasing price of animal source foods and grains (11). Low-income countries often face a double burden of nutritional insufficiencies among infants and children combined with greater access to nutrition-poor food later in life. This has been found to increase the risk for CVD later in life (11).

Migrating from rural to urban areas is shown to increase blood pressure due to changing dietary patterns. Figure 8 shows that, on average, urban areas have a higher prevalence of hypertension than rural areas (16). Finally, smoking rates are also increasing among youth in several regions of the world due to urbanization. Tobacco manufacturers aggressively market to cities of LMIC. Unfortunately, children are most affected by these campaigns, as they are more impressionable (8).

**Mortality disparities.** In comparison to high-income countries, total years of life lost (YLL) to disease are more than 4 times higher in LIMC and more than double in middle-income countries. More than two-thirds of total YLL are caused by communicable diseases, maternal and perinatal conditions, as well as nutritional deficiencies. As the burden of CVD risk factors increases in LMIC countries, the proportion of deaths due to CVD is projected to increase, especially in LMIC countries, as displayed in Figure 9. In contrast, the same causes account for only about one-quarter of lives lost in middle-income countries and fewer than 10% of lives lost in high-income countries (Fig. 10) (11).

**STROKE MORTALITY EXCEEDS ISCHEMIC HEART DISEASE MORTALITY.** CVD-associated stroke mortality exceeded ischemic heart disease mortality in 74 WHO member countries in a global analysis of WHO cause-specific mortality data and World Bank national income data. China, Africa, and South America had a disproportionately higher burden of stroke (Fig. 11). Specifically, in the country with

**Table 1** Age-Adjusted Prevalence (% of Population) of Heart Disease and Stroke by Sex, 2004

| | Heart Disease | | Stroke | |
|---|---|---|---|---|
| Country | Males | Females | Males | Females |
| Austria | 12.2 | 7.3 | 5.2 | 3.5 |
| Belgium | 18.8 | 11.8 | 3.9 | 4.2 |
| Denmark | 10.8 | 7.6 | 6.5 | 4.6 |
| France | 19.3 | 9.8 | 3.7 | 3.5 |
| Germany | 14.3 | 9.3 | 5.6 | 3.1 |
| Greece | 14.9 | 10.7 | 4.1 | 3.5 |
| Italy | 12.7 | 9.1 | 3.8 | 2.5 |
| Netherlands | 14.7 | 8.9 | 5.0 | 4.8 |
| Spain | 11.4 | 10.0 | 2.4 | 1.8 |
| Sweden | 20.3 | 13.0 | 6.3 | 3.6 |
| Switzerland | 9.5 | 5.4 | 2.9 | 2.2 |
| Total SHARE | 15.4 | 9.9 | 4.5 | 3.5 |
| United States (HRS) | 26.4 | 19.7 | 6.6 | 5.5 |
| England (HRS) | 19.0 | 16.0 | 3.2 | 2.5 |

HRS = Health Retirement Survey; SHARE = Survey of Health, Ageing, and Retirement.

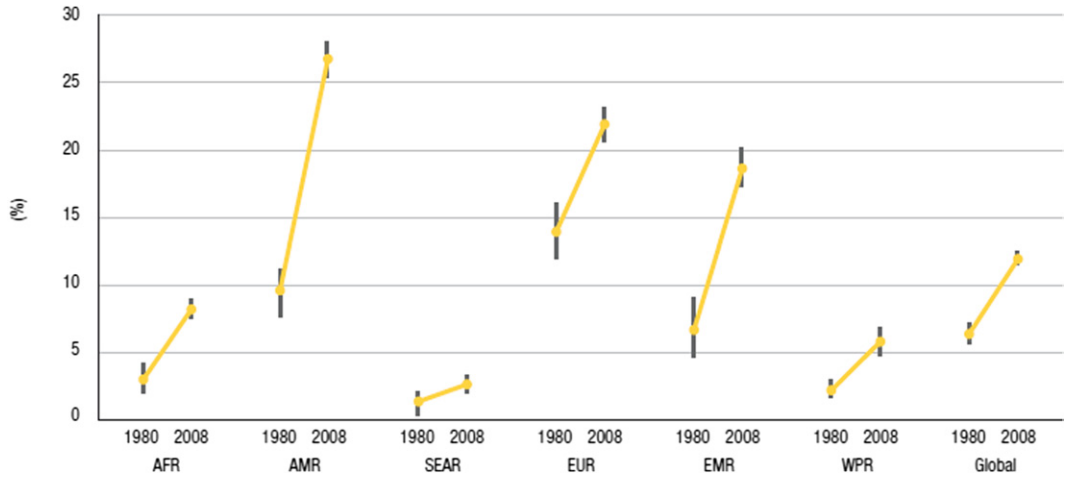


**Figure 3** Change Over Time in Mean BMI by WHO Region, 2009

AFR = African region; AMR = Americas region; BMI = body mass index; EMR = Eastern Mediterranean region; EUR = European region; SEAR = South-East Asia region; WHO = World Health Organization; WPR = West Pacific region. Source: World Health Organization (11).

the second largest excess, China, stroke mortality rate was 19.9% of total all-cause mortality compared with the 8.0% attributed to ischemic heart disease. Conversely, Australia, much of Europe, North America, and the Middle East experienced a higher burden of ischemic heart disease (Fig. 11) (17).

**Global CVD initiatives.** As CVD becomes a bigger health concern in the developing world, the United Nations political declaration on NCD resolved to reduce premature death due to NCDs by 25%. To respond to the declaration, a task force consisting of representatives from professional societies (American College of Cardiology Foundation [ACCF], American Heart Association (AHA), World Heart Federation, European Heart Network, and European Society of Cardiology) convened to establish risk factor reduction targets. The targets to be reached by 2025 include the following:

- 10% relative reduction in overall alcohol consumption
- 15% relative reduction in mean proportion of total energy intake from saturated fatty acids
- Stop the increasing obesity prevalence
- 10% relative reduction in the prevalence of insufficient activity

**Table 2** World Health Organization Abbreviations

| Abbreviation | WHO Region |
|---|---|
| AFR | African Region |
| AMR | Region of the Americas |
| SEAR | South-East Asia Region |
| EUR | European Region |
| EMR | Eastern Mediterranean Region |
| WPR | Western Pacific Region |

WHO = World Health Organization.

- 25% relative reduction in prevalence of high blood pressure
- 20% relative reduction in high total cholesterol
- 30% relative reduction in mean population intake of salt
- 30% relative reduction in smoking prevalence (2).

The UnitedHealth Chronic Disease Initiative, together with the National Heart, Lung, and Blood Institute, has pledged $34 million over 5 years to support a network of collaborating centers of excellence to help combat chronic diseases, including CVD, in developing countries (18). A research institution in each center within a developing country is paired with at least 1 institution in a developed country, and each center is responsible for carrying out research tailored to local or regional needs (19).

A similar initiative is planned to improve medical education and research capability in Sub-Saharan Africa. The National Institutes of Health and the President's Emergency Plan for AIDS relief collaborated to award funding to the Medical Education Partnership Initiatives to address shortages in specialized training. One clear need is cardiology training in Sub-Saharan Africa. For example, Zimbabwe has 3 trained cardiologists (2 adult cardiologists and 1 pediatric cardiologist). The main medical school in Zimbabwe received a Medical Education Partnership Initiatives–based grant (Cerebrovascular, Heart Failure, Rheumatic Heart Disease Interventions Strategy grant) to integrate modern cardiovascular training within existing medical school education to improve health outcomes and improve CVD research capacity (20).

It should also be noted that access to up-to-date biomedical research within the developing world is a key component to improving CVD care. The Health InterNetwork

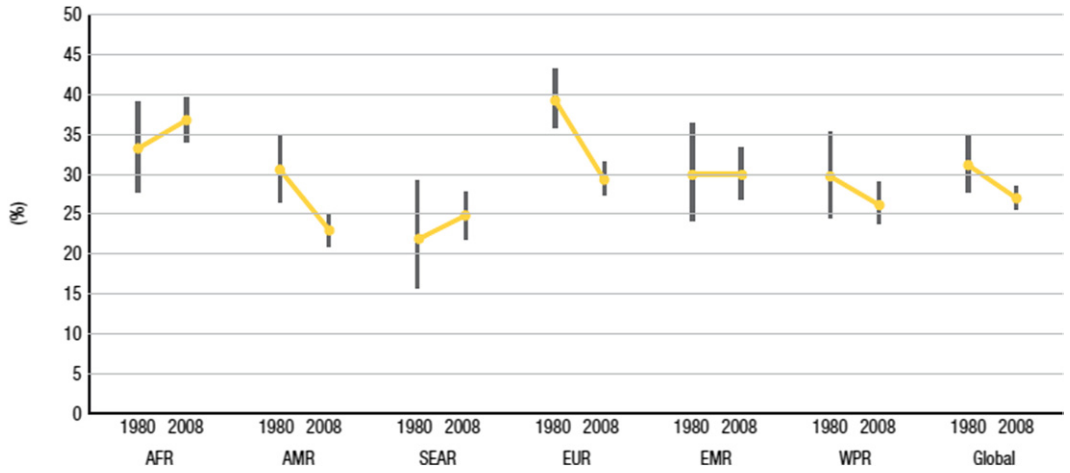


**Figure 4** **Prevalence of Elevated Blood Pressure (SBP ≥140 mm Hg or DBP ≥90 mm Hg) Among Adults Over 25 Years by WHO Region, 1980 to 2008**

DBP = diastolic blood pressure; SBP = systolic blood pressure; other abbreviations as in Figure 3. Source: World Health Organization (11).

Access Research Initiative provides free online access to >7,500 journal titles in the biomedical and health literature to 105 academic institutions in developing countries. The project is expected to continue until at least 2015 (21).

## Changing Dynamics of Payment and Delivery

Economic pressure is causing the healthcare industry to adopt new paradigms of care that service more people at lower costs. The most recent national spending projections from the Centers for Medicare and Medicaid Services (CMS) estimate that U.S. healthcare spending will grow at an average annual rate of 5.7% from 2011 through 2021, rising from 17.9% of the gross domestic product ($2,495.8 billion) to 19.6% ($4,781.0 billion) (Fig. 12) (22,23).

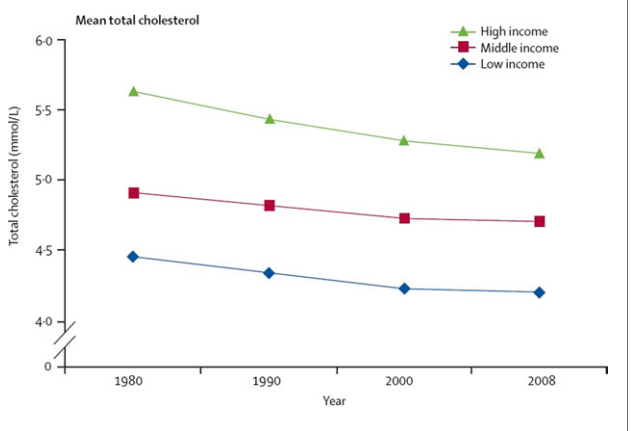


**Figure 5** **Change Over Time in Mean Total Cholesterol by Country Income Category**

**Green** = high income; **red** = middle income; **blue** = low income. Source: Anand et al. Stemming the global tsunami of cardiovascular disease. Lancet 2011 Feb 12.

Mirroring the national trend of increasing costs, the AHA's recent projections show cardiovascular care cost tripling from $272.5 billion in 2010 to an estimated $818.1 billion in 2030 (24). Figure 13 shows the projected direct and indirect costs of all CVD, 2010 to 2030.

Between 2010 and 2030, real (2008$) total direct medical costs of CVD are projected to triple, from $272.5 billion to $818.1 billion (Table 4). Because it has a higher prevalence than other CVD conditions, hypertension is the most expensive component of CVD (24).

Real indirect costs for all CVDs are estimated to increase from $171.7 billion in 2010 to $275.8 billion in 2030, an increase of 61% (Table 4). Congestive heart disease has the highest indirect cost and is expected to continue to account for 40% of all CVD indirect costs (Table 4) (24).

It is important to note that these CVD projections were made under the assumption that the status quo will be maintained in CVD prevention and treatment trends (e.g., no increase in the use of generic drugs).

Roehrig and Rousseau (25) suggest that prior health spending research has overly emphasized so-called treated prevalence, namely, the number of people receiving treatment for a given condition, rather than correctly accounting for the effects of cost per case trends. Examining treated prevalence, clinical prevalence (the number of people with a given disease, treated or not) and cost per case across all medical conditions between 1996 and 2006, they found three-fourths of the increase in real per capita health spending was attributable to growth in cost per case, whereas treated prevalence accounted for about one-fourth of spending growth. They conclude that most of the treated prevalence effect is due to an increase in the share of eligible people being treated rather than to an increase in clinical prevalence of diseases, and suggest that efforts to curb

**Table 3** Proportion of Population in OECD Countries Who Smoke, 2010*

| Rank | OECD Countries | 2010 |
|---|---|---|
| 1 | Greece | 31.9 |
| 2 | Chile | 29.8 |
| 3 | Ireland | 29.0 |
| 4 | Hungary | 26.5 |
| 5 | Estonia | 26.2 |
| 5 | Spain | 26.2 |
| 7 | Turkey | 25.4 |
| 8 | Czech Republic | 24.6 |
| 9 | Poland | 23.8 |
| 10 | France | 23.3 |
| 11 | Austria | 23.2 |
| 12 | Italy | 23.1 |
| 13 | Korea | 22.9 |
| 14 | Germany | 21.9 |
| 15 | United Kingdom | 21.5 |
| 16 | Netherlands | 20.9 |
| 17 | Belgium | 20.5 |
| 18 | Switzerland | 20.4 |
| 19 | Denmark | 20.0 |
| 20 | Japan | 19.5 |
| 20 | Slovak Republic | 19.5 |
| 22 | Finland | 19.0 |
| 22 | Norway | 19.0 |
| 24 | Slovenia | 18.9 |
| 25 | Israel | 18.6 |
| 25 | Portugal | 18.6 |
| 27 | New Zealand | 18.1 |
| 28 | Luxembourg | 18.0 |
| 29 | Canada | 16.3 |
| 30 | Australia | 15.1 |
| 30 | United States | 15.1 |
| 32 | Iceland | 14.3 |
| 33 | Sweden | 14.0 |
| 34 | Mexico | 13.3 |
| | OECD average | 21.1 |

*Or nearest available year. Source: OECD Health Data 2012 (13).
OECD = Organization for Economic Cooperation and Development.

health spending should focus more on reining in cost per case (25). Table 5 shows the growth rate in real per capita spending along with cost per case and treated prevalence percentages for cardiovascular conditions between 1996 and 2006 (25).

Addressing rising costs, along with expanding coverage and improving healthcare delivery, is a key focus of the Affordable Care Act (ACA) approved by Congress in 2010 with key provisions, albeit modified concerning the expansion of the Medicaid program, upheld in 2012. Table 6 lists provisions related to cost control enacted by the law (26).

Table 7 lists current CMS Innovation Center initiatives (29,30); Figure 14 shows percentage of total U.S. healthcare spending by payment sources (2010).

**Care coordination.** Addressing fragmented care through better coordination is considered an approach that may improve healthcare quality. Nonphysician professionals are being seen as a resource to alleviate pressure created by physician shortages. Various healthcare reform efforts are under way to develop teams of allied healthcare practitioners who will be able to provide team-based care for chronically ill patients. Interdisciplinary teams are a key component to provide chronic disease management and transitional care delivered in newer models of care such as accountable care organizations (ACOs).

The most significant model currently undergoing testing and development to understand the dynamics of team-based care is the patient-centered medical home (PCMH) (31,32). The CMS is currently running the federally qualified health center advanced primary care practice demonstration to determine whether the PCMH can improve quality of care, promote better health, and lower costs. As of October 2011, approximately 500 practices were enrolled in the demonstration (33).

In an effort to alleviate potential obstacles in the creation of PCMHs, the CMS Innovation Center has committed funding to multiple PCMH efforts. These include pilot projects aimed at improving quality of care for vulnerable populations and implementation of the PCMH model in medical settings. The CMS has designated these efforts as the Health Care Innovation Awards and recently distributed $122.6 million to 26 health centers in May

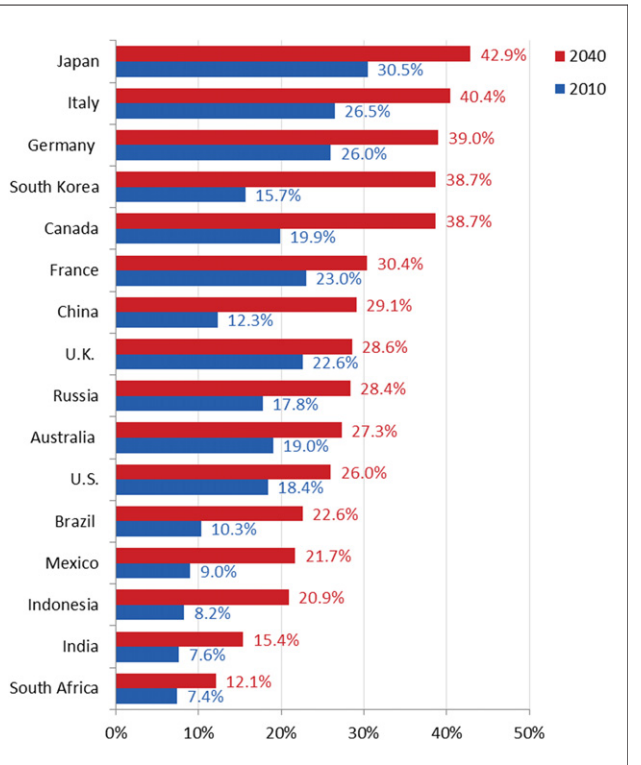


**Figure 6** Elderly (Age 60 Years and Older), as Percent of Population in 2010 and 2040

**Red bars** = 2040; **blue bars** = 2010. Source: UN Population Division, World Population Prospects, 2010 Revision. United Nations, 2011.

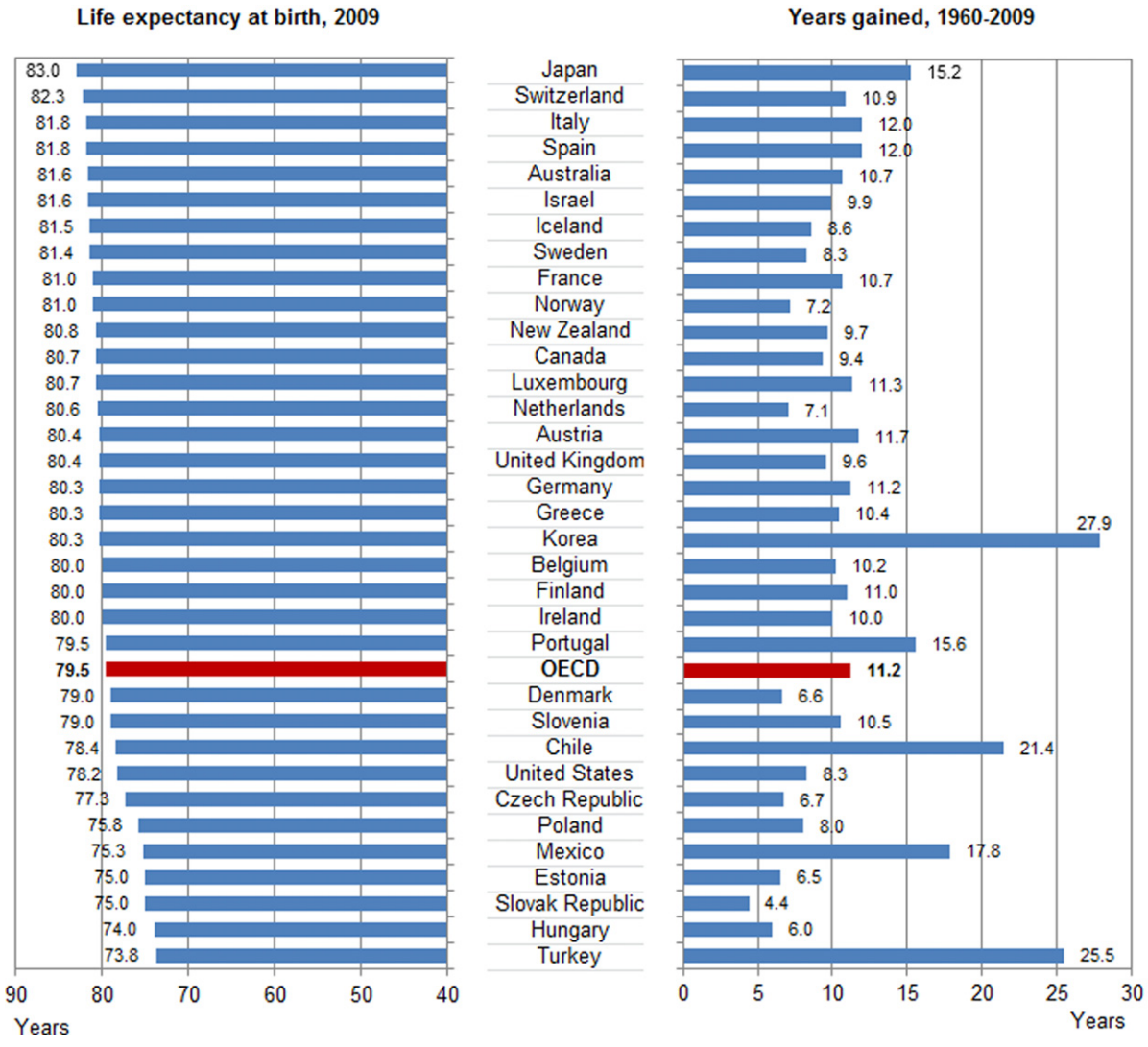


**Figure 7** **Life Expectancy at Birth, 2009 (or Nearest Year Available), and Years Gained Since 1960**

OECD = Organization for Economic Cooperation and Development. Source: OECD 2012. OECD Factbook 2011–2012: Economic, Environmental and Social Statistics. OECD Publishing. Available at: http://www.oecd-ilibrary.org/economics/oecd-factbook_18147364.

2012. The CMS Innovation Center budgeted to disperse up to $1 billion to grantees that primarily serve Medicare, Medicaid, and children under the Children's Health Insurance Program who will be transitioning to patient-centered care and dispersed a second batch of funding in June 2012 (34).

Along with the focus of the CMS on underserved populations, the Innovation Center has helped fund a multistate project for 12 Veterans Health Association-affiliated hospitals. These hospitals have been given $20.75 million through the Health Care Innovation Awards endeavor to identify high-risk patients and to improve coordination of care for these patients. Part of the care coordination process will include transitioning primary care practices within targeted communities to PCMHs. Funding will also support employee training and new positions that will be specifically needed in transitions clinics (34).

**Accountable care organizations.** The ACO program, which involves groups of hospitals, physicians, and other clinicians that are responsible for the range of care of specified groups of patients, requires a significant investment of resources by participating providers and has been the most prominent of the reform efforts. Currently, a pilot program is in place to test the ability of participating institutions to facilitate coordination and cooperation to improve quality of care and reduce costs (35). Participating institutions will be evaluated, and must perform in the top 30th percentile for 70% of the 32 quality measures established in the Medicare physician group practice demonstration (PGPD) (Fig. 15) (36).

