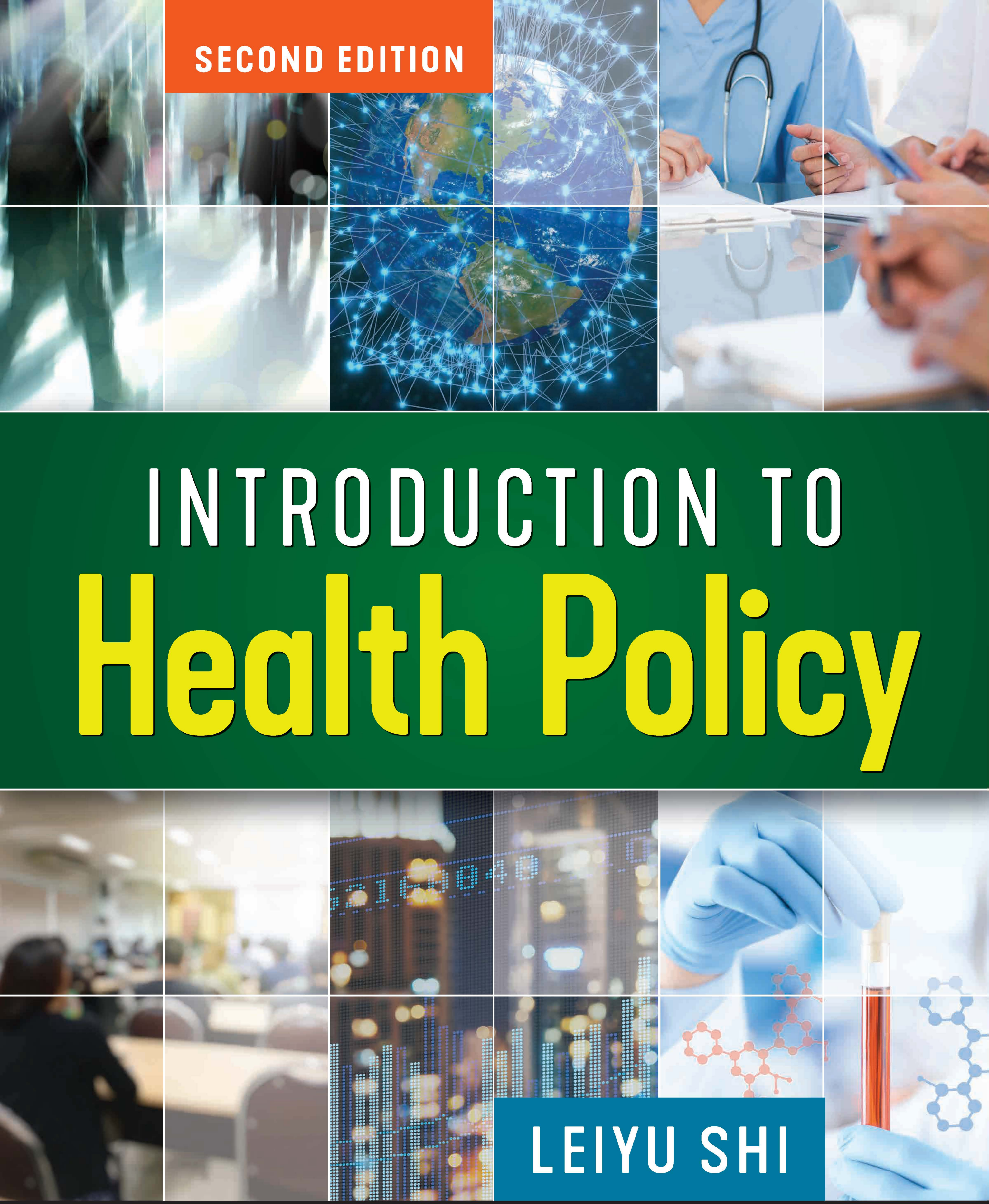

SECOND EDITION

INTRODUCTION TO Health Policy

LEIYU SHI

INTRODUCTION TO
Health Policy

HAP/AUPHA Editorial Board for Undergraduate Studies

SECOND EDITION

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Health Policy

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GATEWAY
TO HEALTHCARE MANAGEMENT

HAP

AUPHA

Health Administration Press, Chicago, Illinois
Association of University Programs in Health Administration, Washington, DC

23 22 21 20 19 5 4 3 2 1

Library of Congress Cataloging-in-Publication Data

Names: Shi, Leiyu, author.
Title: Introduction to health policy / Leiyu Shi, Gateway to Healthcare Management.
Description: Second edition. | Chicago, Illinois : Health Administration Press, HAP ; Washington, D.C. : Association of University Programs in Health Administration, AUPHA, [2019] | Includes bibliographical references and index.
Identifiers: LCCN 2018040567 (print) | LCCN 2018041419 (ebook) | ISBN 9781640550261 (ebook) | ISBN 9781640550278 (xml) | ISBN 9781640550285 (epub) | ISBN 9781640550292 (mobi) | ISBN 9781640550254 (print : alk. paper)
Subjects: LCSH: Medical policy—History. | Health care reform. | Public health—International cooperation.
Classification: LCC RA393 (ebook) | LCC RA393 .S473 2019 (print) | DDC 362.1—dc23
LC record available at https://lccn.loc.gov/2018040567

The paper used in this publication meets the minimum requirements of American National Standard for Information Sciences—Permanence of Paper for Printed Library Materials, ANSI Z39.48-1984. ♾™

Acquisitions editor: Jennette McClain; Manuscript editor: Lori Meek Schuldt; Project manager: Andrew Baumann; Cover designer: James Slate; Layout: Cepheus Edmondson

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I dedicate this book to my wife, Ruoxian,
and my children, Sylvia, Jennifer, and Victor Shi.

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PART II **Health Policymaking**

PART III **Health Policy Issues**

PART IV **Health Policy Research**

DETAILED CONTENTS

PART I Introduction

PART II Health Policymaking

PART III Health Policy Issues

PART IV Health Policy Research

PREFACE

US policymakers have been struggling for years to find solutions to our healthcare challenges. Thus, healthcare reform is among the top priorities of almost every administration. This introductory textbook on US health policy covers the related areas of health policymaking, critical health policy issues, health policy research, and an international perspective on health policy and policymaking. The book offers the following features:

- Real-world cases to exemplify the theories and concepts presented from a variety of perspectives, including the hospital setting, public health, managed care, ambulatory care, and extended care
- Exhibits and extra feature boxes (Learning Points, For Your Consideration, Key Legislation, Research from the Field, International Policymaking, Global Health Impact, and others) that present background information on concepts, examples, and up-to-date information
- Learning objectives and key points
- Discussion questions

ORGANIZATION OF THE BOOK

This book is organized in four parts: an introduction, an overview of health policymaking, a health policy issues section, and a discussion of health policy research and analysis. Chapter 1, the sole chapter in part I, introduces key terms related to, and the determinants of, health and health policy. It lists the key stakeholders in health policymaking and presents important reasons for studying health policy. The chapter lays the foundation for the rest of the book.

Part II—containing chapters 2, 3, and 4—examines the policymaking process at the federal, state, and local levels; in the private sector; and in international settings. Chapter 2 focuses on the policymaking process at the federal level of the US government. Important activities within the three policymaking stages—policy formulation, policy implementation, and policy modification—are described. The key characteristics of health policymaking in the United States are analyzed, and the role of interest groups in making policy is discussed.

Chapter 3 focuses on the US policymaking process at the state and local levels and in the private sector, which includes the research community, foundations, and private industry. Examples of policy-related research by private research institutes and foundations are described. The impact of the private sector's services and products on health and policy is illustrated using the fast-food industry as well as tobacco and pharmaceutical companies as examples.

Chapter 4 discusses international health policymaking. The World Health Organization (WHO) is presented as an example of an international agency involved in policymaking related to health and major health initiatives. Three countries—Canada, Sweden, and China—are highlighted to illustrate diverse policymaking processes in distinct geographic regions. The experiences of these countries show that different political systems and policymaking processes lead to diverse approaches to population health and healthcare delivery.

Part III—encompassing chapters 5, 6, and 7—examines the policy issues related to social, behavioral, and medical care health determinants; to people from diverse or medically or socially vulnerable populations; and to international health. Chapter 5 describes how US healthcare is financed and delivered. Private and public health insurance programs are summarized, and the subsystems of healthcare delivery—managed care plans, safety net providers, public health programs, long-term care services, and military-operated healthcare—are introduced. After summarizing the major characteristics of US healthcare delivery, the chapter provides examples of health policy issues related to financing (cost containment) and delivery (healthcare workforce, professional accreditation, antitrust regulations, patient access to care, and patient rights).

Chapter 6 defines medically and socially vulnerable populations and discusses the dominant healthcare policy issues related to those populations. People from diverse populations include members of racial or ethnic minorities, the uninsured, people with low socioeconomic status, the elderly, people with chronic illness, people with mental illness, women and children, people with disabilities, the homeless, and people with HIV/AIDS. In each segment, the magnitude of the problem is summarized and a detailed discussion of the policies and strategies meant to address the problem is presented.

In chapter 7, dominant health policy issues in the international community are discussed, with examples given for select countries, to help students understand not only international health policy applications but also the field of global health. The chapter begins by examining issues shared by developed countries, such as modifying health systems to better serve aging and diverse populations while maintaining high-quality care at a low cost. It then discusses challenges faced by developing nations, such as controlling the spread of disease, creating and maintaining high-functioning health systems with limited resources, and dealing with the burdens of morbidity and mortality associated with poverty. Several emerging issues are also illustrated that could affect global health in the future.

Part IV—comprising chapters 8, 9, and 10—presents an overview of policy analysis, focusing on examples of commonly used quantitative and qualitative methods. Chapter 8 introduces health policy research (HPR) and highlights the discipline's defining characteristics, including applied, policy-relevant, ethical, multidisciplinary, scientific, and population-based studies. The HPR process is summarized, and the chapter concludes with a discussion of ways to communicate findings and the challenges in implementing those findings in practice.

Chapter 9 illustrates commonly used methods in HPR. Quantitative methods include experimental research, survey research, evaluation research, cost–benefit analysis, and cost-effectiveness analysis. Because evaluation research is closely tied to policy research, the process involved in this type of research is described in greater detail. Qualitative methods include participant observations, in-depth interviews (including focus groups), and case studies. Examples of published studies using these methods are provided.

Chapter 10 provides an example that illustrates the key steps in health policy analysis: assessing the determinants of a health problem, identifying a policy intervention to address the problem, critically evaluating the policy intervention, and proposing next steps in addressing the problem.

New to This Edition

This second edition has retained most of the features of the first edition. In addition, significant updates have been made in the following key areas.

Case Studies

Each of the chapter-opening case studies from the first edition has been revised or replaced, and a new, second case study has been added to chapters 1–9.

Healthcare Reform

The latest developments in healthcare reform and legislation have been incorporated into the book, especially in chapters 2 and 3 and in the many additions to the chapters in part III.

INTERNATIONAL HEALTH POLICY

The international health policy chapters (chapters 4 and 7) have broadened in scope with more examples from the array of countries discussed in the book. New WHO initiatives have also been added.

UPDATED CONTENT THROUGHOUT

Content, references, and data (including in relevant exhibits) have been updated throughout. New and revised content includes coverage of the impact of the Affordable Care Act, new healthcare reform directions, the patient-centered medical home, accountable care organizations, precision medicine and big data, state and local healthcare reform activities, private-sector initiatives, and the pharmaceutical industry. More examples of applications in research have been added.

ACKNOWLEDGMENTS

My PhD advisee Sarika Rane Parasuraman contributed chapter 10 (an applied example) and is hereby acknowledged. The editorial staff of Health Administration Press have provided hands-on assistance in editing the manuscript. Of course, all errors and omissions remain my responsibility.

Leiyu Shi

INSTRUCTOR RESOURCES

This book's Instructor Resources include a test bank, PowerPoint slides for each chapter, and answer guides for the book's discussion questions.

For the most up-to-date information about this book and its Instructor Resources, go to ache.org/HAP and search for the book's order code (2374).

This book's Instructor Resources are available to instructors who adopt this book for use in their course. For access information, please e-mail hapbooks@ache.org.

PART I

INTRODUCTION

The introduction, which consists of chapter 1, provides an overview of health policy. It defines key terms related to health policy, reviews the framework of health determinants, and outlines the concept of health policy formulation. In addition, the chapter introduces topics related to health policy, including stakeholders, major types of health policies, and the importance of studying health policy. The introduction provides readers with a foundation for examining how health policy is established in the United States and elsewhere.

CHAPTER 1

OVERVIEW OF HEALTH POLICY

> *I have never had a policy. I have simply tried to do what seemed best each day, as each day came.*
>
> —Abraham Lincoln

> *The health and vitality of our people are at least as well worth conserving as their forests, waters, lands, and minerals, and in this great work the national government must bear a most important part.*
>
> —Theodore Roosevelt

LEARNING OBJECTIVES

After completing this chapter, you should be able to

- define key terms related to health policy,
- appreciate the influence of health determinants,
- understand the framework of health policy formulation,
- identify the stakeholders in health policy,
- describe the major types of health policies, and
- discuss the importance of studying health policy.

CASE STUDY 1

HEALTHCARE REFORM: HILLARY CLINTON AND BARACK OBAMA

Two major healthcare reform initiatives have played out on the US political landscape since the late twentieth century: the Health Security Act, developed by the Clinton administration in the 1990s and spearheaded by First Lady Hillary Clinton, which failed to pass into law, and the Affordable Care Act (ACA), drafted by the Obama administration, which became federal law in March 2010.

The hallmark of the Clinton plan was its universal coverage mandate, which required all employers to contribute to a pool of funds to cover the costs of insurance premiums for their workers, with caps on total employer costs and subsidies for small businesses. Competition among private health plans and a cap on the growth of insurance premiums were to have held costs in check, and additional financing was to have been provided through savings from cuts in projected Medicare and Medicaid spending and increased taxes on tobacco (Oberlander 2007; Pesko and Robarts 2017).

The Obama plan focused on reforming the private health insurance market, extending insurance coverage to the uninsured, providing better coverage for those with preexisting conditions, improving prescription drug coverage in Medicare, and extending the life of Medicare trust fund accounts. The ACA was expected to be financed through taxes, such as a 40 percent tax on “Cadillac” insurance policies (policies that offer the richest benefits) and taxes on pharmaceuticals, medical devices, and indoor tanning services (KFF 2013), and through other offsets or provisions of the law that reduce the overall cost of enacting legislation, such as penalties on uninsured individuals.

The political landscape in 2009, as President Barack Obama’s healthcare reform initiative was being debated, was similar to that in the early 1990s: Both the Clinton and Obama administrations were affiliated with the Democratic Party, both chambers of the US Congress were controlled by Democrats, and national opinion strongly favored healthcare reform (Sack and Connelly 2009).

However, whereas the Obama reform initiative became law, the earlier Clinton healthcare reform package was defeated in Congress. Although Americans supported healthcare reform in theory, the Clinton plan was derailed by the heavy opposition of the medical and insurance industries and by antitax rhetoric. The disenchantment of the electorate following that failed effort helped Republicans gain control of the House of Representatives and Senate in the 1994 election (Trafford 2010), which all but guaranteed that any further Democratic-designed proposal would fail due to increasing political polarization in Congress.

After Republican president Donald Trump took office in January 2017, the Trump administration and the Republican-controlled Congress put forth many efforts to “repeal and replace” the ACA. However, as of mid-2018, none of these attempts had succeeded.

Case Study 2

Healthcare Reform After the ACA

Healthcare reform continues to be a deeply partisan issue in US politics, and political gridlock in Congress has made efforts at reform challenging. Since 2010, Republicans in Congress have unsuccessfully attempted to repeal the ACA, voting more than 60 times to repeal or alter the law (Cowen and Cornwall 2017). In January 2016, the Republican-controlled House and Senate passed a bill that would have repealed the ACA, but President Obama, a Democrat, promptly vetoed it. The Congressional Budget Office (CBO) review of the proposal concluded that the bill would have canceled health insurance for 22 million people by 2018 (Cubanski and Neuman 2018). In the 2016 presidential election campaign, every Republican candidate vowed to "repeal and replace" the ACA (Jost 2015). In January 2017, within hours of taking office, President Trump issued his first executive order, moving to dismantle parts of the ACA (Davis and Pear 2017).

On March 7, 2017, Republicans introduced the two bills that constitute the original American Health Care Act (AHCA) of 2017, H.R. 1628, to partially repeal the ACA. The Trump administration announced its support for AHCA. On March 12, 2017, the CBO released its budget analysis, projecting that 52 million Americans would be left uninsured under the AHCA and those with insurance would have to pay higher premiums through 2020. On May 4, 2017, the House narrowly passed the AHCA, by a vote of 217–213, and sent the bill to the Senate for deliberation. On June 22, 2017, the Senate released a discussion draft for an amendment to the bill, which would rename it the Better Care Reconciliation Act of 2017. On July 28, 2017, the bill was returned to the calendar after the Senate rejected several amendments, including the Health Care Freedom Act, or the "skinny bill," that would have repealed the ACA's individual mandate retroactive to 2016 and the employer mandate through 2025.

Does this legislation point to a new phase of healthcare reform whose success hinges on support from both major political parties? As Wilensky (2017) suggested, Republicans and Democrats might need to find a way to work together to enact comprehensive healthcare reform beyond the ACA.

Or, does it signal a new approach toward dismantling the ACA through the administrative process, such as policy implementation? In reaction to Congress's repeated failure to repeal the ACA, on October 12, 2017, President Trump issued Executive Order 13813, directing federal agencies to expand the use of *association health groups*—groups of small businesses that pool together to buy health insurance (Trump 2017).

The Tax Cuts and Jobs Act of 2017, passed and signed into law in December 2017, effectively repealed the mandate in the ACA that required all Americans to have health insurance. Although the ACA was still the law of the land during the first year of the Trump administration, many of its components were being modified in Trump's second year.

gross domestic product
The value of all goods and services produced within a country for a given period; a key indicator of the country's economic activity and financial well-being.

At 16.9 percent of the nation's total economic activity—also known as the **gross domestic product**—healthcare spending in the United States leads all countries in overall and per capita measures (OECD 2018). Yet the US healthcare system does not perform well compared with those of other industrialized countries. A 2010 World Health Organization (WHO) report ranked the US health system thirty-seventh among 191 countries (Tandon et al. 2018). In addition, a Commonwealth Fund study on healthcare performance ranked the United States behind ten other industrialized countries—Australia, Canada, France, Germany, the Netherlands, New Zealand, Norway, Sweden, Switzerland, and the United Kingdom—on the basis of quality, efficiency, access, equity, and health outcome measures (Davis, Schoen, and Stremikis 2014). The US healthcare system also ranked last in a recent survey of eleven nations (Commonwealth Fund 2017).

Why have health policies tended to fail in the United States while they appear to succeed in other countries? The answer might be found in the context—the United States—and the determinants of health and health policy in the country.

The main purpose of this chapter is to present a framework of health policy determinants and discuss their impact in the United States. Understanding this framework will help the reader appreciate factors that contribute to health policy development in general and in the United States in particular. The chapter first defines key concepts related to health policy and later discusses the importance of studying health policy, including an awareness of its international perspective. The stakeholders of health policy are also presented and analyzed as key parts of the policy context.

HEALTH DEFINED

WHO (1946) defines *health* as "not merely the absence of disease or infirmity but a state of complete physical, mental and social well-being." This broad definition recognizes that health encompasses biological and social elements in addition to individual and community well-being. Health may be seen as an indicator of personal and collective advancement. It can signal the level of an individual's well-being as well as the degree of success achieved by a society and its government in promoting that well-being (Shi and Stevens 2010). This definition of health implies that issues such as poverty, lack of education, discrimination, and other social, cultural, and political conditions found around the world are essentially public health issues.

However, health is also the result of personal characteristics and choices. This concept is the source of the fundamental tension in public health and has been a major topic of discussion in the United States in the twenty-first century. Major debates continue over whether people can be forced to take actions to ensure their own health, such as buying health insurance (e.g., the "individual mandate" in the ACA), or be prohibited from performing actions that are unhealthy, such as limiting soft drinks in schools. Health policy in the United States must attempt to balance the good of the public health with personal liberty,

KEY LEGISLATION

What Is the Status of Healthcare Reform in the United States?