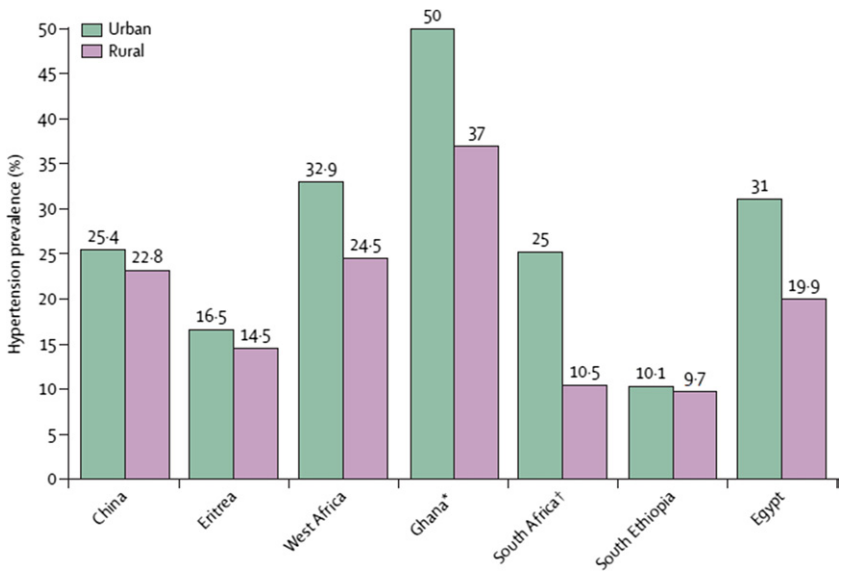


**Figure 8** **Difference in Prevalence of Hypertension in Urban and Rural Regions**

**Green bars** = urban; **lavender bars** = rural. Source: Ibrahim and Damasceno (16).

From 2005 to 2010, CMS conducted the PGPD to model how physician groups could share in savings when they spent less than projected. All 10 organizations that participated in PGPD reached 30 of the 32 quality measures after 5 years for patients with coronary artery disease, congestive heart failure, hypertension, diabetes, and cancer screenings. On average, the PGPD organizations increased their quality scores by 12 percentage points on heart failure, 6 percentage points on coronary heart disease, and 4 percentage points on hypertension (36). Subsequent analysis determined that PGPD organizations saved an average of $114 per Medicare beneficiary and $532 per dually eligible

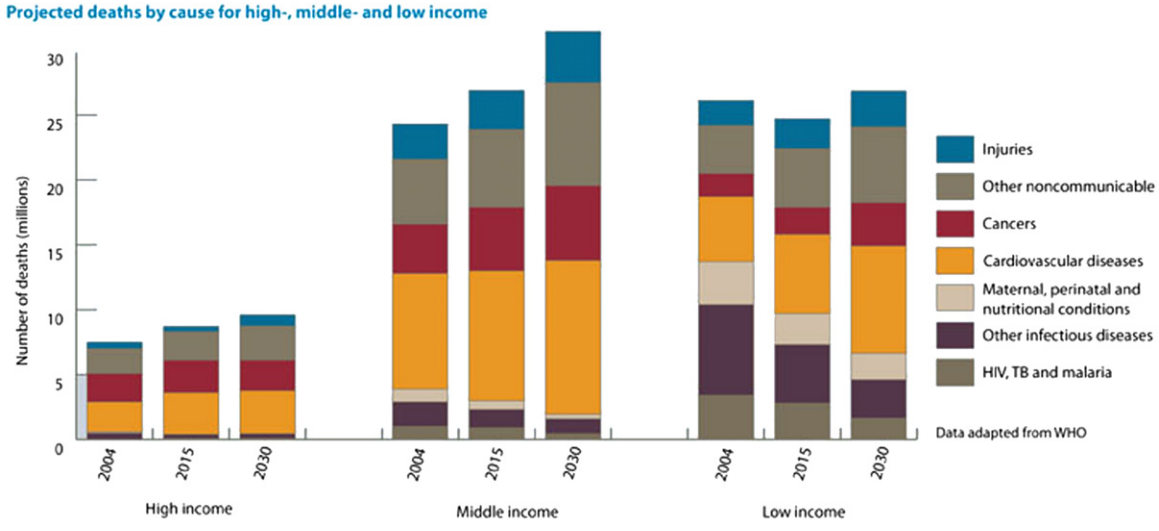


**Figure 9** **Project Mortality Trends Globally by Income Category**

**Blue** = injuries; **taupe** = other noncommunicable diseases; **red** = cancers; **gold** = cardiovascular diseases; **beige** = maternal, perinatal, and nutritional conditions; **brown** = other infectious diseases; and **olive brown** = human immunodeficiency virus, tuberculosis, and malaria. Source: Agyemang C. Cardiovascular diseases in poor resource settings. Available at: http://gm.stijlfabriek.com/issues/issue-10/cardiovascular-diseases-in-poor-resource-settings/. Accessed June 2012.

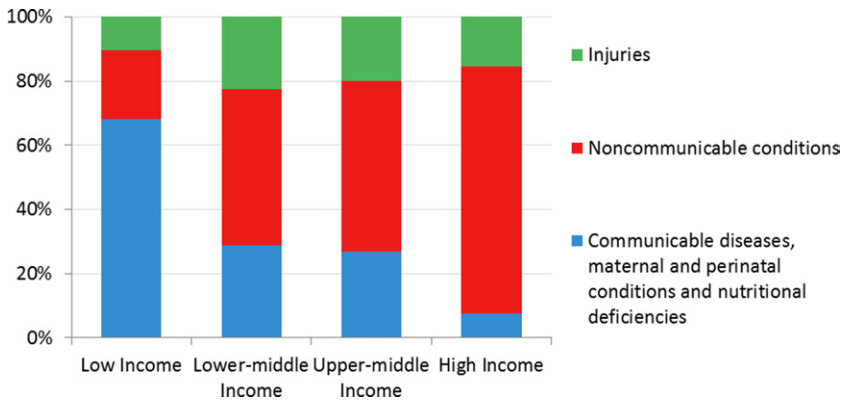


**Figure 10** **Proportion of YLL Due to Premature Mortality by Broad Cause and Country-Income Group, 2004**

YLL = years of life lost. Source: World Health Organization. GBD 2004 Summary Tables. 2008. Available at: http://www.who.int/evidence/bod. Accessed October 2012.

beneficiaries annually. However, the savings varied greatly across practices, from a savings of $655 per capita to spending $749 more per capita annually (37).

**CMS quality initiatives.** In addition to these programs from the Innovation Center, CMS is implementing the value-based purchasing, quality measure, and resource use measurement programs in an effort to move away from the current fee-for-service program (38).

The hospital value-based purchasing program under CMS will begin in the 2013 fiscal year (39). The 2013 year is considered a "dry run" and will generate reports for hospitals on the basis of the quality measures to educate them on the performance methodology but will not have any financial consequences. Eligible hospitals will be evaluated on 12 clinical process of care and 8 hospital consumer assessment of healthcare providers and systems measures, with clinical care measures accounting for 70% of the score. Measures are displayed in Tables 8 and 9 (40).

The Physician Compare website will soon publish physician performance measures, much like Hospital Compare, a CMS-funded website that publically reports hospital performance measures. There are no financial incentives tied to these performance measures but they will be available for the public to review. The physician quality reporting system examines quality measures for services to Medicare beneficiaries and offers incentive payments to high performers, utilizing data from claims, registries, electronic health records (EHR), and the group practice reporting option tool. The CMS intends for these data to be published on

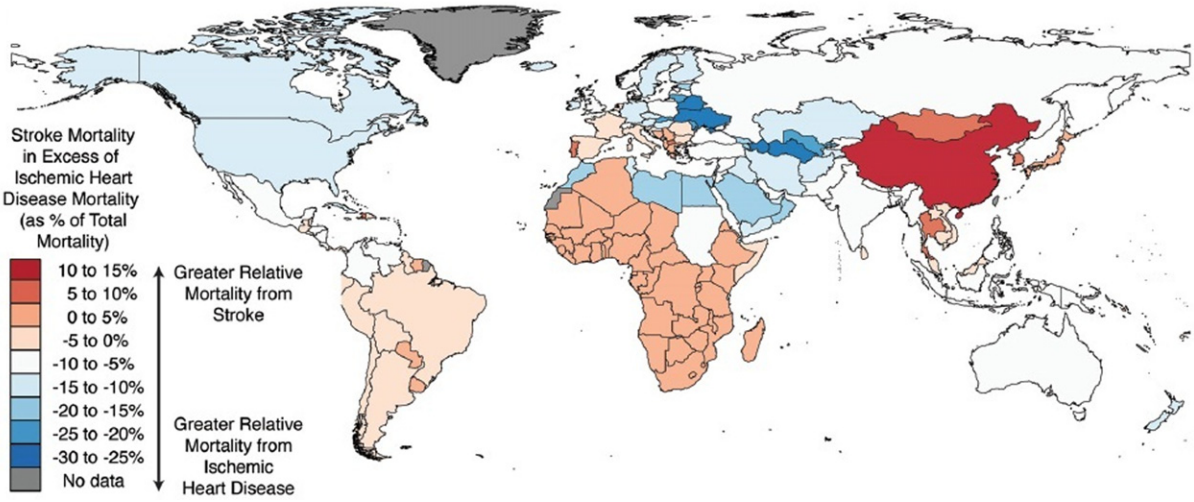


**Figure 11** **Geographic Distribution of Relative Mortality From Stroke and Ischemic Heart Disease**

Source: Kim and Johnston (17).

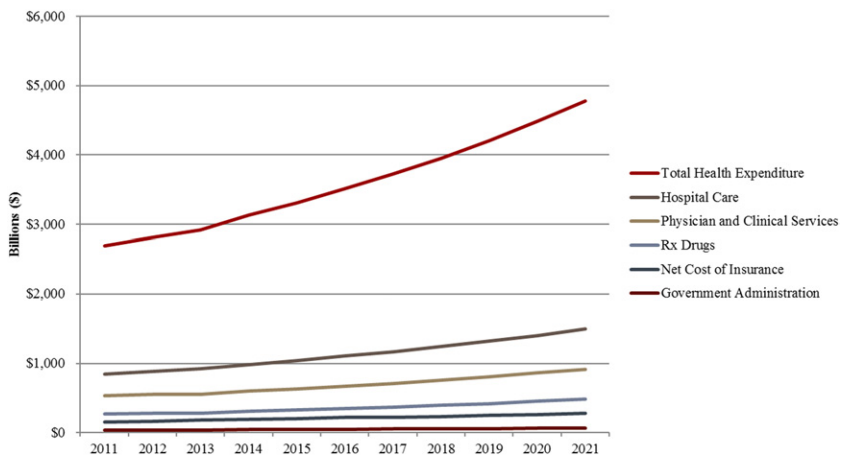


**Figure 12** National Healthcare Expenditure Projections by Expenditure Type, 2011 to 2021

**Red** = total health expenditure; **dark brown** = hospital care; **light brown** = physician and clinical services; **gray** = prescription drugs; **black** = net cost of insurance; **dark red** = government administration. Source: Centers for Medicare and Medicaid Services (22).

Physician Compare by January 1, 2013. Beginning in 2015, there will be penalties for physicians who do not report to the website (41).

The physicians resource use measurement and reporting program will be incorporated into the value-based payment modifier program by providing individualized feedback to providers, including how they compare to their peers. The CMS incorporates cost and quality information when calculating potential reimbursements. The CMS will apply a value-based payment modifier based on performance measures beginning in 2015. Beginning in 2017, the value-based payment modifier scheme will be applied to most physicians who submit claims under the Medicare physician fee-for-service schedule (42).

**Measure Application Partnership.** The Department of Health and Human Services has contracted with the National Quality Forum, a consensus-based organization, to convene Measure Application Partnership as the body that helps coordinate and provide upstream recommendations on performance measure use. Utilizing what is termed "families of measures," this approach is intended to help move the field toward a more patient-driven, integrated, and synchronized approach to measuring healthcare performance by giving implementers a pre-screened group of measures carefully selected to work cohesively in pursuit of specific healthcare improvement goals (43).

For the first series of recommendations, Measure Application Partnership reviewed 676 measures across the topics

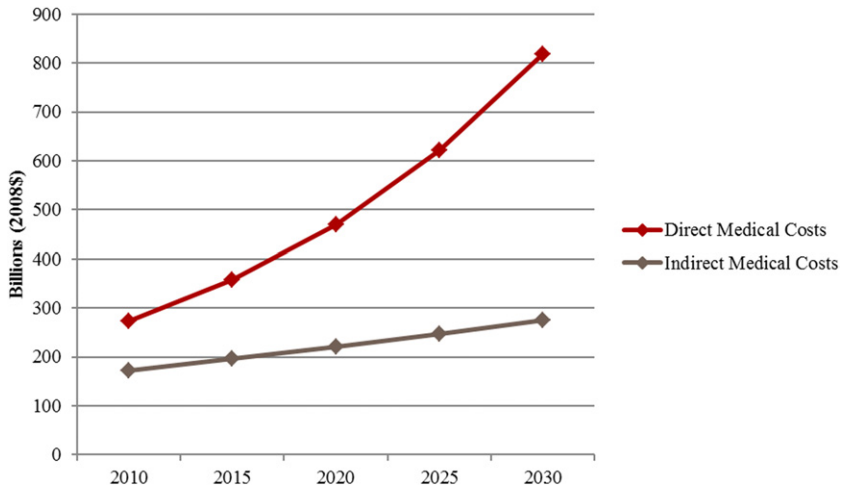


**Figure 13** Projected Direct and Indirect Costs of CVD, 2010 to 2030

**Red** = direct medical costs; **brown** = indirect medical costs. CVD = cardiovascular disease. Source: Heidenreich et al. (24).

**Table 4** Projected Direct Medical Costs and Indirect (Lost Productivity) Costs of Cardiovascular Disease, 2010 to 2030, United States

| | 2010 | 2015 | 2020 | 2025 | 2030 |
|---|---|---|---|---|---|
| Direct medical cost | | | | | |
| All cardiovascular cisease* | 272.5 | 358.0 | 470.3 | 621.6 | 818.1 |
| Coronary heart disease | 35.7 | 46.8 | 61.4 | 81.1 | 106.4 |
| Heart failure | 24.7 | 32.4 | 42.9 | 57.5 | 77.7 |
| Hypertension | 69.9 | 91.4 | 119.1 | 155.0 | 200.3 |
| Hypertension as risk factor | 130.7 | 170.4 | 222.5 | 293.6 | 389.0 |
| Stroke | 28.3 | 38.0 | 51.3 | 70.0 | 95.6 |
| Indirect medical cost | | | | | |
| All cardiovascular disease* | 171.7 | 195.7 | 220.0 | 246.1 | 275.8 |
| Coronary heart disease | 73.2 | 82.8 | 92.0 | 101.5 | 112.3 |
| Heart failure | 9.7 | 11.3 | 13.0 | 15.1 | 17.4 |
| Hypertension | 23.6 | 27.2 | 31.0 | 35.1 | 39.8 |
| Hypertension as risk factor | 25.4 | 29.3 | 33.3 | 37.8 | 42.8 |
| Stroke | 25.6 | 29.7 | 34.0 | 38.9 | 44.4 |

*Includes hypertension, coronary heart disease, heart failure, stroke, and cardiac dysrhythmias, rheumatic heart disease, cardiomyopathy, pulmonary heart disease, and other or ill-defined heart disease.

of safety, care coordination, cardiovascular conditions, and diabetes; and recommended 55 safety, 62 care coordination, 37 cardiovascular, and 13 diabetes measures for inclusion in the measure families (44). The cardiovascular measures are provided in Table 10.

**Cardiovascular procedure trends.** In 2010, an estimated 7.5 million inpatient cardiovascular procedures were performed in the United States. Of these procedures, 4.3 million were performed on males and 3.1 million on females (45). Figure 16 displays a detailed breakdown of inpatient procedures from 1993 to 2010 from the Nationwide Inpatient Sample. Figure 17 displays the trends of cardiovascular procedures from 2007 to 2010 based on the National Hospital Discharge Survey. Figure 18 displays a decade of procedure trends for all cardiac stents. From 2000 to the peak in 2006, the number of cardiac stent procedures increased by 52%. The number of stent procedures subsequently declined by 40% from 2006 to 2010.

Medicare data from 1999 to 2008 showed the number of procedures done in cardiovascular care in the United States is growing simultaneously with the rising cost to treat cardiovascular diseases (24). From 1999 to 2009, the number of inpatient cardiovascular procedures increased by 22% (based on the National Center for Health Statistics data) (46). Among Medicare beneficiaries, it was found that invasive procedures (coronary, peripheral vascular, and electrophysiological procedures) did not contribute substantially to the increase of cardiovascular procedures and are, in fact, decreasing. Figure 19 displays the trends of growth of services provided by categories of services. Among noninvasive procedures, nuclear stress testing increased 3.2-fold, peripheral vascular ultrasonography increased 2.8-fold, event monitoring grew 2.6-fold, transthoracic and transesophageal echocardiography grew 90% and 70%, respectively, and electrocardiography increased 28% (47).

Noninvasive procedures (electrophysiological monitoring, resting imaging, transesophageal echocardiography, and stress testing) grew 70% from 1999 to 2008 (47). However, studies indicate the growth rate of noninvasive diagnostic imaging utilization leveled off from 2005 to 2008. From

**Table 5** Decomposition of Real Per Capita Health Spending Growth, 1996 to 2006

Exhibit 1

| Category/Condition[a] | Nominal Spending (Billions of Dollars) 1996 | Nominal Spending (Billions of Dollars) 2006 | Real Per Capita Spending Growth (%) | Component: Cost Per Case (%) | Component: Treated Prevalence (%) | Subcomponent: Clinical, at 2% Ceiling (%) | Subcomponent: Proportion Treated (%) |
|---|---|---|---|---|---|---|---|
| Circulatory system | 115.9 | 200.4 | 2.3 | 0.4 | 1.8 | 0.3 | 1.6 |
| Heart conditions | 65.3 | 93.3 | 0.3 | −0.1 | 0.5 | 0.1 | 0.4 |
| Coronary heart disease | 46.3 | 59.8 | −0.7 | 0.0 | −0.7 | −0.7 | 0.0 |
| Congestive heart failure | 7.1 | 15.5 | 4.6 | 0.4 | 4.2 | 2.0 | 2.2 |
| Dysrhythmias | 9.9 | 14.0 | 0.2 | −2.0 | 2.2 | 1.5 | 0.7 |
| Cerebrovascular disease | 16.1 | 18.8 | −1.7 | 0.2 | −1.8 | −2.6 | 0.7 |
| Hypertension | 15.2 | 38.7 | 6.3 | 1.8 | 4.5 | 2.0 | 2.5 |
| Hyperlipidemia[b] | 4.5 | 22.9 | 14.0 | 1.1 | 12.9 | 2.0 | 10.9 |

Source: Roehrig and Rousseau (25). [a]Medical conditions are not all-inclusive, so expenditures by condition sum to less than category totals. [b]Hyperlipidemia is mapped to the endocrine chapter in the International Classification of Diseases-Ninth Revision (ICD-9), but is included under circulatory here.

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**Table 6 Patient Protection and Affordable Care Act (P.L. 111–148), Cost Containment Provisions**

| Cost Containment | Provision |
|---|---|
| Administrative simplification | • Simplify health insurance administration by adopting a single set of operating rules for eligibility verification and claims status (rules adopted July 1, 2011; effective January 1, 2013), electronic funds transfers and healthcare payment and remittance (rules adopted July 1, 2012; effective January 1, 2014), and health claims or equivalent encounter information, enrollment and disenrollment in a health plan, health plan premium payments, and referral certification and authorization (rules adopted July 1, 2014; effective January 1, 2016). Health plans must document compliance with these standards or face a penalty of no more than $1 per covered life. (Effective April 1, 2014.) |
| Medicare | • Restructure payments to Medicare Advantage (MA) plans by setting payments to different percentages of Medicare fee-for-service (FFS) rates, with higher payments for areas with low FFS rates and lower payments (95% of FFS) for areas with high FFS rates. Phase in revised payments over 3 years beginning in 2011, for plans in most areas, with payments phased in over longer periods (4 years and 6 years) for plans in other areas. Provide bonuses to plans receiving 4 or more stars, based on the current 5-star quality rating system for MA plans, beginning in 2012; qualifying plans in qualifying areas receive double bonuses. Modify rebate system with rebates allocated based on a plan's quality rating. Phase in adjustments to plan payments for coding practices related to the health status of enrollees, with adjustments equaling 5.7% by 2019. Cap total payments, including bonuses, at current payment levels. Require MA plans to remit partial payments to the Secretary if the plan has a medical loss ratio of <85%, beginning 2014. Require the Secretary to suspend plan enrollment for 3 years if the medical loss ratio is <85% for 2 consecutive years and to terminate the plan contract if the medical loss ratio is <85% for 5 consecutive years.<br>• Reduce annual market basket updates for inpatient hospital, home health, skilled nursing facility, hospice, and other Medicare providers, and adjust for productivity. (Effective dates vary.)<br>• Freeze the threshold for income-related Medicare Part B premiums for 2011 through 2019, and reduce the Medicare Part D premium subsidy for those with incomes >$85,000/individual and $170,000/couple. (Effective January 1, 2011.)<br>• Establish an Independent Payment Advisory Board composed of 15 members to submit legislative proposals containing recommendations to reduce the per capita rate of growth in Medicare spending if spending exceeds a target growth rate. Beginning April 2013, require the Chief Actuary of the Centers for Medicare and Medicaid Services (CMS) to project whether Medicare per capita spending exceeds the average of Consortium for Performance Improvement (CPI)-U and CPI-M, based on a 5-year period ending that year. If so, beginning January 15, 2014, the Board will submit recommendations to achieve reductions in Medicare spending. Beginning January 2018, the target is modified such that the Board submits recommendations if Medicare per capita spending exceeds gross domestic product per capita plus 1%. The Board will submit proposals to the President and Congress for immediate consideration. The Board is prohibited from submitting proposals that would ration care, increase revenues, or change benefits, eligibility, or Medicare beneficiary cost sharing (including Parts A and B premiums), or would result in a change in the beneficiary premium percentage or low-income subsidies under Part D. Hospitals and hospices (through 2019) and clinical laboratories (for 1 year) will not be subject to cost reductions proposed by the Board. The Board must also submit recommendations every other year to slow the growth in national health expenditures while preserving quality of care by January 1, 2015. The Secretary of Health and Human Services (HHS) is directed to implement the Board's proposals automatically unless Congress affirmatively acts to alter the Board's proposals or to discontinue the automatic implementation of such proposals (27).<br>• Reduce Medicare Disproportionate Share Hospital (DSH) payments initially by 75% and subsequently increase payments based on the percent of the population uninsured and the amount of uncompensated care provided. (Effective fiscal year 2014.)<br>• Eliminate the Medicare Improvement Fund. (Effective upon enactment.)<br>• Allow providers organized as an accountable care organization (ACO) that voluntarily meet quality thresholds to share in the cost savings they achieve for the Medicare program. To qualify as an ACO, organizations must agree to be accountable for the overall care of their Medicare beneficiaries, have adequate participation of primary care physicians, define processes to promote evidence-based medicine, report on quality and costs, and coordinate care. (Shared savings program established January 1, 2012.)<br>• Create an Innovation Center within the CMS to test, evaluate, and expand in Medicare, Medicaid, and CHIP different payment structures and methodologies to reduce program expenditures while maintaining or improving quality of care (see Table 7). Payment reform models that improve quality and reduce the rate of cost growth could be expanded throughout the Medicare, Medicaid, and CHIP programs. (Effective January 1, 2011.)<br>• Reduce Medicare payments that would otherwise be made to hospitals by specified percentages to account for excess (preventable) hospital readmissions. (Effective October 1, 2012.) |
| Medicaid | • Reduce Medicare payments to certain hospitals for hospital-acquired conditions by 1%. (Effective fiscal year 2015.)<br>• Increase the Medicaid drug rebate percentage for brand name drugs to 23.1 (except the rebate for clotting factors and drugs approved exclusively for pediatric use increases to 17.1%); increase the Medicaid rebate for non-innovator, multiple source drugs to 13% of average manufacturer price. (Effective January 1, 2010.) Extend the drug rebate to Medicaid managed care plans. (Effective upon enactment.)<br>• Reduce aggregate Medicaid DSH allotments by $.5 billion in 2014, $.6 billion in 2015, $.6 billion in 2016, $1.8 billion in 2017, $5 billion in 2018, $5.6 billion in 2019, and $4 billion in 2020. Require the Secretary to develop a methodology to distribute the DSH reductions in a manner that imposes the largest reduction in DSH allotments for states with the lowest percentage of uninsured or those that do not target DSH payments, imposes smaller reductions for low-DSH states, and accounts for DSH allotments used for 1115 waivers. (Effective October 1, 2011.)<br>• Prohibit federal payments to states for Medicaid services related to healthcare acquired conditions. (Effective July 1, 2011.) |
| Prescription drugs | • Authorize the Food and Drug Administration to approve generic versions of biologic drugs and grant biologics manufacturers 12 years of exclusive use before generics can be developed. (Effective upon enactment.) |
| Waste, fraud, and abuse | • Reduce aggregate Medicaid DSH allotments by $.5 billion in 2014, $.6 billion in 2015, $.6 billion in 2016, $1.8 billion in 2017, $5 billion in 2018, $5.6 billion in 2019, and $4 billion in 2020. Require the Secretary to develop a methodology to distribute the DSH reductions in a manner that imposes the largest reduction in DSH allotments for states with the lowest percentage of uninsured or those that do not target DSH payments, imposes smaller reductions for low-DSH states, and accounts for DSH allotments used for 1115 waivers. (Effective October 1, 2011.)<br>• Reduce waste, fraud, and abuse in public programs by allowing provider screening, enhanced oversight periods for new providers and suppliers, including a 90-day period of enhanced oversight for initial claims of DME suppliers, and enrollment moratoria in areas identified as being at elevated risk of fraud in all public programs, and by requiring Medicare and Medicaid program providers and suppliers to establish compliance programs. Develop a database to capture and share data across federal and state programs, increase penalties for submitting false claims, strengthen standards for community mental health centers, and increase funding for antifraud activities. (Effective dates vary.) |

Data for 2010 show the Centers for Medicare and Medicaid Services (CMS) as the largest single payer entity in the United States, responsible for almost 40% of NHE (Fig. 14) (28). Due to its large share of the payer market, reform efforts implemented by CMS often have the most significant effects on care delivery models.

**Table 7 Current Centers for Medicare and Medicaid Innovation Center Initiatives**

| Initiative | Initiative Start Date | Length | Participants/Locations | Total Funding | Number of Beneficiaries Affected |
|---|---|---|---|---|---|
| Primary care transformation | | | | | |
| Comprehensive primary care initiative demonstration | Fall 2012 | 4 yrs | 500 primary care practices in AR, CO, NJ, NY, OH, OK, OR | $322 million | 313,00 Medicare |
| Federally qualified health center (FQHC) advanced primary care practice demonstration | November 2011 | 3 yrs | 500 FQHCs in 44 states | $49.7 million | 195,000 Medicare |
| Multipayer advanced primary care practice demonstration | Phase-in begins July 2011 | 3 yrs | NC, ME, MI, MN, NY, PA, RI, VT | $283 million* | 332,000 Medicare |
| Independence at home | Summer 2012 | 3 yrs | 15 independent practices and 3 consortia | $15 million* | 10,000 Medicare |
| Bundled payments for care improvement | | | | | |
| Bundled payment for care improvement initiative | 2012 | 3 yrs | TBD | $118 million | Not available |
| Accountable care organizations | | | | | |
| Pioneer accountable care organization model initiative | January 2012 | 3 yrs (potential 2-yr extension) | 32 ACOs | $77 million | 860,000 Medicare |
| Accelerated development learning sessions | June 2011 | 3 sessions completed | Available to all developing or existing ACOs | $1.5 million | Not available |
| Advanced payment accountable care organization model initiative | April or July 2012 | Payments end June 2014 | Physician-based and rural ACOs in the shared savings program | $175 million | 650,000 Medicare |
| Physician group practice transition demonstration | January 2012 | Up to 3 yrs | 10 group practices initially, 3 switched to pioneer ACO model | $500,000 (administrative cost)* | 87,700 Medicare |
| Medicare-Medicaid enrollees | | | | | |
| State demonstrations to integrate care for Medicare-Medicaid enrollees | April/May 2011 | 18 months with extension option | CA, CO, CT, MA, MI, MN, NY, NC, OK, OR, SC, TN, VT, WA, WI | $15 million | Not available |
| Financial alignment model demonstrations | January 2013 | 3 yrs | 38 states and DC have submitted letters of intent | TBD | 2 million Medicare-Medicaid enrollees |
| Capacity to spread innovation | | | | | |
| Partnership for patients | April 2011 | Ongoing | 26 hospital engagement networks | $500 million | Not available |
| Innovation advisors program | January 2012 | Ongoing | 200 advisors | $5.9 million | Not available |
| Health care innovation challenge | May 2012 | 3 yrs | 50 states | $1 billion | Not available |
| Other | | | | | |
| Medicaid emergency psychiatric demonstration | Spring 2012 | 3 yrs | 11 states and DC | $75 million* | Not available |
| Medicaid incentives for prevention of chronic diseases program | September 2011 | 5 yrs | 10 states | $100 million* | Not available |

*Funding based on other statutory authorities. Sources: Centers for Medicare and Medicaid Innovation: one year of innovation, CMS, 2012; and Centers for Medicare and Medicaid Innovation: what we're doing, CMS, 2012.

TBD = to be determined.

2000 to 2005, the growth rate was on average 4.1% and declined to 1.4% from 2005 to 2008 (48). Further evidence indicates that among Medicare beneficiaries volume of imaging services has decreased in 2010 and 2011 (49).

Preventable hospital readmissions have been identified as a significant driver of costs, estimated at $25 billion annually (50). An estimated 20% of Medicare beneficiaries are readmitted to the hospital within 30 days and 34% within 90 days, costing an estimated $17.5 billion annually (51,52). Effective October 1, 2012, CMS implemented the Readmissions Reduction Program, reducing payments to hospitals with excess readmissions (53).

**Comparative effectiveness research.** Comparative effectiveness research, a controversial topic in the industry, is a main focus of the Patient-Centered Outcomes Research Institute. The Institute has committed approximately $120 million of research funding through the end of 2012 to support its initial research agenda (see the following list), in addition to the $30 million awarded for pilot projects. As of April 2012, 50 pilot projects were approved to receive funding for up to 2 years, at a total of approximately $15 million per year (54).

The Patient-Centered Outcomes Research Institute's Five Priorities are as follows:

1. Assessment of prevention, diagnosis, and treatment options: comparing the effectiveness and safety of alternative prevention, diagnosis, and treatment options to see which ones work best for different people with a particular health problem.
2. Improving healthcare systems: comparing health system-level approaches to improving access, supporting patient

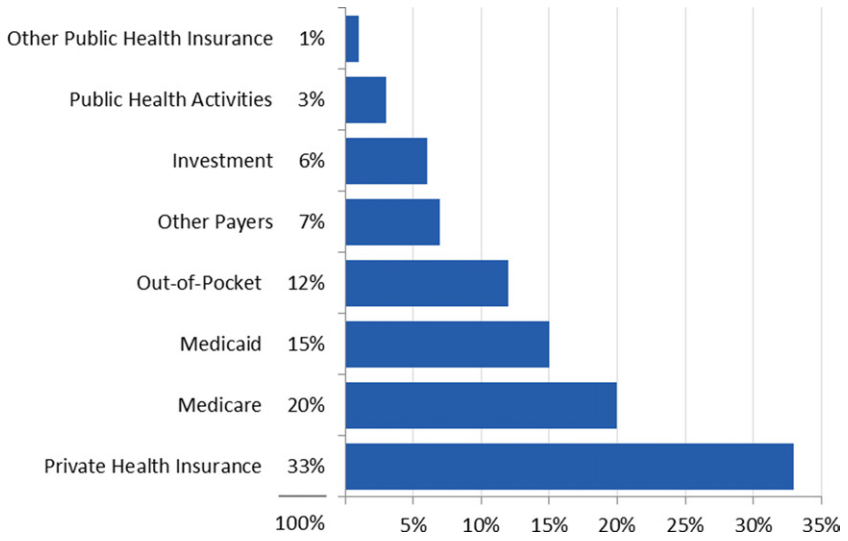



**Figure 14** **Percentage of Total U.S. Healthcare Spending by Payment Sources, 2010**

Source: California Health Care Foundation. U.S. Healthcare Spending: Health Care Costs 101. Oakland, CA: California Health Care Foundation, 2012.

self-care, innovative use of health information technology, coordinating care for complex conditions, and deploying workforce effectively.

3. Communication and dissemination research: comparing approaches to providing comparative effectiveness research information, empowering people to ask for and

| Physician Group Practice Demonstration Quality Measures | | | |
|---|---|---|---|
| Diabetes Mellitus | Congestive Heart Failure | Coronary Artery Disease | Preventive Care |
| HbAlc Management | Left Ventricular Function Assessment | Antiplatelet Therapy | Blood Pressure Screening |
| HbAlc Control | Left Ventricular Ejection Fraction Testing | Drug Therapy for Lowering LDL Cholesterol | Blood Pressure Control |
| Blood Pressure Management | Weight Measurement | Beta-Blocker Therapy –Prior MI | Blood Pressure Control Plan of Care |
| Lipid Measurement | Blood Pressure Screening | Blood Pressure | Breast Cancer Screening |
| LDL Cholesterol Level | Patient Education | Lipid Profile | Colorectal Cancer Screening |
| Urine Protein Testing | Beta-Blocker Therapy | LDL Cholesterol Level | |
| Eye Exam | Ace Inhibitor Therapy | Ace Inhibitor Therapy | |
| Foot Exam | Warfarin Therapy for Patients HF | | |
| Influenza Vaccination | Influenza Vaccination | | |
| Pneumonia Vaccination | Pneumonia Vaccination | | |

**Figure 15** **Physician Group Practice Demonstration Quality Measures**

Ace = angiotensin-converting enzyme; Exam = examination; Hb = hemoglobin; HF = heart failure; LDL = low-density lipoprotein; MI = myocardial infarction. Source: Dept Health and Human Services. Medicare Physician Group Practice Demonstration: physicians groups continue to improve quality and generate savings under Medicare physician pay-for-performance demonstration, July 2011.

**Table 8** Clinical Process of Care Under Value-Based Purchasing Reimbursement Model

| | |
|---|---|
| **Acute myocardial infarction** | |
| AMI-7a | Fibrinolytic therapy received within 30 min of hospital arrival |
| AMI-8 | Primary PCI received within 90 min of hospital arrival |
| **Heart failure** | |
| HF-1 | Discharge instructions |
| **Pneumonia** | |
| PN-3b | Blood cultures performed in the ED prior to initial antibiotic received in hospital |
| PN-6 | Initial antibiotic selection for CAP in immunocompetent patient |
| **Health care associated infections** | |
| SCIP-Inf-1 | Prophylactic antibiotic received within 1 h |
| SCIP-Inf-2 | Prophylactic antiobiotic selection for surgical patient |
| SCIP-Inf-3 | Prophylactic antibiotics discontinued within 24 h after surgery |
| SCIP-Inf-4 | Cardiac surgery patients with controlled 6 AM post-operative serum glucose |
| **Surgeries** | |
| SCIP-Card-2 | Surgery patients on a beta-blocker prior to arrival that received beta-blocker during the perioperative period |
| SCIP-VTE-1 | Surgery patients with recommended venous thromboembolism prophylaxis ordered |
| SCIP-VTE-2 | Surgery patients who received appropriate venous thromboembolism prophylaxis within 24 h |

Source: Centers for Medicare and Medicaid Services (40).
AMI = acute myocardial infarction; Card = cardiac; ED = emergency department; HF = heart failure; Inf = infection; PCI = percutaneous coronary intervention; PN = pneumonia; VTE = venous thromboembolism.

use the information, and supporting shared decision making between patients and their providers.

4. Addressing disparities: identifying potential differences in prevention, diagnosis or treatment effectiveness, or preferred clinical outcomes across patient populations and the health care required to achieve best outcomes in each population.
5. Accelerating patient-centered outcomes research and methodological research: improving the nation's capacity to conduct patient-centered outcomes research, by building data infrastructure, improving analytic methods, and training researchers, patients, and other stake holders to participate in this research (55).

**Health information technology.** The federal government has committed in excess of $27 billion over 10 years to increase the use of EHR. Many physicians and practices agree that EHR can improve clinical decision making and patient outcomes and are already making the transition from paper to EHR use in their practice (56).

MEANINGFUL USE CRITERIA. The use of EHR is encouraged by CMS through an incentive program that provides financial benefits for physicians and care centers that show "meaningful use" of EHR. The primary component of meaningful use is utilizing EHR in a meaningful manner—in other words, to exchange health information electronically to improve care and to submit quality measures. Between 2011 and 2016, each clinician who is eligible under the meaningful use criteria can receive up to $63,750 in total payments for demonstrating meaningful EHR use and may be eligible for both Medicare and Medicaid incentives as well (57).

One aspect of the meaningful use criteria for EHR incentives (both Medicare and Medicaid) is participation in clinical quality measures. Clinical quality measures assess observations, processes, experience, treatment, and outcomes of patient care. Professionals eligible for EHR incentives are required to report 6 clinical quality measures, whereas hospitals and acute care centers are required to report 15 (57).

Hospitals and other providers have until 2015 to utilize electronic medical records before they incur penalties (58). Nearly 46% of clinical sites, ranging from solo practices to hospitals, had adopted EHR as of January 2012 (59). Conversely, only 58% of eligible hospitals and 25% of eligible physicians have enrolled in the meaningful use incentive program, and 16% of eligible hospitals and 6% of eligible professions have received payments thus far (58).

It is admittedly more difficult for smaller practices to adopt EHR and be eligible for meaningful use incentives. Reasons for this vary, but include the financial cost of implementing EHR, concerns about what the return of investment will be once adopted, and the fact that EHR technology may become obsolete. It is, therefore, somewhat surprising that only 21% of small practices reported resistance to EHR adoption compared with 32% of practices with more than 11 physicians (60). Figure 20 displays the disparities in EHR adoption as of 2011 (61).

Certain inpatient providers are not eligible for meaningful use incentives. These include long-term care facilities, rehabilitation hospitals, and psychiatric hospitals, all of which are less likely to adopt EHRs. One study found that only 6% of long-term acute care hospitals, 4% of rehabilitation hospitals, and 2% of psychiatric hospitals had minimum basic EHRs, and obstacles for providers to take advantage of the meaningful use incentive continue (62).

There is a great need for advanced health information technology implementation to achieve quality improvement and patient-centered care. As investigators of a *Health*

**Table 9** Patient Experience of Care Measures Under Value-Based Purchasing Reimbursement Model

| |
|---|
| 1. Nurse communication |
| 2. Doctor communication |
| 3. Hospital staff responsiveness |
| 4. Pain management |
| 5. Medicine communication |
| 6. Hospital cleanliness and quietness |
| 7. Discharge information |
| 8. Overall hospital rating |

Source: Centers for Medicare and Medicaid Services (40).

**Table 10** Chronic Cardiovascular Conditions Family of Measures by Level of Analysis Along the Patient-Focused Episode of Care

| | Primary Prevention | | Evaluation and Initial Management | | Follow-Up Care |
|---|---|---|---|---|---|
| | Outpatient | Inpatient | Outpatient | Inpatient | Outpatient |
| Clinician group/individual | Smoking cessation/tobacco use (0028, 1406)* | Smoking cessation/tobacco use | HF functional status | HF functional status | Afib medications— anticoagulation (1525)* |
| | | | | | HF medications—ACE/ARB (0081)* |
| | Lifestyle management—weight/obesity (0024, 0421)* | | | | HF medications—beta-blocker (0083)* |
| | Blood pressure control (0018)* | | | | HF medications—ACE/ARB, beta-blocker persistence |
| | Lipid control | | | | |
| | Lifestyle management—diet/nutrition | | | | |
| | Lifestyle management—activity/exercise | | | | |
| | Cardiometabolic risk | | | | |
| | Resource use (1598 and 1604)* | | | | |
| Provider/facility | Smoking cessation/tobacco use | Smoking cessation/tobacco use (1651, 1654)* | HF functional status | HF functional status | HF medications—beta-blocker (0083)* |
| | | | Mortality—HF (0229)* | Mortality—HF (0229)* | HF medications—ACE/ARB, beta-blocker persistence |
| | Lipid control | | | | |
| | Lifestyle management—weight/obesity | | | | HF early identification of decompensated HF |
| | Lifestyle management—diet/nutrition | | | | |
| | Lifestyle management—activity/exercise | | | | |
| | Cardiometabolic risk | | | | |
| System | Lifestyle management—weight/obesity (0024)* | | Mortality | | HF medications—ACE/ARB, beta-blocker persistence |
| | Blood pressure control (0018)* | | HF functional status | | |
| | Smoking cessation/tobacco use | | | | |
| | Lipid control | | | | |
| | Blood pressure control | | | | |
| | Screening | | | | |
| | Lifestyle management—diet/nutrition | | | | |
| | Lifestyle management—activity/exercise | | | | |
| | Cardiometabolic risk | | | | |
| | Resource use (1598 and 1604)* | | | | |
| Community | Smoking cessation/tobacco use (1406, 1651, 1654)* | | Mortality | | HF medications—ACE/ARB, beta-blocker persistence |
| | Lifestyle management—weight/obesity (0024, 0421)* | | HF functional status | | |
| | Blood pressure control (0018)* | | | | |
| | Cardiometabolic risk | | | | |
| | Lipid control | | | | |
| | Lifestyle management—diet/nutrition | | | | |
| | Lifestyle management—activity/exercise | | | | |
| | Resource use (1598 and 1604)* | | | | |

*High-leverage opportunities represent areas where the task force has identified measures to populate the family; other entries are considered gaps. For additional detail, see National Quality Forum (44).
ACE = angiotensin-converting enzyme; Afib = afibrillation; ARB = angiotensin-receptor blocker; HF = heart failure.

*Affairs* paper noted (62), continuing medical education is a potential avenue by which to improve HIT competencies and increasing EHR adoption; if offered, continuing medical education could allow more clinicians to be eligible for meaningful use incentives over the next 10 years.

## Workforce

Increasing demand, changing business requirements, and provider restructuring have created significant concerns regarding the capacity of the current and future medical workforce to meet the needs of patients. Recent physician surveys found that nearly one-third intend to retire in the next 10 years, and more than three-quarters of physicians are somewhat pessimistic or very pessimistic about the future of the medical profession (63,64).

**Physician workforce.** In 2010, there were 258.7 active physicians per 100,000 U.S. residents and 219.5 physicians who were active in patient care per 100,000 residents in the

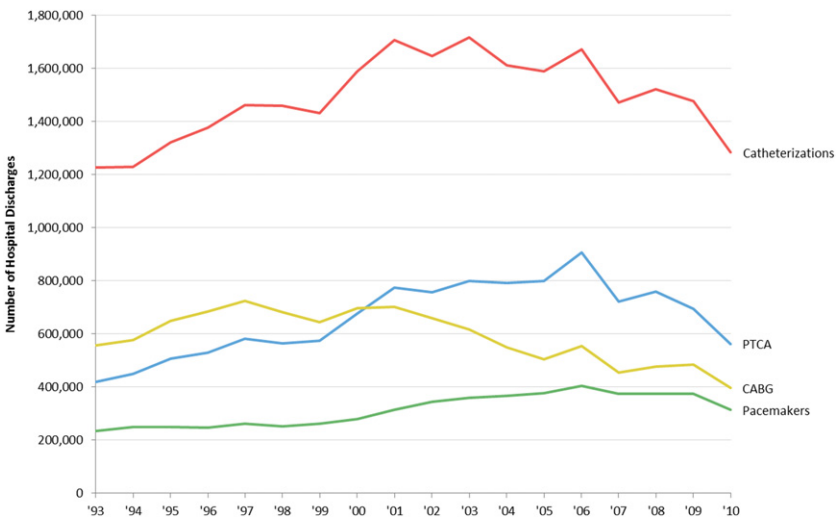



**Figure 16** **Trends in Number of Cardiovascular Procedures, United States, 1993 to 2010**

Note: In-hospital procedures only. CABG = coronary artery bypass graft surgery; PTCA = percutaneous transluminal coronary angioplasty. Source: Agency for Healthcare Research and Quality. Center for Delivery, Organization, and Markets, Healthcare Cost and Utilization Project: Nationwide Inpatient Sample, 1993–2010.

United States (65). However, the distribution of physicians was highly variable between states, with a surfeit of physicians being clustered in northeastern states in comparison to the southeast (Table 11, Fig. 21).

On the basis of projections made by the Association of American Medical Colleges, it is expected that the United States will be short 91,500 to 130,600 physicians by 2025 (Fig. 22) (66).

The projections from Figure 22 reflect the current supply and utilization of physicians and disease burdens applied to future population trends. Assumptions in this model are based on speculated utilization shifts due to the ACA. These include increased physician utilization rates for people over 45 years of age; decreased working hours of physicians due to sex and generational trends; growth in medical school graduates; and growth in productivity

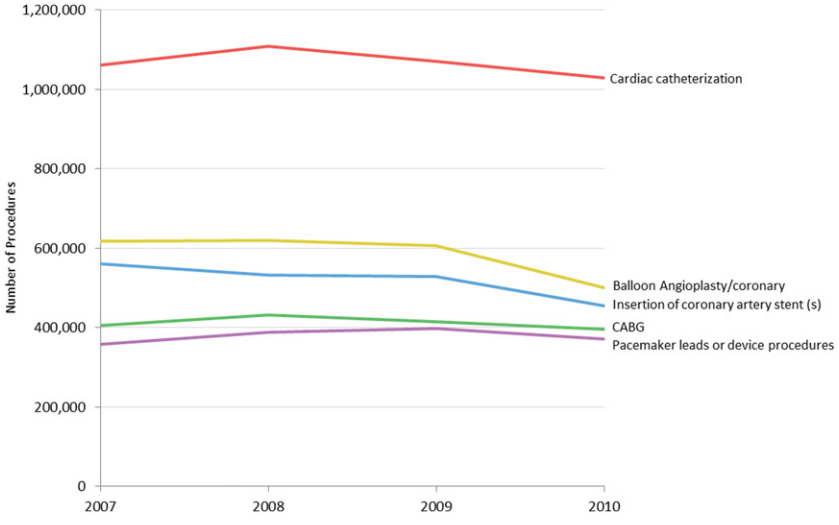



**Figure 17** **Number of Discharges From Short-Stay Hospitals by Procedure Category, 2007 to 2010, National Hospital Discharge Survey**

CABG = coronary artery bypass graft surgery. Source: Centers for Disease Control and Prevention. Number of all-listed procedures for discharges from short-stay hospitals by procedure category: United States, 2007–2010. Available at: http://www.cdc.gov/nchs/data/nhds/4procedures/2010pro4_numberproceduresex.pdf. Accessed June 2012.


**Figure 18** **Trends in Cardiac Stents, United States, 2000 to 2010**

Note: In-hospital procedures only. Source: Agency for Healthcare Research and Quality. Center for Delivery, Organization, and Markets, Healthcare Cost and Utilization Project: Nationwide Inpatient Sample, 2000–2010. 2012. Available at: http://hcupnet.ahrq.gov/. Accessed October 2012.

(66). The ACA seeks to address the workforce shortage by authorizing the following:

- $250 million to support training of >16,000 new primary care providers for fiscal years 2010 to 2014;
- $320 million over the same period to increase the number of primary care residency positions, to expand training opportunities for physician assistants and nurse practitioners, and to create nurse-managed health clinics;
- A 10% bonus for fiscal years 2011 to 2016 under the Medicare fee schedule for family physicians, internists, geriatricians, nurse practitioners, and physician assistants—aimed at narrowing the income gap between primary care providers and medical specialists;
- A requirement that states increase Medicaid payment rates to Medicare levels in fiscal years 2013 and 2014 for providers who deliver certain primary care services; and
- creation of a 15-member Health Care Workforce Commission, designed to assess the demand for healthcare workers and whether it is being met (67).

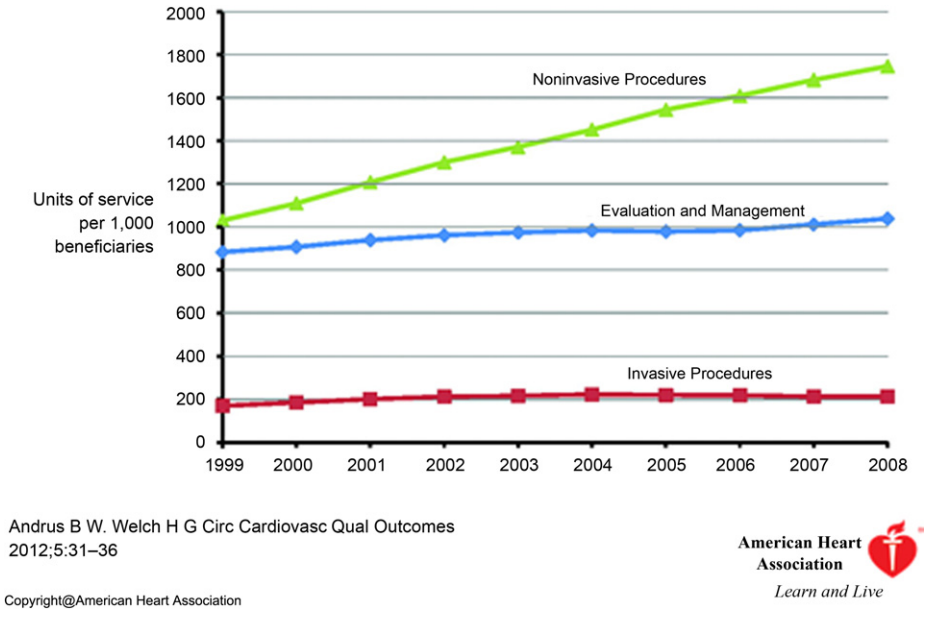
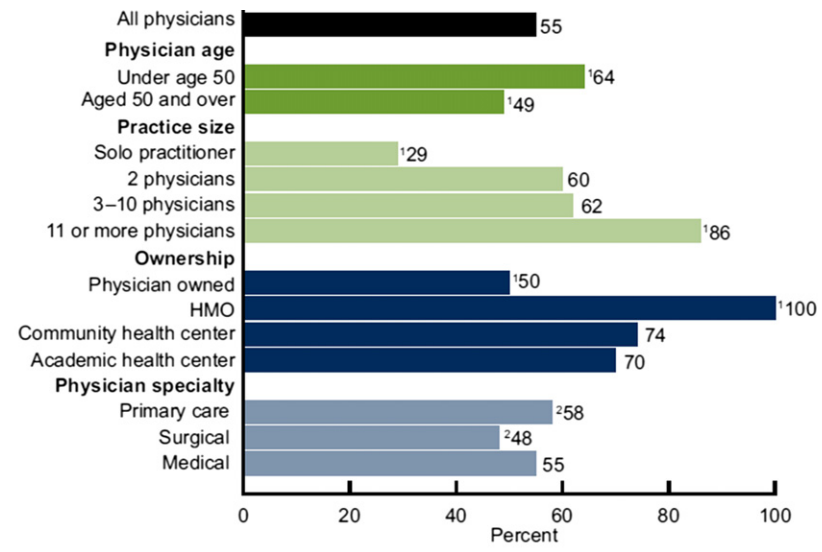



**Figure 19** **Trends of Growth of Services Provided by Categories of Services, 1999 to 2008**

Source: Andrus and Welch (47).




[1]Differences in adoption between this category and all others are statistically significant ($p < 0.01$).
[2]Significant difference between primary care and surgical specialists ($p < 0.01$).
NOTES: Adoption consists of physicians who use a health record system that is all or partially electronic (excluding systems solely for billing). The sample includes nonfederal, office-based physicians and excludes radiologists, anesthesiologists, and pathologists. HMO is health maintenance organization.
SOURCE: CDC/NCHS, Physician Workflow study, 2011.

**Figure 20** **Percentage of EHR Systems Adoption, by Physician Age, Practice Size, Ownership, and Specialty, 2011**

EHR = electronic health record; HMO = health maintenance organization. Source: Jamoom et al. (61).

The Physician's Foundation survey of 13,575 physicians in 2012 noted the following:

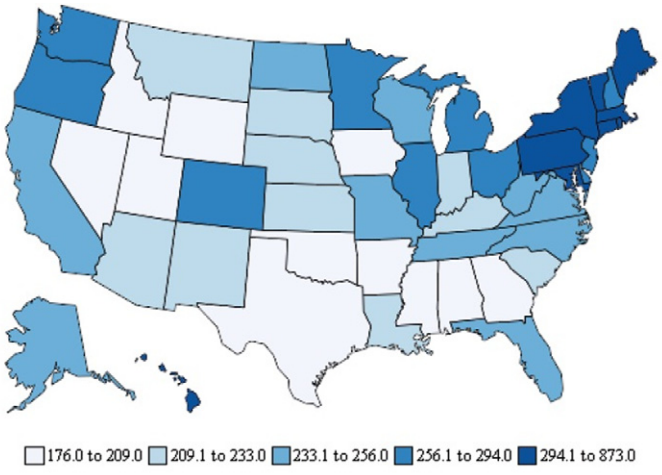
- More than three-quarters of physicians—77.4%—are somewhat pessimistic or very pessimistic about the future of the medical profession.
- More than 84% of physicians agree that the medical profession is in decline.
- The majority of physicians—57.9%—would not recommend medicine as a career to their children or to other young people.
- More than one-third of physicians would not choose medicine if they had their careers to do over.
- Physicians are working 5.9% fewer hours than they did in 2008, resulting in a loss of 44,250 full-time equivalents (FTEs) from the physician workforce.