In the United States, *healthcare reform* typically denotes a government-sponsored program that strives to make health insurance available to the uninsured. Heretofore, healthcare reform has not quite addressed how healthcare should be delivered, such as in resource allocations across preventive, primary, and tertiary care settings. Although universal health insurance is a difficult goal to realize, incremental reforms have been successful when political and economic environments were favorable. The first such program came in the form of the Old Age Assistance program, which was enacted as part of the 1935 Social Security Act and provided direct financial assistance to needy elderly persons.

Full health insurance for the elderly became available under the Medicare program, as did health insurance for the indigent under the Medicaid program. Both programs were created in 1965 under the Great Society reforms of President Lyndon Johnson in an era when civil rights and social justice had taken central stage in the United States. Later, authorized under the Balanced Budget Act of 1997, the State Children's Health Insurance Program—later renamed the Children's Health Insurance Program—was developed, whereby states can use federal funds to cover children up to age 19 through their existing Medicaid programs.

One of the most significant healthcare reform efforts resulted in the Affordable Care Act of 2010, designed to bring about major changes to the delivery of US healthcare. The key objective of the ACA was to provide most, if not all, Americans with health insurance coverage.

often a difficult compromise to make. Indeed, the conflict between the WHO definition of health and many of the social, cultural, and political issues surrounding the US healthcare system is one of the most important areas of debate for health policymakers.

PHYSICAL HEALTH

The most common measure of physical health is **life expectancy**—the anticipated number of remaining years of life at any stage. Exhibit 1.1 shows the ten countries ranking highest in their population's life expectancy as of 2015 and includes the US ranking for comparison.

Although good or positive health status is commonly associated with the definition of *health*, the most frequently used indicators measure, instead, lack of health or incidence of poor health—for example, **mortality**, **morbidity**, **disability**, and various indexes that combine these factors. One such measure is **quality-adjusted life years**, which combines mortality and morbidity in a single index. The Learning Point box titled "Measures of Mortality, Morbidity, and Disability" lists categories by which each indicator is measured.

life expectancy
Anticipated number of years of life remaining at a given age.

mortality
Number of deaths in a given population within a specified period.

morbidity
Incidence or prevalence of diseases in a given population within a specified period.

disability
A physical or mental condition that limits an individual's ability to perform functions considered normal.

quality-adjusted life years
A combined mortality–morbidity index that reflects years of life free of disability and symptoms of illness.

Exhibit 1.1
Top Ten Countries with the Longest Life Expectancy, with the United States as Comparison

		Life expectancy at birth (years)		
Rank	**Country (state/territory)**	**Overall**	**Male**	**Female**
1	Japan	83.9	80.8	87.1
2	Switzerland	83.0	80.8	85.1
3	Spain	83.0	80.1	85.8
4	Italy	82.6	80.3	84.9
5	Australia	82.5	80.4	84.5
6	Iceland	82.5	81.2	83.8
7	Norway	82.4	80.5	84.2
8	France	82.4	79.2	85.5
9	Sweden	82.3	80.4	84.1
10	Korea	82.1	79.0	85.2
26	United States	78.8	76.3	81.2

Source: Data from OECD (2018).

MENTAL HEALTH

In contrast to physical health, measures of mental health are limited. The major categories of mental health measures are mental conditions (e.g., depression, disorder, distress), behaviors (e.g., suicide, drug or alcohol abuse), perceptions (e.g., perceived mental health status), satisfaction (e.g., with life, work, relationships), and services received (e.g., counseling, drug treatment).

Mental illness ranks second, after ischemic heart disease, as a nationwide burden on health and productivity (SAMHSA 2016). An estimated 17.9 percent of the US adult population in 2014 had at least one diagnosable mental disorder, only 41 percent of whom received any treatment (SAMHSA 2016). Serious mental illness costs the United States $193.2 billion in lost earnings per year (SAMHSA 2016). Mental illness is a risk factor for death from suicide, cardiovascular disease, and cancer. Mental health problems are frequently associated with social problems. For example, with easy access to guns, mental health often contributes to gun violence in both public and private settings.

SOCIAL WELL-BEING

The most commonly used measure of relative social well-being is socioeconomic status (SES). An SES index typically considers such factors as education level, income, and occupation. Quality of life is another common measure and may include the ability to perform various roles (e.g., self-care, family care, social functioning), perceptions (e.g., emotional well-being,

LEARNING POINT
Measures of Morbidity, Mortality, and Disability

Morbidity measures

- Incidence of specific diseases: number of new cases in a defined population within a specified period
- Prevalence of specific diseases: number of instances in a defined population within a specified period

Mortality measures

- Crude (unadjusted for any other factors) death rate
- Age-specific death rate
- Condition-specific death rate
- Infant death rate
- Maternal death rate

Disability measures

- Restricted activity days (e.g., bed days, work-loss days)
- Limitations in performing activities of daily living (i.e., bathing, dressing, toileting, getting into or out of a bed or a chair, continence, eating)
- Limitations in performing instrumental activities of daily living (i.e., doing housework and chores, grocery shopping, preparing food, using the phone, traveling locally, taking medicine)

pain tolerance, energy level), and living environment (e.g., pollution levels, crime prevalence). A third set of social well-being measures, often used by sociologists, is composed of **social contacts** and **social resources**. Examples of social contacts include visits with family members, friends, and relatives and participation in social events, such as membership activities, professional conferences, and church gatherings. The social contacts factor can be used as an indicator of social resources by determining whether an individual can rely on social contacts for needed support and company and whether the people involved in these contacts meet the individual's needs for care and love.

social contacts
The frequency of social activities a person undertakes within a specified period.

social resources
Interpersonal relationships with social contacts and the extent to which the individual can rely on the people involved in these contacts for support.

PUBLIC HEALTH DEFINED

In the early twentieth century, Winslow (1920) defined *public health* as "the science and the art of preventing disease, prolonging life, and promoting physical health and efficiency through organized community efforts for the sanitation of the environment, the control of community infections, the education of the individual in principles of personal hygiene, the organization of medical and nursing service for the early diagnosis and preventive treatment of disease, and the development of social machinery which will ensure to every individual in the community a standard of living adequate for the maintenance of health." It focuses on prevention and involves the efforts of society as a whole. Public health is intended to protect lives and improve the health of populations around the globe. Today, the Johns Hopkins Bloomberg School of Public Health emphasizes the continued importance of public health in its school motto, "Protecting Health, Saving Lives—Millions at a Time."

Whereas healthcare is intended to treat, influence, and care for individuals, public health operates on a larger scale. The field is described by the American Public Health Association (APHA 2018) as one that "promotes and protects the health of people in the communities where they live, learn, work and play."

Public health has broad implications for a population. Successful public health activities and initiatives can save money by promoting healthy living and prevention, thus reducing healthcare costs and disease burden. In addition, these activities can improve quality of life, help children thrive, and reduce the suffering caused by ill health in a population (APHA 2018). The practice of public health leads to both direct benefits (e.g., healthier children, less chronic disease, less need for acute care) and indirect benefits (e.g., fewer days missed from school and work; increased funding available for other initiatives, such as education) for a society.

It is important to remember that public health, healthcare, and health policy are interconnected areas of study and practice. All three have great influence on health.

WHAT ARE THE DETERMINANTS OF HEALTH?

determinants of health
Factors that influence health status. Typically, they include socioeconomic status, environment, behaviors, heredity, and access to medical care.

Numerous theories on the **determinants of health** have been proposed since the mid-twentieth century. Blum (1974) offered a framework called Force Field and Well-Being Paradigms of Health, which suggests four major influences—the force fields—on health: environment, lifestyle, heredity, and medical care. According to Blum, the most important force field is the environment, followed by lifestyle and heredity. Medical care has the least impact on health and well-being.

Twenty-first-century models focus on socioeconomic context and health behaviors. For example, the Dahlgren and Whitehead (2006) model divides factors that influence health into two categories. *Fixed factors*, the first category, are unchangeable, such as age, sex, and genetic makeup. The second category is composed of *modifiable factors*, such as individual lifestyle choices; social networks and community conditions; the environment in which one lives and works; and access to important goods and services, such as education, sanitation, food, and healthcare. The factors in the second category form layers of influence around the population, and modifying them positively can improve population health.

Ansari and colleagues (2003) proposed a public health model of the determinants of health in which these factors are categorized into four major groups: social determinants, healthcare system attributes, disease-inducing behaviors (see the Learning Point box titled “Prominent Theories on the Causes of Disease”), and health outcomes.

A conceptual framework developed by the WHO Commission on Social Determinants of Health (2008) focuses on socioeconomic and political context; structural determinants and socioeconomic position; intermediary determinants, such as material circumstances, socioenvironmental circumstances, behavioral and biological factors, social cohesion, and the healthcare system; and the impact on health equity and well-being measured as health outcomes.

LEARNING POINT

Prominent Theories on the Causes of Disease

Many of the historically dominant theories related to health focus on disease rather than well-being. The three most prominent theories of disease causality are germ theory, lifestyle theory, and environmental theory.

Germ theory gained prominence in the nineteenth century with the rise of bacteriology (Metchnikoff, Pasteur, and Koch 1939). Essentially, the theory holds that every disease has a specific cause, which should be identifiable. Knowledge of the cause allows for the discovery of a cure. Microorganisms, the general causal agent identified by germ theory, are thought to act independently of the environment. Furthermore, the individual who serves as the host of the microorganism is the source of the disease, which may then be transmitted from one person to another—a process known as *contagion*. Strategies to address the disease focus on identifying people with symptoms and providing follow-up medical treatment. Much of biomedical research is still based on germ theory. The traditional concept of the agent, host, and environment as the epidemiological triangle—*epidemiology* is the study of factors controlling the presence or absence of a disease—is also based on the single-cause, single-effect framework of germ theory.

Lifestyle theory tries to isolate specific behaviors (e.g., exercise, diet, smoking, drinking) as causes of a disease and identifies solutions on the basis of improving or changing these behaviors. As with germ theory, lifestyle theory defines problems as they relate to individuals and focuses solutions on individually tailored interventions.

Environmental theory considers the general health and well-being of individuals more than it does disease. It maintains that health is best understood by examining the larger context of community. Traditional environmental approaches focused on poor sanitation, which was connected to certain infectious diseases. With industrialization and its by-products of overcrowding and filth, contemporary environmental approaches examine the impact of production and consumption on emerging health problems. Environmental theory considers disease to be influenced by environmental and social factors. It contends that solutions should be developed through policy and regulation and focused on systems rather than on individuals and medical treatment.

Similarly, the US Department of Health and Human Services (HHS) publication *Healthy People 2020* embraced a holistic approach by considering the range of personal, social, economic, and environmental factors that determine the health status of individuals or populations (HHS 2010). Planning is now under way for the HHS Healthy People 2030 initiative and includes establishing a framework for the initiative (including the vision, mission, foundational principles, plan of action, and overarching goals) and identifying new objectives (HHS 2018). In the first phase of the process, an expert advisory committee will develop recommendations for the HHS secretary on the framework and implementation of Healthy People 2030. Input from members of the public and relevant stakeholders will guide the development of recommendations. During the second phase, a federal interagency workgroup will use the advisory committee's recommendations to establish objectives for Healthy People 2030 (Haskins 2017). Exhibit 1.2 delineates the evolution of the Healthy People initiatives and their respective overarching goals.

Exhibit 1.3 provides an overview of health determinants—environment, individual characteristics, and medical care (discussed in greater detail in the sections that follow)—as

Exhibit 1.2
Evolution of Healthy People Initiatives

	Target year			
	1990	**2000**	**2010**	**2020**
Overarching goals	• Decrease mortality: infants to adults • Increase independence among older adults	• Increase span of healthy life • Reduce health disparities • Achieve access to preventive services for all	• Increase quality and years of healthy life • Eliminate health disparities	• Attain high-quality, longer lives free of preventable disease, disability, injury, and premature death • Achieve health equity; eliminate disparities • Create social and physical environments that promote good health • Promote quality of life, healthy development, and healthy behaviors across life stages
No. of topic areas	15	22	28	42
No. of objectives/ measures	226	312	1,000	approximately 1,200

Source: Healthy People Initiatives of 1990, 2000, 2010, and 2020 (HHS 2010).

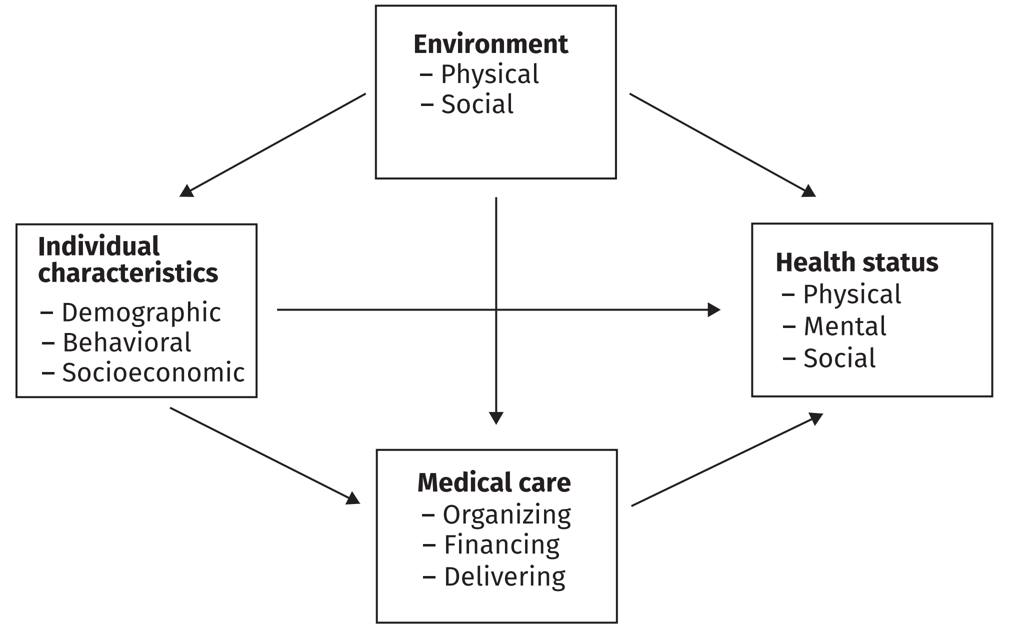


Exhibit 1.3 Conceptual Framework of Health Determinants

they interact to influence health status. For example, although individual characteristics and medical care affect health on their own, they also interact to become another type of factor influencing health.

ENVIRONMENT

The environment in this context is composed of the physical and social dimensions of an individual's existence over which the individual has little or no control. These dimensions exert influence at the family, community, and policy levels of society. Environmental determinants have a greater impact on health than the medical care system does.

Physical Dimension

The use of energy sources (e.g., oil, coal) by a population creates certain health hazards in the physical environment. Those hazards can present themselves in the form of air, noise, or water pollution, resulting in hearing loss, infectious disease, gastroenteritis, cancer, emphysema, and bronchitis. To address the impact of climate change, WHO has launched the Climate and Health Country Profile Project (see the For Your Consideration box titled "WHO Climate and Health Country Profile Project").

FOR YOUR CONSIDERATION

WHO Climate and Health Country Profile Project

According to WHO (2018), the Climate and Health Country Profile Project "aims to raise awareness of the health impacts of climate change, support evidence-based decision making to strengthen the climate resilience of health systems, and promote actions that improve health while reducing carbon emissions. The profiles provide country-specific estimates of current and future climate hazards and the expected burden of climate change on human health, identify opportunities for health co-benefits from climate mitigation actions, and track current policy responses at national level."

The project has been expected to track national progress on climate action in the health sector through a WHO climate and health country survey conducted every two years and designed to provide updated information on such aspects as adaptation and resilience measures, climate and health finance, disease surveillance, emergency preparedness, leadership and governance, mitigation action in the health sector, and national vulnerability and adaptation assessments (WHO 2018).

The first set of Climate and Health Country Profiles was released in late 2015 and included more than 40 countries (WHO 2018). Based on the evidence presented in these profiles, WHO (2015) contended that "placing a price on polluting fuels that reflected their health impacts would be expected to cut outdoor air pollution deaths by approximately half, reduce carbon dioxide emissions by over 20 percent, and raise approximately $3 trillion per year in revenue—over half the total value of health spending by all of the world's governments." Collection of data for a second set of profiles was expected to be completed in late 2017, the results of which would be compiled and presented in 2019 (WHO 2018).

Social Dimension

The social environment is reflected in a nation's political, economic, and cultural preferences, which exert significant influence on the health of the population. Characteristics of an environment's social dimension include behavioral health factors and demographic trends. In the United States, for example, rates of psychological stress, homicide, suicide, and other behavioral health indicators can be attributed in part to crowding, isolation, and other social environmental factors. In terms of population trends, the increase in the number of elderly—those aged 65 years or older—as a proportion of the total population will place increasing pressure on healthcare systems around the world.

INDIVIDUAL CHARACTERISTICS RELATED TO HEALTH

Demographic, behavioral, and socioeconomic conditions shape individual characteristics, which explain much of the variation in health status within populations. As discussed in the following paragraphs, these factors interact with and are influenced by the environment, thereby affecting individuals' health.

Demographics

Age, gender, and race or ethnicity are strongly associated with health. Advancing age, for example, contributes to arthritis, diabetes, atherosclerosis, and cancer. Gender health is influenced in part by the social construct of gender characteristics, such as the association between masculine identity and risk-taking.

People also experience significant differences in health status depending on their race or ethnic origin. Explanations for these differences include SES, behaviors, social circumstances, level of access to healthcare services (CDC 2005a; Filice and Joynt 2017; Gupta et al. 2018; James et al. 2017; Shi 1999; Shi, Lee, Chung, et al. 2017; Shi, Lee, Haile, et al. 2017; Shi and Stevens 2010), and factors that are associated with particular racial or ethnic groups (CDC 2012b).

Behaviors

The leading causes of death in the United States have shifted since the beginning of the twentieth century. In 1900, infectious diseases such as diphtheria, tuberculosis, measles, and pneumonia caused 797 per 100,000 deaths in the United States; by the end of the twentieth century, infectious diseases caused fewer than 100 per 100,000 deaths while chronic diseases such as heart disease and cancer caused significantly higher mortality (Armstrong, Conn, and Pinner 1999). This "epidemiologic transition" supports the idea that behavioral risk factors—including poor dietary habits, cigarette smoking, alcohol abuse, lack of exercise, and unsafe driving—tend to predict higher risk for certain chronic diseases and mortality. See exhibit 1.4 for examples of the association between risk factors and leading causes of death.

The level of behavioral risk factors exhibited by a population is related to SES. For example, the prevalence of smoking is greater among those with less education; in 2011, 45.3 percent of Americans who had obtained a GED (General Educational Development) certificate reported being a current cigarette smoker, compared with only 5 percent of those who held graduate degrees (CDC 2012a). Behavioral risk factors are divided into three categories: leisure activity risks, consumption risks, and employment participation and occupational risks (Dever 2006). These categories are determined in part by the collective decisions made by individuals in a particular group that affect their health. The degree of control they have in these decisions varies by category: Individuals have the least control over employment and occupational factors, more control over consumption factors, and the greatest control over leisure activity–related factors.

Destructive behaviors related to employment and occupational risks are usually difficult for individuals to control. To offset such risks, the federal government created regulatory

Exhibit 1.4
The Association Between Health Behaviors and Leading Causes of Death

	Cause of death					
Health behavior	**Heart disease**	**Cancers**	**Stroke**	**Diabetes**	**Cirrhosis**	**Homicide**
Smoking	X	X				
High blood pressure	X		X			
High cholesterol	X					
Poor diet	X	X		X		
Obesity	X			X		
Lack of exercise	X					
Stress	X					X
Alcohol abuse		X			X	X
Drug misuse	X					X
Unsafe driving						X

agencies, such as the Occupational Safety and Health Administration, that require employers to maintain safe workplaces and practices.