**Table 11** **Highest 5 Rates and Lowest 5 Rates of Active Physicians per 100,000 Population in 2010**

| States With Highest Rates | | States With Lowest Rates | |
|---|---|---|---|
| Massachusetts | 415.5 | Utah | 197.8 |
| Maryland | 368.7 | Wyoming | 193.0 |
| New York | 347.5 | Arkansas | 189.6 |
| Rhode Island | 332.6 | Idaho | 184.2 |
| Connecticut | 331.1 | Mississippi | 176.4 |

Data source: AAMC Center for Workforce Studies. 2011 State Physician Workforce Data Book, November 2011. Available at: https://www.aamc.org/download/263512/data/statedata2011.pdf.

- Physicians are seeing 16.6% fewer patients per day than they did in 2008, a decline that could lead to tens of millions of fewer patients seen per year.
- Physicians spend more than 22% of their time on nonclinical paperwork, resulting in a loss of some 165,000 FTEs.
- More than 60% of physicians would retire today if they had the means.
- Physicians are not uniform in their opinions—younger physicians, female physicians, employed physicians, and primary care physicians are generally more positive about their profession than are older physicians, male physicians, practice owners, and specialists.
- More than 52% of physicians have limited the access Medicare patients have to their practices or are planning to do so.
- More than 26% of physicians have closed their practices to Medicaid patients.
- In the next 1 to 3 years, more than 50% of physicians plan to cut back on patients, work part-time, switch to concierge medicine, retire, or take other steps that would reduce patient access to their services.
- More than 59% of physicians indicate passage of the ACA (i.e., "health reform") has made them less positive about the future of health care in America.
- More than 82% of physicians believe doctors have little ability to change the healthcare system.




Source: July 1, 2010 population estimates are from the U.S. Census Bureau (Release date: February, 2011). Physician data are from the AMA Physician Masterfile (December 31, 2010).

**Figure 21** **Total Active Physicians per 100,000 Population, 2010**

Source: Association of American Medical Colleges. Center for Workforce Studies: 2011 State Physician Workforce Data Book. November 2011. Available at: https://www.aamc.org/download/263512/data/statedata2011.pdf.

- Nearly 92% of physicians are unsure where the health system will be or how they will fit into it 3 to 5 years from now.
- More than 62% of physicians said ACOs are either unlikely to increase healthcare quality and decrease costs or that any quality/cost gains will not be worth the effort.
- Physicians are divided on the efficacy of medical homes, and many (37.9%) remain uncertain about their structure and purpose.
- More than 47% have significant concerns that EHR poses a risk to patient privacy.
- More than 62% of physicians estimate they provide ≥$25,000 each year in uncompensated care (64).

Jackson Healthcare's 2012 physician survey (n = 2,218) found that the majority of physicians surveyed (84%) expect to continue practicing medicine through 2013. The remaining 16% plan to transition to part-time, retire, or leave medicine, or they are considering doing so (Fig. 23) (63). Fourteen percent said they will most likely retire or leave medicine within the next 5 years. Thirty-four percent will do so within the next 10 years. Specialists reported the following (63): oncologists and hematologists, 57% said they would retire by 2022; otolaryngologists, 49% said they would retire in the next decade; general surgeons, 49% said they would retire by 2022; cardiologists, 45% said they would retire in the next decade; and urologists, 42% said they would retire by 2022.

**Cardiovascular workforce.** The ACC and the Lewin Group's 2009 workforce study (Fig. 24) found that a significant shortage of cardiologists working in the United States exists (Fig. 25), and this shortage is projected to worsen

| Year | Supply – All Specialties | Demand – All Specialties | **Shortage – All Specialties** | Shortage – Primary Care[2] | Shortage – Non-Primary Care[3] |
|---|---|---|---|---|---|
| **2008** | 699,100 | 706,500 | **7,400** | 7,400 | 0 |
| **2010** | 709,700 | 723,400 | **13,700** | 9,000 | 4,700 |
| **2015** | 735,600 | 798,500 | **62,900** | 29,800 | 33,100 |
| **2020** | 759,800 | 851,300 | **91,500** | 45,400 | 46,100 |
| **2025** | 785,400 | 916,000 | **130,600** | 65,800 | 64,800 |

**Figure 22** **Projected Supply and Demand, FTE Physicians Active in Patient Care, 2008 to 2025**

FTE = full-time equivalent. [2]Primary care includes physicians whose specialty is listed as internal medicine, family medicine or pediatrics in the AMA Masterfile. [3]"Non-primary care" includes physicians in all specialties except primary care specialties. Source: Association of American Medical Colleges. The Impact of Health Care Reform on the Future Supply and Demand for Physicians: Updated Projections Through 2025. June 2010. Available at: https://www.aamc.org/download/158076/data/updated_projections_through_2025.pdf.

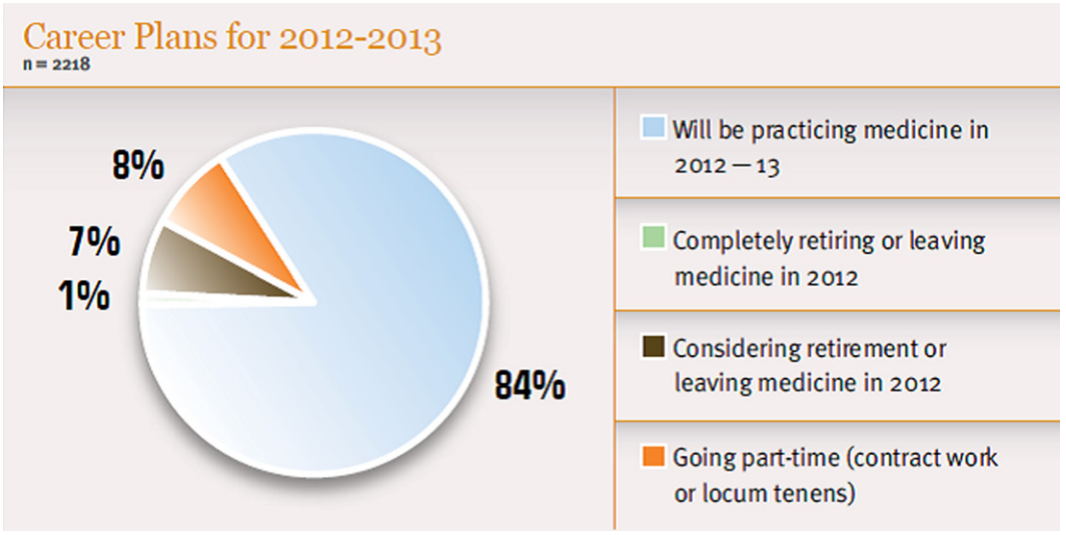



**Figure 23** Physician Career Plans, Jackson Healthcare 2012 Physician Survey

Source: Jackson Healthcare (63).

over the next 2 decades. These projections are based on the demands of physician lifestyle, demographics, technological advances, healthcare reform, and economic growth (68).

If various measures, including an increase in fellowship training and more efficient use of nonphysician practitioners, are not taken, general cardiology may experience a shortage of >15,000 practitioners by 2025 (Fig. 26). Even with proactive measures taken, it is still projected the field will be approximately 8,000 practitioners short of general cardiology needs. Projections also indicate that by 2025, interventional cardiology will still be short of approximately 2,000 physicians, equal to the current shortage (68).

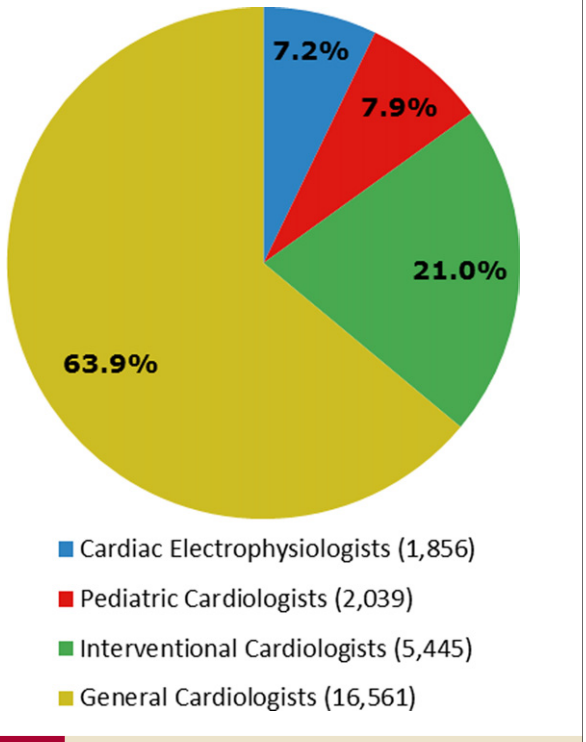



**Figure 24** Cardiologists by Subspecialty, 2008 (n = 25,901)

Source: The Lewin Group, Inc. and Association of American Medical Colleges (69).

Current shortages of pediatric cardiologists and cardiac electrophysiologists are expected to be eliminated by 2025 (69).

**Cardiovascular workforce growth modest.** Current growth in the cardiovascular workforce is moderate relative to the overall physician workforce. Between 1995 and 2007, there was a 19.2% increase in cardiologists compared with a 28.6% increase in all physicians. Increases in the ratio of cardiologists per 100,000 older persons were also lower than increases seen for physicians overall (70).

A disparity exists in the geographic distribution of cardiologists, with a lower cardiologist ratio per 100,000 older persons in the western regions of the United States (Fig. 27) (70). In a national survey of rural hospitals, 35% reported a shortage of cardiologists. The region with the highest reported need for cardiologists was the southeast region followed by the southwest region (Fig. 28) (71).

The United States will also be short of approximately 2,000 cardiothoracic surgeons by 2030 (72). The AHA similarly found that the need for cardiothoracic surgeons will increase by 46% from now until 2025, whereas the active supply of cardiothoracic surgeons is projected to decline by 21% (73).

**Retirement and workforce supply.** Retirement rates will affect the supply of cardiologists in the near future. Currently, 43% of general cardiologists, 31% of pediatric cardiologists, and 21% of interventional cardiologists are over the

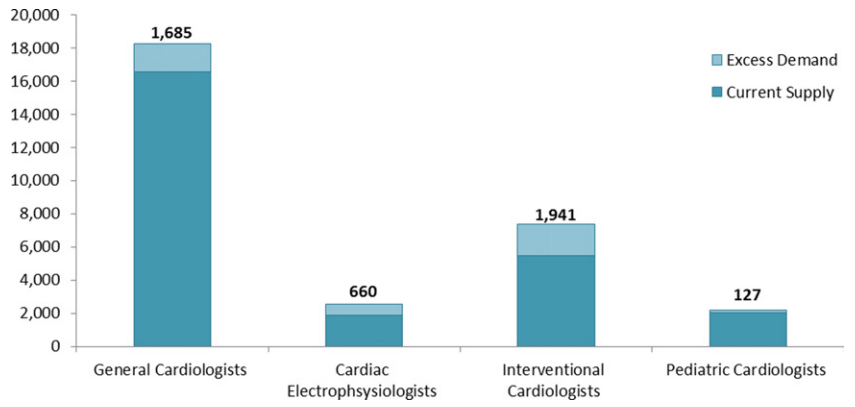



**Figure 25** **Excess Demand for Cardiologists by Subspecialty, 2008**

**Light teal** = excess demand; **dark teal** = current supply. Source: The Lewin Group, Inc., and Association of American Medical Colleges (69).

age of 55 years. Some 50% of cardiothoracic surgeons are currently over the age of 55 years as well, and many are expected to retire in the next 10 years (73).

More than one-half of cardiologists today are still clinically active in some fashion, but failing health, professional dissatisfaction, and inadequate compensation often contribute to early retirement. With increasing regulation in medicine—including the need to undergo recertification—additional influences may also factor into a cardiologist's decision to retire early.

Economic pressures may force some older cardiologists to prolong their career. Alternatively, a growing number of physicians may simply reduce the number of hours worked, all of which can influence projected workforce shortages (68).

**Medical school enrollment.** More than 690,000 first-time and reapplying applicants tried to enroll in U.S. medical schools in 2011 to 2012. Of these, >32,000 were first-time applicants, up by 2.6% from the previous year. The Association of American Medical Colleges also predicts that first-year medical school enrollment will surpass 20,000 in 2014 to 2015, and that by the year 2018, enrollment will increase by 30% compared to 2002 and 2003 (74).

First-year enrollment in Doctor of Osteopathic Medicine (DO) programs is expected to double by 2014 to 2015 compared with 2002. Combined, MD and DO enrollment

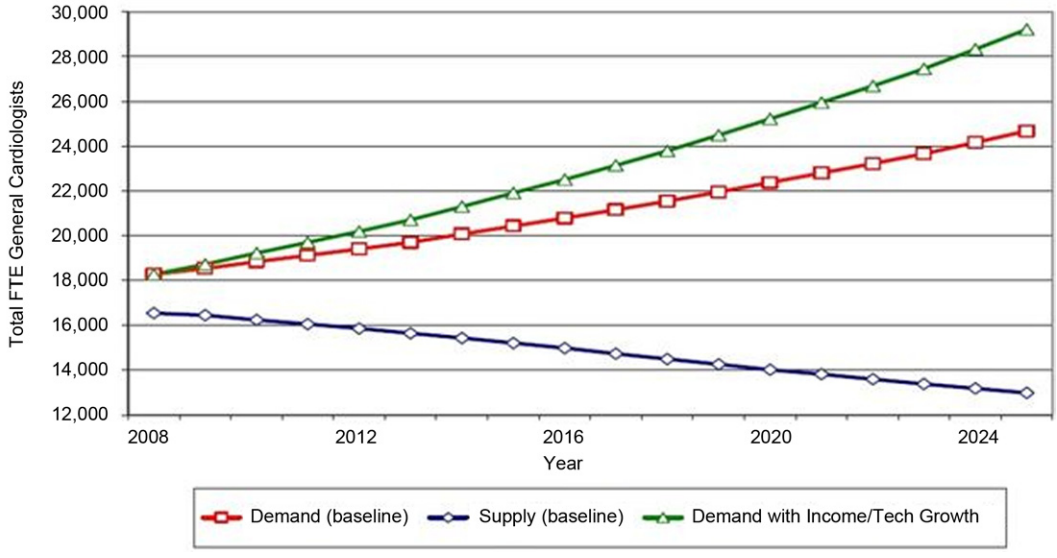



**Figure 26** **Baseline Supply and Demand for FTE General Cardiologists**

**Red** = demand (baseline); **purple** = supply (baseline); **green** = demand with income/technology growth. FTE = full-time equivalent.
Source: The Lewin Group, Inc., and Association of American Medical Colleges (69).

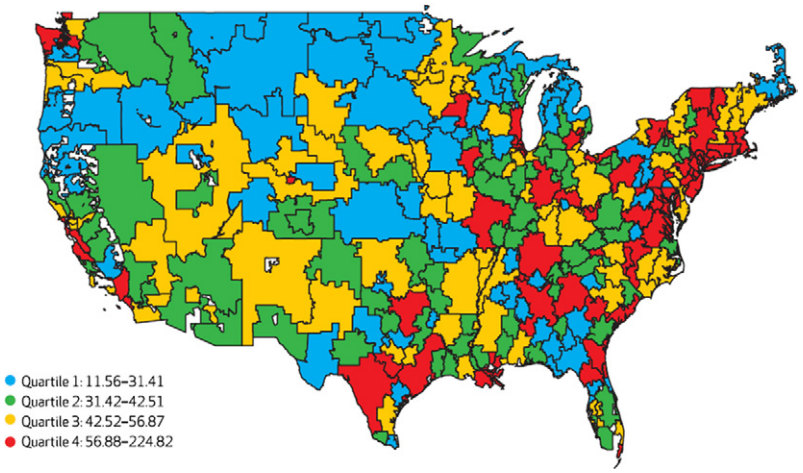



**Figure 27** **Ratio of Cardiologists to 100,000 People Ages 65 Years and Older, 2007**

Source: Aneja et al. (70).

is expected to grow by more than one-third over enrollment levels seen in 2002 to 2003 (Table 12).

Over the last 5 academic years, the number of cardiology programs and the fellows they train has increased in the fields of cardiology, interventional cardiology, and pediatric cardiology. Table 13 displays the increasing number of these fellows for each academic year. Conversely, a decrease was seen in the number of fellows in thoracic surgery and cardiac electrophysiology during this same period (75).

**Women in cardiovascular medicine.** Unlike medicine overall, women currently make up only a small proportion of all cardiologists. However, this may be changing, as representation of women in subspecialty training in cardiology has almost doubled in the past 10 years from 10% in 1996 to 18% in 2004.[68] In 2008, women accounted for 29.0% of pediatric cardiologists, 12.1% of general cardiologists, 9.3% of cardiac electrophysiologists, and 3.4% of interventional cardiologists (Fig. 29) (69). Overall, women accounted for 43% of medical residents in 2010 to 2011; however, the proportion of women among cardiovascular trainees was significantly smaller (Fig. 30) (75).

**Minorities in the cardiovascular workforce.** Approximately 30% of the population in the United States is either Hispanic or African American (76), but minorities, including black, Hispanic, and Native Americans, account for only 6% of practicing physicians. Black and Hispanic fellows were slightly better represented as 13% of internal medicine residents and 10% of cardiology fellows in 2006 to 2007.

A higher percentage of black trainees are now in cardiology fellowships than in other internal medicine subspecialties, but the proportion is still lower than that for internal medicine graduates as a whole. The proportion of Hispanics completing internal

| Most commonly reported specialty physician shortages† | All states (*n*=343) *n* (%) 'yes' | New England through Virginia[1] (*n*=31) *n* (%) 'yes' | Southeast - east of Mississippi River[2] (*n*=38) *n* (%) 'yes' | Upper and Central Midwest[3] (*n*=102) *n* (%) 'yes' | Southwest[4] (*n*=114) *n* (%) 'yes' | Rocky Mountains[5] (*n*=16) *n* (%) 'yes' | West Coast[6] (*n*=37) *n* (%) 'yes' | $\chi^2$ test for regional differences |
|---|---|---|---|---|---|---|---|---|
| Psychiatry | 160 (46.6) | 21 (67.7) | 17 (44.7) | 45 (43.3) | 56 (48.7) | 4 (25.0) | 17 (43.6) | $p = 0.093$ |
| General surgery | 137 (39.9) | 15 (48.4) | 13 (34.2) | 38 (48.4) | 54 (47.0) | 5 (31.3) | 12 (30.8) | $p = 0.290$ |
| Neurology | 125 (36.4) | 10 (32.3) | 16 (32.3) | 33 (31.7) | 53 (46.1) | 2 (12.5) | 11 (28.2) | $p = 0.043$ |
| Cardiology | 120 (35.0) | 11 (35.5) | 17 (44.7) | 26 (25.0) | 51 (44.3) | 3 (18.8) | 12 (30.8) | $p = 0.026$ |
| Obstetrics-gynecology | 118 (34.4) | 10 (32.3) | 8 (21.1) | 28 (26.9) | 51 (44.3) | 6 (37.5) | 15 (38.5) | $p = 0.051$ |

[1]CT, ME, MA, NH, RI, VT, NJ, NY, DE, DC, MD, PA, VA, WV; [2]AL, FL, GA, KY, MS, NC, SC, TN ; [3]IL, IN, MI, MN, OH, WI, IA, KS, MO, NE; [4]AR, LA, NM, OK, TX; [5]CO, MT, ND, SD, UT, WY; [6]AZ, CA, HI, NV, AK, ID, OR, WA.

†Frequencies and national percentages for specialties that were less frequently reported as shortages were: 97 emergency medicine (27.3%); 68 pathology (19.2%); 56 orthopedic surgery (15.8%); 83 radiology (23.4%); 55 urology (15.5%); 49 dermatology (13.8%); 44 gastroenterology (12.4%); 39 anesthesiology (11.0%); 32 oncology (10.4%). State not provided by 12/355 respondents.

**Figure 28** **Rural Hospital CEO Reponses Regarding Need for Specialist Physicians in Their Community**

National Rural Chief Executive Officer (CEO) Survey, 2008. We wish the response rate would have been higher to increase confidence in the findings (overall response rate of 34.4%) , but it is difficult to get even rural hospital CEOs to respond to surveys. Of course, careful assessment of the supply/demand balance, market, and referral characteristics would be important related to assessing need for cardiologist in a particular rural location. You will note our comment in the limitation section that the percents we report are based on CEO perceptions/responses. Source: MacDowell et al. (71).

**Table 12** Medical and Osteopathic Actual and Projected First-Year Enrollment Growth, 2002, 2010, 2015 (Existing Schools)

| | 2002 | 2010 | | | 2015 | | |
|---|---|---|---|---|---|---|---|
| | Enrollment | Enrollment | # Increase | % Increase | Enrollment | # Increase | % Increase |
| M.D. | 16,488 | 18,665 | 2,177 | 13% | 20,181 | 3,693 | 22% |
| D.O. | 3,079 | 5,233 | 2,154 | 70% | 6,222 | 3,143 | 102% |
| Total | 19,567 | 23,898 | 4,331 | 22% | 26,403 | 6,836 | 35% |

Source: Center for Workforce Studies. Results of the 2010 Medical School Enrollment Survey, 2011. Available at: https://www.aamc.org/download/251636/data/enrollment2011.pdf. Accessed June 2012.

medicine has increased over the last few years, but not in cardiology. Barriers to pursuing a career in medicine for minorities include the financial burden of paying for education as well as lack of role models (Fig. 31) (68).

**International medical graduates.** Approximately 30% of the cardiology workforce is now made up of international medical graduates. International medical school graduates recently accounted for 36% of general cardiology fellows, 41% of interventional cardiology fellows, 33% of cardiac electrophysiology fellows, and 22% of pediatric cardiology fellows (75). Unlike minority graduates, international medical graduates appear to be relatively unaffected by specialty compensation or length of training in deciding on cardiology as a career (68). International medical graduates are more likely to remain active in practice than U.S. graduates and to work full-time to an older age, which again is likely to have an impact on potential workforce shortages (Fig. 32).

**Global workforce.** In 2000, it was estimated that 1.5 million healthcare professionals from developing countries were working in industrialized nations, to the obvious detriment of the poorer countries in which they were trained. Factors behind the migration of healthcare professionals are varied but include low salaries in the country of origin, occupational safety hazards, especially in relation to human immunodeficiency infection, inadequacy of facilities and medicine, and a lack of post-graduate training and continuing professional development (Fig. 33) (77).

At 45%, internal medicine has the largest percentage of international medical graduates now participating in U.S. training programs, but their numbers are increasing in cardiology, and international medical graduates now make up more than half of interventional cardiology fellows (78). Nevertheless, it is plausible that changing conditions globally and in the United States may affect the future supply of international medical graduates.

Economic conditions and increased demand for cardiovascular services in their home country—or a worsening economic climate in the United States—may diminish the attractiveness for international medical graduates to practice in the United States. The loss of trained medical graduates also represents a substantial economic loss to their countries of origin, and regulations may be altered to ensure a greater proportion of international medical graduates either do not leave to begin with or at least return home to practice (68).

Concerns over whether care provided by physicians educated abroad differs from U.S.-trained physicians have been expressed. One study found no differences in mortality rates for patients with heart failure or a heart attack between the 2 care groups (79).

**Nursing workforce.** In 2001, the national vacancy rate for registered nurses was >10%. Furthermore, in 15% of hospitals, the shortage was >20% (80). Between 2001 and 2008, the number of registered nurses working full time in both hospital and nonhospital settings increased by some 476,000, with the largest growth in FTE registered nurses seen among those between the ages of 50 and 64 years working in hospitals (Fig. 34). Despite this, current projections indicate there will be a shortfall of 260,000 nurses by 2025 (81).

## Cardiovascular Drugs and Devices

The pharmaceutical and medical device industries are facing several challenges created by the cost-containment effects of healthcare reform efforts and slow economic activity, a changing regulatory environment, and increasing pressure to show value related to clinical outcomes (82,83).

**Table 13** Number of Programs and Fellows by Specialty for the Past 5 Academic Years

| | 2006–2007 | | 2007–2008 | | 2008–2009 | | 2009–2010 | | 2010–2011 | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Programs | Fellows | Programs | Fellows | Programs | Fellows | Programs | Fellows | Programs | Fellows |
| Cardiovascular disease | 174 | 2,300 | 177 | 2,351 | 180 | 2,415 | 180 | 2,444 | 183 | 2,493 |
| Clinical cardiac electrophysiology | 92 | 168 | 95 | 166 | 97 | 170 | 96 | 174 | 98 | 155 |
| Interventional cardiology | 128 | 279 | 130 | 285 | 134 | 291 | 134 | 287 | 135 | 290 |
| Pediatric cardiology | 48 | 304 | 49 | 304 | 51 | 326 | 50 | 356 | 53 | 378 |
| Thoracic surgery | 85 | 270 | 81 | 244 | 77 | 223 | 72 | 219 | 69 | 223 |
| Vascular surgery | 95 | 208 | 96 | 215 | 97 | 238 | 101 | 245 | 102 | 251 |

Source: Accreditation Council for Graduate Medical Education (75).