Individuals have more control over consumption than over occupation-related behaviors; however, environmental factors, such as availability of affordable, healthy foods, play a significant role in the extent of their control. Consumption risks include overeating (resulting in obesity), high cholesterol intake (heart disease), alcohol consumption (motor vehicle accidents), alcohol addiction (liver cirrhosis), cigarette smoking (chronic bronchitis and emphysema, lung cancer, aggravating heart disease), drug dependency (suicide, homicide, malnutrition, accidents, social withdrawal, acute anxiety), and excessive glucose or sugar intake (dental caries, obesity, hyperglycemia, diabetes).

Unlike the risks related to employment and occupation, those that accompany leisure and consumption activities are relatively unregulated, with the exception of efforts to control the use of illegal drugs and the purchase of tobacco and alcohol products by underage youth. Leisure-related destructive behaviors include sexual promiscuity and unprotected sex (which can result in sexually transmitted diseases, including AIDS, syphilis, and gonorrhea) and limited or no exercise (which may lead to overweight and obesity and aggravate other health conditions).

Socioeconomic Status

The major components of SES are income, education, and occupational status. SES is a strong and consistent predictor of health status. Individuals with low SES suffer disproportionately from most diseases and experience higher rates of mortality than those with midlevel or high-level SES. For example, after controlling for access to medical care, studies show that countries providing universal health insurance, such as England, report the same SES–health relationships as those found in the United States, which does not yet offer universal health insurance (Acheson 1998; Cormman et al. 2015).

SES influences health to the extent to which individuals and populations are exposed to physical and social threats; have knowledge of health conditions; encounter adverse environmental conditions, such as pathogens and carcinogens; and are exposed to undesirable social conditions, such as crime.

MEDICAL CARE

Most items that we buy and sell are commodities—goods and services whose worth can be calculated as a monetary value, that serve a specific (rather than an intrinsic or esoteric) purpose, and that can be exchanged with other similar products (Doty 2008). Medical care differs from traditional commodities in four important ways. First, the demand for medical care is derived; that is, it stems from the demand for a more fundamental commodity—health itself.

The second difference is the presence of the **agency relationship**. Because patients generally lack the technical knowledge to make health-related decisions, they delegate this authority to their physicians with the expectation that physicians will act for patients as patients would for themselves if they had the appropriate expertise.

agency relationship
In healthcare, delegation by the patient of some authority to make decisions and perform actions on the patient's behalf to an expert such as a physician or other healthcare provider.

If physicians were to act solely in the interests of patients, the agency relationship would be virtually indistinguishable from normal consumer behavior. However, physicians' decisions typically reflect the physicians' self-interests as well as the interests of their patients. Those self-interests may arise from pressures imposed by professional colleagues and institutions, adherence to medical ethics, or a desire to make good use of available resources.

One implication of the agency relationship is that medical care may or may not be provided, depending on the payer of services for the patient. For example, physicians who treat members of a **health maintenance organization (HMO)** may have an incentive to restrict the number of hospital admissions they order because HMO patients' care is prepaid; that is, the physician will not be paid more to provide more services. Acting on this incentive means that the physician is acting as an *imperfect agent*.

health maintenance organization (HMO)
A managed care organization that integrates medical care with payment and typically requires the use of a specified panel of providers.

The third difference between medical care provision and the provision of other products and services is that healthcare pricing varies according to who pays the fees. Because most patients are covered by insurance, the amount paid by patients out-of-pocket at the point of care for most medical services is often significantly lower than the total payment made to the provider.

The fourth difference is that medical care service provision is influenced by its environment, whereas other commodities are not. In other words, the social, economic, demographic, technological, political, and cultural contexts dictate how, when, where, and to whom healthcare services are offered, which is not true of other products and services. For example, of the forces currently reshaping the healthcare industry, the number of uninsured people (social context) is a major factor driving health insurance reform debates.

POLICY DEFINED

A *policy* is a decision made by an authority about an action—either one to be taken or one to be prohibited—to promote or limit the occurrence of a particular circumstance in a population. In the United States, the authority charged with making policy is a legislative, executive, or judicial body operating under the purview of a federal, state, or local public administration. Public policy—decision making that affects the general population or significant segments thereof—is meant to improve the conditions and general welfare of the population or subpopulations under its jurisdiction. Other countries, however, may have different mechanisms of developing policies (see the For Your Consideration box titled "Dominant Political Systems of the World").

Although public policies are intended to serve the interests of the public at large, the term *public* has different interpretations according to the political context in which it is applied. For example, policymakers tend to be most responsive to the views and wishes of constituents who are politically active and communicate directly with their representatives.

FOR YOUR CONSIDERATION
Dominant Political Systems of the World

Democracy—political system that allows for each individual to participate either directly or through elected representatives (United States, Canada)

Republic—political system in which the government remains mostly subject to the people, and leaders can be recalled (France, Egypt, India)

Monarchy—political system in which the inherited ruler (monarch) is head of state, the constitution limits the monarch's power, and others make laws (United Kingdom, Denmark, Kuwait, Spain, Sweden)

Communism/Socialism—political system based on the ideology of communism as taught by Karl Marx, Vladimir Lenin, or Mao Zedong, often dominated by a single party or an elite group of people (China, Russia, Cuba)

Dictatorship—political system in which a single person (dictator) is the main individual ruling the country, not restricted by constitutions or parliaments (Zimbabwe, Uzbekistan, North Korea)

In the private sector, authority is conferred to the executive or board of directors of an organization. *Private policy*—policy that affects the private organization only—is meant to improve the conditions and general welfare of the employees of that organization. Because private organizations function in the larger social (public) environment, private policies must take into account the spirit of public policies.

HEALTH POLICY DEFINED

Miller (1987, 15) defined *health policy* as "the aggregate of principles, stated or unstated, that . . . characterize the distribution of resources, services, and political influences that impact on the health of the population." This definition and others focus on US federal or public-level health policy and do not reflect non-US political systems nor account for the fact that private-sector policy also influences health.

Therefore, in this book we define **health policy** as policy that pertains to or influences the attainment of health. In terms of the determinants-of-health framework, health policy refers to legislation that may influence—directly or indirectly—social and physical environments, behaviors, SES, and availability of and accessibility to medical care services. Health policies affect groups or classes of individuals, such as physicians, the poor, the elderly, and children. They can also affect types of organizations, such as medical schools, HMOs, nursing homes, medical technology producers, and employers. On the basis of this broad definition, health consequences may result from virtually all major policies, such as Social Security mandates, national defense–related guidelines, labor policies, and immigration policies.

health policy
Legislation over individuals, organizations, or society whose goal is to improve health for the general population or subpopulations.

Furthermore, in the United States, each branch and level of government can influence health policy. For example, both the executive and legislative branches at the federal, state, and local levels can establish health policies, and the judicial branch at each level can uphold, strike down, or modify existing laws affecting health and healthcare. Examples of public, or government, health policy include legislative and regulatory efforts to ensure air and water quality and support for cancer research.

Health policies can also be made through the private sector. Examples of private-sector health policies are the decisions made by insurance companies regarding their product lines, pricing, and marketing and by employers regarding health benefits, such as leave policies, work site health promotion, and insurance coverage.

Health policy must be distinguished from **healthcare policy**, which refers to that part of health policy pertaining to the financing, organization, and delivery of care. Healthcare policy may cover the training of health professionals; licensing of health professionals and facilities; administration of public health insurance programs, such as Medicare and Medicaid; deployment of electronic health records; efforts to control healthcare costs; and regulation of private health insurance. Whereas the predominant goal of health policy is to improve population health, the goals of healthcare policy are typically to provide equitable and efficient access to high-quality healthcare services.

healthcare policy
The part of health policy specifically related to the financing, delivery, and governance of health services for the general population or subpopulations within a jurisdiction.

FOR YOUR CONSIDERATION
The United States as an Individualist Culture?

The American political culture is characterized by some observers as being rooted in a distrust of power—particularly government power—and a preference for volunteerism and self-rule in small, homogeneous groups with limited purposes. How would you describe the political culture of average Americans? Do you agree or disagree with the characterization posed here? Provide examples to support your answer.

TYPES OF HEALTH POLICY

The scope of health policy is determined by the political and economic system of a country. In the United States, where pro-individual and pro-market sentiments tend to dominate (see the For Your Consideration box titled "The United States as an Individualist Culture?"), health policies are likely to be fragmented, incremental, and noncomprehensive. National policies and programs are typically crafted to reflect the notion that local communities are in the best position to identify strategies to address their unique needs. However, the types of changes that can be enacted at the community level are clearly limited. Next, we summarize the two major types of health policies: regulatory and allocative.

Regulatory Health Policies

regulatory policies
Regulations or rules that impose restrictions and are intended to control the behavior of a target group by monitoring the group and imposing sanctions if it fails to comply.

Health policies may be used as regulatory tools that call on the government to prescribe and control the behavior of a particular target group by monitoring the group and imposing sanctions if it fails to comply. Examples of **regulatory policies** include prohibition of smoking in public places, licensure requirements for medical professions, and processes related to the approval of new drugs. State insurance departments across the country regulate health insurance companies in an effort to protect customers from default on coverage in the case of a company's financial failure, excessive premiums, or deceptive practices.

Private health policies can also be regulatory. For example, physicians set standards of medical practice and hospitals undergo assessments from accreditation service organizations, such as The Joint Commission, to ensure compliance with all standards.

Allocative Health Policies

distributive policies
Regulations that provide benefits or services to targeted populations or subpopulations, typically as entitlements.

redistributive policies
Deliberate efforts to alter the distribution of benefits by taking money or property from one group and giving it to another.

Allocative health policies involve the direct provision of income, services, or goods to certain groups of individuals or institutions. They can be distributive or redistributive. **Distributive policies** spread benefits across society. Examples include the funding of medical research through the National Institutes of Health, provision of public health and health promotion services, training of medical personnel, and construction of healthcare facilities. **Redistributive policies** take money or power from one group and give it to another. This approach typically creates visible beneficiaries and payers. Examples include means-tested social insurance programs such as Medicaid, which uses tax revenue from the more affluent population to provide free or low-cost health insurance to the poor, to subsidize the welfare program, and to fund public housing. It should be pointed out that Medicare and Social Security are not redistributive policies nor "entitlements" because they are supported by funds collected through deductions from the income of working people before their retirement and then distributed later to members of that same population after their retirement.

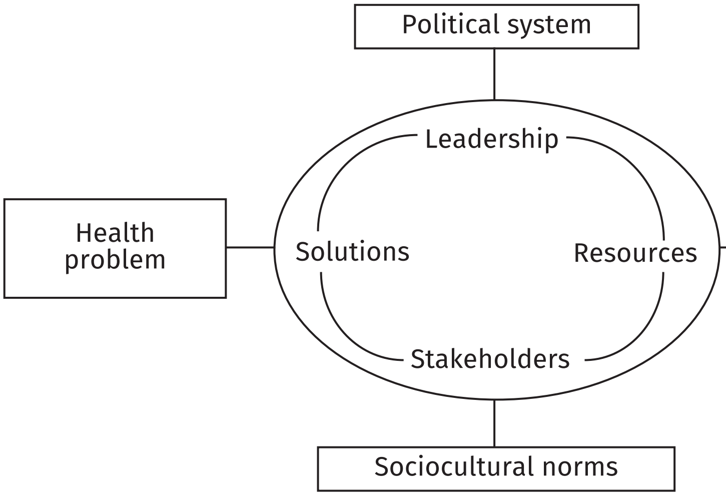
WHAT ARE THE DETERMINANTS OF HEALTH POLICY?

As noted earlier, the framework for health determinants includes four major categories: environment, health status, medical care, and individual characteristics (shown earlier in exhibit 1.3). The framework for *health policy determinants* is presented in exhibit 1.5. Broad determinants include the nature of the health problem, the sociocultural norms that influence the perception of the problem, and the political system within which the health policy is formulated. The inner circle of the framework shows the narrower determinants:

- Potential solutions to the identified health problem
- Views and efforts of the stakeholders
- Demonstrated leadership of the policymakers
- Available resources needed to implement the health policy

This general framework may be applied to health policies at the national, state, or local level; to public and private policies; and to health policies in the United States and

EXHIBIT 1.5
A Conceptual Framework of Health Policy Determinants



elsewhere. The remainder of this section describes these components in greater detail, and chapters 2 through 4 illustrate the application of this framework in various settings.

BROAD DETERMINANTS OF HEALTH POLICY

Among the broad determinants of health policy are the nature of the health problem, sociocultural norms, and the political system of the country, each of which is discussed in this section.

Health Problem

The nature of the health problem is typically the first consideration of policy, the significance of which is determined by its magnitude and severity. *Magnitude* indicates the reach of the problem. If the health problem affects a large segment of the population (e.g., heart disease, diabetes), it is considered widespread. *Severity* denotes the extent to which the problem is urgent. See the Learning Point box titled "Infectious Disease Epidemics: Severe Acute Respiratory Syndrome and Influenza" for examples.

LEARNING POINT

Infectious Disease Epidemics: Severe Acute Respiratory Syndrome and Influenza

Severe acute respiratory syndrome (SARS) is a serious form of viral pneumonia that can result in acute respiratory distress and, sometimes, death. It first came to the attention of Asian health officials in February 2003. In just a few months, it had spread throughout North America, South America, Europe, and Asia, affecting 8,098 individuals in more than 25 countries. Of those infected, 774 died. The 2003 SARS epidemic demonstrated how quickly an infectious respiratory disease could spread across the world and registered among the most severe health problems in the twenty-first century.

Influenza (flu) is a contagious respiratory illness caused by influenza viruses, which can cause mild to severe illness. Serious outcomes of flu infection can result in hospitalization or even death. More than 130 million doses of flu vaccine were distributed in the 2017–2018 winter season. Although the impact of flu varies, it places a substantial burden on the health of people in the United States each year. The Centers for Disease Control and Prevention (CDC) estimates that influenza resulted in between 9.2 million and 35.6 million illnesses, between 140,000 and 710,000 hospitalizations, and between 12,000 and 56,000 deaths annually from 2010 to 2017.

Source: CDC (2005b, 2017).

Sociocultural Norms

Sociocultural norms reflect the accepted values, beliefs, attitudes, and behaviors of a society or group. These norms play a significant role in the public's perception of the nature of a health problem, the role of the government versus individuals in addressing that problem, and the type of solution or policy implemented to manage it. For example, mental illness carries a social stigma in many cultures. Although poor mental health has long been a pervasive problem in the United States and elsewhere, relatively little public action has been taken to promote improvements in mental health status, care, and treatment.

Political System

Although a democratically governed country is more likely to develop health policies that reflect the public's interests (officials are publicly elected and presumably represent the electorate's interests), the process of policy development is typically more difficult in democratic systems than in single-rule governments, not only because the development of legislation in a democracy is arduous but also because the public's interests are rarely coherent. In authoritarian (single-party) countries, policies can be developed more quickly but may not truly reflect the public's interests.

NARROW DETERMINANTS OF HEALTH POLICY

The narrow determinants of health policy include solutions, stakeholders, leadership, and resources, each of which is discussed in this section.

Solutions

Potential solutions to a health problem facilitate policy development. If solutions do not emerge, policymakers may direct their efforts away from full-fledged policy consideration and toward finding a solution, likely by initiating a research study. If a health problem has more than one potential solution, policy research and analysis is conducted to identify the optimal solution given the political climate, available resources, and expectations of prominent stakeholders.

Stakeholders

Entities or individuals who have a direct or indirect role in the development of policy are considered stakeholders. The influence of stakeholders is particularly strong in a democracy, as elected officials often cater to the interests of their constituency—either to fulfill a campaign promise or to gain reelection. Policy is more likely to be enacted when the positions of the various stakeholders converge. The next major section in this chapter describes the key stakeholders in US health policy.

Leadership

No matter how significant the problem or how determined the stakeholders, health policy addressing a particular problem will not appear on the policy agenda without the approval of the governing body's leader. The first case study at the beginning of this chapter demonstrates the contrasting leadership styles of President Barack Obama and former First Lady Hillary Clinton. The For Your Consideration box titled "Quotes from Selected US Presidents" reflects the leadership styles of a number of US presidents throughout the nation's history and provides clues as to how they governed.

FOR YOUR CONSIDERATION

Quotes from Selected US Presidents

Associate yourself with men of good quality if you esteem your own reputation; for 'tis better to be alone than in bad company.

—George Washington

To be good, and to do good, is all we have to do.

—John Adams

It is by a thorough knowledge of the whole subject that [people] are enabled to judge correctly of the past and to give a proper direction to the future.

—James Monroe

If your actions inspire others to dream more, learn more, do more, and become more, you are a leader.

—John Quincy Adams

Any man worth his salt will stick up for what he believes right, but it takes a slightly better man to acknowledge instantly and without reservation that he is in error.

—Andrew Jackson

While men inhabiting different parts of this vast continent cannot be expected to hold the same opinions, they can unite in a common objective and sustain common principles.

—Franklin Pierce

The test of leadership is not to put greatness into humanity, but to elicit it, for the greatness is already there.

—James Buchanan

I don't like that man. I must get to know him better.

—Abraham Lincoln

FOR YOUR CONSIDERATION
Quotes from Selected US Presidents *(continued)*

If you always support the correct principles then you will never get the wrong results!

—Andrew Johnson

The object of love is to serve, not to win.

—Woodrow Wilson

[People] are not prisoners of fate, but only prisoners of their own minds.

—Franklin D. Roosevelt

It is amazing what you can accomplish if you do not care who gets the credit.

—Harry S. Truman

Efforts and courage are not enough without purpose and direction.

—John F. Kennedy

A leadership is someone who brings people together.

—George W. Bush

Change will not come if we wait for some other person or some other time. We are the ones we've been waiting for. We are the change that we seek.

—Barack Obama

Resources

Not even the most effective policy can be implemented without the available financial and administrative resources. Financial feasibility tests are conducted during the policy development process to ensure that adequate funds are available and to verify that the benefits will outweigh the costs. Administrative feasibility studies examine how policy can be translated into programs and carried out under an existing or new infrastructure.

Stakeholders of Health Policy

As shown in the framework of health policy determinants (exhibit 1.5), stakeholders frequently exert a powerful influence on health policy development. Indeed, as shown in later chapters, stakeholders influence not only the formulation of health policy but also its implementation and modification.

interest group
A collective of individuals or entities that hold a common set of preferences on a particular health issue and often seek to influence policymaking or public opinion.

lobbying
Activities seeking to influence an individual or organization with decision-making authority.

One type of stakeholder is the **interest group**. Interest groups are composed of individuals or entities that at least nominally present a unified position on their preferences regarding a particular health problem or its solution. **Lobbying** by organized interest groups is a common component of the political process in a democracy. Because stakeholders often differ in their positions and preferences, and coalition building is usually specific to an issue, interest groups are not always static, and their formations typically depend on the particular health problem under policy consideration. The following paragraphs introduce the major stakeholders in US health policy.

Consumers and patients. Consumers and patients are typically the intended beneficiaries of health policy, because they suffer the consequences of a health problem that could be the target of health policy. However, consumers have diverse health problems, and yet the prioritization of those problems is not always determined by consumers. Furthermore, consumers with the same health problem may have diverse interests and different cultural norms. Consumers' views may also be influenced by their own economic status, such as whether they currently have health insurance coverage. For example, those without insurance are more likely to favor a government program or reform that expands insurance coverage. Those with insurance coverage are more concerned with lowering the premiums or copayments for their insurance coverage. The more their interests converge and the more organized they become as a collective, the more likely consumers are to influence policy development.

Healthcare providers. Healthcare providers—individuals who provide direct patient care—include physicians, nurses, dentists, pharmacists, and other health professionals. Traditionally, healthcare providers value autonomy and have an interest in preserving the prestige and expertise associated with their careers. The size and diversity of the US healthcare workforce often result in a less-than-unified voice in the healthcare provider community—for example, between physicians and nonphysicians, primary care doctors and specialists, and public health and medical care.