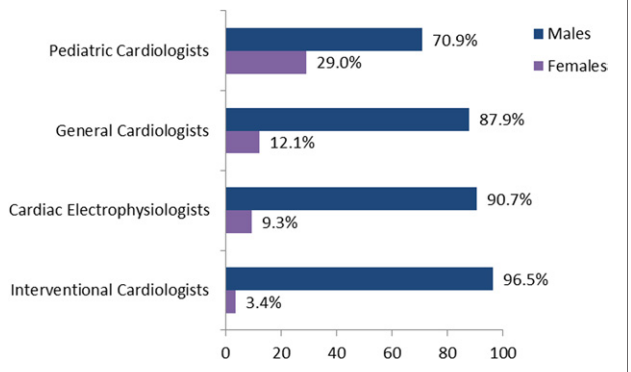



**Figure 29** **Cardiologists by Specialty and Sex, 2008**

**Dark blue bars** = males; **purple bars** = females. Source: The Lewin Group, Inc., and Association of American Medical Colleges (69).

**Pharmaceuticals.** Worldwide, pharmaceutical sales growth declined to between 4% and 6% in 2010 from the 7% growth rate recorded in 2009. Other global pressures slowing growth of pharmaceutical sales in 2010 were price cuts in Japan—the world's second largest market after the United States—and cuts to publically funded health budgets in Europe (84). The industry is also facing an unprecedented wave of patent expirations, leading to a projected cumulative loss of $78 billion in worldwide sales during 2010 to 2014, with nearly half of this erosion expected to occur due to the loss of patents in 2011 for major blockbuster drugs. (Figure 35 shows the projected replacement ratio for 2012 [85].)

The replacement ratio in a given year is the ratio of revenue from new products (that is, those launched in the previous 5 years) to the revenue lost from declining products (for example, due to generic competition). This ratio is a measure of research and development sufficiency; a ratio of <1 reflects a failure to replace former successful products with new revenue drivers. The data (86) are based on each company's major prescription drug portfolio (the collection of branded drugs, each of which is projected to achieve at least $500 million in annual sales) and were compiled before the mergers of Pfizer and Wyeth, and Merck and Schering-Plough.

Growth in emerging international markets such as China and Brazil will likely offset the generic competition for many of the world's top selling drugs. In 2014, global pharmaceutical sales are projected to approach $1.1 trillion as drug sales in emerging markets are expected to grow by up to 17% (84).

The growth of generic drugs has been beneficial to the consumer, allowing them more access to treatment options and also reducing costs to the system. An IMS analysis found the following related to the use of generics in the United States: the use of generic prescription drugs in place of their brand name counterparts saved the U.S. healthcare system approximately $931 billion over the past decade (2001 through 2010) (Fig. 36); in 2010, generic use generated $158 billion in savings; and savings from newer generic medicines—those that have entered the market since 2001—continue to increase and account for slightly more than one-third of the total savings (Fig. 36) (87).

Within the cardiovascular medicine market, the top drugs in use have come off patent. At the end of 2011, Pfizer stood to lose $10 billion a year when its patent expired on atorvastatin (Lipitor, the world's top-selling drug) (85). The combination of extended-release niacin plus simvastatin (Simcor) as well as fenofibric acid (Trilipix) similarly lost patent protection in 2011. Patent protection also expired on clopidogrel (Plavix) in 2012. In 2010, sales of clopidogrel in the United States alone were >$6 billion (88). Virtually all of the most widely used angiotensin-II receptor antagonists, including losartan (Cozaar/Hyzaar), irbesartan (Avapro), candesartan (Atacand), and valsartan (Diovan), have either already lost or will soon lose patent protection in the United States (89). Table 14 displays key cardiovascular-related patent expirations along with prior patent year sales.

Despite the revenue loss noted and large demand for new drugs, and the projection of heart disease and stroke as the leading cause of death through 2030 (90), there are only approximately 150 new cardiovascular drugs currently (products outlined in Fig. 37) under development compared with some 700 new drugs in development for the treatment of cancer (91).

Additionally, the number CVD-related new molecular entities approved by the Food and Drug Administration (FDA) has declined since 1999, possibly resulting from reduced investment by the industry. This decline is represented in Table 15 (92). In response to the slowing pace of new drug development from industry, the National Insti-

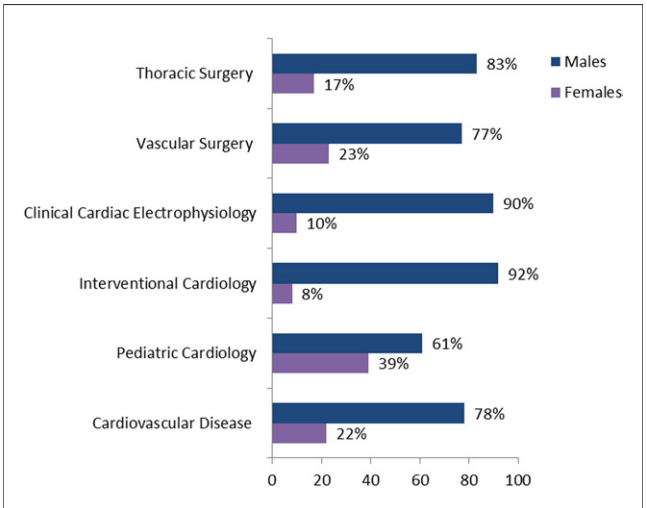



**Figure 30** **Trainees by Subspecialty and Sex, 2010 to 2011**

**Dark blue bars** = males; **purple bars** = females. Number of programs and residents by academic year and specialty and subspecialty, 2010. Source: Accreditation Council for Graduate Medical Education (75).

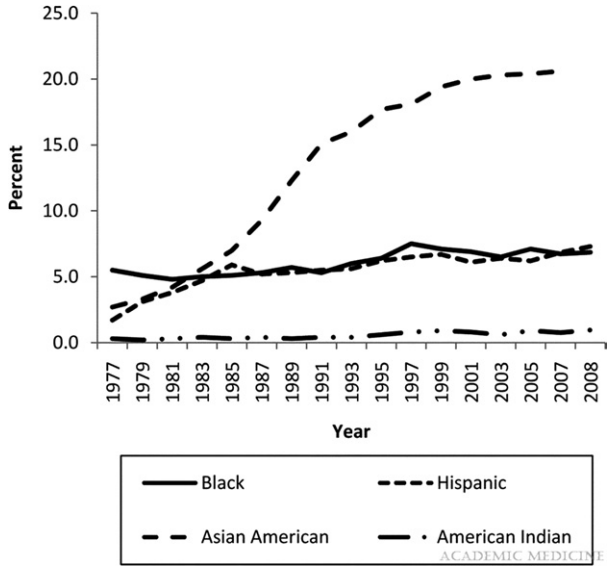



**Figure 31** **Minority Graduation Trends in U.S. Medical Schools, 1977 to 2008**

**Solid line** = black; **dashed line** = Hispanic; **broken line** = Asian American; **dash-dotted line** = American Indian. Source: Sullivan LW, Suez Mittman I. State of diversity in the health professions a century after Flexner. Acad Med 2010;85:193–6.

tutes of Health (NIH) recently proposed a billion-dollar drug development center be established at the agency (93).

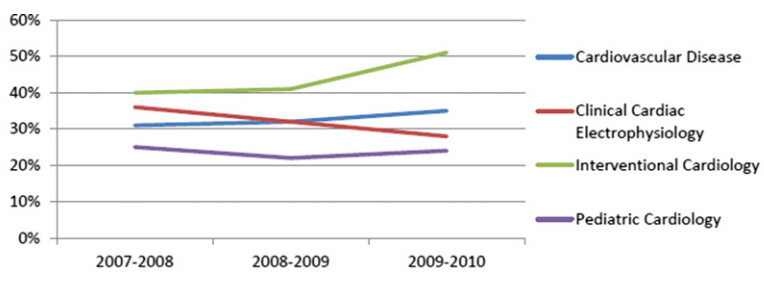
It should be noted that the FDA has approved fewer and fewer drugs overall, not just in CVD, whereas spending on industry-wide research and development has nearly doubled over the past decade to $45 billion a year (94). Figure 38 displays the increasing research and development expenditures for both members of the Pharmaceutical Research and Manufacturers of America and the industry from 1995 to 2010.

**Medical devices.** Lucintel (a market research firm) projects the global cardiovascular device market will reach an estimated $104 billion in 2017 with a compound annual growth rate of 5.2% over the next 5 years (95). A recent pipeline analysis found 114 devices from key manufacturers currently in various phases of development (Fig. 39) (91).

Koncept Analytics projects the coronary stent market to see growth from now through 2015 at a compound annual growth rate of 3.7%, exceeding a total of $8 billion (96). Fourth-generation bioabsorbable stents show the most promise. Results of 3 major trials—ISAR-TEST 3 (Prospective, Randomized Trial of 3 Rapamycin-Eluting Stents With Different Polymer Coating Strategies for the Reduction of Coronary Restenosis), ISAR-TEST 4, and LEADERS (Limus Eluted From a Durable Versus Erodable Stent Coating)—have suggested that the use of biodegradable polymer drug-eluting stents (DES) lead to lower rates of target lesion revascularization, stent thrombosis, and cardiac death and heart attack than DES made of durable polymer (97). Abbott has now initiated the ABSORB II trial in which they will evaluate the safety, efficacy, and performance of the ABSORB bioresorbable vascular scaffold compared with 1 of the company's own DES in patients with heart disease (98).

Several other companies (Medtronic, Biotronic) have also applied for or have received their conformance mark meeting European Union safety and health requirements for their bioabsorbable DES products (99).

Percutaneous devices, including those used to replace aortic and repair mitral valves, entered the U.S. market in 2011 and are projected to account for $1.3 billion of the projected $4.4 billion U.S. cardiovascular surgery market by 2017 (100). Two-year data from Cohort A of the PARTNER (Placement of Aortic Transcatheter Valve Trial) study using the Edwards SAPIEN aortic valve now show comparable mortality rates for patients with transcatheter aortic valve replacement (TAVR) and patients with aortic valves replaced through open-heart surgery in high-risk populations. At 2 years, the difference in stroke risk between the groups became nonsignificant, although valvu-




Source: Accreditation Council for Graduate Medical Education Data Resource Book: Academic Years 2007-2008/2008-2009/2009-2010, ACGME, 2008/2009/2010.

**Figure 32** **Percentage of International Medical Graduate Residents, by Cardiovascular Specialty/Subspecialty**

**Blue** = cardiovascular disease; **red** = clinical cardiac electrophysiology; **green** = interventional cardiology; **purple** = pediatric cardiology. Source: Accreditation Council for Graduate Medicine (78).


**Figure 33** **Global Distribution of Physician Workforce (per 10,000 Population), 2000 to 2009**

Source: World Health Statistics 2010, World Health Organization, 2010.

lar regurgitation remained higher in the TAVR group with adverse prognostic significance (101).

In Cohort B of the PARTNER trial, survival and life quality of nonoperable patients treated with TAVR were significantly improved compared with patients treated with medical management only, and readmissions were fewer (102).

Implantation of the Medtronic CoreValve prosthesis was also recently found to be relatively safe as used in a "real-world" clinical population and was associated with an improvement in hemodynamics at 6-month follow-up (97).

Other percutaneous devices include the Evalve MitraClip, which permits double-orifice repair of mitral regurgitation. The Cardiac Dimensions Carrilon system, the Edwards Monarc system, and the Viacor PTMA system are all indirect coronary sinus devices that have been cited for simplicity and ease of use, whereas the Mitralign percutaneous annuloplasty system, as well as the Guided Delivery System, facilitate direct implantation of a device into the mitral annulus and may overcome limitations of the indirect coronary sinus approach.

In contrast, a substantial unmet need remains for medical devices for pediatric interventional cardiology, and off-label use of approved devices is routine in pediatric medicine. Specifically, a study showed that during a 3-year period, some 595 transcatheter interventions were done in approximately 473 pediatric patients, median age 4.1 years. Off-

| Employment setting, age, and U.S.- and foreign-born status | Employment growth among FTE RNs, 2001–2008 |
|---|---|
| Total growth | 476,000 |
| Age (years) | |
| Hospital | 387,000 |
| Under 35 | 126,000 |
| 35–49 | 31,000 |
| 50–64 | 230,000 |
| Nonhospital | 89,000 |
| Under 35 | 5,700 |
| 35–49 | −55,000 |
| 50–64 | 138,000 |
| U.S.-born | 321,000 |
| Hospital | 268,000 |
| Nonhospital | 53,000 |
| Foreign-born | 155,000 |
| Hospital | 119,000 |
| Nonhospital | 35,500 |

**SOURCE:** Authors' calculations of data from the Current Population Surveys, 1973–2008.

**Figure 34** **Growth in Employment of FTE RNs, by Major Employment Sector, Age, and U.S.- and Foreign-Born Status, 2001 to 2008**

FTE = full-time equivalent; RN = registered nurse. Source: Buerhaus et al. (81).

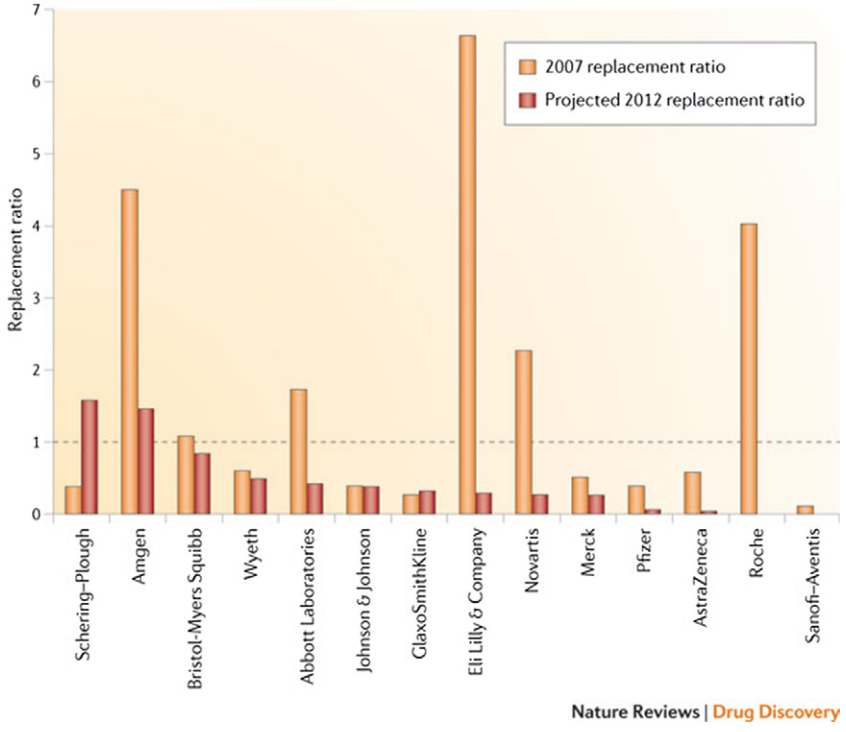



**Figure 35** **Projected Replacement Ratio, 2012**

**Orange bars** = 2007 replacement ratio; **red bars** = projected 2012 replacement ratio. Source: Harrison (85).

label application was used in 63% of all patients and in 99% of stent implantations, 78% of balloon dilations, and 29% of coil embolizations (103).

**FDA approval.** Review times for drugs and biologics increased by 28% from 2003 to 2008, whereas clearance times for medical devices slowed by >40% over roughly the same period. Premarket approval times have lengthened by 75% (104).

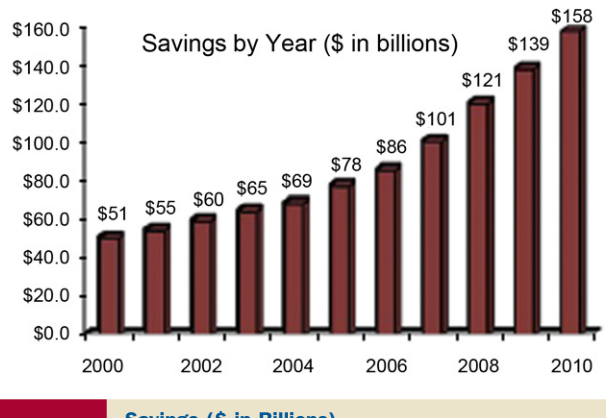



**Figure 36** **Savings ($ in Billions) Due to Generic Drug Use by Year**

Source: Generic Pharmaceutical Association (87).

According to 1 study, companies brought products to patients faster and at a much lower cost in Europe than in the United States. In fact, for low- and moderate-risk devices, it took companies 3 months to 2 years longer to navigate the FDA for clearance or approval than it did for similar approval from European regulators; for higher risk devices, the process took 5 times as long in the United States as it did in Europe. There is as yet no evidence that patient safety in Europe has been compromised by a more efficient approval process (105).

Unlike prescription drugs, medical devices are reviewed by the FDA using 2 standards—pre-market approval, which requires clinical testing and inspections, or the so-called "510(k)" process, which requires the device be similar to an

**Table 14** **Cardiovascular Disease-Related Patent Expirations ENREF 90**

| Drug | Company | Patent Expiration | U.S. Sales in Yr Before Patent Expiration ($ Millions) |
|---|---|---|---|
| Avapro | BMS/sanofi | 3/12 | $281 |
| Plavix | BMS/sanofi | 5/12 | $6,895 |
| Diovan | Novartis | 9/12 | $2,333 |
| Atacand | AZ/Takeda | 12/12 | $110 |
| Integrilin | Merck | 11/14 | $288* |
| Benicar | Sankyo | 4/16 | $1,066† |

*Projections for 2013. †Projections for 2015. Source: Access Communications (91).

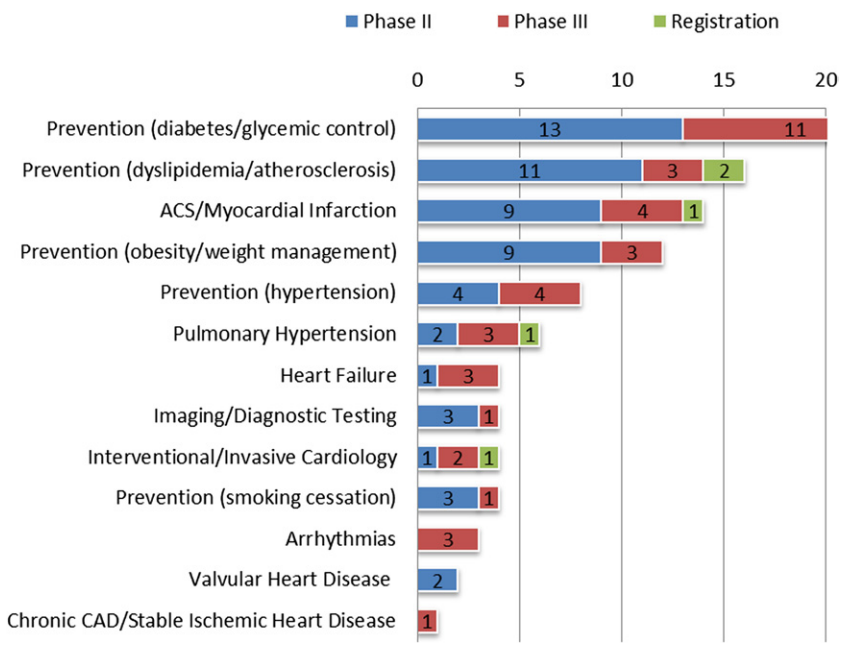



**Figure 37** CV Pipeline Products by ACC-Defined Core Pathway and Phase of Development

**Blue** = Phase II; **red** = Phase III; **green** = Registration. ACC = American College of Cardiology; ACS = acute coronary syndrome; CAD = coronary artery disease; CV = cardiovascular. Source: Access Communications (91).

already marketed device. In an analysis of the FDA's list of device recalls from 2005 to 2009, it was determined that 113 recalls during this interval could cause serious health problems or death (106). Only 19% of these devices had been approved through the pre-marketing process, whereas 71% were cleared through the 510(k) process. Seven percent were exempt from any FDA regulation (107).

These findings suggest that those medical devices recalled for life-threatening or very serious hazards in this review were originally cleared for the market using the less stringent 510(k) process and that there is clearly room to reform the regulatory process to ensure patient safety. Despite a modest increase in funding, there was no corresponding increase in FDA approvals for drugs or devices between 2003 and 2008, as indicated in Table 16.

The FDA is taking steps to reduce approval times for drugs and devices, among them a streamlining of the review process for lower risk medical devices, increasing the efficiency and transparency of the review process, and establishing a new Center Science Council made up of senior FDA experts to ensure timely and consistent decision-making. The FDA and CMS are also considering a joint plan for overlapping evaluation of pre-market medical products to shorten the time it takes for newly approved medical products to be covered by third-party payers (107).

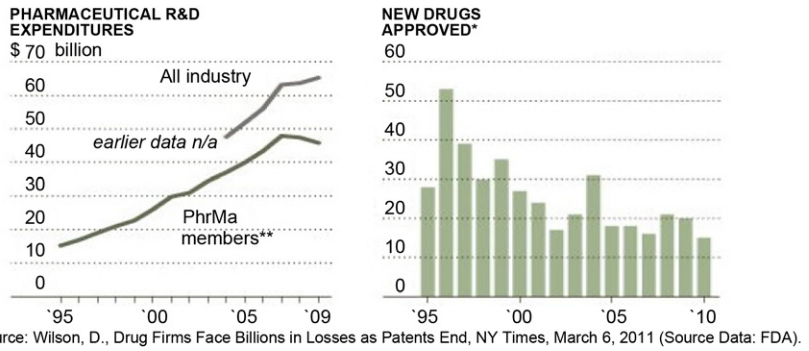
**Post-market surveillance.** Post-market surveillance of medical devices is done passively, meaning that the FDA relies on voluntary reporting of adverse events. As a result, the detection, analysis, and recall for potentially dangerous devices can be slow because of not having an accurate estimate of the adverse impact of a device. Devices like the Riata and Riata ST implantable cardioverter-defibrillator leads, which are prone to high-voltage failure, were not recalled until after their widespread use (108). Although the lead was pulled from the market in 2010 and recalled by the FDA in December of 2011, >79,000 patients in the United

**Table 15** Cardiovascular Disease-Related New Molecular Entities Approved by the Food and Drug Administration

| | Year | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 1996 | 1997 | 1998 | 1999 | 2000 | 2001 | 2002 | 2003 | 2004 | 2005 | 2006 | 2007 | 2008 | 2009 | 2010 |
| NME* | 45 | 41 | 43 | 36 | 26 | 30 | 22 | 26 | 32 | 38 | 26 | 35 | 34 | 37 | 23 |
| CVD related NMEs | N/A | N/A | N/A | 3 | 4 | 4 | 5 | 1 | 1 | 0 | 1 | 3 | 2 | 3 | 1 |
| % CVD related NMEs to total NMEs | N/A | N/A | N/A | 8.3 | 15.3 | 13.3 | 22.7 | 3.8 | 3.1 | 0 | 3.8 | 8.5 | 5.8 | 8.1 | 4.3 |

*2004 to 2010 represent applications for new molecular entities (NMEs) filed under New Drug Applications (NDAs) and therapeutic biologics filed under Original Biologic License Applications (BLAs). 2001 to 2003 represent NMEs but not therapeutic biologics. Source: Mehta (92).

CVD = cardiovascular disease.




Source: Wilson, D., Drug Firms Face Billions in Losses as Patents End, NY Times, March 6, 2011 (Source Data: FDA).

**Figure 38** **Pharmaceutical Companies Have Spent More on Research and Development Over Time, But Have Discovered Fewer Novel Drugs That Gain FDA Approval**

FDA = Food and Drug Administration; n/a = not available; PhrMa = Pharmaceutical Research and Manufacturers of America. Source: Wilson (94).

States still use the implants (109). To improve post-market surveillance, Congress and the FDA are working to utilize data from EHR, claims data, and clinical registries through the Sentinel Initiative to receive more accurate information (110).

Another major effort to improve market surveillance is the Medical Device Epidemiology Network Initiative. This initiative promotes public–private partnerships to collect and share information about devices after they are marketed to ensure patient safety. The partnerships are currently exploring more novel methodologies to study medical devices to track adverse events and improve patient outcomes (111).

One of the major obstacles to surveillance is that medical device identification is not standardized across hospital systems, manufacturers, and distributions. To remedy this, the FDA intends to use a unique device identification system in the upcoming years to identify device failure rates (112). The Sentinel Assurance for Effective Devices Act of 2012 was submitted to Congress in May to establish a system to identify and analyze adverse events among medical devices (113). The FDA has proposed the unique device identification system rollout to begin in 2013 for implantations and other devices that support human life, such as TAVR, pacemakers, and defibrillators. The rollout for equipment such as radiography, pumps, and surgical drapes is said to begin in 2015 (114).

**New methods of post-market surveillance.** Professional associations and the CMS have begun collaborating to coordinate clinical registries and other relevant databases to track the safety of devices and procedures to enhance post-market surveillance. One example of this collaboration is the transcatheter valve therapy registry that tracks patients undergoing TAVR. Soon after the Edwards SAPIEN transcatheter heart valve was approved by the FDA in 2011, 2 professional associations (the Society of Thoracic Surgeons and ACC) launched the transcatheter valve therapy

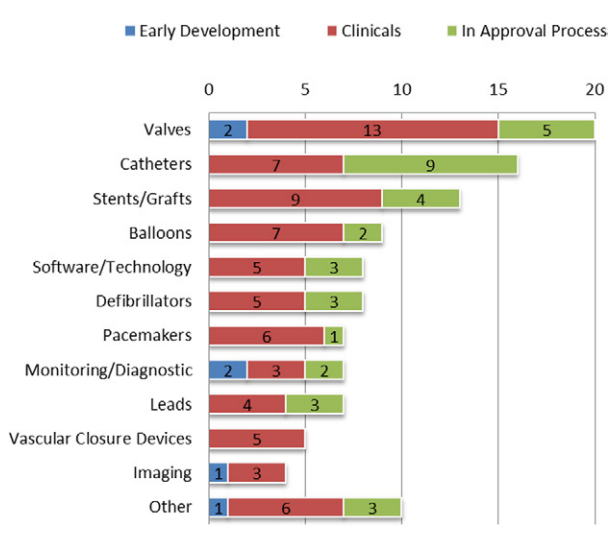



**Figure 39** **CV Devices in Development by Key Manufacturers by Category**

Key device manufacturers were defined as those with the largest presence in the cardiovascular (CV) device segment with active pipelines (includes Medtronic, Boston Scientific, St. Jude Medical, Edwards Lifescience, C.R. Bard, Sorin, Cordis, Abbot Vascular, Coviden, GE Healthcare, Philips, Siemens, Toshiba). **Blue** = in early development; **red** = in clinical trials; **green** = in approval process. Source: Access Communications (91).

**Table 16** **New Drug and Device Approvals by U.S. Food and Drug Administration, 2003–2008**

| Category | 2003 | 2004 | 2005 | 2006 | 2007 | 2008 |
|---|---|---|---|---|---|---|
| New molecular entities | 21 | 31 | 18 | 18 | 16 | 17 |
| Biologic license applications* | | 5 | 2 | 4 | 2 | 3 |
| f41Device premarket application approvals† | 33 | 46 | 32 | 38 | 25 | 25 |

*The Food and Drug Administration reported biologic license approvals beginning in 2004. †Numbers include instruments, implantables, patient monitoring, diagnostic devices, and in vitro tests. Source: Dorsey et al. (130).

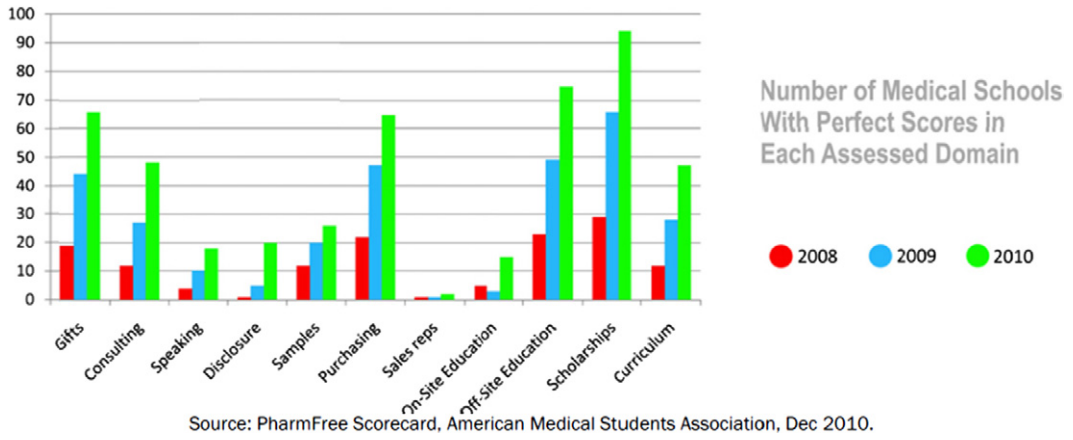



**Figure 40** **Number of Medical Schools With Perfect Scores in Each Assessed Domain, 2010**

**Red bars** = 2008; **blue bars** = 2009; **green bars** = 2010. Source: American Medical Association.

registry to track safety and long-term health outcomes of patients who undergo TAVR (115). Information from the transcatheter valve therapy registry is linked to the Social Security Death Master File as well as to other CMS databases to track the long-term health outcomes and can be utilized by the FDA for post-market surveillance (116).

Similar registries have also been mandated by CMS for coverage determinations and tracking of patient outcomes. For example, patients receiving an implantable cardioverter-debrillator are required to participate in the implantable cardioverter-debrillator registry sponsored by the Heart Rhythm Society and ACCF for Medicare coverage. Registries operated by professional societies for devices with significant expense and risk are gaining value because CMS and other payers are interested in measuring patient outcomes (117).

Additionally, 4 professional associations (American Association for Thoracic Surgery, ACCF, Society for Cardiovascular Angiography and Interventions, and The Society of Thoracic Surgeons) collaborated to publish an Expert Consensus Document on TAVR to advise payers, providers, and other stake holders on safely incorporating TAVR into their practice (116). To ensure national standards for patients

| | Maine | | West Virginia | |
|---|---|---|---|---|
| Type of Effect | Compared With New Hampshire | Compared With Rhode Island | Compared With Kentucky | Compared With Delaware |
| On percentage of claims that are for brands | | | | |
| Statins | −0.81 (−1.22 to −0.39)[b] | −5.29 (−5.45 to −5.13)[c] | 0.26 (−12.82 to 13.34) | −2.62 (−4.74 to −0.49)[b] |
| SSRIs | 3.73 (3.20 to 4.25)[c] | −0.72 (−1.18 to −0.26)[b] | 1.09 (−4.13 to 6.31) | −0.53 (−0.77 to −0.28)[b] |
| On out-of-pocket prescription costs ($ per 30-d supply) | | | | |
| Statins | 0.77 (−1.94 to 3.48) | 0.77 (−3.03 to 4.58) | −2.64 (−9.41 to 4.16) | −2.12 (−8.50 to 4.27) |
| SSRIs | 0.02 (−0.51 to 0.55) | −0.69 (−1.88 to 0.51) | −1.78 (−5.72 to 2.15) | −3.01 (−14.52 to 8.49) |
| On out-of-pocket costs + insurer payments ($ per 30-d supply) | | | | |
| Statins | −2.08 (−7.19 to 3.02) | −6.33 (−13.87 to 1.21) | 3.06 (−23.39 to 29.52) | −0.11 (−13.83 to 13.61) |
| SSRIs | 0.08 (−0.05 to 0.22) | −2.74 (−4.46 to −1.03)[b] | 0.73 (−18.23 to 19.69) | −0.99 (−14.44 to 12.45) |

Abbreviation: SSRI, selective serotonin reuptake inhibitors.
[a] Numbers in parentheses indicate the 95% CI. All regressions include dummy variables for exclusivity expiration of brand drugs, dummy variables for seasonality of state claims, state fixed effects, and year fixed effects. Standard errors are clustered by state. There were 156 observations in each set of comparisons.
[b] $P < .05$.
[c] $P < .01$.

**Figure 41** **Effect of Physician Payment Disclosure Laws on Prescribing and Expenditures[a]**

SSRI = selective serotonin reuptake inhibitor. Source: Arch Intern Med 2012;172:819–21; doi:10.1001/archinternmed.2012.1210.

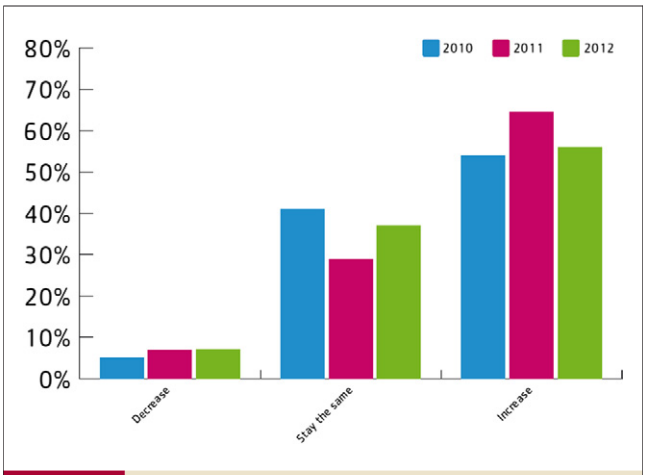



**Figure 42** Expected Change in Investment in Aggregate Spend Reporting and Disclosure Compliance, 2010 to 2012

**Blue bars** = 2010; **red bars** = 2011; **green bars** = 2012. Source: Pelletier (125).

undergoing TAVR, a national coverage determination analysis was requested of CMS. In May 2012, CMS approved reimbursement for providers that perform TAVR given the following conditions are met: the valve and implantation system have FDA premarket approval; 2 cardiac surgeons independently evaluate the patient; the patient is under the care of a multidisciplinary heart team at a hospital qualified to perform TAVR; both the interventional cardiologist and cardiac surgeons are involved with the implantation; and the heart team and hospital participate in a TAVR registry (118).

## Relationships With Industry

The Physician Payment Sunshine Act, a section of the ACA, was created to disclose payments to physicians from private industry (pharmaceutical and medical device companies). It was scheduled to be implemented in January 1, 2012, but CMS delayed the implementation to 2013 to address logistical issues and data accuracy (119).

A number of academic medical centers and states have implemented new policies that more strictly manage relationships between physicians and industry. For example, in 2010, Harvard's Partners Healthcare capped payments its physicians can receive for serving on corporate boards at $5,000 a day. In the same year, Massachusetts required conflict-of-interest (COI) policies be posted on its public health website, and an increasing number of universities have placed a ban on gifts from pharmaceutical companies (120).

Simultaneously, a number of pharmaceutical companies including GlaxoSmithKline, Lilly, Merck, and Cephalon have been disclosing payments to physicians on their company websites (120). Newly proposed regulations would also compel researchers funded by the NIH to disclose their financial ties to industry and lower the threshold at which a researcher's financial interest requires disclosure to $5,000. Institutions would also be required to create plans to manage all identified financial COIs under the same proposed rules, and every publicly funded institution would similarly have to disclose all significant COIs online. Investigators, in turn, would be required to undergo COI training before engaging in publicly funded research, and training would be required every 2 years thereafter (121).

Most medical schools in the United States have implemented COI policies governing industry interactions at the schools. As a measurement of these interactions, the American Medical Student Association developed a PharmFree Scorecard that grades medical schools according to their COI policies (122). In 2012, 102 of 152 medical schools in the United States received a grade A or grade B for their COI polices, up from 79 in the previous year. The trends of schools achieving perfect grades on the PharmFree Scorecard is displayed in Figure 40 (123). Furthermore, one-third of U.S. medical schools incorporated COI policies into their curriculum (120).

A recent study of physician prescribing habits in Maine and West Virginia, which both enacted payment-disclosure legislation in 2004, found that, in Maine, prescribing of branded selective serotonin reuptake inhibitors was actually 3.7 percentage points higher than in New Hampshire, a state that did not enact them. The prescribing patterns for statins showed little difference across states with the enacted legislation (Maine and West Virginia) compared to those without legislation (Kentucky and Delaware) (Fig. 41) (124).

Responding to this increased pressure for transparency, life science executives (pharmaceutical, biotech, and medical device companies) expect to increase their investment in aggregate

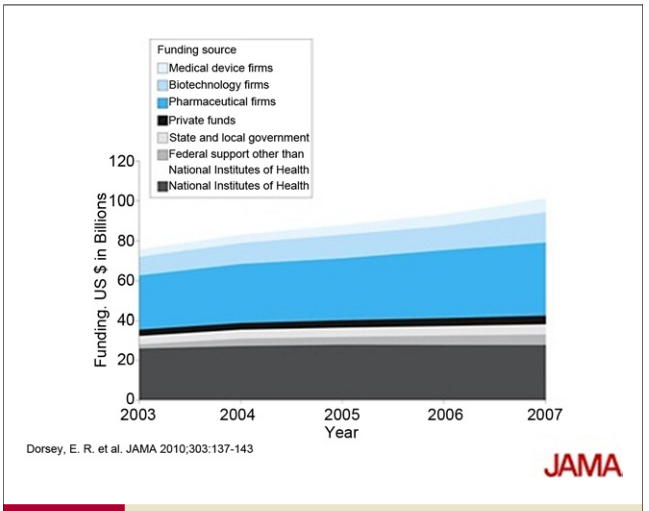



**Figure 43** Funding for Biomedical Research by Source, 2003 to 2007

**Light blue** = medical device firms; **medium blue** = biotechnology firms; **deep blue** = pharmaceutical firms; **black** = private funds; **light gray** = state and local government; **medium gray** = federal support other than National Institutes of Health; and **dark gray** = National Institutes of Health. Source: Dorsey et al (130).

spend reporting and disclosure compliance over the next year (Fig. 42). The expected increase is partly due to federal regulations and the trend of global transparency.

Additionally, 88% of attendees surveyed at the Fourth Annual Life Sciences Meeting Management Forum said they already had a system in place to track physician payments, and 76% were already testing their systems (125).

## Funding for Biomedical Research

For the 2013 fiscal year, $140.8 billion of President Obama's proposed $3.8 trillion budget has been allocated to research and development (126,127). Funding recommendations for federal research for the fiscal year 2013 include $30.7 billion to the NIH (128), $7.4 billion to the National Science Foundation, and $583 million to the Department of Veterans Affairs medical and prosthetics research program (129).

The NIH is the largest federal contributor to biomedical research, accounting for 84% of total federal funding in 2007 (130,131). In 2011, the NIH allocated a total of $2.1 billion to cardiovascular research. More specifically, $1.2 billion was allocated to heart disease research, $317 million to stroke research, and $437 million to coronary heart disease research (131).

The National Heart, Lung and Blood Institute, an institute within the NIH, has been funding the Cardiovascular Research Network (CVRN), which brings together researchers and databases from 15 integrated health plan members of the NIH health maintenance organization research. This network has access to the EHR of >11 million patients, and the electronic database of the CVRN offers significant potential for a broad array of research opportunities (132).

The NIH awarded >$13 million to the CVRN for research regarding heart failure, atrial fibrillation, and CVD surveillance (133). A $7.2 million grant from the National Heart, Lung, and Blood Institute is supporting the development of an integrated surveillance system that will provide comprehensive information regarding the burden of CVD in the United States (131).

From 2003 to 2007, funding for biomedical research increased by 14%, to a total of $101.1 billion in 2007, a considerably higher annual growth rate than the 7.8% growth reported for the years 1994 and 2003. The growth in

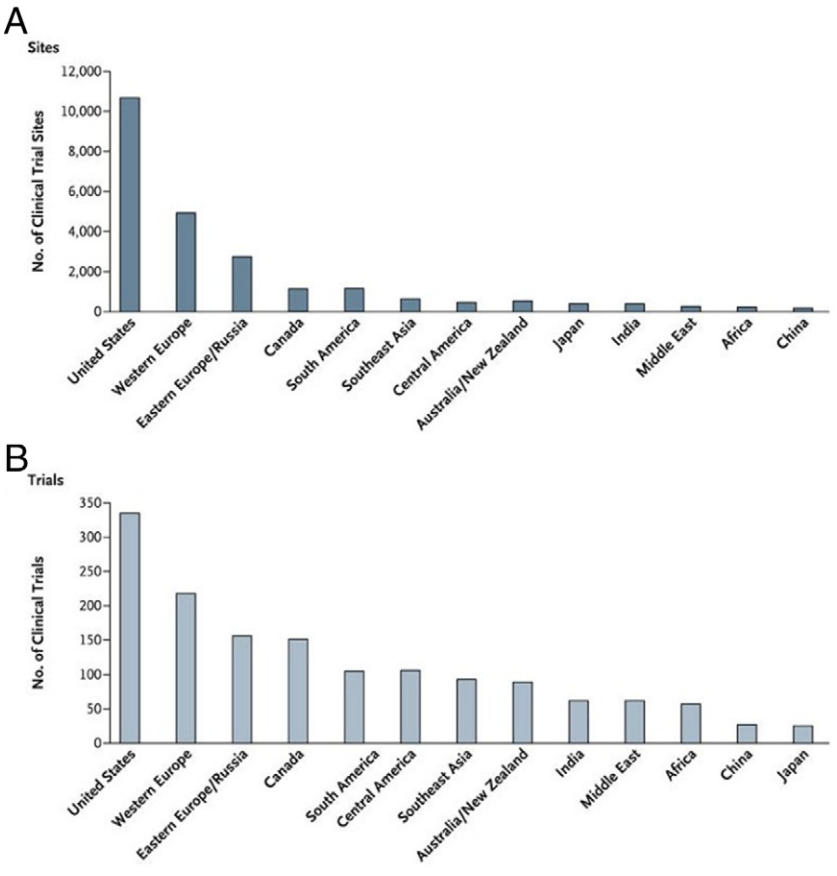



**Figure 44** Open Phase III Clinical Trials Globally in 2007 by the 20 Largest U.S. Pharmaceutical Companies

**(A)** Sites. **(B)** Trials. Source: Glickman et al. (136).

| Variable | 1993 mean | 1993 SD | 2005 mean | 2005 SD |
|---|---|---|---|---|
| **PUBLIC HEALTH AGENCY CHARACTERISTICS** | | | | |
| Per capita public health spending | $34.68 | $33.08 | $40.84 | $42.52 |
| Agency governed by local board of health | 64.41% | | 57.42% | |
| Agency operates as centralized unit of state agency | 10.27% | | 7.83% | |
| **COMMUNITY CHARACTERISTICS** | | | | |
| Population size (1,000s) | 108.63 | 340.60 | 131.44 | 426.42 |
| Population per square mile (1,000s) | 475.08 | 1,841.46 | 484.04 | 1,842.57 |
| Community located within a metropolitan area | 51.05% | | 50.48% | |
| Percent of: | | | | |
| Population nonwhite | 14.33 | 17.93 | 19.27 | 17.36 |
| Population 65 or older | 14.39 | 3.91 | 14.07 | 4.00 |
| Population with college degree | 15.85 | 8.25 | 19.59 | 9.53 |
| Population unemployed | 6.21 | 2.42 | 5.64 | 2.26 |
| Population below federal poverty level | 15.65 | 7.04 | 11.92 | 4.79 |
| Population non–English speaking | 1.07 | 1.77 | 1.73 | 2.32 |
| Population uninsured | 13.66 | 4.65 | 13.52 | 4.50 |
| **MEDICAL CARE RESOURCES** | | | | |
| Active physicians per 100,000 population | 138.04 | 133.83 | 169.24 | 159.23 |
| Hospital beds per 100,000 population | 384.16 | 320.51 | 320.60 | 372.81 |
| Federally qualified health center serves community | 48.33% | | 46.57% | |
| **HEALTH OUTCOMES** | | | | |
| Infant deaths per 1,000 live births | 8.76 | 3.50 | 7.03 | 3.22 |
| Deaths per 100,000 population from: | | | | |
| Influenza | 36.11 | 17.66 | 27.28 | 15.52 |
| Cancer | 215.46 | 56.16 | 219.49 | 57.99 |
| Heart disease | 225.02 | 78.87 | 194.09 | 76.95 |
| Diabetes | 23.47 | 10.58 | 28.67 | 14.41 |
| Total deaths per 100,000 population | 1,020.97 | 256.59 | 980.62 | 270.68 |
| Number of observations | 2,026 | | 2,300 | |

**SOURCE** Authors' analysis of linked data from the National Association of County and City Health Officials' National Profile of Local Health Departments, the Census Bureau's Census of Governments and *Consolidated Federal Funds Report*, the Health Resources and Services Administration's Area Resource File, and the Centers for Disease Control and Prevention's Compressed Mortality File. **NOTE** SD is standard deviation.

**Figure 45** **Characteristics of the Study Communities, 1993 and 2005**

Source: Mays and Smith (138).

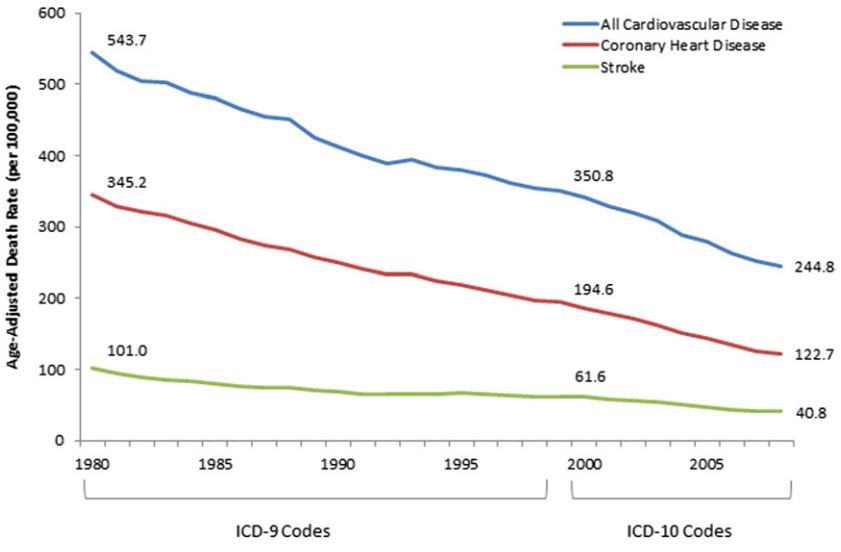



**Figure 46** **Age-Adjusted Death Rates for Cardiovascular Disease, Coronary Heart Disease, and Stroke, 1980 to 2008**

**Blue line** = all cardiovascular disease; **red line** = coronary heart disease; and **green line** = stroke. ICD = International Classification of Diseases. Source: National Institutes of Health, National Heart, Lung and Blood Institute. Morbidity and Mortality: 2012 Chart Book on Cardiovascular, Lung, and Blood Diseases. Available at: http://www.nhlbi.nih.gov/resources/docs/2012_ChartBook_508.pdf.

funding for biomedical research is displayed in Figure 43. Industry was the largest source of funding in 2007, accounting for 58% of the total, followed by the federal government, which accounted for 33%. Taken together, support from pharmaceutical, biotechnology, and medical device companies increased by 25% (adjusted for inflation) from 2003 to 2007, where it peaked at $58.6 billion (130).

The biopharmaceutical industry spent an estimated $67.4 billion on research and development in 2010. Between 2000 and 2010, 333 drugs or biologics were approved by the FDA. Each drug takes 10 to 15 years to be developed and approved, and on average costs approximately $1.3 billion (134).

Although the pharmaceutical industry is sponsoring more research and development, more clinical trials are moving to developing countries (135). A study from the *New England Journal of Medicine* noted that the shift is due to the more cost intensive and complex regulatory environments in the United States and Western Europe. The funding required for clinical trials in the United States often exceeds the federal funding allotted for biomedical research. Figure 44 displays the open phase 3 clinical trials by the number of sites and trials by the top 20 largest U.S. pharmaceutical companies in 2007. The FDA reported that the number of regulated investigations conducted outside of the United States has grown by 15% annually.

There are concerns regarding clinical trials conducted abroad. One concern is ethical oversight. In a study of researchers in developing countries, 56% reported that their studies were reviewed by a local institutional review board or ministry of health. Further concerns regarding the generalizability of the results have been discussed by the FDA relating to potential genetic and socioenvironmental factors that affect treatment efficacy among patient populations in developing countries (Fig. 45) (136).

## Cardiovascular Prevention

Cardiovascular prevention efforts are receiving growing attention in an effort to offset the increasing burden of disease and to stem rising healthcare costs. Federal efforts, public agencies, and employers are developing strategies addressing risk factors associated with CVD.

The debate continues around which approach has had the greatest impact on reducing mortality from coronary heart disease: better control of cardiovascular risk factors or the use of medical interventions (137). An analysis of the effect of increased public health spending on mortality found that public health spending is not significantly associated with overall mortality; however, increased public health spending correlated with lower heart disease-related mortality rates (138).

**Table 17** Deaths from Coronary Heart Disease That Were Prevented or Postponed as a Result of Changes in Population Risk Factors

| | Absolute Level of Risk Factor‡ | | Change in Risk Factor | | | | Deaths Prevented or Postponed | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Beta Regression Coefficient for Change in Mortality Rate§ | Relative Risk | Best Estimate | Minimum Estimate | Maximum Estimate | Best Estimate | Minimum Estimate | Maximum Estimate |
| Risk Factor† | 1980 | 2000 | Absolute Change | Relative Change (%) | | | No. of Deaths | | | Percent of Total Reduction | | |
| Smoking prevalence (%) | 36.3 | 24.6 | −11.7 | −32.2 | | | 39,925 | 34,955 | 52,435 | 11.7 | 10.2 | 15.3 |
| Men | | | | | | 2.52 | | | | | | |
| Women | | | | | | 2.14 | | | | | | |
| Systolic blood pressure (mm Hg) | 129.0 | 123.9 | −5.1 | −4.0 | | | 68,800 | 53,730 | 105,060 | 20.1 | 15.7 | 30.7 |
| Men | | | | | −0.0334 | | | | | | | |
| Women | | | | | −0.0413 | | | | | | | |
| Total cholesterol (mmol/l) | 5.67 | 5.33 | −0.34 | −6.1 | | | 82,830 | 58,455 | 95,570 | 24.2 | 17.1 | 28.0 |
| Men | | | | | −0.9458 | | | | | | | |
| Women | | | | | −0.9121 | | | | | | | |
| Physical inactivity (%) | 29.6 | 27.3 | −2.3 | −7.8 | — | | 17,445 | 8,340 | 29,035 | 5.1 | 2.4 | 8.5 |
| Men | | | | | | 1.27 | | | | | | |
| Women | | | | | | 1.33 | | | | | | |
| BMI | 25.6 | 28.2 | +2.6 | 10.1 | | | −25,905 | −14,430 | −40,405 | −7.6 | −4.2 | −11.8 |
| Men | | | | | 0.0297 | | | | | | | |
| Women | | | | | 0.0297 | | | | | | | |
| Diabetes prevalence (%) | 6.5 | 9.4 | +2.9 | 44.2 | — | | −33,465 | −23,885 | −43,330 | −9.8 | −7.0 | −12.7 |
| Men | | | | | | 1.93 | | | | | | |
| Women | | | | | | 2.59 | | | | | | |
| Total risk factors | | | | | | | 149,635 | 117,165 | 198,360 | 43.8 | 34.3 | 58.0 |

*Percentages may not sum to 100 because of rounding. BMI denotes body-mass index (the weight in kilograms divided by the square of the height in meters). To convert the values for cholesterol to milligrams per deciliter, divide by 0.02586. Data sources are described in the Supplementary Appendix. †The total adult population in 1980 was 177,745,055. For systolic pressure, the numbers of deaths exclude patients receiving treatment for hypertension, and for total cholesterol, the numbers exclude patients receiving statins. ‡Data are from the National Center for Health Statistics, except for data on physical inactivity, which are from the Behavioral Risk Factor Surveillance System. §The change in the mortality rate per unit of measurement for the risk factor is shown. Source: Ford et al. (140).