Healthcare organizations. Healthcare organizations are the institutional settings in which healthcare providers work or provide care to patients. Traditional settings include hospitals (inpatient and outpatient) and community-based offices. Organizational settings now also include diagnostic imaging centers, occupational health centers, and psychiatric outpatient centers, among others. Administrators of these institutions may share an interest, for example, in serving their customers and maintaining the financial well-being of their institutions at the same time (see the For Your Consideration box titled "Interests Common to Healthcare Administrators"). However, like healthcare providers, different healthcare institutions have different priorities and interests, often tied to consumers, services, and payments.

FOR YOUR CONSIDERATION
Interests Common to Healthcare Administrators

Healthcare administrators are responsible for overseeing a health facility or department. According to the Health Careers Center (2004), they "plan, coordinate, and supervise" all activities in their area, including the work of staff members. Healthcare administrators also take responsibility for developing and implementing standards, operating procedures, and organizational policies that help the facility operate at peak efficiency, and they can be involved in developing and expanding programs in new areas, such as medical research and preventive care.

Payers and insurers. Payers and insurers can be private (commercial or other private enterprise) or public (government-operated entity). Private insurance is offered by commercial insurance companies (e.g., Aetna, Prudential); Blue Cross/Blue Shield; self-insured employers; and managed care organizations (MCOs), such as an HMO or a **preferred provider organization (PPO)**. Public insurance includes federally funded programs such as **Medicare**, which provides insurance for the elderly and certain individuals with disabilities; **Medicaid**, for the indigent; TRICARE, for US Department of Defense active military service personnel and their families; and Veterans Affairs programs, for former armed forces personnel. One interest that private insurance companies and MCOs have in common is maintaining their share of the health insurance market; in contrast, a main interest of public payers is ensuring coverage for vulnerable populations at reasonable costs.

Regulators. In addition to providing public insurance for the elderly and indigent, the government functions as a regulator, seeking to make sure that basic services are provided, their quality is maintained by the providers, and the overall cost of providing care in the community or sector is contained.

Medical device and pharmaceutical manufacturers. Manufacturers of medical equipment and drugs have a vested interest in health policy, especially with regard to payments for the use of their products. With the rapid advancement of science and technology, numerous devices and types of equipment have been developed for medical use, such as fetal monitors, computerized electrocardiograph machines, and magnetic resonance imaging machines. Such equipment is useful in the diagnosis of diseases but is expensive.

Educational and research institutions. Health policy affects the type and quantity of healthcare providers to be trained, making educational institutions another significant stakeholder. Similarly, research facilities are affected by health policy that directs the types of research to be conducted.

Businesses and corporations. American businesses and corporations have a keen interest in health policy that, among other issues, mandates healthcare coverage levels. These stakeholders seek to minimize the cost they incur for providing health insurance as a benefit to their employees.

preferred provider organization (PPO)
A managed care organization that offers unrestricted provider options to enrollees and discounted fee arrangements to providers.

Medicare
Federal government insurance plan for persons aged 65 years or older, individuals with disabilities who are entitled to Social Security benefits, and people who have end-stage renal (kidney) disease.

Medicaid
Jointly administered federal and state insurance plan for the indigent.

WHY IS IT IMPORTANT TO STUDY HEALTH POLICY?

Understanding how health policy is developed is the first step toward influencing policy. And only by knowing the health policy determinants and how they manifest in particular contexts can one appreciate the key features of policy development (see the For Your Consideration box titled "Why Is an International Perspective of Health Policy Useful?").

In addition, the study of health policy allows an individual or a group the ability to engage in efforts to improve it. For example, *policy entrepreneurs*—those who work from outside the government to introduce and implement innovative ideas into public-sector practice—are instrumental in bringing new ideas and fundamentally changing the usual way of practice.

FOR YOUR CONSIDERATION

Why Is an International Perspective of Health Policy Useful?

Countries vary in their demographics, population health needs, and social norms, but they share commonalities, such as population aging and leading causes of death. Learning from the best practices of other countries—compared with a country developing its own evidence-based approaches—can significantly shorten the time in which the country improves healthcare delivery. Incorporating global trends in health policymaking may also help exert influence on global health policy (Jones, Clavier, and Potvin 2017). Just as the US experience and lessons can benefit other countries as they consider healthcare delivery reform, so, too, can the United States learn from the experiences of other countries in expanding its health policy options. One result of this convergence of international health policies is the increase in similarity of global trends.

Industrialized countries need not limit their examination to other developed countries; the experiences of developing countries can also be instructive (Dixon and Alakeson 2010; Modisenyane, Hendricks, and Fineberg 2017). Such countries tend to focus on basic and community-oriented public health and primary care, which may prove instructive for developed countries as they struggle to control costs and improve outcomes.

Furthermore, the importance of health policy itself is another reason to study it. As shown in the framework of health determinants (exhibit 1.3), policy is an integral component of environmental health determinants. Improvements to policy development, such as ensuring that a policy truly addresses a critical health problem and that it is developed in an expeditious manner, can significantly improve a population's overall health. In addition, policy influences other determinants of health and therefore must be thoroughly understood to enhance the country's health system.

KEY POINTS

- Health determinants, such as environment and social structure, interact with biological factors and medical care to determine an individual's health status.
- Health policy formulation is influenced by broad determinants (health problems, sociocultural norms, and political system) and narrow determinants (solutions, stakeholders, leadership, and resources).
- The major stakeholders in US health policy include consumers and patients, healthcare providers, healthcare organizations, payers and insurers, regulators, medical device and pharmaceutical manufacturers, educational and research institutions, and businesses and corporations.

- US health policy has evolved over time and will continue to change in response to new health concerns and interests.

CASE STUDY QUESTIONS

CASE STUDY 1

After researching the events surrounding the healthcare reform initiatives undertaken by the Clinton, Obama, and Trump administrations, answer the following questions:

1. What factors might explain why the Obama plan succeeded? What events may have caused the Clinton plan and Trump's initial attempts to fail?
2. How do you think the failure of the Clinton healthcare reform effort influenced the outcome of the congressional election that followed?
3. Why does health reform continue to be controversial despite widespread opinion in favor of change?

CASE STUDY 2

After researching the current developments in healthcare reform, answer the following questions:

1. What are the similarities and differences in the ACA between the Obama administration and the beginning of the Trump administration?
2. Why do the Republican and Democratic parties have sharp disagreements over how healthcare reform should take place in the United States? Which segments of the American public do they represent?
3. Why is healthcare reform so arduous in the history of the United States? In addition to the presidency and Congress, what are the other determinants for successful healthcare reform?

FOR DISCUSSION

1. How is *health* defined?
2. What are the major determinants of health? How do they interact?
3. What is health policy, and what are its determinants?
4. Who are the stakeholders of health policy? What kinds of concerns does each stakeholder have about the current US healthcare system?
5. What are the major types of health policies? Cite an example of each type.
6. Why is it important to study health policy?
7. Why is it important to have an international perspective in health policy development?

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PART II

HEALTH POLICYMAKING

This section consists of three chapters that describe how health policy is made in the United States and elsewhere in the world. Chapter 2 describes policymaking at the US federal level, and chapter 3 illustrates the process at the US state and local levels and in the private sector. Chapter 4 covers health policymaking by international agencies such as the World Health Organization and provides examples of the process in selected countries. The spectrum of health policymaking presented in these chapters is intended to provide students with a broad perspective of health policy development. Such knowledge is critical in preparing students to examine the specific health issues commonly addressed by health policy in the United States and in other countries.

CHAPTER 2

FEDERAL HEALTH POLICYMAKING

> *In any moment of decision the best thing you can do is the right thing, the next best thing is the wrong thing, and the worst thing you can do is nothing.*
>
> —Theodore Roosevelt

> *If your actions inspire others to dream more, learn more, do more, and become more, you are a leader.*
>
> —Andrew Jackson

LEARNING OBJECTIVES

After completing this chapter, you should be able to

- understand the US policymaking process at the federal level,
- discuss the policy formulation stage,
- provide examples of the types of health and healthcare policies developed,
- understand the policy implementation stage,
- describe the policy modification stage,
- analyze the characteristics of health policymaking in the United States, and
- appreciate the role of interest groups in US health policymaking.

CASE STUDY 1

THE DEVELOPMENT OF MEDICARE AND MEDICAID

In 1965, the US Congress passed amendments to the Social Security Act, creating the Medicare and Medicaid programs. With this legislation, for the first time in US history, the government assumed direct responsibility for paying some of the healthcare costs on behalf of two vulnerable population groups: the elderly (Medicare) and the poor (Medicaid).

Prior to 1965, these populations were forced to rely on their own resources, limited public programs, or charity from hospitals and individual physicians to obtain healthcare services. The unemployed, too, received little assistance, as private health insurance—the only widely available source of payment for healthcare—was available primarily to middle-class working people and their families.

In the United States, government assistance for the poor and the elderly emerged as a solution when the market alone did not ensure access to care for these vulnerable populations. Most poor and elderly individuals could not afford the increasing costs of healthcare without assistance. Moreover, because the health status of these groups was significantly worse than that of the general population, the poor and the elderly required a higher level of healthcare services. The elderly, in particular, experienced higher incidence and prevalence of disease compared with younger groups.

Through the legislative process, a three-tier program was developed. The first two tiers constituted Part A and Part B of Medicare, as outlined in Title XVIII of the Social Security Amendments. Medicare Part A finances hospital insurance and partial nursing home coverage for the elderly, and Part B covers their physicians' bills.

The third tier of publicly financed insurance, Medicaid, as set forth in Title XIX of the Social Security Amendments, extends federal matching funds to the states to cover healthcare costs for the poor. Recipients of Medicaid are deemed eligible on the basis of means testing—establishing financial need—administered by each state. Medicaid is available to the indigent of all age groups.

Although adopted simultaneously, Medicare and Medicaid reflect sharply different traditions. Medicare has received broad grassroots support and carried no inherent class distinction; Medicaid, on the other hand, is burdened by the stigma of public welfare. Medicare has uniform national standards for eligibility and benefits, whereas Medicaid varies from state to state in eligibility and benefits. Medicaid, in essence, ushered in a two-tier system of medical care delivery whereby recipients may experience more limited access than the privately insured, because the reimbursement fees set by the government are low and, as a consequence, some physicians refuse to accept Medicaid patients.

CASE STUDY 2

THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996

The Health Insurance Portability and Accountability Act (P.L. 104–191, 110 Stat 2023 [1996]), known as HIPAA, is a law designed to improve the efficiency and effectiveness of the US healthcare system. HIPAA was passed on August 21, 1996, and consists of two parts. Title I of HIPAA protected health insurance coverage when people lost or changed their job and addressed issues such as preexisting conditions. Title II of HIPAA, known as the administrative simplification provisions, specified standards for the new but expanding use of electronic transmission of health information. At the time, Congress also recognized that developments in electronic technology could endanger the privacy of health information. Thus, HIPAA mandated the development of nationwide security standards and safeguards for the use of electronic healthcare information (Brailer and Blumenthal 2010).

In accordance with the administrative simplification provisions, the US Department of Health and Human Services (HHS) developed the two-part HIPAA Privacy and Security Rule, which addressed the use and disclosure of individuals' identifiable health information by the covered entities. The effective compliance date of the Privacy Rule was April 14, 2003 (CDC 2003). The Privacy Rule defined *protected health information* (PHI) as "any information held by a covered entity which concerns health status, the provision of healthcare, or payment for healthcare that can be linked to an individual" (CDC 2003).

The Security Rule, which complemented the Privacy Rule, had an effective compliance date of April 21, 2005 (HHS 2003). Whereas the Privacy Rule pertains to all PHI, the Security Rule specifically addresses electronically stored PHI (ePHI) and specifies three types of security safeguards required for compliance: administrative, physical, and technical (HHS 2017). Specifically, administrative safeguards are policies and procedures designed to clearly show how the entity will comply with the act; physical safeguards control physical access to areas of data storage to protect against inappropriate access; and technical safeguards protect communications containing PHI transmitted electronically over open networks.

In March 2006, HHS established the Enforcement Rule, which specified penalties for the failure of covered entities to fully comply with the HIPAA Privacy and Security Rules, instituted procedures for investigations and hearings for violations, and specified fines for avoidable breaches of ePHI resulting from failure to follow safeguards (HHS 2006).

HIPAA was greatly strengthened in 2009 with the introduction of the Health Information Technology for Economic and Clinical Health (HITECH) Act, which widened the scope of privacy and security protections and increased the penalties for HIPAA violations (Blumenthal 2010). With the primary goal of promoting and expanding the adoption of health information technology and meaningful use, the HITECH Act also included rules to improve privacy and security. The HITECH Act stipulated that entities covered by HIPAA must report data breaches that affect 500 or more persons to HHS, the news media, and the people affected by the data breaches. This requirement was subsequently extended in the Final Omnibus Rule of March 2013.

The Final Omnibus Rule of 2013 is the most recent act of legislation in HIPAA history. The rule filled gaps in the existing Security Rule and breach notification portions of the HITECH Act, and it made the most extensive changes since HIPAA was first implemented. The most important changes included specifying the encryption standards of ePHI, establishing more objective standards for assessing a data breach, and holding HIPAA business associates to the same standards for protecting PHI as covered entities (Goldstein and Pewen 2013).

The Final Omnibus Rule has achieved its goals of making covered entities more aware of the HIPAA safeguards and HITECH Act provisions to which they must adhere. Many healthcare organizations have taken measures to comply, such as using secure messaging solutions for internal communications, encrypting data on computer networks and portable devices, and implementing initiatives to archive e-mails securely. As health information technology rapidly advances and demands for access to more extensive health information grow, continuous policy efforts are needed to enhance the digitization of health data, on the one hand, and build public trust in data sharing, on the other.

In the United States, health policymaking takes place in the federal, state, and local governments as well as in the private sector, but it is federal health policy that has the most profound impact on care delivery. This chapter presents health policymaking at the federal level. Chapter 3 considers the process at other levels of government and in the private sector in the United States, and chapter 4 discusses the processes adopted in the international arena.

THE US POLITICAL SYSTEM

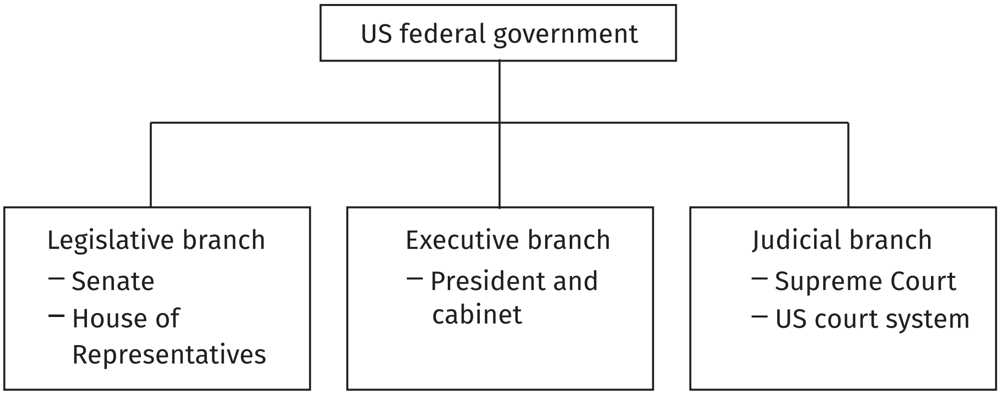
The political system in the United States operates through three branches of government: legislative, executive, and judicial (as illustrated in exhibit 2.1).

LEGISLATIVE BRANCH

The legislative branch of the federal government is referred to as the US Congress and is composed of two chambers: the House of Representatives and the Senate. Congress is the most active of the three branches in policymaking by way of the statutes or laws it enacts. This body of **legislators** operates by virtue of three powers that drive its influence in health policymaking:

legislator
An individual responsible for making or enacting laws.

Exhibit 2.1
The US Political System—Federal Level



1. The US Constitution grants Congress the *power to use any reasonable means not directly prohibited by the Constitution to carry out the will of the people*. With this mandate, Congress can enact laws influencing a broad array of health policy issues.
2. Congress possesses the *power to tax*, which allows it to regulate—albeit indirectly—the health behavior of individuals, organizations, and states. Taxes on cigarettes, for example, are intended to reduce individuals' cigarette consumption; tax exemptions for employer health benefits are designed to promote increased insurance coverage for working people.
3. Congress is granted the *power to spend*. It allocates funding as it deems appropriate to support the public's health through federal programs, such as Medicare. It may also restrict the manner in which states use those funds, such as establishing minimum requirements for basic services offered by the joint federally and state-funded Medicaid program.

EXECUTIVE BRANCH

The president of the United States and the department heads—referred to as cabinet members—within the president's administration constitute the executive branch of the federal government. This branch crafts **legislation** that reflects the administration's preferred policies and attempts to convince legislators to enact those policies. Executive branch members also make policies by establishing rules and regulations used to implement statutes and laws.

legislation
Law made by the government to achieve a particular objective.

JUDICIAL BRANCH

statutory authority
The capacity to enforce legislation on behalf of the government as granted by the US Constitution.

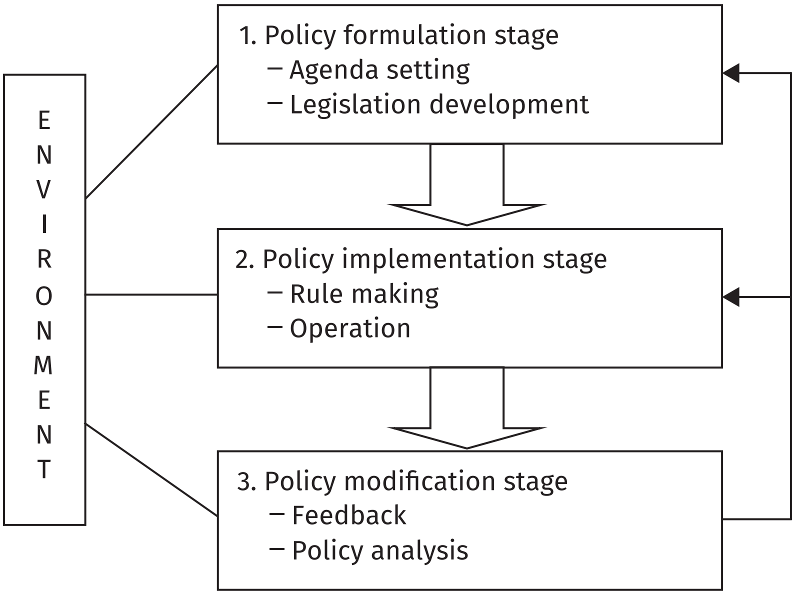
The judicial branch, made up of the US court system, influences health policy through its **statutory authority** to interpret the law. Whenever a court interprets a *statute* (a law enacted by a legislative body), establishes a judicial precedent, or interprets the US Constitution, it makes policy. The courts also have the power to declare that federal or state laws are unconstitutional. Because federal judges are appointed for life, they are generally not subject to the types of conflicts of interest that may accompany the reelection efforts of legislators and the president.

POLICYMAKING PROCESS AT THE FEDERAL LEVEL

The three major stages of policymaking are policy formulation, policy implementation, and policy modification. Exhibit 2.2 displays a framework of health policymaking at the federal level (Longest 2016).

The relationships among the three stages of policymaking are not as straightforward as they may seem. On the one hand, they are consecutive. Policy formulation, which includes setting the policy agenda and developing the related legislation, begins the policymaking process. That stage is followed by policy implementation, which includes making the rules and putting them into operation. Policy modification concludes the process. In this stage,

EXHIBIT 2.2 The Process of Health Policymaking



Source: Information from Longest (2016).

policies are adjusted as necessary to accommodate real-world application.

On the other hand, the three stages are interactive and reinforcing. For example, the rules and regulations proposed in the implementation stage to solidify the policy often become the laws and policies themselves. Policymaking rarely forgoes modification; as time passes, new priorities and needs arise, which in turn affect the formulation of new policies (see the For Your Consideration box titled "Public Policy as Health Policy"). The sections that follow describe the three stages of the policymaking process in greater detail.

FOR YOUR CONSIDERATION
Public Policy as Health Policy

Health policies often develop as a by-product of existing public policies. For example, important changes in the US healthcare system came about after the end of World War II in 1945. Policies were implemented to exclude fringe benefits from income or Social Security taxes, and the Supreme Court ruled that employee benefits, including health insurance, could be legitimately included in the collective bargaining process. Used to compete for skilled workers, employer-provided health insurance benefits grew rapidly in the mid-twentieth century.

What other health policy initiatives were developed as the result of public policy changes?

POLICY FORMULATION

The two main components of the policy formulation stage are agenda setting and legislation development.

Agenda Setting

Agenda setting refers to the selection of a health problem as a policy target. A health problem can come to the attention of policymakers through multiple pathways. When several pathways converge on a health problem, its chances of appearing on the policy **agenda** are increased (see the Key Legislation box titled "Mental Health Parity and Addiction Equity Act"). Here we describe the most common pathways to agenda setting.

agenda setting
The ability to influence the priorities of issues for policy consideration.

agenda
Issues targeted for policy consideration.

KEY LEGISLATION
Mental Health Parity and Addiction Equity Act

The Mental Health Parity and Addiction Equity Act (MHPAEA) of 2008 requires health insurers and group health plans to provide the same level of benefits for mental health or substance abuse treatment and services that they do for medical and surgical care. The Affordable Care Act (ACA) of 2010 further expanded MHPAEA requirements by ensuring that qualified plans offered on the ACA health insurance marketplace cover many behavioral health treatments and services (Center for Consumer Information and Insurance Oversight 2018). Whereas the

(continued)

KEY LEGISLATION
Mental Health Parity and Addiction Equity Act *(continued)*

regulations of MHPAEA approved in 2008 only applied to the commercial market and not to Medicaid and the Children's Health Insurance Program (CHIP), the final regulation published in 2013 applies these changes to Medicaid and CHIP as well (HHS 2013). This MHPAEA regulation also promotes greater consistency of care for patients across states.

The last regulation of MHPAEA helps ensure equitable treatment at intermediate levels of care, such as in residential and intensive outpatient settings; transparency as required by health plans and by law, including disclosure rights; equity among all plan standards, including geographic limits, facility-related limits, and network quality; and the removal of ambiguous or unnecessary modifications to the parity rule (HHS 2013).

Impact of the health problem. The health problems that lead to legislative action typically either affect the general population or have a concentrated impact on a small but visible subpopulation. For example, *bioterrorism*—the deliberate release of viruses, bacteria, or other germs (agents) to cause illness or death in people, animals, or plants (CDC 2006; Shi and Singh 2017)—emerged as a health problem targeted for policymaking following 9/11, the September 11, 2001, terrorist attacks on the World Trade Center in New York and the Pentagon in Washington, DC. To help prevent, protect against, and respond to any future acts of terrorism in the United States, President George W. Bush signed into law the Homeland Security Act of 2002, ushering in a new era in health protection in the United States (see the For Your Consideration box titled "Homeland Security Act").

Public opinion. Policy action is most likely when public interest is high and the degree of conflict or dispute is low. Individuals tend to be concerned with the potential impact of

FOR YOUR CONSIDERATION
Homeland Security Act

The Homeland Security Act (HSA) of 2002, formulated following the 9/11 terrorist attacks, created the US Department of Homeland Security and the new, cabinet-level position of secretary of Homeland Security. The primary mission of this department is to prevent terrorist attacks within the United States, reduce the vulnerability of the United States to terrorism, and minimize the damage and assist in the recovery from terrorist attacks that occur within the United States.

HSA has a significant impact on US foreign and domestic policies. How do you think it has affected health policy in the United States and abroad? Can you think of examples?

new healthcare bills on their personal lives and well-being (see the For Your Consideration box titled “Public Opinion and Policymaking: Universal Healthcare”). Policymakers must structure their issues in terms of the concerns of the broad public to achieve high relevance and support (see the Learning Point box titled “What Research Says About the Impact of Public Opinion”).

FOR YOUR CONSIDERATION

Public Opinion and Policymaking: Universal Healthcare

The persistent failure of the United States to create a universal healthcare system is an example of the influence that the public holds over healthcare policy. Although US residents generally believe that offering healthcare to all is “the right thing to do,” they also express concern that its implementation could adversely affect their own financial status—for example, by paying for tax or insurance premiums to cover the previously uninsured.

What do you think? Should the United States expand coverage mandated by the Affordable Care Act to all US residents as a universal approach to healthcare? How would you frame universal coverage legislation to address the concerns of the public at large?

LEARNING POINT

What Research Says About the Impact of Public Opinion

The relationship between public opinion and policymaking has been the subject of numerous studies in the twenty-first century. A 2003 review found that the impact of public opinion on policy was substantial and that the prominence of the policy enhanced the impact of public opinion. In addition, the impact of opinion remained strong even when taking into account the activities of political organizations and elites (Burstein 2003). Another study found that the “mood of the public” was often aligned with Supreme Court decisions, with a more liberal mood suggesting liberal decisions and a more conservative mood suggesting conservative decisions. When researchers tried to understand why this was so, through quantitative data and statistical methods, the reasons were still not clear (Epstein and Martin 2010). A third study concluded that citizens sometimes had influence over a democratic government, and the movement of a policy tended to be in the direction of public opinion; however, three caveats must be considered. First, politicians and policy entrepreneurs had room to maneuver policy in ways that were not visible to the public. Second, the causal impact of public opinion was hard to independently assess, given the ability of politicians to shape views, as well as contradictions in public views across policy issues. Third, the extent of responsiveness varied widely across

(continued)

LEARNING POINT
What Research Says About the Impact of Public Opinion *(continued)*

issues and at given points in time (Manza and Cook 2002). Additional research on the impact of public opinion on health policy is needed to further classify and understand these conclusions.

When considering public opinion on government programs in general, one study demonstrated that the delivery mechanism of a government program could dramatically affect citizens' likelihood of supporting that program. Americans were found to be more favorably disposed toward government interventions through taxes than through more direct channels. Citizens' responsiveness to particular delivery mechanisms often varied with ideology. In the same study, conservative support for tax breaks was much higher than for otherwise identical cash payment programs across the board, while this effect was relatively muted for liberals (Haselswerdt and Bartels 2015).

The relationship between public opinion and healthcare reform received significant attention in the second decade of the twenty-first century. One study reported that gubernatorial ACA announcements and grant activity increased support for the ACA in nearby states, reflecting spillover effects that influenced opinions in other states. States were more likely to emulate other states with similar ACA policy preferences when deciding when to announce their ACA decisions (Pacheco and Maltby 2017). A 2017 infographic highlighted public opinion on healthcare reform in the United States (Kirzinger et al. 2017). When considering public opinion across party lines, both Democrats and Republicans noted that lowering out-of-pocket costs for healthcare was a top priority. Consensus on other topics varied, with more Republicans viewing ACA repeal as a top priority (63 percent versus 21 percent) and more Democrats viewing lowering the cost of prescription drugs as a priority (67 percent versus 55 percent). In March 2017, 49 percent of the public viewed the ACA favorably while 44 percent viewed it unfavorably, and 64 percent of the public supported guaranteeing a certain level of health coverage for seniors and low-income people, even if the federal government's spending and role increased (Kirzinger et al. 2017).

When considering public views of Medicaid, Kaiser Family Foundation (KFF) polls found that a majority of the public (74 percent) held a favorable view of Medicaid, although this figure varied slightly across party lines (84 percent of Democrats, 76 percent of independents, and 61 percent of Republicans). A majority of Americans believed that Medicaid worked well for low-income people and that spending should not be decreased, yet only about 40 percent of Americans reported being aware that the House of Representatives had passed a plan that made major reductions to Medicaid funding. Republicans were more likely to support reducing federal funding for Medicaid expansion but were divided in their opinions concerning how Medicaid should be funded (KFF 2017).

Several organizations have collected public opinion data related to healthcare and policy, including the Pew Research Center, American National Election Studies, General Social Survey, National Annenberg Election Survey, and Gallup Poll (Michigan State University 2018). Research on the impact of public opinion on public policy continues.

Presidential involvement. The president may form a **policy position** on the basis of input from a variety of sources, including personal interests; recommendations of advisers, cabinet members, and agency chiefs; campaign information; expert opinions; and public opinion polls. The president must firmly believe in the merits of an issue to be a strong advocate for a targeted policy. For example, President Barack Obama, a Democrat, declared a major goal of his administration to be a drastic reduction in the number of Americans who have no health insurance coverage. His healthcare agenda was accepted as public policy through the passage of the ACA in 2010, which was achieved by uniting the Democratic Party behind this cause. The election of Republican Donald Trump as president in 2016, combined with the retention of a Republican majority in the House and Senate, raised uncertainty about the future of the ACA, the structure and funding of the country's public health insurance programs (Medicare, Medicaid, and CHIP), and the future direction of health policy in the United States (Marmor and Gusmano 2018).

policy position
The stand taken regarding a particular issue. A president's policy position often influences the focus and orientation of legislation.

Legislator interest. Legislators influence agenda setting by championing a health issue that either they personally embrace or their constituents demand. The late Senator Edward "Ted" Kennedy (D-MA), for example, became a national leader and advocate for improving mental health care following the diagnosis of his son Patrick with bipolar disorder.

Media coverage. In a democracy whose fundamental freedoms include freedom of the press, the media—newspapers, magazines, radio, television, websites, and even social media—serve as a layer of checks and balances outside of the government's purview to guard against the abuse of power by public officials.

In addition, the media heightens awareness of issues through investigative reporting and frequent exposure of findings, which may produce strong public reaction that leads to new regulations and laws. The reporting of Walt Bogdanich (1987) for the *Wall Street Journal* is such an example. Bogdanich documented evidence that poorly trained laboratory technicians were misreading Pap tests, leading to false diagnoses of cervical cancer or missed diagnoses (Otten 1992). His reporting prompted Congress to pass the Clinical Laboratory Improvement Amendments in 1988, prescribing minimum standards of training, testing, and workloads for laboratory technicians. As another example, the media advocacy activities implemented by the Florida Tobacco Control Program contributed to the passage of tobacco product placement ordinances in Florida (Niederdeppe, Farelly, and Wenter 2007). Media interventions can significantly influence policymakers by shaping public opinion, which in turn exerts pressure on policymakers to respond (Bou-Karroum et al. 2017; Waitzkin and Hellander 2016).

Legislation Development

Legislation development at the federal level takes place through the federal legislative process and the work of House and Senate committees.

Federal Legislative Process

Exhibit 2.3 summarizes the progression of US federal legislation, and the steps are described in greater detail in this section.

A bill introduced in Congress—either the House or the Senate—is assigned to a congressional committee by the **Speaker of the House** or the **Senate majority leader**. The committee chair forwards the bill to the appropriate subcommittee, which in turn forwards it to potentially affected agencies, holds hearings and hears testimony, and may amend the bill. The subcommittee and then the full committee may recommend the bill for consideration by the entire body of Congress, not recommend it, or defer it by **tabling legislation**.

Assuming the bill is approved by the committee, the full House or Senate hears it and may make an **amendment**; the bill can be approved with or without amendments and is then sent to the other chamber for consideration. The bill may go back and forth between the chambers several times for reconciliation before an identical version can be considered and approved by both chambers.

After the House and Senate have approved an identical bill, it is presented to the president for a signature. The president has three options in acting on legislation:

1. Sign the legislation, at which point it becomes law.
2. **Veto**, or reject, the legislation, whereby the bill dies if a two-thirds majority of Congress cannot override the veto.
3. Neither sign nor otherwise act on the legislation, and it either
    - automatically becomes law after 21 days if Congress is in session or
    - results in a "pocket veto" if fewer than 21 days remain in the congressional session.

For an example of healthcare legislation signed into law by the president, see the Key Legislation box titled "Medicare Prescription Drug, Improvement, and Modernization Act of 2003."

KEY LEGISLATION
Medicare Prescription Drug, Improvement, and Modernization Act of 2003

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (P.L. 108-173), also called the Medicare Modernization Act (MMA), is a federal law of the United States that was enacted in 2003 (CMS 2018b). The MMA was signed into law by President George W. Bush on December 8, 2003, after passing in Congress (US Congress 2003).

The MMA's most highly touted feature is the introduction of an entitlement benefit for prescription drugs, through tax breaks and subsidies (US Congress 2003). In the years since

Speaker of the House
The presiding officer of the US House of Representatives, typically chosen from the majority party of the House.

Senate majority leader
Senate leader elected by the party that holds majority in the US Senate. The majority leader serves as the chief Senate spokesperson for the party and is responsible for scheduling the legislative and executive business of the Senate.

tabling legislation
An action undertaken by Congress to postpone consideration of a bill.

amendment
Change or addition to a piece of legislation under consideration in the US House of Representatives or Senate. Amendments can also be introduced in Congress to change a current federal law.

veto
As a verb, to unilaterally stop an official action; as a noun, the authority to do so.

KEY LEGISLATION

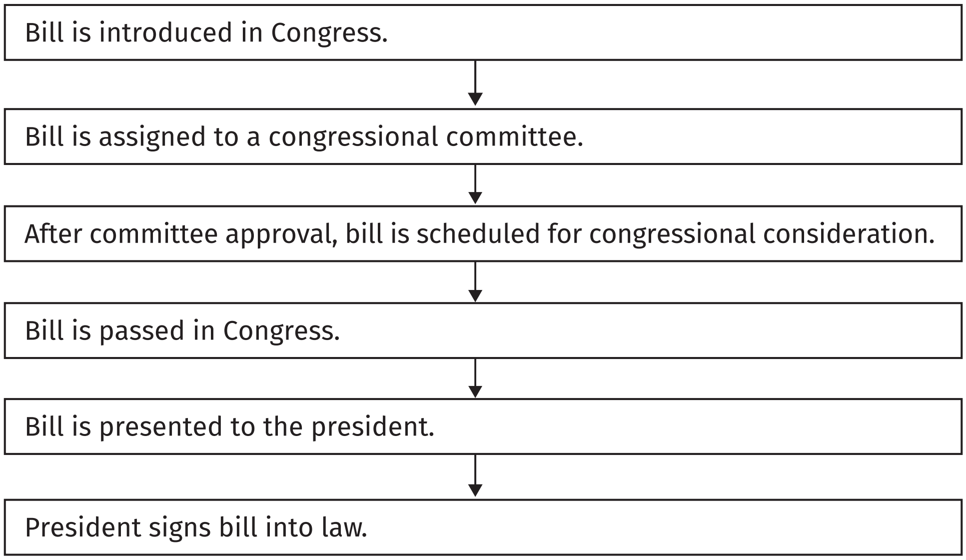
Medicare Prescription Drug, Improvement, and Modernization Act of 2003 *(continued)*

the creation of Medicare in 1965, the role of prescription drugs in patient care has significantly increased. As new and expensive drugs have come into use, patients—particularly senior citizens at whom Medicare was targeted—have found prescriptions harder to afford. The MMA was designed to address this problem. The benefit is funded in a complex way, reflecting diverse priorities of lobbyists and constituencies. The MMA provides a subsidy for large employers to discourage them from eliminating private prescription coverage to retired workers (a key AARP goal), prohibits the federal government from negotiating discounts with drug companies, and prevents the government from establishing a formulary, but it does not prevent private providers such as health maintenance organizations from doing so.

Rural, independent pharmacies may be negatively affected by MMA implementation as business shifts from cash to third-party reimbursement. The high degree of variation among states also has potentially important implications for the implementation of Prescription Drug Plan regions under the MMA (Fraher et al. 2005).

The projected price tag of a universal Medicare prescription drug benefit makes it more difficult to spend additional tax dollars on healthcare for other US populations. Regardless of whether this sea change in philosophy reduces the absolute dollars spent on healthcare for the elderly, it is certain to reduce the public-sector dollars spent on healthcare for the elderly (Channick 2006).

Exhibit 2.3
The Progression of Federal Legislation



House and Senate Committees

Committees, subcommittees, and legislative panels within both the House and the Senate directly influence legislation. For those most relevant to healthcare, see the Helpful Resources box titled "Congressional Committees Involved in Health-Related Legislation." Some implications of this fragmentation are discussed later in the chapter.

POLICY IMPLEMENTATION

After legislation has been signed into law, it is forwarded to the appropriate agency for implementation. The government's principal agency for implementing many of the health laws is HHS, whose mission is to protect the health of all Americans and provide essential human services, especially for those least able to help themselves (HHS 2018). The following operating divisions within HHS focus on specific areas of health concern:

- Administration for Children and Families
- Administration on Aging
- Agency for Healthcare Research and Quality

HELPFUL RESOURCES
Congressional Committees Involved in Health-Related Legislation

The House *Committee on Ways and Means* (http://waysandmeans.house.gov) has sole jurisdiction over Medicare Part A, Social Security, unemployment compensation, public welfare, and healthcare reform.

The House *Energy and Commerce Committee* (https://energycommerce.house.gov) oversees legislation relating to telecommunications, consumer protection, food and drug safety, public health, air quality and environmental health, energy supply and delivery, and interstate and foreign commerce in general. This committee has jurisdiction over Medicaid, Medicare Part B (shared with Ways and Means), and matters of public health.

The House *Committee on Appropriations* (http://appropriations.house.gov) and its Labor, Health and Human Services, Education, and Related Agencies subcommittees are responsible for allocating and distributing federal funds for individual health programs (except those for Medicare and Social Security, which are funded through the Social Security Trust Fund).

The Senate *Committee on Health, Education, Labor and Pensions* (http://help.senate.gov) focuses on health, education, and workplace issues by proposing changes to the healthcare system, the minimum wage, working conditions and compensation, and welfare and labor laws.

The Senate *Committee on Finance* (http://finance.senate.gov) and its Subcommittee on Health, similar to the Ways and Means Committee in the House, have jurisdiction over taxes and revenues, including matters related to Social Security, Medicare, Medicaid, and Maternal and Child Health (Title V of the Social Security Act).

- Agency for Toxic Substances and Disease Registry
- Centers for Disease Control and Prevention (CDC)
- Centers for Medicare & Medicaid Services (CMS)
- Food and Drug Administration
- Health Resources and Services Administration
- Indian Health Service
- National Institutes of Health
- Office of Inspector General
- Substance Abuse and Mental Health Services Administration

The assigned agency develops rules and regulations (the rule-making component), and the proposed rules and regulations are published in the ***Federal Register*** for public comment and reaction before they are finalized. Then they are put into operation.

Federal Register
A publicly accessible source that publishes presidential and federal agency documents; a daily publication of the US federal government.

Rule Making

Rule making refers to the process by which implementation agencies set detailed rules and regulations for the application of laws. In this process, experts from multiple disciplines and backgrounds, such as science, economics, and industry, are brought together to agree on the rules by which the new law will be enforced. During the preliminary stage of information collection and as part of the comment or negotiation period, the public—both individuals and groups—may also have the opportunity to provide input on the terms of the proposed rule. After the rules or regulations are finalized, they become the guidelines for operationalizing the law.

Operation

Legislation is operationalized by the HHS agency assigned to develop the regulations to implement or enforce it. This portion of the implementation process focuses on carrying out the rules or regulations in an *efficient* and *effective* manner: The program must meet economic constraints while delivering concrete services to the target population (for an example of a newer program facing such challenges, see the Key Legislation box titled "Medicare Access and CHIP Reauthorization Act of 2015"). The ability to attain the policy objective depends on the presence of a host of requirements, including the following:

- The logic of the potential solution is sound.
- The structure is in place.
- Program activities are designed to reflect the policy intent and logic model (see Shi, Oliver, and Huang [2000] for a discussion of logic models).

- Program activities are carried out effectively and efficiently.
- Unintended outcomes will not jeopardize the continuation of the program.
- External factors will not jeopardize the impact of the program.

KEY LEGISLATION

Medicare Access and CHIP Reauthorization Act of 2015

The Medicare Access and CHIP Reauthorization Act (MACRA) of 2015, commonly called the "Permanent Doc Fix," is a US statute (US Congress 2015; US GPO 2015) that revises the Balanced Budget Act of 1997 and changes the payment system for doctors who treat Medicare patients.