BMI = body mass index.

| | Framingham[6] | SCORE[7] | ASSIGN–SCORE[8] |
|---|---|---|---|
| Data | Prospective studies: Framingham Heart Study and Framingham offspring study. Latest version includes both | Pooled prospective studies | SHHEC Prospective study |
| Population | General population in Framingham, Mass. Baselines: 1968–1971, 1971–1975, 1984–1987 | 12 Prospective studies from 11 European countries. Baselines: 1972–1991 | Random sample from general population in Scotland. Baseline 1984–1987 |
| Sample type | Volunteer | Mostly random samples from general population, some occupational cohorts | Random |
| Sample size | 3969 Men and 4522 women | 117 098 Men and 88 080 women | 6540 Men and 6757 women |
| Statistical methods | Cox (Weibull: earlier versions[14]) | Cox and Weibull | Cox |
| Calculates | 10-Year risk of CHD events originally. Latest version: 10-year risk of CVD events. NCEP ATP III version: 10-year risk of hard coronary events | 10-Year risk of CVD mortality | 10-Year risk of CVD events |
| Age range, y | 30–75 | 40–65 | 30–74 |
| Variables | Gender, age, total cholesterol, HDL cholesterol, SBP, smoking status, diabetes, hypertensive treatment | Gender, age, total cholesterol or total cholesterol/HDL cholesterol ratio, SBP, smoking status. Versions for use in high- and low-risk countries | Gender, age, total cholesterol, HDL cholesterol, SBP, smoking (no. of cigarettes), diabetes, area-based index of deprivation, family history |
| Formats | Simplified scoring sheets. Color charts have been generated for some guidelines, eg, JBS and New Zealand guidelines. Online calculators. Portable calculators | Color-coded charts, HeartScore: online and CD-based stand-alone electronic versions | Online calculator |
| Developments | Latest version includes version based on nonlaboratory values only, substituting BMI for lipid measurements | National, updated recalibrations | |
| Recommended by guidelines | NCEP guidelines,[20] CCS guidelines.[5] Other national guidelines recommend adapted versions, including New Zealand[17] | European guidelines on CVD prevention[2] | Recommended by SIGN[21] |
| Web site | Online and downloadable risk calculator available at: www.nhlbi.nih.gov/guidelines/cholesterol/index/htm and www.framinghamheartstudy.com | Online and downloadable risk calculators available at: www.HeartScore.org | Online risk calculator available at: www.assign-score.com |
| Internal validation: discrimination | AUROC: Men 0.76 (0.75–0.78), women 0.79 (0.77–0.81) | AUROC high risk 0.80 (0.80–0.82), AUROC low risk 0.75 (0.73–0.77) | AUROC: Men 0.73, women 0.77 |
| Internal validation: calibration | HL: Men 13.48, women 7.79 | Not specified | Observed 10-year CVD incidence rates: Men 11.7%, women 6.4%. Median ASSIGN score: Men 11.7%, women 6.2% |
| External validation: discrimination | PRIME Study[23]: Belfast 0.68, France 0.66. Dutch study[24]: 0.86 (0.84–0.88). Cleveland Study[25]: 0.57. China[26]: Men 0.75 (0.72–0.78), women 0.79 (0.74–0.85). THIN (UK)[27]: Men 0.74 (0.73–0.74), women 0.76 (0.76–0.76). EPIC Norfolk[28]: 0.71. UK Women (BHHS)[29]: 0.66 (0.62–0.69) | Dutch study[24]: 0.85 (0.83–0.87). Cleveland Study[25]: 0.73. Norwegian Study[30]: Range for different age groups, men 0.65–0.68, women 0.66–0.72. Austrian Study[31]: Men 0.76 (0.74–0.79), women 0.78 (0.74–0.82). Icelandic Study[32]: 0.80 (0.78–0.82). SCORE high 0.80 (0.77–0.82), SCORE low | Not assessed |

**Figure 47** **Characteristics of Current Risk Estimation Systems**

ATP = Adult Treatment Panel; AUROC = area under receiver-operating characteristic curve; BMI = body mass index; CCS = Canadian Cardiovascular Society; CVD = cardiovascular disease; Hb = hemoglobin; HDL = high-density lipoprotein; hs-CRP = high-sensitivity C-reactive protein; JBS = Joint British Societies; LDL = low-density lipoprotein; MI = myocardial infarction; NCEP = National Cholesterol Education Program; SBP = systolic blood pressure; WHO = World Health Organization. The reference citations throughout this figure related to the original source. Source: Cooney et al. (152).

The NIH, National Heart, Lung and Blood Institute reports that the CVD age-adjusted mortality rate dropped from 543.7 per 100,000 in 1980 to 244.8 per 100,000 in 2008. Figure 46 displays the decline of age-adjusted mortality rates from 1980 to 2008 for CVD, coronary heart disease, and stroke with a designation of the transition from International Classification of Disease-Ninth Edition (in italics) (ICD-9) to ICD-10 mortality coding in 1999 (139). Previous studies found that the decline for coronary heart disease from 1980 to 2000 was attributed fairly equally to improvements in treatment (47%) and risk factor control (44%) (140).

Ford et al. (140) modeled the effects of risk factor control, finding that reductions in major risk factors may have accounted for approximately 44% of the decrease in deaths from coronary heart disease from 1980 to 2000 (Table 17). Earlier U.S. studies suggested a similar contribution of approximately 54% of the reduction in deaths between 1968

| QRISK[18] and QRISK2[9] | PROCAM[10] | WHO/ISH[11] | Reynolds Risk Score[12,13] |
|---|---|---|---|
| QRESEARCH database | Prospective study | Methods differ vs other risk estimation functions; not based on prospective data | Randomized controlled trials. Women: Women's Health Study; men: Physician's Health Study II |
| Data collected from 1993 to 2008 | Healthy employees. Baseline: 1978–1995 | Not applicable | Women: Health service employees, baseline 1993–1996. Men: Physicians, baseline 1997 |
| Health records of GP attendees; not random | Industrial employee volunteers; not random | Not applicable | Health service employees; volunteer, not random |
| 1.28 Million (QRISK1) and 2.29 million (QRISK2) | 18 460 Men and 8515 women | Not applicable | 24 558 Women, 10 724 men |
| Imputation of substantial missing data Cox | Cox and Weibull; exploratory analyses with neural networks also[19] | Relative risks associated with risk factors were taken from the Comparative Risk Assessment Project. These were combined with estimated absolute risks for each WHO subregion based on the Global Burden of Disease Study | Cox |
| 10-Year risk of CVD events | Two separate scores calculate 10-year risks of major coronary events and cerebral ischemic events | 10-Year risk of CVD events | 10-Year risk of incident MI, stroke, coronary revascularization, or cardiovascular death |
| 35–74 | 20–75 | 40–79 | 45–80 |
| QRISK1: Gender, age, total cholesterol to HDL cholesterol ratio, SBP, smoking status, diabetes, area-based index of deprivation, family history, BMI, antihypertensive treatment. QRISK2 also includes ethnicity and chronic diseases | Age, gender, LDL cholesterol, HDL cholesterol, diabetes, smoking, SBP | Gender, age, SBP, smoking status, diabetes, with or without total cholesterol. Different charts available for worldwide regions | Gender, age, SBP, smoking, hs-CRP, total cholesterol, HDL cholesterol, family history of premature MI (parent <age 60 y), HbA1C if diabetic |
| Online calculator | Simple scoring sheet and online calculators | Color-coded charts | Online calculator |
| QRISK2 includes interaction terms to adjust for interactions between age and some variables | Recent change in methods (Weibull) allows extension of risk estimation to women and a broader age range | | - |
| NICE guidelines on lipid modification[22] | International Task Force for Prevention of Coronary Disease guidelines | WHO guidelines on CVD prevention[11] | CCS guidelines recommend a choice of either Reynolds or Framingham risk score[5] |
| Online risk calculator available at: www.qrisk.co.uk | Online calculator available at: www.chd-taskforce.com/calculator | Charts downloadable at: www.who.int/cardiovascular_diseases/guidelines/Pocket_GL_information/en/index.html | Online calculator available at: www.reynoldsriskscore.com |
| QRISK2: AUROC Men 0.79 (0.79–0.79), women 0.82 (0.81–0.82) | AUROC 0.82 for coronary events, 0.78 for cerebral ischemic events | Not specified | Women: AUROC 0.808, men: AUROC 0.708 |
| Good correlation between observed and predicted risks in both men and women, presented graphically only, in each decile of risk | Not specified | Not specified | Women 0.62, men 12.9 |
| THIN database (UK)[27]: QRISK1 AUROC, men 0.76 (0.76–0.77), women 0.79 (0.79–0.79) | PRIME Study[23]: Belfast 0.61, France 0.64 | Not assessed | Not assessed |

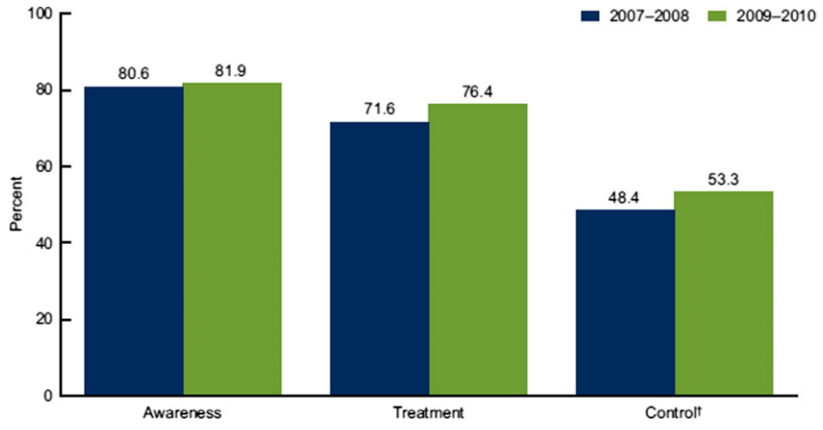
**Figure 47** **Continued**

and 1976 (141), and approximately 50% between 1980 and 1990 (142). The investigators note that "most of the changes in treatments and risk factors between 1980 and 2000 led to reductions in deaths from coronary heart disease with 2 major exceptions: increases in BMI accounted overall for about 26,000 additional deaths from coronary heart disease in 2000 and increases in the prevalence of diabetes for about 33,500 additional deaths" (140).

Despite mixed evidence on the optimal mix of prevention approaches, it is clear that they each have positive effects on CVD. Thus, the ACA allocated $15 billion in federal funding to prevention efforts related to CVD (143). Under these provisions, an estimated 54 million Americans will receive preventive services. Reimbursement rates will also be increased for preventive services for Medicare and Medicaid beneficiaries (144).

The U.S. Preventive Services Task Force developed the following CVD-specific recommendations that will be covered under Medicare, Medicaid, and non-grandfathered insurance plans (plans established after March 23, 2010):

- Aspirin to prevent CVD in men (ages 45 to 79 years) and women (ages 55 to 79 years)
- High blood pressure screening for all adults
- Cholesterol screening for men (over age 35 years) and women (over age 45 years)
- Type 2 diabetes screening for adults with sustained high blood pressure (135/80 mm Hg)
- Healthy diet counseling (intensive behavioral dietary counseling) for adults with risk factors for CVD
- Obesity screening and counseling for adults and children (behavioral interventions to promote weight loss)




†Significant difference between the two time periods.
NOTE: Access data table for Figure 2 at http://www.cdc.gov/nchs/data/databriefs/db107_tables.pdf#2.
SOURCE: CDC/NCHS, National Health and Nutrition Examination Survey.

**Figure 48** **Age-Adjusted Awareness, Treatment, and Control of Hypertension Among Adults With Hypertension: United States, 2007 to 2010**

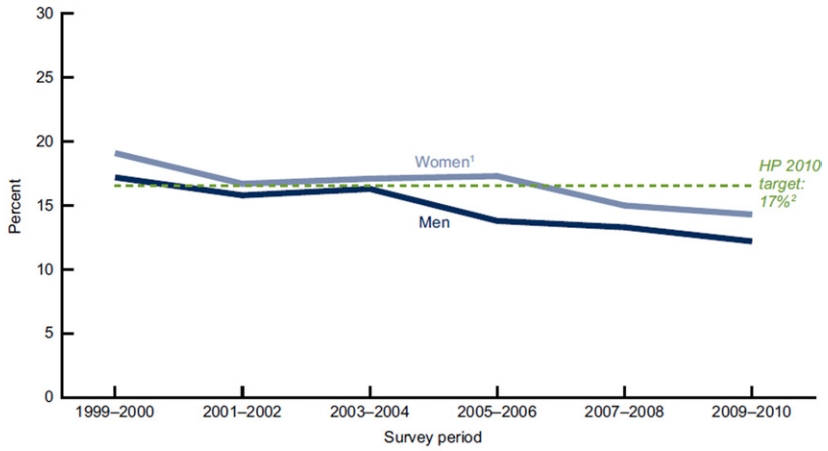
**Blue bars** = 2007 to 2008; **green bars** = 2009 to 2010. Source: Yoon et al. (156).

- Tobacco use counseling for pregnant and nonpregnant adults (counseling varies by status) (145).

Non-grandfathered insurance plans are required to fully cover specified preventive health services on the premise that people are more likely to take advantage of preventive care practices if they are not responsible for copays or other deductibles (146,145).

Employers have shown interest in addressing risk factors at the workplace. Studies of workplace wellness programs suggest that healthcare costs are reduced and health outcomes improve when risk factors are reduced (147).

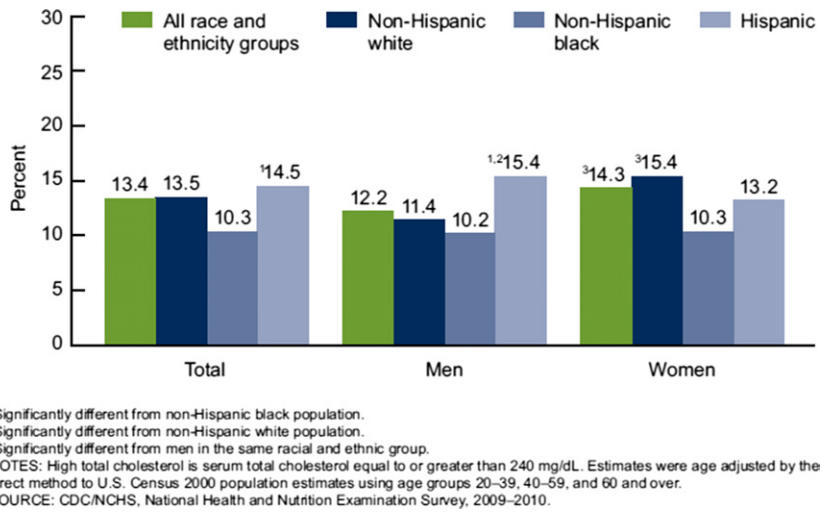
**Risk estimation frameworks.** Cooney et al. (148–151) report that all current CVD prevention guidelines stress the need to consider the likely impact of all risk factors before making clinical management decisions and, in most cases, to recommend a system of evaluating combined risk factor effects. They go on to provide a comparison of the Framingham system, the best known both nationally and interna-




¹Significant decreasing trend ($p < 0.005$).
²Healthy People 2010 Objective (12-14).
NOTE: High total cholesterol is serum total cholesterol level equal to or greater than 240 mg/dL. Estimates were age adjusted by the direct method to U.S. Census 2000 population estimates using age groups 20–39, 40–59, and 60 and over. Access data table for Figure 2 at:
http://www.cdc.gov/nchs/data/databriefs/db92_tables.pdf#2.
SOURCE: CDC/NCHS, National Health and Nutrition Examination Surveys, 1999–2010.

**Figure 49** **Trends in Percentage of Adults Age 20 Years and Older With High Total Cholesterol: United States, 1999 to 2010**

HP = Healthy People. Source: Carroll et al. (160).




[1]Significantly different from non-Hispanic black population.
[2]Significantly different from non-Hispanic white population.
[3]Significantly different from men in the same racial and ethnic group.
NOTES: High total cholesterol is serum total cholesterol equal to or greater than 240 mg/dL. Estimates were age adjusted by the direct method to U.S. Census 2000 population estimates using age groups 20–39, 40–59, and 60 and over.
SOURCE: CDC/NCHS, National Health and Nutrition Examination Survey, 2009–2010.

**Figure 50** **Percentage of Adults Age 20 Years and Older With High Total Cholesterol, by Sex, Race, and Ethnicity: United States, 2009 to 2010**

**Green bars** = all race and ethnicity groups; **dark blue bars** = non-Hispanic white; **dark gray bars** = non-Hispanic black; and **medium gray bars** = Hispanic. Source: Carroll et al. (160).

tionally and the most commonly used framework, to other commonly used systems recommended by guidelines on CVD prevention (Fig. 47) (152).

**Risk factor control.** HYPERTENSION. Uncontrolled hypertension is the leading attributable risk factor for CVD (i.e., stroke, myocardial infarction, heart failure, renal failure) and mortality worldwide (153–155). Hypertension is a prevalent condition affecting approximately 1 in 3 adults in the United States (28.6%) (Fig. 48) (156). Among adults with hypertension in 2009 to 2010, 81.9% were aware of their hypertension, and 76.4% reported currently taking prescribed medication to lower their blood pressure (Fig. 48). There was no change from 2007 to 2008 in the awareness and treatment of hypertension (Fig. 48) (156).

Resistant hypertension, defined as blood pressure that remains above goal (>140/90 mm Hg) despite the concurrent use of 3 different classes of antihypertensive agents at optimal doses, including a diuretic) (155), is estimated to affect approximately 12% of the population according to analysis of National Health and Nutrition Examination Survey data between 2003 and 2006 (157). As the U.S. population ages and the incidence and prevalence of obesity rises, the prevalence of resistant hypertension is projected to increase to 15% to 30% (154,158).

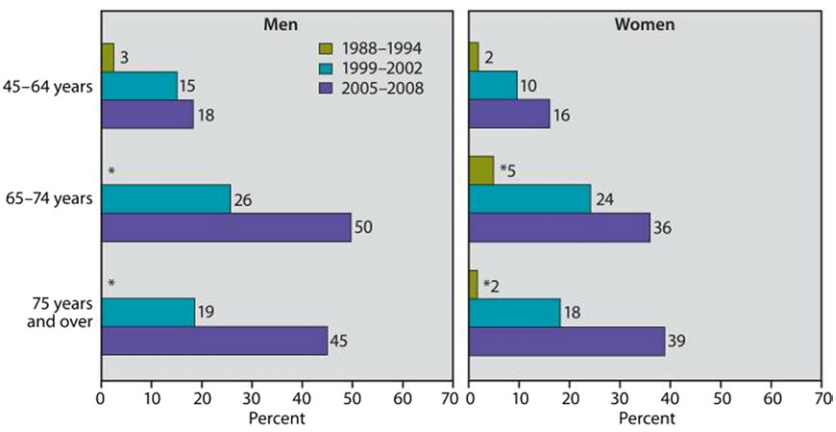



**Figure 51** **Statin Drug Use in Past 30 Days Among Adults ≥45 Years of Age, by Sex and Age**

Statin drug use in the past 30 days among adults ≥45 years of age, by sex (men **[left panel]**; women **[right panel]**) and age, in United States, 1988 to 1994 **(gold bars)**, 1999 to 2002 **(teal bars)**, and 2005 to 2008 **(purple bars)**. *Estimates are considered unreliable. Source: National Center for Health Statistics (161).

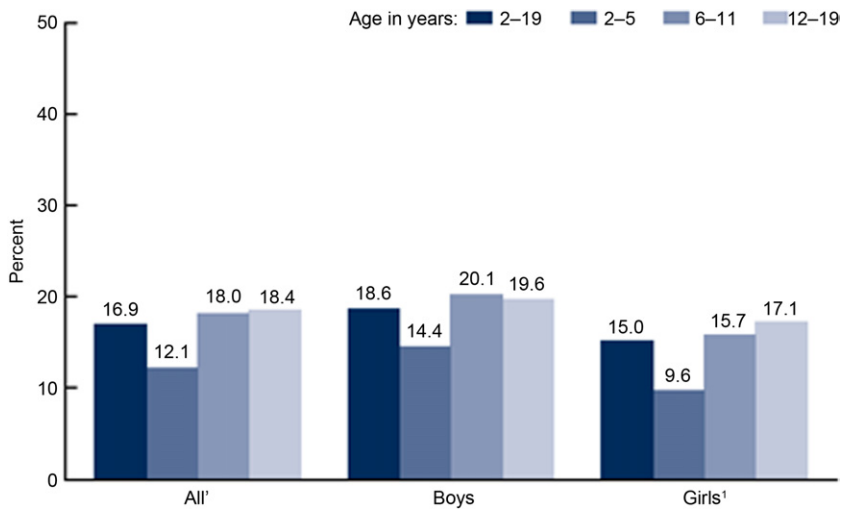



**Figure 52** **Prevalence of Obesity Among Children and Adolescents Ages 2 to 19 Years, by Sex and Age: United States 2009 to 2010**

**Dark blue bars** = 2 to 19 years; **dark-medium blue bars** = 2 to 5; **medium-light blue bars** = 6 to 11; **light blue bars** = 12 to 19. Source: National Center for Health Statistics (161).

Renal denervation is a potentially important emerging option for managing resistant hypertension and is currently available in the European Union and Australia. The procedure utilizes a radiofrequency catheter that is inserted into the renal artery to disrupt the renal sympathetic nervous system. Medtronic has developed a Symplicity catheter system for this procedure and is the first company to receive FDA approval to study the technique in the United States. Catheter systems are also being developed by several other device companies and numerous studies of this therapy are in progress. As of August 2012, clinicaltrials.gov lists 45 studies on renal denervation: completed, 1; active, not recruiting, 9; recruiting, 31; and not yet recruiting, 4.

**DYSLIPIDEMIA.** There is a growing recognition that a target-based approach to lipids may not be the best strategy and is not strongly based on trial evidence. Not all drugs that reduce low-density lipoprotein (LDL) have been shown to reduce patient risk—and some have paradoxically increased risk. Moreover, no large trial tested a target strategy—they were trials of fixed doses of specific drugs. Also, the benefit of statins has generally been shown to be consistent across initial levels of LDL. As a result, some experts are advocating statins over a target that may be reached with a variety of drugs, including those that have not been shown to improve outcomes. Also, some experts are advocating a strategy to treat based on patient risk rather

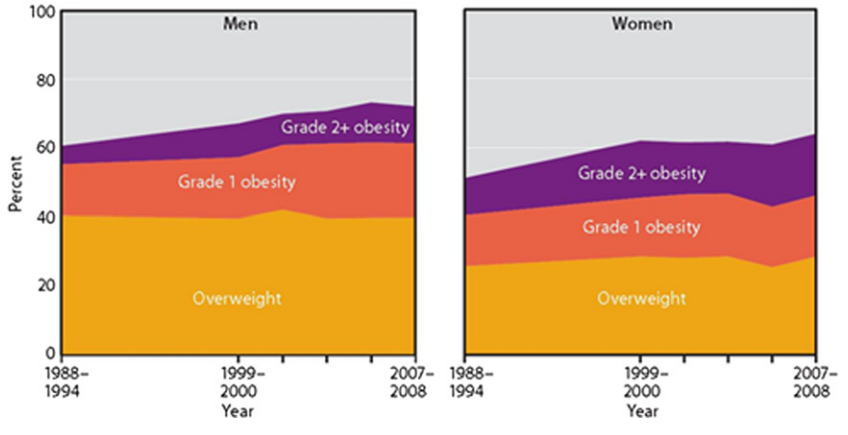



**Figure 53** **Overweight and Obesity Among Adults ≥20 Years of Age, by Sex: United States, 1988 to 1994 Through 2007 to 2008**

**(Left panel)** Men. **(Right panel)** Women. Source: National Center for Health Statistics (161).

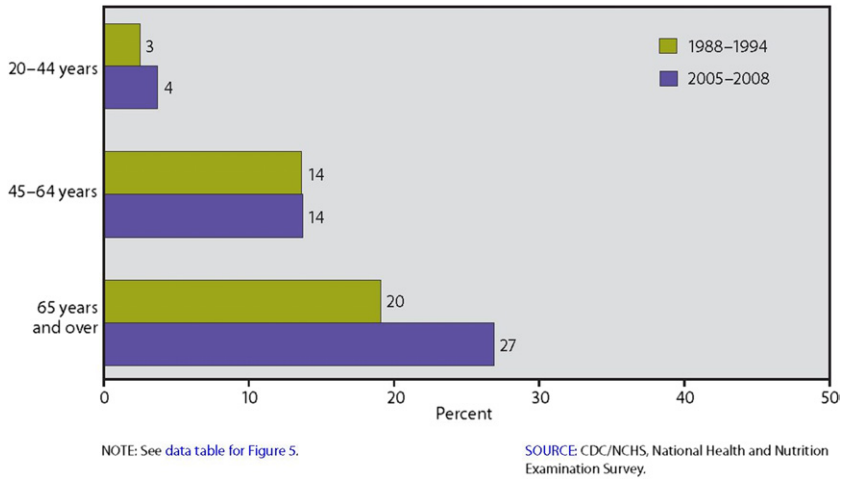



**Figure 54** **Diabetes Prevalence Among Adults ≥20 Years of Age, by Age: United States, 1988 to 1994 and 2005 to 2008**

**Gold bars** = 1988 to 1994; **blue bars** = 2005 to 2008. Source: National Center for Health Statistics (161).

than lipid levels because the absolute benefit is predicated on the risk not the lipid level (159).

Lipid levels among U.S. adults are declining. Between 1999 and 2000, 18.3% of men and women had high total cholesterol count—defined as 240 mg/dl or higher. This dropped to 13.4% in 2009 to 2010 (displayed in Fig. 49). The U.S. Hispanic population is reported to have the highest percentage of adults (over 20 years of age) with high total cholesterol levels (Fig. 50) (160).

**STATINS AND LDL CHOLESTEROL REDUCTION.** There is substantial evidence supporting the use of statin therapy to reduce LDL cholesterol and subsequent risk of coronary heart disease. From 1988 to 1994 through to 2005 and 2008, the use of statin therapy in U.S. adults 45 years of age increased 12-fold, from 2% to 25% (Fig. 51). The documented decline in total cholesterol in the U.S. population is likely attributable to increased use of the statins at least in part (161). There is, however, disagreement on the use of statins for primary prevention of coronary heart disease for persons at high-risk but who show no symptoms (162,163).

The ACCORD (Action to Control Cardiovascular Risk in Diabetes) trial and the Fenofibrate Intervention and Event Lowering in Diabetes trial found that that fenofibrate did not reduce cardiovascular morbidity or mortality over that produced by a statin alone (164). However, the ACCORD trial and other previous research indicated there is potential benefit to men to include fibrate treatment for those with elevated triglycerides and low high-density lipoprotein (HDL) cholesterol after using statin therapy to reduce LDL

| Cohort | 1997–1998 | 1999–2000 | 2001–2002 | 2003–2004 | Rate difference of cohort 2003–2004 vs. 1997–1998 | *P* for trend | Multivariate HRR for cohort 2003–2004 vs. 1997–1998 |
|---|---|---|---|---|---|---|---|
| CVD mortality | | | | | | | |
| DM (age-adjusted) | 9.5 (7.8–11.3) | 7.0 (5.7–8.3) | 8.3 (6.4–10.3) | 5.6 (4.5–6.7)† | −4.0 (−6.0 to −1.9) | 0.001 | 0.60 (0.46–0.77) |
| No DM (age-adjusted) | 3.7 (3.4–4.0) | 3.3 (3.0–3.6) | 3.2 (2.9–3.5) | 3.3 (2.9–3.6) | −0.4 (−0.9 to 0.1) | 0.07 | 0.89 (0.78–1.03) |
| Age-adjusted difference (DM vs. no DM) | 5.8 (4.1–7.6) | 3.7 (2.4–5.0) | 5.1 (3.1–7.1) | 2.3 (1.2–3.4) | | | |
| HRR (DM vs. no DM) | 2.38 (2.97–3.89) | 2.04 (1.68–2.47) | 2.35 (1.87–2.96) | 1.64 (1.32–2.06) | | | |
| All-cause mortality | | | | | | | |
| DM (age-adjusted) | 20.3 (17.6–22.9) | 17.9 (15.5–20.4) | 21.1 (18.5–23.7) | 15.1 (13.2–17.1)* | −5.2 (−8.5 to −1.8) | 0.02 | 0.77 (0.65–0.90) |
| No DM (age-adjusted) | 9.5 (9.0–10.0) | 8.7 (8.2–9.2) | 9.1 (8.5–9.6) | 9.0 (8.5–9.6) | −0.5 (−1.3 to 0.3) | 0.36 | 0.97 (0.89–1.05) |
| Age-adjusted difference (DM vs. no DM) | 10.8 (8.1–13.4) | 9.2 (6.8–11.7) | 12.0 (9.4–14.7) | 6.1 (4.0–8.2) | | | |
| HRR (DM vs. no DM) | 1.94 (1.70–2.20) | 1.86 (1.62–2.13) | 2.02 (1.79–2.28) | 1.54 (1.35–1.77) | | | |
| Cancer mortality | | | | | | | |
| DM (age-adjusted) | 3.3 (2.4–4.2) | 3.5 (2.6–4.4) | 4.5 (2.9–6.1) | 3.0 (2.2–3.8) | −0.3 (−1.5 to 0.9) | 0.93 | 0.95 (0.66–1.37) |
| No DM (age-adjusted) | 2.6 (2.4–2.9) | 2.4 (2.1–2.7) | 2.7 (2.3–3.0) | 2.6 (2.4–2.9) | 0.0 (−0.4 to 0.4) | 0.58 | 1.03 (0.89–1.20) |
| Age-adjusted difference (DM vs. no DM) | 0.7 (−0.3 to 1.6) | 1.1 (0.2–2.0) | 1.8 (0.2–3.4) | 0.4 (−0.5 to 1.2) | | | |
| HRR (DM vs. no DM)‡ | 1.24 (0.94–1.65) | 1.47 (1.11–2.96) | 1.36 (1.04–1.78) | 1.16 (0.86–1.57) | | | |

Data are deaths per 1,000 person-years except where indicated as HRR (95% CI). DM, diabetes. *P value for test of heterogeneity across years, by diabetes status: <0.05. †P value for test of heterogeneity across years, by diabetes status: <0.01. ‡Age, sex, race/ethnicity, education (analyses across years, within diabetes status also controlled for diabetes duration).

**Figure 55** **All-Cause and CVD-Related Mortality Rates (Deaths per 100,000 Person-Years), by Cohort and DM Status**

CVD = cardiovascular disease; CI = confidence interval; DM = diabetes mellitus; HRR = hazard rate ratio. Source: Gregg et al. (177).

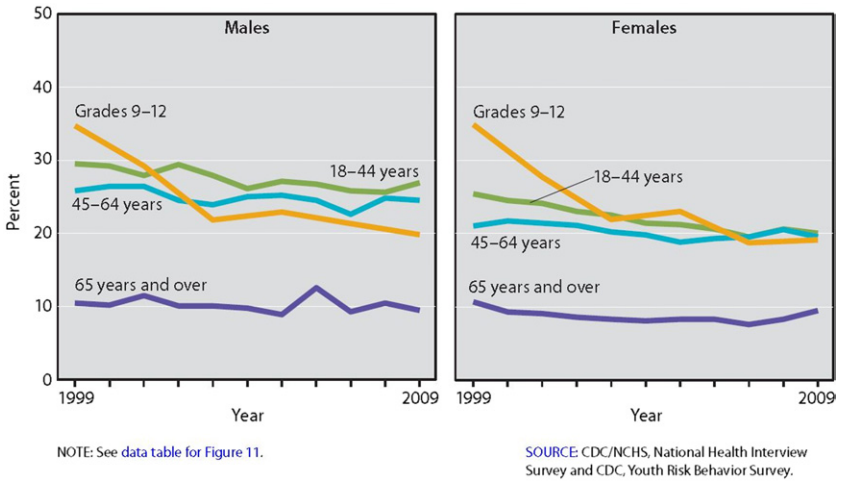



**Figure 56** **Cigarette Smoking Among Students in Grades 9 to 12 and Adults ≥18 Years of Age, by Sex, Grade, and Age: United States, 1999 to 2009**

**(Left panel)** Males. **(Right panel)** Females. Source: National Center for Health Statistics (161).

cholesterol (165). Further efforts have been directed toward the development of drugs that raise HDL cholesterol, reducing LDL cholesterol at the same time.

The first version of cholesteryl ester transfer protein inhibitors, torcetrapib, proved to cause excess deaths. A new version, anacetrapib, has not be shown to increase the risk of cardiovascular events, and the drug was associated with a 138% rise in HDL cholesterol and a 40% drop in LDL in 1 clinical trial (166). Based on early data, some 30,000 patients were to receive anacetrapib starting in 2011 to test whether adding the drug to a statin further reduces morbidity and mortality (167). Another version of transfer protein inhibitors, dalcetrapib, was tested but in mid 2012 phase III clinical trials ended because it was not found to significantly increase HDL cholesterol and lower LDL cholesterol (168).

**OBESITY.** Obesity is usually defined by BMI, where persons with a BMI of ≥30 kg/m$^2$ are considered to be obese and those with a BMI >35 kg/m$^2$ are grade 2 obese (161). Excess body weight is associated with excess morbidity and mortality from CVD (169), and grade 2+ obesity significantly increases mortality risk (170). From 1999 to 2000 through 2009 to 2010, the prevalence of obesity increased from 13.8% to 15.0% among girls and from 14% to 18.6% among boys in the United States. Figure 52 displays the current prevalence by age group among adolescents.

Among women in the same time period, there was an increase in the prevalence of obesity (33.4% to 35.8%). In 1999, the prevalence of obesity in men was approximately 27.5%; 10 years later, that number had risen to 35.5%. In terms of numbers, this means 12.5 million children, 40.6 million women, and 37.5 million men were obese in 2009 to 2010 (171,172). Figure 53 displays obesity rates among men and women.

**DIABETES MELLITUS.** Approximately 8% of the population or 18.8 million people in the United States have been diagnosed with diabetes, the great majority of them with type 2 diabetes (173). Another 7 million people have undiagnosed diabetes, and some 79 million have pre-diabetes (174).

Type 2 diabetes is also affecting younger and younger people. It is now estimated that 215,000 children and adolescents under the age of 20 years have diabetes (174). The incidence of diabetes is also increasing in the United States, in parallel with increasing obesity rates (173). By 2050, the Centers for Disease Control and Prevention predict as many as 1 in 3 adults in the United States could have diabetes if current trends continue (175). Figure 54 depicts the increasing prevalence of type 2 diabetes among U.S. adults.

Approximately two-thirds of persons with diabetes die from heart disease or stroke (173). Those with diabetes also have triple the risk of stroke compared with persons who have normal blood sugar levels (176). However, as the death rates of CVD decreases for the general population, the proportion of CVD-related deaths among diabetic patients has decreased, as shown in Figure 55. According to Gregg et al. (177), among diabetic adults, the CVD death rate declined by 40%, and all-cause mortality declined by 23% between 1997 and 2006. There was no difference in the rates of decline in mortality between diabetic men and women. The excess CVD mortality rate associated with diabetes (i.e., compared with nondiabetic adults) decreased by 60% (from 5.8 to 2.3 CVD deaths per 1,000), whereas the excess all-cause mortality rate declined by 44% (from 10.8 to 6.1 deaths per 1,000) (177).

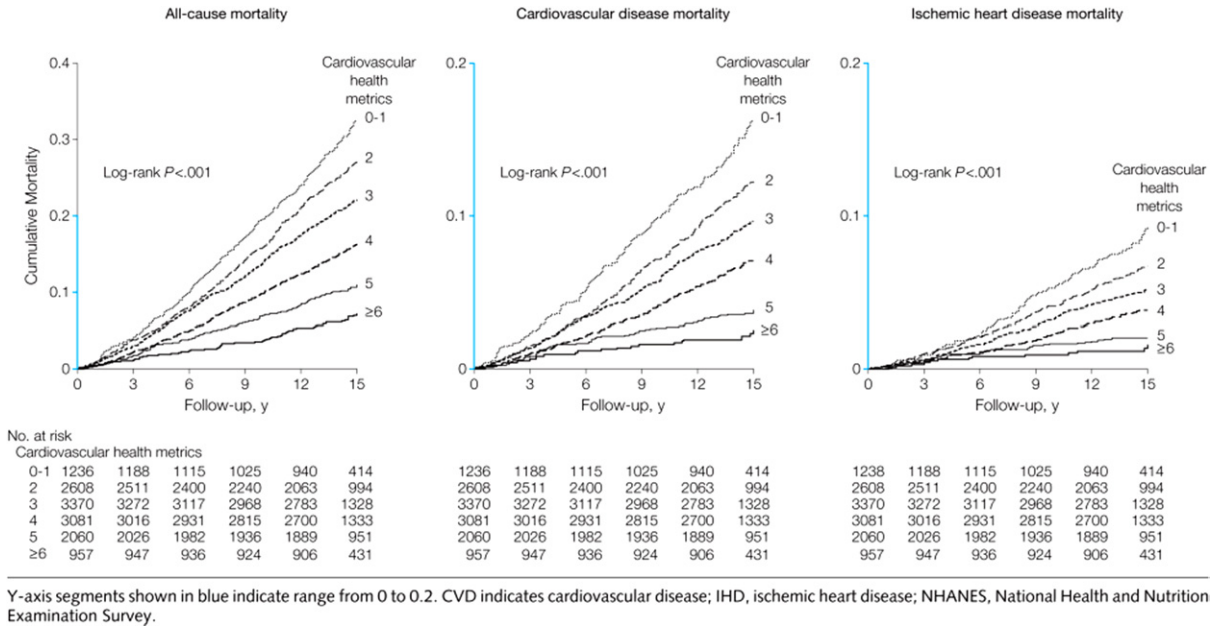



**Figure 57** **Trends in CV Health Metrics and Associations With All-Cause and CVD Mortality Among U.S. Adults**

The Y-axis segments shown in **blue** indicate range from 0 to 0.2. Source: Yang Q et al. (187).

Careful glycemic control is currently considered the cornerstone of diabetes management, and research has shown that reaching and maintaining treatment goals can result in a decreased risk of diabetes-related complications, lower costs, and less healthcare utilization (174,178). The ADA and the Academy of Clinical Endocrinology/American Association of Clinical Endocrinologists have published specific glycemic goals for managing adult, nonpregnant patients with diabetes (174,179), which emphasize the importance of an individualized approach to the management of type 2 diabetes by selecting agents and regimens tailored to the unique needs of patients (178).

However, although there has been some recent improvement in the percentage of people with diabetes who have achieved treatment goals over the last few years (180), <50% of people with diabetes achieve the ADA's recommended hemoglobin A1c goal of <7.0% (176), and 67% do not achieve the American Association of Clinical Endocrinologists' A1c goal of ≤6.5% (181).

**SMOKING.** It is estimated that 40% of all heart disease is related to smoking (46). Smoking is also a major risk factor for stroke, approximately doubling the risk for ischemic stroke and increasing the risk of subarachnoid hemorrhage by twofold to fourfold (182). Smoking rates have been declining since the 1960s when the Surgeon General first warned of the health effects of cigarettes. In 1965, 41.7% of adults smoked; in 2010, that number had dropped to 19.3%. Figure 56 shows declining smoking rates across different age groups.

**Table 18** **"ABCS" Indicators—Comparison of 2017 Million Hearts' Goals With 2011 PINNACLE Registry Data Submitting Practices**

| Indicator | Definition | Baseline | 2017 Goal | Comparable PINNACLE Measure* | SD |
|---|---|---|---|---|---|
| Aspirin | People with increased risk of CVD who take aspirin | 47% | 65% | 83% | ±15.3 |
| Blood pressure | People with HTN who have controlled BP | 46% | 65% | 69% | NA |
| Cholesterol | People diagnosed with high cholesterol who have it properly controlled | 33% | 65% | 98% | ±2.5 |
| Smoking | Decrease population of smokers | 19% | 17% | 41% | ±34.9 |
| Sodium intake | Decrease average sodium intake | 3.5 g/day | 20% reduction | NA | NA |
| Artificial transfat consumption | Decrease amount of artificial transfat consumption | 1% of calories/day | 50% reduction | NA | NA |

*Total across all practices, year ending second quarter 2011. Source: American Heart Association. Million Hearts Campaign and the Role of the American Heart Association. Available at: http://www.telligenhitrec.org/c/document_library/get_file?uuid=d1ff5a8f-d86c-45e1-8cac-3616dcb39496&groupId=10309. Accessed June 2012.

ABCS = aspirin for people at risk, blood pressure control, cholesterol management, and smoking cessation; BP = blood pressure; CVD = cardiovascular disease; HTN = hypertension; NA = not available; PINNACLE = Practice Innovation And Clinical Excellence.

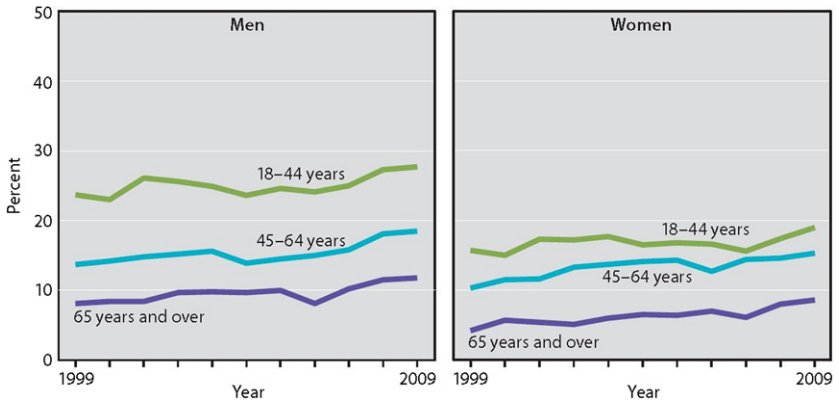
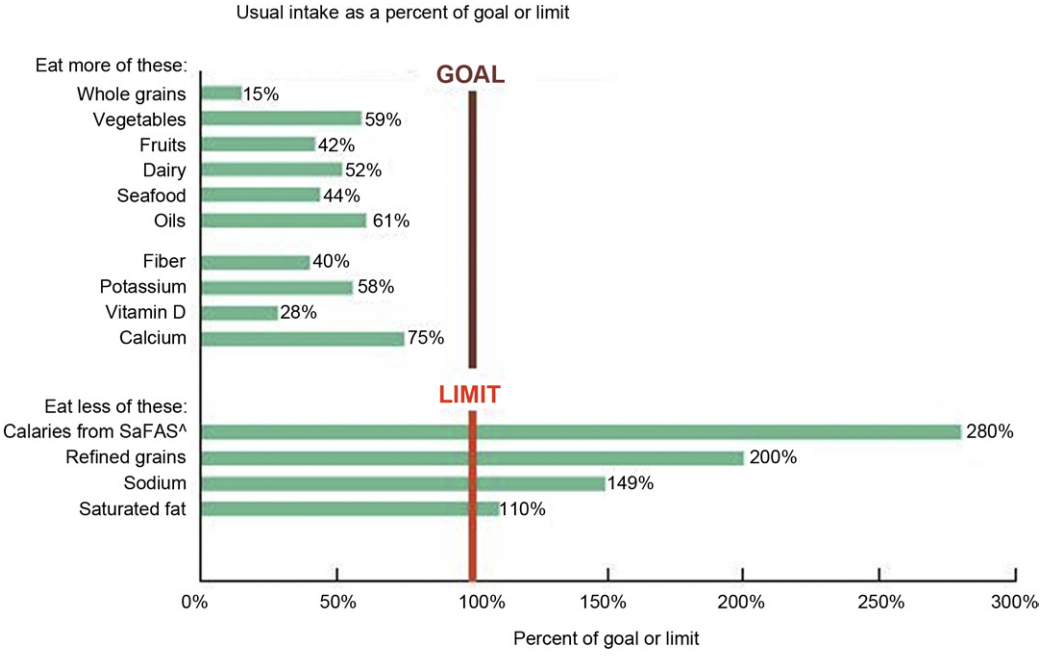



**Figure 58** **Participation in Leisure-Time Aerobic and Muscle-Strengthening Activities Meeting 2008 Federal Physical Activity Guidelines for Adults ≥18 Years of Age, by Sex and Age: United States, 1999 to 2009**

(**Left panel**) Men. **(Right panel)** Women. Source: National Center for Health Statistics (161).

A 2008 study of patients hospitalized for coronary artery disease, heart failure, and nonvalvular atrial fibrillation (or any combination of the 3), reported that 10.6% were current smokers and 36.5% of them were former smokers (183). Another study found that approximately 13% of patients with coronary artery disease were current smokers (184). Smoking has also been shown to diminish the benefits of statins, worsen hypertension, and contribute to CVD morbidity and mortality (185).




^SoFAS-solid fats and added sugars.
Note Bars show average intakes for all individuals (ages 1 or 2 years or older, depending on the data source) as a percent of the recommended intake level or limit. Recommended intakes for food groups and limits for refined grains and solid fats and added sugars are based on amounts in the USDA 2000 calorie food pattern. Recommended intakes for fibre, potassium, vitamin D, and calcium are based on the highest AI or RDA for ages 14 to 70 years. Limits for sodium are based on the UL and for saturated fat on 10% of calories. The protein foods group is not shown here because, on average, intake is dose to recommended levels.

Based on data from: U.S. Department of Agriculture, Agricultural Research Service and U.S. Department of Health and Human services, Centers for Disease Control and Prevention. What we eat in America, NHANES 2001-2004 or 2005-2006.

**Figure 59** **How Do Typical American Diets Compare to Recommended Intake Levels or Limits?**

AI = adequate intake level; RDA = recommended daily allowance; SoFAS = solid fats and added sugars; UL = upper limit; USDA = U.S. Department of Agriculture. Source: USDA. Choose My Plate: Guidelines. Available at: www.mypyramid.gov/guidelines/policydoc.pdf. Accessed June 2012.

**Million Hearts Initiative.** A significant public private campaign launched in 2011 targeting cardiovascular prevention is the Million Hearts Initiative, the goal of which is to prevent 1 million cardiovascular events over the next 5 years. Through improved management of the 4 "ABCS" indicators—aspirin for people at risk, blood pressure control, cholesterol management, and smoking cessation—the Million Hearts Initiative hopes to reduce the current annual heart attack and stroke rate by 10% (Table 18) (173).

The ACC is moving forward with its participation in the Million Hearts Initiative. The College has offered comments on the blood pressure control and lipid management measures. Concerns were raised that pushing all patients to the 140/90 mm Hg blood pressure target may put some at risk due to the potential for unintended consequences, and that the lipid management measure should not be based solely on a target LDL (<100 mg/dl) and may be too simplistic based on recent evidence.

To improve the measures, the ACC/AHA Task Force on Performance Measures has offered to commission 1 or more studies to compare the effectiveness of these different measures. If the ACC/AHA/Physician Consortium for Performance Improvement blood pressure and lipid measures are superior to the Healthcare Effectiveness Data and Information Set measures when used at the physician and practice levels, then it would be demonstrated with actual evidence of impact on clinical outcomes of interest at the population level (186).

**IDEAL CVD HEALTH BEHAVIORS.** The great majority of the population does not meet ideal cardiovascular health metrics, as defined by the AHA. These 7 behaviors or health metrics include not smoking; being physically active; having normal blood pressure, blood glucose levels, total cholesterol, and weight; and eating a healthy diet. According to the latest National Health and Nutrition Examination Survey, only 1.2% of a representative sample of 44,959 U.S. adults achieved all 7 health metrics, whereas only 8.8% of the same cohort achieved 6 or more (187).

For the select proportion of persons who did meet 6 or more of the AHA's health metrics, all-cause mortality was 51% lower than for persons who achieved 1 or fewer cardiovascular health metrics; and CVD mortality was 76% lower for the highest achievers versus the lowest achievers. Mortality from ischemic heart disease was 70% lower, again in favor of the highest health metric achievers versus the lowest.

These findings support prevention strategies aimed at improving CVD risk factors as a highly significant way in which to reduce morbidity and mortality caused by CVD (173). Figure 57 depicts the differences in morbidity and mortality according to the health metrics achieved.

**INCREASE REGULAR PHYSICAL ACTIVITY.** The AHA also defines "ideal" levels of physical activity as either ≥150 min/week of moderate intensity activity or ≥75 min/week of vigorous intensity activity or ≥150 min/week of moderate and vigorous activity combined (173).

On the same survey, 45.2% of the population achieved ideal levels of physical activity, whereas another 22.9% achieved AHA-defined levels of intermediate activity, namely, 1 to 149 min/week of moderately intense activity or the same amount of moderate and vigorous activity combined, or 1 to 74 min/week of vigorous activity. Some 31.9% of the population reported no levels of physical activity in 2010 (173). Figure 58 shows trends in physical activity across different age groups out to 2009.

The prevalence of physical activity has marginally increased among U.S. adults since the late 1980s (188), but the majority of adults are still not physically active enough to meet the guidelines for optimal health (187). Inadequate amounts of physical activity are widely acknowledged to be a major contributor to the rising rates of obesity in the United States (189).

**HEALTHY DIETARY CHANGES CRITICAL.** The AHA measures how healthy a person's diet is by assigning 1 point to each specific dietary component for a score of 0 to 5. Components include consumption of fruits and vegetables ≥4 cups a day; fish, ≥2 3.5-oz servings/week; fiber-rich whole grains ≥3 1-oz equivalent servings per day; sodium ≤1,500 mg/day, and sugar-sweetened beverages ≤36 oz/week. According to National Health and Nutrition Examination Survey data, 22.3% of the population had a healthy diet score of ≥2 components from 2005 to 2010, a 3.1% increase from 1999 to 2004 (187). Figure 59 shows how a typical American diet compared with recommended intake levels of various food components.

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**Key Words:** cardiology economic environment ■ cardiology political environment ■ cardiology practice trends ■ cardiology social environment ■ cardiology statistics.

**APPENDIX**

**For a table on chronic cardiovascular conditions family of measures, please see the online version of this article.**