As described by Saleh and Shaffer (2016), MACRA led to the formation of two reimbursement paradigms: the merit-based incentive payment system (MIPS) and alternative payment models (APMs). MACRA effectively repealed the CMS sustainable growth rate (SGR) formula while combining several CMS quality-reporting programs. As such, MACRA represents an unparalleled acceleration toward reimbursement models that recognize value rather than volume. MACRA's primary provisions include changes to the way Medicare physicians are reimbursed, increased funding, and extension of CHIP (Orszag and Emanuel 2010). MACRA-related regulations also address incentives for use of health information technology by physicians and other providers. Under MACRA, the HHS secretary is tasked with implementation of MIPS, which consolidates three incentive programs into one, for eligible physicians (CMS 2018a).

The United States is set to transition from a fee-for-service system, which has allowed physicians and providers to bill Medicare and Medicaid for services they provided to their patients, to a pay-for-performance system, using MIPS, APMs, and accountable care organizations. The new model will now require the provider to provide information on the quality of service being given, how valuable it is to the patient, and the accountability that the provider has to the treatment being performed (Hirsch et al. 2016). In replacing the SGR with MIPS, MACRA paves the way for better benchmarks by providing a strong incentive for physicians to participate in APMs (US Congress 2015). Where evidence of their effectiveness is strong, bundled payments can be mandated. The proposal by Medicare to mandate bundled payments for joint replacements and to transition to a regional benchmark is encouraging, although many aspects of it are problematic (Miller 2015).

MACRA is the most influential health legislation since the ACA and represents a cohesive movement toward value-based payment reform. MACRA contains several untested rulings that will require detailed attention from orthopedic surgeons and healthcare institutions. Although MACRA has eliminated the historical frustrations associated with SGR, surgeons must now choose which payment model to pursue. Future decisions will need to incorporate a more comprehensive look at the advantages and disadvantages of MIPS and APMs in each unique practice environment to determine which approach will best serve patients in the short and long terms.

Other factors may also emerge in the operational stage of policy implementation, such as unexpected events or influence from additional determinants (see chapter 1) that may compromise policy success. An example of uncontrolled determinants is the current prevalence of diabetes and obesity. Since the 1970s, the rate of diabetes and its main contributing factor, obesity, has steadily increased, triggering major—albeit largely failed—policy initiatives to combat this health problem. One reason these initiatives failed is that they focused on changing behaviors (e.g., exercise, diet) but did not address other, larger environmental and social determinants that contribute to unhealthy behaviors. Examples of these determinants include a sedentary and stressful work or living environment; easy and cheap access to unhealthy food; limited access to safe, open space; and lack of facilities for exercise.

Policy Modification

Policy modification refers to revisions to the rules or regulations pertaining to a piece of original legislation in order to enhance the legislation's benefits to the targeted population, reduce its negative consequences, refine its policy objectives, or address other related issues. Policy modification typically takes place after the policy has been implemented and incorporates lessons learned from implementation. It may also occur during agenda setting, where existing similar policies inform the formulation of the new policy; legislation development, where the new development, any budgetary changes, or beneficiary demands dictate the adjustment of policy; rule making, where bureaucracy prompts the operationalizing of policy into regulations and interest groups to use their resources to maximize benefits or minimize negative consequences; and operation, where administrative structure and budgetary constraints often determine the scope of the enacted program (Committee for a Responsible Federal Budget 2016; Forest et al. 2015; Longest 2016).

The need to modify a policy can arise for a number of reasons, including the following.

Change in the logic model. In the course of implementing a policy, new evidence or theory comes to light that indicates weakness in the logic behind the policy. When the logic itself is flawed, it must be corrected by modifying the logic model (Brown and Best 2017; Shi, Oliver, and Huang 2000). This revision often necessitates revision of the policy itself.

Consequences of implementation. Although policymakers try to anticipate potential consequences, not all consequences can be foreseen, particularly if new events take place during policy implementation or if the consequences are negative for the policy beneficiaries or other stakeholders.

Policy analysis and evaluation. Results of policy evaluation often provide important insights into the modification of an existing policy. The Congressional Research Service is a legislative agency within the Library of Congress that provides Congress with information and analyses on already implemented policy.

Resource constraints. The economic climate may decline following a policy's implementation, and a particular issue may no longer be a priority in the face of an economic downturn and budget cuts.

Changing goals. The policy goals of one administration may differ from those of the next. As the administration of the US government changes every four years (in addition to the more frequent changes in Congress), many policy priorities change accordingly.

Interest group involvement. In the American democracy, interest groups influence policies at the modification stage as well as at the formulation and implementation stages. Interest groups that are adversely affected by a policy often expend extra effort to overturn or modify the enacted policy.

Oversight. The executive, legislative, and judicial branches each have **oversight** responsibility for enacted legislation. The following are examples for each branch:

- *Legislative branch*: Any congressional committee with **jurisdiction** over a particular policy can hold oversight hearings to review its progress and assess modification needs.
- *Executive branch*: In addition to the agencies assigned to a piece of legislation, the **Office of Management and Budget (OMB)** plays a critical role in supervising, assessing, and ensuring the successful implementation of a policy.
- *Judicial branch*: The courts may become involved in policy modification by ruling on how laws are interpreted and enforced, especially in disputes over the interpretation, application, and constitutionality of laws.

Incremental nature of policy development. In the American political landscape, radical policy is rarely enacted; most policies are incremental and evolve over time. In fact, the nature of policy development dictates modification of existing policies. Revisions to the 1935 Social Security Act have spanned decades, as a prime example.

oversight
Activities to review, monitor, or supervise the process of formulating, implementing, and modifying public policy.

jurisdiction
The authority to interpret and apply the law.

Office of Management and Budget (OMB)
The largest component of the Executive Office; implements and enforces the commitments and priorities of the president and assists executive departments and agencies across the federal government.

ATTRIBUTES OF HEALTH POLICYMAKING IN THE UNITED STATES

US health policymaking is shaped by a number of important characteristics, as described in this section: the government's subordinate role to the private sector in the healthcare market, the fragmentation of government programs, the incremental approach to reform, and the importance of congressional support.

GOVERNMENT IN SUBORDINATE ROLE TO THE PRIVATE SECTOR

Because the federal government takes a subordinate role to the private sector in providing healthcare services and private insurance plans, policymaking by government is limited to addressing market failures or deficiencies. For example, left alone, the healthcare market could not ensure adequate insurance coverage for the elderly (who tend to be sicker) or the poor (who typically cannot afford the premiums). Therefore, government intervened and created health insurance plans for the elderly (Medicare) and the poor (Medicaid). One consequence of government intervention is that policies tend to be implemented piecemeal, addressing one market deficiency at a time rather than in a comprehensive and coordinated manner.

FRAGMENTED GOVERNMENT PROGRAMS

The fragmentation of the American political institution is reflected in the development of health policy legislation. Healthcare programs are similarly fragmented among federal, state, and local governments, which pursue their own policies with limited coordination. Exhibit 2.4 provides an example of the variability in healthcare insurance that has emerged.

INCREMENTAL APPROACH TO REFORM

Such fragmentation inevitably leads to incremental change rather than systematic reform. Compromises struck in the resolution of issues also contribute to the piecemeal nature of healthcare reform. Consider the broadening of the Medicaid program since its start in 1965. Rather than adopt a single, comprehensive initiative, Medicaid underwent numerous disjointed expansion efforts in the 1980s and 1990s (see the Key Legislation box titled "Social Security Act").

EXHIBIT 2.4 Example of Fragmented Healthcare Programs: Funding of Health Insurance

The employed	Predominantly covered by voluntary private insurance to which they and their employers make contributions
The elderly	Funded by Social Security tax revenues (Medicare Part A) and government-subsidized voluntary insurance for physician, supplementary, and prescription drug coverage (Medicare Parts B and D)
The poor	Covered by Medicaid, which is financed with federal, state, and local revenues
Special population groups (e.g., veterans; American Indians; members of the armed forces, Congress, and the executive branch of government)	Covered by the federal government directly

KEY LEGISLATION
Social Security Act

The 1935 Social Security Act is a landmark policy that established the Social Security program for the elderly. Since its enactment, a number of health-related modifications have been made.

- Kerr-Mills Act (1960): established a program of medical assistance for the medically indigent elderly
- Medicare and Medicaid (1965): created as insurance programs for the elderly and the poor, respectively
- Expansion of public coverage (1967): expanded Medicaid to cover eligible children up to age 21 and mandated improvement in the quality of care provided in nursing homes
- Professional standards review organizations (1972): created to monitor the quality and medical necessity of services provided to Medicare recipients
- Block grant program (1974): consolidated federal–state social services programs, limits federal matching funds while giving states more flexibility in prioritizing services than they had prior to the program's implementation
- Prospective payment system (1983): instituted predetermined payments set by diagnosis-related groups
- Temporary Assistance for Needy Families (1997): replaced Aid to Families with Dependent Children program placed under Social Security Act
- State Children's Health Insurance Program for low-income citizens (1997): added to Social Security Administration

IMPORTANCE OF CONGRESSIONAL SUPPORT

As exhibit 2.5 shows, most of the important US health legislation was passed when both congressional chambers were controlled by the same party. When the president is of the same party affiliation, chances of success are even greater.

For example, President Lyndon B. Johnson achieved passage of Medicare and Medicaid in 1965 not only by virtue of his leadership skills but also because he was operating in an unusually favorable political environment for advancing legislation. Johnson was a Democrat serving at a time when Congress was also dominated by the Democrats. Johnson mobilized the public and Congress behind the bill and efficiently shepherded it through the legislative process. As a result, the Social Security Amendments of 1965 were signed into law, setting the stage for the creation of Medicare and Medicaid. The ACA is another example. With a solid Democratic majority in Congress, President Obama quickly pushed the ACA even without a single Republican voting in favor of it. President Trump wanted to do something similar—that is, to "repeal and replace Obamacare," as he called the ACA—but this time

Exhibit 2.5
Relationship Between Health Legislation and Party Affiliation

Date	Legislation	President	Senate	Congress
1921	Maternity and Infancy Act	**Republican**	**Republican**	**Republican**
1935	Social Security Act	**Democrat**	**Democrat**	**Democrat**
1937	National Cancer Institute Act	**Democrat**	**Democrat**	**Democrat**
1944	Public Health Service Act	**Democrat**	**Democrat**	**Democrat**
1946	National Mental Health Act	**Democrat**	**Democrat**	**Democrat**
1946	Hospital Survey and Construction Act	**Democrat**	**Democrat**	**Democrat**
1952	Immigration and Nationality Act	**Democrat**	**Democrat**	**Democrat**
1956	Dependents Medical Care Act	*Republican*	*Democrat*	*Democrat*
1963	Health Professions Educational Assistance Act	**Democrat**	**Democrat**	**Democrat**
1963	Clean Air Act	**Democrat**	**Democrat**	**Democrat**
1965	Social Security Amendments	**Democrat**	**Democrat**	**Democrat**
1971	Comprehensive Health Manpower Training Act	Republican	*Democrat*	*Democrat*
1972	Consumer Product Safety Act	Republican	*Democrat*	*Democrat*
1973	Health Maintenance Organization Act	Republican	*Democrat*	*Democrat*
1974	Employee Retirement Income Security Act	Republican	*Democrat*	*Democrat*
1983	Social Security Amendments	Republican	Republican	Democrat
1990	Americans with Disabilities Act	Republican	*Democrat*	*Democrat*
1990	Ryan White Comprehensive AIDS Resources Emergency Act	Republican	*Democrat*	*Democrat*
1996	Health Insurance Portability and Accountability Act	Democrat	*Republican*	*Republican*
1997	State Children’s Health Insurance Program	Democrat	*Republican*	*Republican*
2000	Minority Health and Health Disparities Research and Education Act	Democrat	*Republican*	*Republican*
2002	Health Care Safety Net Amendments	Republican	Democrat	Republican
2005	Patient Safety and Quality Improvement Act	**Republican**	**Republican**	**Republican**
2008	Health Care Safety Net Act	Republican	*Democrat*	*Democrat*
2009	American Recovery and Reinvestment Act	**Democrat**	**Democrat**	**Democrat**
2010	Patient Protection and Affordable Care Act	**Democrat**	**Democrat**	**Democrat**

Note: **Bold** indicates both houses of Congress are controlled by the same party and the president is affiliated with that party. *Italics* indicate both houses of Congress are controlled by the same party and the president is affiliated with a different party.

with Republicans in control of Congress. His initial efforts did not succeed, as a result of a slim Republican majority and disagreements within the ranks of the Senate Republicans, and he turned his attention toward other issues.

ROLE OF INTEREST GROUPS IN US HEALTH POLICYMAKING

Interest groups' efforts to promote their positions affect health policy just as they do any other policy debate in American politics. Each group aims to protect its best interests, and although most groups are satisfied with their benefits, the result for any single group may be less than optimal.

Organizations tend to be effective at demanding health policy. They usually have the resources to advance their interests, even as those interests tend to be more focused, and enjoy the diverse interests of individuals. Well-organized interest groups

- combine and concentrate their members' resources;
- pursue an active agenda to influence all phases of policymaking, from formulation to implementation to modification; and
- represent a variety of individuals and entities.

In this section we discuss the traditional types of interest groups involved in health policymaking in the United States—physicians, senior citizens, hospitals, insurance companies, and pharmaceutical research and manufacturing firms. See also the Learning Point box titled "Interest Groups New to Healthcare Policymaking."

PHYSICIANS

Physicians as a group have difficulty lobbying for their interests because they represent many specialties. The American Medical Association (http://ama-assn.org) represented only 18.2 percent of US physicians in 2012, down from its peak of 70 percent in the 1960s. Other medical groups include the American Academy of Pediatrics (www.aap.org), Physicians for a National Health Program (www.pnhp.org), the American Society of Anesthesiologists (www.asahq.org), and the Society of Thoracic Surgeons (www.sts.org). These groups come together on issues that pose a potential threat to the interests of physicians as a whole, as in 1992, when the Health Care Financing Administration (now CMS) changed the reimbursement system from fee-for-service to the Resource-Based Relative Value Scale (physicians did not prevail in their efforts to overturn the policy). Other issues of interest to some physician groups are income maintenance, professional autonomy, and malpractice reform.

LEARNING POINT
Interest Groups New to Healthcare Policymaking

Two relatively new types of interest groups have emerged in the health policymaking paradigm: corporate America and healthcare consumers.

Corporate America
Business has emerged as a singular interest group, albeit one with two prongs: large employers and small employers. The health policy concerns of American employers are often shaped by the extent to which they are expected to provide health insurance benefits to their employees, their employees' dependents, and their retirees. In general, they are likely to pay attention to health policies that affect worker health or labor–management relations.

Healthcare Consumers
The health policy spectrum has expanded to include consumer interests. Among the more vocal voters on this issue were members of the Tea Party movement, which became known for its demonstrations in Washington, DC, and around the United States prior to and during the passage of the ACA in 2010. This uniquely American populist political movement represented both ultraconservative and libertarian interests, calling for reductions in government spending, the national debt, and the federal budget deficit and opposing taxation and expansion of insurance coverage to those who were uninsured before the ACA. Tea Party–affiliated candidates ran as Republicans and won enough seats in the House and Senate in the 2010 elections to tip the majority from Democratic to Republican, but in 2012, far fewer ran and only a handful won (Gray 2012), and the movement's influence waned thereafter.

SENIOR CITIZENS

AARP (www.aarp.org) assists people aged 50 or older by providing them with information, advocating for their needs, and offering specific services. It advocates expanding the financing of public benefits for the elderly to cover housing, food, income, and health. AARP supported the Medicare Prescription Drug Improvement and Modernization Act of 2003, but it did not oppose the proposed Medicare cuts in the ACA, perhaps because AARP's interests in the funding of Medicare were outweighed by its support of a national healthcare system.

HOSPITALS

The American Hospital Association (www.aha.org) represents approximately 5,000 hospitals, health systems, health networks, and other providers of care in issues of national health policy development, legislation, regulation, and legal concerns. The implications of **administrative simplification**, the reduction of bad debt write-offs, and profitability are among the current topics of interest to hospitals in general.

administrative simplification
Provision in the Health Insurance Portability and Accountability Act and the Affordable Care Act that aims to reduce administrative costs through the adoption of electronic transactions and standardization of operating rules.

HEALTH INSURANCE COMPANIES

America's Health Insurance Plans (www.ahip.org) represents nearly 1,300 health insurance companies. This organization supports health insurers in the effort to ensure that affordable healthcare coverage is expanded to include all Americans. Among the issues holding insurers' interest are the elimination of cost shifting and the implications of administrative simplification.

PHARMACEUTICAL RESEARCH AND MANUFACTURING FIRMS

The Pharmaceutical Research and Manufacturers of America (PhRMA; www.phrma.org) represents US pharmaceutical research and biotechnology companies by supporting their efforts to discover new medicines. PhRMA also alerts its members to changes in health policy and attempts to influence policy formulation related to the approval and monitoring of drugs and pharmaceutical devices (see the For Your Consideration box titled "'Big Pharma' and Influence on US Health Policy" and the Learning Point box titled "Pharmacist 'Gag Clauses'").

FOR YOUR CONSIDERATION
"Big Pharma" and Influence on US Health Policy

According to the Commonwealth Fund, US spending on pharmaceuticals exceeded $1,000 per person by 2015, between 30 percent and 190 percent higher than nine other high-income countries (Sarnak et al. 2017). This difference was attributed to the higher prices of drugs in the United States, as well as a lack of price-control strategies and centralized price negotiations. The pharmaceutical industry argues that medicines are a small share of healthcare spending, with prescription medicines consistently accounting for just 10 percent of healthcare spending in the country (PhRMA 2016). However, researchers believe that per capita pharmaceutical spending will increase between 4 percent and 6 percent annually through 2024 (Cox and Kamal 2015). One study found that spending was expected to increase faster than any other major medical good or service in the period between 2017 and 2026—at 6.3 percent per year, on average (Cuckler et al. 2018).

In the most recent healthcare reform, the ACA of 2010, the pharmaceutical industry felt only a modest impact. The ACA made several changes to the Medicaid drug rebate program, including increasing the minimum rebate from 15.1 percent to 23.1 percent for pharmaceutical companies.

FOR YOUR CONSIDERATION

“Big Pharma” and Influence on US Health Policy *(continued)*

This change meant that the government could recoup costs for medicines in the form of rebates from manufacturers (Baghdadi 2017). In addition, the branded prescription drug fee is a tax levied on the prescription drug industry that is split among pharmaceutical companies based on their prescription drug market share (IRS 2018). This tax is estimated to bring in more than $27 billion over ten years (Joint Committee on Taxation 2010). It is argued that the pharmaceutical industry conceded on these rebates and taxes in an effort to avoid more significant reforms to the drug market. Pharmaceutical companies’ primary concerns with the potential revision of the ACA include reductions in federal Medicaid funding, which could lead to lower revenue if states cut back on these benefits; the impact of tax and trade reforms on their supply chains; and consumers seeking more and larger discounts from pharmaceutical companies and turning to generic prescriptions where possible (PwC Health Research Institute and Strategy 2017).

The pharmaceutical industry argues that lower drug prices may inhibit the ability to conduct research and develop innovative drugs in the future. However, a 2017 analysis found that the premiums pharmaceutical companies earned from charging high prices in the United States were more than the companies spend globally on research and development (Yu, Helms, and Bach 2017). Another study found that the median cost of developing a single cancer drug was $648 million, while the median revenue for such a drug was $1,658.4 million (Prasad and Mailankody 2017). These findings challenge the pharmaceutical industry’s argument that high drug costs are a reflection of the research and development behind them.

Pharmaceutical companies spend a significant amount of money to influence politicians, given their interest in keeping their revenues and profit margins high in an age of health policy uncertainty and reform. In 2016, about 90 percent of the members of the House of Representatives and all but three of the 100 Senate members accepted campaign contributions from drug companies. During the 2017–2018 election cycle, these numbers stood at about 88 percent of the members of the House and 94 percent of the Senate (Center for Responsive Politics 2018b). PhRMA, the leading pharmaceutical lobbying group, raised its lobbying expenditures from $17.2 million in 2014 to $25.8 million in 2017 (Center for Responsive Politics 2018a). A nonprofit group, Partnership for Safe Medicines, has ties to PhRMA and has recently emerged in lobbying to block drugs from being imported from Canada. Drugs can be three times more expensive in the United States than they are in Canada, which pushes the interest in this legislation (Kopp and Bluth 2017).

The ties between the pharmaceutical industry and the federal government are often viewed as loose, as employees often go through a “revolving door,” switching employment between the two entities. One report found that nearly 340 former congressional staffers now work for pharmaceutical companies or their lobbying firms. The same analysis showed that more than a dozen former drug industry employees now have jobs on Capitol Hill, often on committees that handle healthcare policy (Lupkin 2018). This finding brings into question the relationships that exist between pharmaceutical companies and government staff.

LEARNING POINT
Pharmacist "Gag Clauses"

Pharmacists are not allowed to inform patients about less costly ways to obtain their medicines. The National Conference of State Legislatures (2018) recently published a report focusing on consumers being charged higher prices because pharmacists are not allowed to offer other options to patients with health insurance. The lobbyist for drug benefit companies, the Pharmaceutical Care Management Association, has filed to block at least one state action in North Dakota, citing "onerous new restrictions on pharmacy benefit managers" (Pear 2018).

KEY POINTS

- ➤ The major stages of policymaking are policy formulation, policy implementation, and policy modification.
- ➤ Characteristics of US health policymaking include a fragmented governing system, strong influence of public opinion, and incremental (rather than radical) changes.
- ➤ Interest groups have become increasingly influential in the policymaking processes, representing a wide variety of healthcare stakeholders.

CASE STUDY QUESTIONS

CASE STUDY 1

On the basis of your research of the events leading to the enactment of Medicare and Medicaid legislation and your knowledge of these programs, answer the following questions:

1. Why did the United States forgo attempts to achieve universal health insurance in favor of focusing on insurance for the elderly and the poor?
2. What are the major similarities and differences between Medicare and Medicaid?

CASE STUDY 2

Based on your research of the events leading to the enactment of HIPAA and the ensuing legislation and your knowledge of information and safety, answer the following questions:

1. Why is it necessary to collect patient information, and why it is also important to safeguard its privacy?

2. What essential personal information is often collected by healthcare providers, and how is it used?
3. What are the methods commonly used to safeguard the privacy of PHI, and how effective are they?

FOR DISCUSSION

Find examples of policymaking in the health sector at the US federal level, and answer the following questions:

1. How is the policymaking process demonstrated in your examples?
2. Which components of policymaking are evident in each stage of the process?
3. How do the stages influence each other?
4. Which characteristics of health policymaking do the examples illustrate?
5. What interest groups were involved in your examples of policymaking? What were their roles in the making of that policy?
6. What policymaking successes and failures can you identify in the examples?

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CHAPTER 3

HEALTH POLICYMAKING AT THE STATE AND LOCAL LEVELS AND IN THE PRIVATE SECTOR

> *A policy is a temporary creed liable to be changed, but while it holds good, it has got to be pursued with apostolic zeal.*
>
> —Mohandas Gandhi

> *One voice can change a room. And if one voice can change a room, then it can change a city. And if it can change a city, it can change a state. And if it can change a state, it can change a nation, and if it can change a nation, it can change the world. Your voice can change the world.*
>
> —Barack Obama

LEARNING OBJECTIVES

After completing this chapter, you should be able to

- describe features of the US state-level policymaking process and political system and provide examples of state healthcare legislation,
- discuss features of the US local government policymaking process and local political system and provide examples of local healthcare legislation,
- address the health policy–related activities of private health research institutes and foundations,
- understand the implications for the US healthcare system of private industry policies and practices, and
- appreciate the attributes of health policy development at the US state and local levels and in the private sector.

CASE STUDY 1

MASSACHUSETTS HEALTHCARE REFORM

In 2006, Massachusetts enacted landmark legislation to provide health insurance coverage to nearly all state residents (KFF 2012). The legislation led to the creation of the Commonwealth Care health insurance program to provide subsidized coverage for individuals whose income is below 300 percent of the federal poverty level. It also developed a health insurance exchange for individuals and small businesses to purchase insurance at more affordable rates than could be obtained on the open market. The state's Medicaid program was expanded and merged with the Children's Health Insurance Program (CHIP) to form MassHealth. Children from a family whose income is up to 300 percent of the federal poverty level are covered by this program.

As part of this legislation, Massachusetts mandated that residents purchase health insurance coverage or be charged a penalty of up to $912. In addition, employers with 11 or more employees are required to contribute to health insurance coverage for their employees or pay an annual fair-share contribution of up to $295 per employee.

As of 2012, the percentage of residents without insurance in Massachusetts had declined to 6.3 percent, in comparison to the 2006 level of 10.9 percent uninsured (KFF 2012). Uninsurance in Massachusetts was about one-third that of the rest of the United States (18.4 percent). Employer health coverage remains the most common type of insurance, but MassHealth (the public insurance plan) and Commonwealth Care (which provides subsidies for families and individuals to purchase private coverage) have grown substantially (KFF 2012; Saluja et al. 2016).

Community health centers and safety net hospitals play a dominant role in caring for those Massachusetts residents who now have health insurance as a result of the state healthcare reform legislation. In addition, they continue to provide care for those who remain uninsured.

The Massachusetts experience with healthcare reform legislation provides a real-world case study demonstrating the potential to significantly reduce the number of uninsured through an individual mandate combined with affordable health coverage options. It illustrates the state's role in bringing about real healthcare reform affecting healthcare access and delivery.

CASE STUDY 2

CONNECTICUT OPIOID RESPONSE INITIATIVE

According to the Connecticut Department of Mental Health and Addiction Services, admission for heroin addiction has increased since 2011, and heroin has replaced alcohol as the primary drug reported at admission for substance abuse treatment within the state, with heroin and other opiates accounting for 42 percent of admissions in fiscal year 2016 (Giard 2017). Connecticut

Governor Dannel P. Malloy charged the Alcohol and Drug Policy Council (ADPC), a statewide stakeholder group, with comprehensively addressing Connecticut's opioid crisis. The Connecticut Opioid REsponse (CORE) team—a partnership among academic, medical, and public health organizations and state agencies—supports the work of the ADPC by using evidence-based strategies to achieve measurable outcomes that have a prompt impact on the number of opioid overdose deaths in Connecticut (Fiellin et al. 2016). The CORE initiative has two main functions: (1) to serve as a means to convey strategies and methods likely to immediately treat opioid use disorder and reduce overdose events, and (2) to provide metrics and measures that may be used to monitor and track progress over time (Fiellin et al. 2016). Namely, CORE identifies strategies and associated metrics to address the opioid crisis in Connecticut.

The strategic plan involved a multistage process of data gathering from Connecticut stakeholders, evaluation of evidence-based practices, and stakeholder engagement (Fiellin et al. 2016). First, a three-month data-collection process led by Yale University's Schools of Medicine and Public Health sought recommendations from stakeholders throughout the state. In addition, the team evaluated evidence-based practices from other states and countries. Review and integration of these data helped identify Connecticut's specific data needs and key questions. Recommendations were further reviewed with regard to scientific strength, potential three-year impact on overdose mortality, and availability of a measurable outcome that could be monitored to determine strategic priority.

These efforts resulted in the following six strategies (Fiellin et al. 2016):

1. Increase access to high-quality treatment with methadone and buprenorphine.
2. Reduce overdose risk, especially among those individuals at the highest risk.
3. Increase adherence to opioid prescribing guidelines among providers, especially those providing prescriptions associated with an increased risk of overdose and death.
4. Increase access to and track use of naloxone.
5. Increase data sharing across relevant agencies and organizations to monitor and facilitate responses, including rapid responses to outbreaks of overdoses and other opioid-related events.
6. Increase community understanding of the scale of opioid use disorder, the nature of the disorder, and the most effective evidence-based responses to promote treatment uptake and decrease stigma.

Based on the evolving nature of the opioid epidemic, and an evolving evidence base, the CORE initiative team plans to evaluate its strategies, tactics, and metrics annually and adjust as needed.

Although US health policies are developed primarily at the federal level, state and local governments and industries in the private sector (nonfederal arenas) also engage in health policymaking. This chapter focuses on health policymaking in these arenas. First, state-level health policymaking is presented; that discussion is followed by sections covering local government and private-sector health-related policy influencers. The attributes of health policymaking in these sectors are also summarized.

republican
A type of democratic government in which the head of state is not a monarch; governmental activities and affairs are open to all interested citizens.

STATE GOVERNMENT STRUCTURE

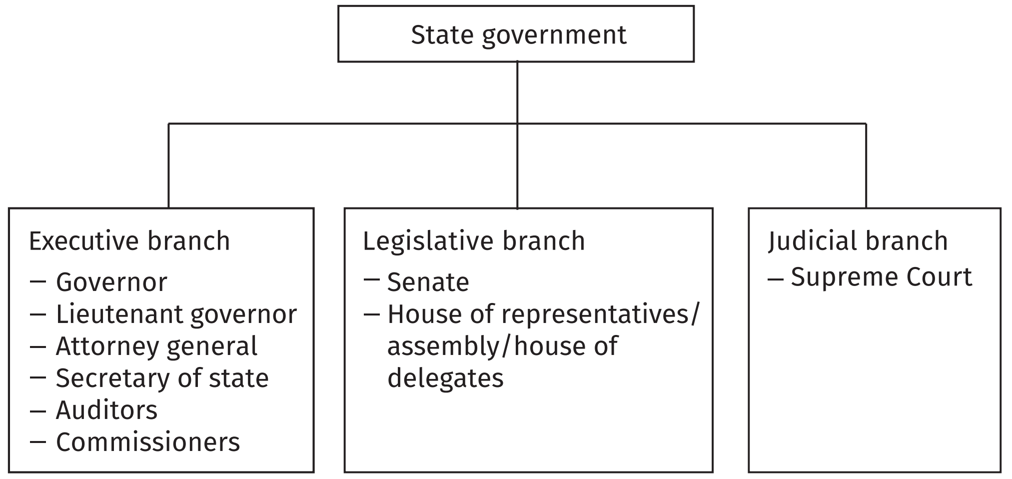
The federal and state sectors share a common government structure composed of the legislative, executive, and judiciary branches. However, each state also has its own constitution and bill of rights, which together define the structure and function of the state government and the local governments within the state's boundary (Longest 2016). Following is a brief discussion of the typical state political system.

POLITICAL SYSTEM

State governments are modeled after the US federal government in that each is composed of executive, legislative, and judicial branches (exhibit 3.1). States are bound by the US (federal) Constitution to maintain a **republican** form of government, although they are not specifically required to adhere to the three-branch system. The executive branch of the state government is headed by the governor and other **state executives**, such as the lieutenant governor, the attorney general, the secretary of state, auditors, and commissioners. All state

state executives
Officials in the executive branch of state government. Examples include the governor, who is the chief executive of a state or territory, and the attorney general, who serves as the main legal adviser to the state government and has executive responsibility for law enforcement.

EXHIBIT 3.1
The US State Political System



state legislature
The legislative body of a US state, also called the general assembly or legislative assembly.

governors are directly elected by the people, as are most other positions in their executive branch. The exact structure of the executive branch varies from state to state.

The state legislative branch is the main lawmaking body of the government; it also approves the state budget and fulfills other functions of government. As in the federal government, the **state legislature** consists of two chambers: a house of representatives—known in some states as the assembly or house of delegates—and a senate (except Nebraska, which has only one chamber in its legislature). In most states, senators are elected by the state's voters to four-year terms, and members of the house are elected to two-year terms.

A state's judiciary is generally headed by its version of the US Supreme Court (with exceptions; for example, New York's Supreme Court is actually the trial-level court, and the state's highest court is referred to as the Court of Appeals). This highest state court hears appeal cases from lower-level state courts; no trials are held in state supreme courts. Decisions made by a state supreme court are binding unless they do not adhere to the US Constitution, in which case its decisions may be appealed in the US Supreme Court. The exact structure of the courts and the rules governing judicial appointments and elections are determined on a state-by-state basis, either through state legislation or by the state constitution.

Policymaking Process at the State Level

The policymaking process at the state level can vary substantially from state to state. In general, however, states apply the same legislative system as the federal government does (see, e.g., Maryland General Assembly 2006; State Legislature of Alaska 2018; West Virginia Legislature 2018). The idea for a new law can come from an elected representative, a group of elected representatives, the governor, or any other concerned citizen or interest group. The proposed law is drafted into a bill, which is then sponsored by an elected member of either the state's senate chamber or its lower chamber (e.g., house of representatives, general assembly). Although a bill must be introduced into the legislature by a representative or senator, both legislators and interest groups draft significant amounts of legislation.

Bills can be introduced in either chamber of the legislature, where they are reviewed by committees. Many states require that the bill also be accompanied by a financial projection showing the budgetary impact of the potential law. The bill goes through three readings before being voted on by the elected representatives. Often, amendments are made after each reading, and the merits of the bill are debated among the members.

After it passes one chamber, the bill proceeds to three readings in the other chamber. The same process of debates and amendments is followed. After both houses have agreed on and passed a final version of the bill, it goes to the governor to be signed into law. In many states, the governor has the authority to veto a bill that is passed by both chambers so that it does not become law. In other states, the governor's veto can be overridden by a favorable vote of two-thirds or more of the members in both houses so that the bill becomes law even without the governor's support.

EXAMPLES OF STATE HEALTHCARE LEGISLATION

The power and responsibility of states to establish laws that protect the public's health and welfare derive from the US Constitution. The focus of healthcare legislation can range from promoting health (including environmental protection, occupational health, safe food services, and injury prevention) to providing health services (such as public health nursing, communicable disease control, family planning and prenatal care, and nutritional counseling). See exhibit 3.2 for examples of state health policies, review the Learning Point box titled "Illustration of State Involvement in Health Policy Development" for a description of health policy activity in Oregon, and read the Learning Point box titled "State Initiatives on Health Promotion and Disease Prevention" to understand state involvement in health promotion and disease prevention activity as well as efforts to address the healthcare needs of its vulnerable citizens.

EXHIBIT 3.2
Examples of State Responsibilities Through Health Policy

- Serve as a major payer of healthcare services; an average of 28.2 percent of all state expenditures were Medicaid related in 2015 (Medicaid and CHIP Payment and Access Commission 2016).
- Fund CHIP, health insurance benefits for state employees and other public-sector workers, and stand-alone state programs that provide health services to the uninsured.
- Regulate the state healthcare system (e.g., licensing and monitoring health professionals and health-related organizations, regulating the state private health insurance industry).
- Establish and monitor compliance with quality standards for environmental protection.
- Provide safety net facilities through support of local health departments and community-based healthcare organizations and through programs that provide charity care to low-income populations.
- Provide subsidies for graduate medical education and support large-scale educational campaigns.

LEARNING POINT
Illustration of State Involvement in Health Policy Development

Known as a leader in state healthcare reform (Health Care for All Oregon 2017), Oregon's Legislative Assembly passed House Bill 2009 in 2009, which established the Oregon Health Authority (OregonLive 2018). The legislation created an insurance exchange—a federal subsidy–eligible set of standardized healthcare plans regulated by the state from which individuals

(continued)

LEARNING POINT
Illustration of State Involvement in Health Policy Development *(continued)*

may purchase health insurance—through the Oregon Health Authority for individuals and small businesses that do not have group health insurance (Oregon Legislative Assembly 2009).

The law also expanded the Oregon Health Plan to cover low-income working families and allocated an additional $5 billion to the Medicaid plan over the following ten years. The Oregon Health Plan is the Medicaid program for Oregon and is overseen by the Oregon Health Authority. Its purpose was to make healthcare more accessible to the working poor while rationing insurance benefits. President Bill Clinton approved the plan in 1993 but required a revision to ensure access for people with disabilities. In 2011, Oregon House Bill 3650, which contained the proposed revision, was passed by the state legislature, and Oregon Senate Bill 1580 was signed into law, establishing Coordinated Care Organizations (CCOs). A CCO is a network of all types of healthcare providers who care for people covered under the Oregon Health Plan. CCOs integrate physical, mental, and dental care for better care and better health outcomes at lower costs. CCOs focus on preventing illness and disease, improving quality of care, and managing existing health conditions to keep patients healthy.

Other provisions contained in House Bill 2009 called for expanding the use of electronic health records through the Oregon Health Authority, establishing quality standards for hospitals and healthcare providers, and mandating that health insurance companies disclose their administrative costs and executive salaries to maintain transparency and accountability. As with the federal reforms included in the Affordable Care Act (ACA) of 2010, lifetime maximum limits on health benefits were eliminated, insurers were prohibited from taking health coverage away from those already enrolled in a plan, and children who were unmarried could stay on their parents' health insurance plan until age 26 (Oregon Legislative Assembly 2009). The ACA was also expected to provide some financial support for the reforms in Oregon's House Bill 2009.

The state's efforts were largely successful. A report by the Oregon Health Authority (2017) showed that by 2017, about 94 percent of people in Oregon had health insurance coverage.

LEARNING POINT
State Initiatives on Health Promotion and Disease Prevention

All US states and the District of Columbia receive federal grants to initiate their own health promotion and disease prevention programs (CDC 2018a). These programs focus on a variety of health problems, such as promoting wellness culture in the workplace, increasing access to healthy food, and improving physical activity. These programs have the common goal of improving environments to make healthy living easier. Four examples of these programs are provided here.

LEARNING POINT

State Initiatives on Health Promotion and Disease Prevention *(continued)*

Exercise and Dietary Modification to Combat Obesity in Michigan

Strong evidence indicates that physical inactivity and excess calorie intake are the primary causes of obesity, not only for adults but also for young children (CDC 2017b). To address this public health concern, Michigan has worked on various activities such as partnering with the local Farmer's Market Association to accept Supplemental Nutrition Assistance Program cards (formerly known as food stamps) and providing funding to local health jurisdictions to promote physical activity with walking campaigns. One highly successful project involved working with school districts and community organizations to enhance physical activity standards and healthy eating habits in early care and education settings (i.e., licensed childcare centers and in-home childcare settings) across the state. As a result of this five-year project, 226 centers and homes improved children's physical activity through activities such as 60 minutes of adult-led playtime every day, and 194 centers and homes made children's diets healthier by adding more fruits and vegetables to meals or encouraging parents to bring healthy snacks for children. To sustain the program, Michigan is making efforts to expand these improvements in every childcare center and in-home childcare setting in the state (CDC 2016b).

Healthier Retail Environments in Rural Wisconsin

A 2013 study found that In Wisconsin, about 38 percent of adults consumed fruits and 26 percent of adults ate vegetables less than once a day (Young et al. 2017). In addition, rural residents often have limited access to nutrient-dense, fresh produce because most *corner stores*—small retail shops that sell groceries and other household items—in rural Wisconsin lack a variety of fruits and vegetables. To make healthy options more convenient for local residents, the Wisconsin Division of Public Health (DPH) partnered with the University of Wisconsin Extension and 11 community-based organizations in 2015 to promote and expand the Wisconsin Corner Store Assessment tool for corner stores across the state. The tool guides corner stores through an assessment of areas for improvement, informing them on factors such as placement and shelf space of healthy foods in the store (Young et al. 2017).

This state program achieved the most desirable results in rural Lincoln County. Many corner stores in Lincoln County now offer much healthier food and drink options in their communities through multiple strategies, including coupons for healthy foods, point-of-purchase promotions, and displays of healthy products. To build on this success, the DPH decided to expand this program to gas stations in Lincoln County (CDC 2014; Young et al. 2017). Milwaukee County also launched a similar initiative to encourage corner stores to sell healthy foods by using such strategies as fresh produce signage, in-store demonstrations, and store redesign (Young et al. 2017).

Dietary Interventions in Philadelphia Healthcare Settings

In the state of Pennsylvania, the Philadelphia Department of Public Health launched the Good Food, Healthy Hospitals (GFHH) initiative, a healthy food and beverage option promotion

(continued)

LEARNING POINT
State Initiatives on Health Promotion and Disease Prevention *(continued)*

targeting patients, staff, and visitors in local hospitals (Bartoli 2018). Providing hospital patients suffering from chronic diseases with a healthy diet is a key component of chronic disease management, the department found, and many of the hospitals in Philadelphia serve residents of low-income areas where few fresh and healthy food options are available. The Common Market (a nonprofit organization) and the American Heart Association partnered with the Philadelphia Department of Public Health in 2014 to implement the GFHH initiative. Specifically, they encouraged hospitals to adopt five GFHH food standards that applied to purchased foods and beverages, cafeteria meals, patient meals, catering, and vending machines. Each standard came with specific guidelines. For example, the patient meal standard prohibited deep frying as a method of food preparation (Bartoli 2018).

As of June 2017, 15 hospitals had signed a pledge and committed to adopt GFHH standards. In their first year of implementation, all of these hospitals had met the minimum guidelines for at least one of the five GFHH standards, and half of them had achieved this goal for multiple standards. Most hospitals reported increased sales of healthy items even in their first year of implementation. One local medical center's cafeteria reported increased sales of unsweetened waters by 83 percent compared with the previous year, after following a GFHH price reduction guideline. Most important, these hospitals credited the GFHH standards with helping to shape hospital policies around healthier food and beverage options (Bartoli 2018).

Bike Share Program in California

Considering that the obesity rate for adults in Sacramento County, California, increased dramatically, by nearly 29 percent from 2001 to 2011, the California Department of Public Health (CDPH) collaborated with five state agencies to initiate a bike share program that motivated state employees to use free bicycles for business and personal trips during weekdays (Rosenhall 2018). The initial results were encouraging: From May 2015 to May 2016, 235 CDPH employees had enrolled and made more than 900 trips, biking a total of more than 3,000 miles (CDC 2016a; Rosenhall 2018). The program thus accomplished the dual benefits of improving employee fitness and decreasing environmental pollution from cars. City officials, taking notice of the CDPH program's success, worked to establish a bike share program for the Sacramento metropolitan area. The new bike rental service, called Social Bicycles, debuted on May 17, 2018, with a fleet of several dozen bicycles available in downtown Sacramento and along the West Sacramento waterfront and with plans for an increase to about 900 bikes by the end of the year (Bizjak 2018).

In some instances, an initiative instigated by a private-sector group to address an urgent public health problem may garner support from the state. For example, see the case in the Learning Point box titled "West Virginia's Drug-Free Moms and Babies."

LEARNING POINT

West Virginia's Drug-Free Moms and Babies

In 2015, West Virginia led the nation in drug overdose mortality among US states, with a rate of 41.5 deaths per 100,000 people (Mullins 2017). High rates of drug addiction, including but not limited to opiates, were also believed to affect neonatal outcomes and child health. To address this growing problem, a group of West Virginia neonatologists and pediatricians met with members of the Perinatal Partnership and coders in 2014 to address neonatal outcomes for infants being born to opioid-addicted mothers (Mullins 2017). Specifically, the group sought to "develop a standardized definition for neonatal withdrawal and guidance on documenting exposure and withdrawal among newborns" (Mullins 2017).

The group examined how the Drug Free Moms and Babies Project—a medical and behavioral health program for women during and after pregnancy—leveraged collaborative relationships to achieve positive outcomes for mothers and babies through a comprehensive, integrated approach including prevention, early intervention, addiction treatment, and recovery support services (Mullins 2017; West Virginia Department of Health and Human Services 2018). The three-year project was supported through funding from the West Virginia Department of Health and Human Resources; the Division of Behavioral Health and Health Facilities; the West Virginia Office of Maternal, Child and Family Health; and the Claude Worthington Benedum Foundation (West Virginia Department of Health and Human Services 2018). Four pilot sites were selected for the project to represent a cross-section of types and services—rural and urban, large and small, public and private—from which 354 women completed the program (West Virginia Department of Health and Human Services 2018; Towner 2017).

Overall, the program resulted in improved identification, increased collaboration among partners, greater availability of case management, and an increase in self-referrals (Mullins 2017). Urine tests screened for the presence of illegal drugs throughout the process, and the percentage of those testing positive markedly decreased over the nine months of the program participants' pregnancies (Towner 2017). Between 72 percent and 95 percent of the mothers tested negative for illicit substances at the time of delivery (Mullins 2017). Representatives from the West Virginia Department of Health and Human Resources noted the following lessons learned: (1) this kind of initiative requires time, flexibility, and patience; (2) client trust takes time to develop and affects early enrollment; (3) transportation and child care present significant barriers to enrollment; (4) comorbidities are common and complicate the treatment process; (5) coordination of care with physicians in private practice is difficult; (6) postpartum follow-up is challenging; (7) recovery coaching services can be difficult to locate and manage; and (8) plans for sustainability should be incorporated early in the program (Mullins 2017).

LOCAL GOVERNMENT STRUCTURE

Local US governments typically fall into one of two levels: county or municipality (e.g., cities, towns, villages). Counties—called *boroughs* in Alaska and *parishes* in Louisiana—may be further divided into townships. Service districts, such as school districts and police and fire protection districts, may be congruent with county or municipal boundaries or set their own borders.

The structures of county and municipal governments vary greatly, but they all follow the **democratic** model. States assign powers to the local governments rather than to individuals; however, mayors, city council members, and members of other governing bodies are usually elected directly by local residents. Laws are typically passed by majority votes at local council sessions.

democratic
Processes carried out in the representative tradition of government by the people, as through free elections.

The powers granted to a given county or municipality often depend on the size of its population. New York City, for example, has millions of residents and controls its own fire, police, and emergency medical services as well as libraries, parks and recreation, public transportation, and public works services. Smaller communities, on the other hand, may rely on county or state governments to provide these services.

POLICYMAKING PROCESS AT THE LOCAL GOVERNMENT LEVEL

As with state policymaking, the legislative process can vary significantly between counties and cities or towns (see, e.g., Erie County Legislature 2018; Metropolitan Government of Nashville and Davidson County, Tennessee 2018; Monroe County 2017b). However, in general, local government structures follow the same democratic process to make laws as that used by federal and state legislatures. The exception is that local legislatures and councils typically have only one chamber, unlike the federal and state legislatures. Proposals for new laws are written into resolutions—also referred to as referrals, ordinances, or bills. They are brought in front of the county legislature, city council, or other local governing body to be considered.

Resolutions can be introduced by the local government or elected representatives. In some counties, concerned citizens can write a resolution for presentation at the local government meeting. Resolutions are usually reviewed by committees in larger counties or cities and by the entire council or legislature in smaller local governments. The resolution then proceeds through multiple readings—with amendments to the legislation often introduced after each reading—and its merits debated before being voted on by the elected representatives. Some resolutions, such as tax laws, may require a greater than 50 percent majority vote to pass.

After the resolution has passed, it may need to be signed into law by the mayor or council executive. Once they become law, resolutions may continue to be called resolutions or become known as bylaws, local laws, or ordinances.

EXAMPLES OF LOCAL HEALTHCARE LEGISLATION

The public health departments of county and city governments enforce laws that complement state-level healthcare legislation. One of the most common areas for health legislation at the local level is the regulation of tobacco products and smoking in public environments.

To protect children from exposure to secondhand smoke, ten states have enacted laws since 2006 to prevent smoking in cars when children are present (Public Health Law Center 2017a, 2017b). In Monroe County, New York, the local government instituted a general smoking code and a law to prevent adolescent tobacco use (Monroe County 2005, 2017a). Monroe County's smoking laws are part of a wider public health campaign in the state of New York to curb tobacco use and reduce exposure to secondhand and environmental smoke.

In addition, public health campaigns in many US municipalities urge adults and children to be more active and engage in outdoor activities to curb obesity. Examples of such measures include offering healthy lunches and limiting soft drinks in schools and providing portion-control and nutrition information in restaurants, the latter of which is mandatory in some states (Burgermaster et al. 2017; Finch et al. 2016; Sisson et al. 2016).

Private Health Research Institutes

As with federal, state, and local governments, the private sector has contributed to health policy development. Here, the role of private research institutes—also known as think tanks—in influencing health policy is demonstrated through the work of the RAND Corporation.

RAND conducts research and analysis to improve and inform policymaking in the areas of health, education, and national security. With headquarters located in Santa Monica, California, RAND strives to provide objective analysis and operates independently of commercial or partisan ties (RAND Corporation 2018).

The RAND Health division conducts studies on public policy issues related to healthcare reform, health insurance coverage, and the use of information technology in healthcare. Obesity, post-traumatic stress disorder, and complementary and alternative medicine are RAND's public health focus areas. As a well-regarded participant in policymaking circles, RAND is highly influential through its studies and reports. For an example of RAND's work, see the Research from the Field box titled "RAND Health Policy Research: An Assessment of High-Deductible Health Plans."

RESEARCH FROM THE FIELD

RAND Health Policy Research: An Assessment of High-Deductible Health Plans

High-deductible health plans (HDHPs), also known as consumer-directed health plans (CDHPs), have increased in popularity in the twenty-first century as methods for controlling healthcare costs. By shifting more of the cost to the patient through increased deductibles, it is believed that consumers will use less care, especially unnecessary care.

In 2011, researchers at the RAND Corporation conducted a cost assessment of HDHPs (Beeuwkes Buntin et al. 2011). The researchers for this retrospective study looked at data previously

(continued)

RESEARCH FROM THE FIELD

RAND Health Policy Research: An Assessment of High-Deductible Health Plans *(continued)*

collected from the healthcare plan claims and enrollment information reported for 808,707 households by 53 major employers in the United States. Of these employers, 28 offered HDHPs (or CDHPs) to their employees. The increase in healthcare costs for those who enrolled in one of these types of plans for the first time from 2004 to 2005 was compared to the cost increases for those enrolled in traditional healthcare plans during the same period. Similar comparisons were made for the rates of use of preventive care services between the two groups.

Overall, the RAND researchers found that, although healthcare costs increased during the study for both those with HDHPs and those with traditional plans, costs grew at a lower rate for the HDHP group. Similarly, expenditures for families with HDHPs were lower for inpatient and outpatient care and prescription drugs than for families enrolled in traditional health plans; spending on urgent care did not differ between the two groups. The RAND study also found that families who enrolled in HDHPs reduced their use of preventive care services, including childhood immunizations, the rates of which increased among traditional plan users; mammography; cervical cancer screening; and colorectal cancer screening (Beeuwkes Buntin et al. 2011).

Studies such as those conducted by RAND can inform policymakers assessing the effectiveness of government health programs. Under the ACA, for example, deductibles must be waived for preventive healthcare services. Thus, one implication of the RAND study is that communicating information clearly to families enrolled in HDHPs and to employers offering these plans about this provision of the ACA must be a priority if the goal of increasing preventive care is to be met. Moreover, amending regulations to expand the “safe harbor” by allowing HDHP coverage of high-value services and medications for chronic diseases would provide Americans with a plan option that better meets their clinical and financial needs (Fendrick and Soonavala 2017).

PRIVATE HEALTH FOUNDATIONS

In addition to conducting health policy research, private health foundations work to advance policies through grant programs that fund promising social experiments. The Pew Charitable Trusts is an example of one such foundation.

The Pew Charitable Trusts conducts research and public policy work to address the challenges facing the United States and global community. Areas of study include the environment, early education, and public health. The Pew trusts also conduct public opinion polls to study trends in specific issues relevant to Americans. Pew’s mission is to advance solutions to these issues (Pew Charitable Trusts 2018a).

The Pew trusts support health research in six main broad policy areas: communities, governing, environment, health, families, and trends. These main topics are subdivided into more focused areas of study. For example, the health topic encompasses antibiotics, biomedical research, drug safety, food safety, healthcare costs, and medical ethics (Pew Charitable Trusts 2018b). Solutions to problems identified in these areas are policy-oriented, such as supporting mandatory food safety standards (see the Research from the Field box titled "An Example of Pew Health Policy Research: The Kids' Safe and Healthful Foods Project") and organizing informational campaigns to curb the overuse of antibiotics in livestock (Pew Charitable Trusts 2018b).

RESEARCH FROM THE FIELD

An Example of Pew Health Policy Research: The Kids' Safe and Healthful Foods Project

The Kids' Safe and Healthful Foods Project (2013), funded by the Pew Health Group in partnership with other private foundations, aims to improve the food choices available in schools to curb childhood obesity and reform food safety policies in schools to stop the spread of foodborne illnesses. As part of the project, the Pew Health Group works with the US Department of Agriculture (USDA) by providing the agency with evidence-based analysis and policy recommendations.

The three major goals of the Kids' Safe and Healthful Foods Project (2013) are to (1) ensure that the nutrition standards established by the USDA for foods and beverages available in schools are based on scientific evidence, (2) make sure schools have sufficient resources to properly train cafeteria employees and keep cafeteria equipment in good working order, and (3) help the USDA establish and enforce stringent food safety policies for schools. (Prior to the launch of the Kids' Safe and Healthful Foods Project, the USDA nutritional standards for school meals had not been updated in more than 15 years.)

As a result of the project, which is also closely aligned with the White House Task Force on Childhood Obesity, food safety has improved. Under the new school food safety policies that arose from the Healthy, Hunger-Free Kids Act and were guided by the Kids' Safe and Healthful Foods Project, the USDA is required to enhance its communication with other government agencies, including its hold and recall procedures, so that schools are notified of food recalls in a timely manner. The agency must also ensure that food served outside the cafeteria—in classrooms or elsewhere—meets the same safety standards. These additional requirements will help schools to avoid outbreaks of foodborne illness, such as in 2009 when schools may have served students peanut products contaminated with Salmonella because they did not receive the recall notices in time (Kids' Safe and Healthful Foods Project 2013). In 2017, researchers examining 1.7 million meals in an urban school district in the state of Washington found that the overall nutritional quality of meals had increased by 29 percent since the standards took effect. According to a poll conducted by Pew, the Robert Wood Johnson Foundation (RWJF), and the American Heart Association, more than 70 percent of parents surveyed said they supported the updated nutrition standards (Ratliff 2017).

PRIVATE INDUSTRY

Corporate America influences health and health policy primarily through its services or products and its lobbying activities. The fast-food and tobacco industries, for example, have extensive business interests in the United States and around the world, and their products are key influencers of the population's health status. Corporate America can also take a leadership role in promoting better health for employees in the workplace (see the For Your Consideration box titled "Importance of Workplace Health Promotion"), thus setting an example for smaller businesses. Some private enterprises in the United States are even developing their own initiatives to address the delivery of cost-effective, integrated healthcare services.

corporate America
An informal term referring to the corporations based and operating in the United States; they are not under direct governmental control.

FAST-FOOD INDUSTRY

According to an annual Gallup poll, nearly 50 percent of American adults eat **fast food** at least once a week, and 80 percent eat it at least once a month (Dugan 2013). In 2017, Americans spent nearly $291 billion on fast food, a huge increase compared with 1970, when they spent $6 billion (Statista 2018a). In addition to those with drive-through access, fast-food restaurants (also called quick-service restaurants) can be found in airports, hospitals, schools and universities, stadiums, cruise ships, and many other gathering places (CBS News 2002; Statista 2018a; Walker 2001).

fast food
Ready-to-eat, often portable, and inexpensive food available through many outlets in the United States. This type of food tends to be less healthy than homemade food and has been criticized for contributing to the obesity epidemic in the United States.

FOR YOUR CONSIDERATION
Importance of Workplace Health Promotion

About 160 million people in the United States spend half of their waking hours at work, which makes the workplace an essential setting for health promotion and disease prevention. In addition, scientific evidence proves that well-designed workplace health promotion programs can improve population health, reduce healthcare costs, increase worker productivity, and even achieve a desirable return on investment (Baxter et al. 2016; Soler et al. 2010).

In general, fast food is inexpensive, convenient, filling, and prepared quickly for the consumer. Fast food does not require dishes or utensils for eating, is often deep fried, and comes in large portions with uniform specifications. Few fresh vegetables are used because they are difficult to store long term.

The fast-food industry consists mainly of multimillion-dollar national restaurant chains. McDonald's Corporation alone franchised 36,899 restaurants worldwide in 2016 and continues to expand each year (Statista 2018b). It hires more people per year than does any other American organization and is the country's largest purchaser of beef, pork, and potatoes. McDonald's is also the largest owner of retail property in the world and the leading fast-food restaurant chain in the United States, with retail sales of about $36.39 billion in 2016 (Statista 2018b).

In addition to its vast marketing campaigns, the fast-food industry and its suppliers spend large sums lobbying the US government to promote or oppose legislation according to the industry's interests. Worker safety, food safety, and minimum wage laws have historically been opposed by the fast-food industry.

The increased consumption of fast food has contributed to obesity among American adults and children (CBS News 2002; WHO 2017). In addition to the commonly cited factors linking fast-food consumption to obesity (e.g., large amounts of fat, highly processed ingredients), studies have shown that proximity to fast-food outlets is a factor (e.g., Currie et al. 2009; Elliston et al. 2017; Mejia et al. 2015; Rabin 2009; Svastisalee et al. 2016). For example, Currie and colleagues (2009) found that when a fast-food restaurant was located within a tenth of a mile of a school, the obesity rates for children attending the school increased 5.2 percent more than for children who attended a school with a fast-food restaurant at least a quarter of a mile away.

In 2002, a group of obese and overweight children filed a class-action lawsuit against McDonald's, asking the court to award compensation for their obesity-related health problems and requesting that it force McDonald's to improve its nutritional labeling and provide funding for a health education campaign on the dangers of fast food. The lawsuit was dismissed a year later, but it raised important questions about legal accountability for the poor nutritional standards of most fast-food menu items. Mello, Rimm, and Studdert (2003) draw parallels between the fast-food industry's intention to process and manufacture food to be addictive and the tobacco industry's aim to manufacture addictive cigarettes.

Cigarette and Tobacco Industry

The tobacco industry is composed mainly of large, multinational corporate tobacco growers and cigarette manufacturers. The industry carries historical significance in the United States, as tobacco was an important commodity in colonial times. The United States was the world's fourth largest producer of tobacco (following China, India, and Brazil) in 2016 (Statista 2018c). According to the USDA (2016), US farmers harvested about 700 million pounds of tobacco in 2015, and the leading state in tobacco production was North Carolina. About 249 billion cigarettes were sold in the United States in 2017 (CDC 2018b).

Tobacco products are the most heavily taxed consumer product in the United States, when measured by percentage of retail price. The industry is also highly regulated, with quotas set for each farmer's land and the end product graded by USDA inspectors. The sale of tobacco to dealers and warehouses is monitored by the USDA's Agricultural Stabilization and Conservation Service.

According to the American Lung Association (2018a) and the Centers for Disease Control and Prevention (CDC 2018c), smoking cigarettes is the number one preventable cause of morbidity and mortality worldwide. More than 480,000 Americans and 7 million people worldwide die from tobacco smoking–related diseases annually (CDC 2018c; WHO 2018). Smoking causes more deaths in the United States each year than the following causes combined: HIV, illegal drug use, alcohol use, motor vehicle injuries, and firearm-related incidents (CDC 2013, 2017a; HHS 2014). Secondhand smoke contains more than 7,000 chemicals, including hundreds of toxic substances and at least 70 that can cause cancer (CDC 2017c). Chronic lung disease, including lung cancer and chronic obstructive pulmonary disease, accounts for 80 to 90 percent of smoking-related morbidity (CDC 2017a). Every year, smoking-related deaths and diseases cost the United States more than $300 billion, including $170 billion from direct healthcare expenditures and more than $156 billion from lost productivity due to premature death and exposure to secondhand smoke (CDC 2018c).

Despite such statistics illustrating the widely known health risks associated with tobacco products, however, the tobacco industry is highly concentrated—only four companies together accounted for 92 percent of US cigarette sales in 2017 (CDC 2018b)—and has a strong economic incentive to continue to sell its products. In 2016, US tobacco companies spent about $9.5 billion marketing cigarettes and smokeless tobacco in the United States (CDC 2018b, 2018c). Most promotional efforts came in the form of price discounts to wholesalers and retailers (American Lung Association 2018b; CDC 2018b, 2018c). It has been shown that lowering the price of cigarettes increases youth consumption; conversely, with each 10 percent increase in the price of cigarettes, youth consumption drops by 6 to 7 percent (American Lung Association 2018b; Boonn 2017).

PRIVATE INITIATIVES TO ADDRESS HEALTHCARE DELIVERY

Largely disillusioned with the slow pace in healthcare reform and saddled with ever-increasing healthcare expenses for their employees, US private enterprises are experimenting with their own reform initiatives to bring healthcare costs down and develop a more integrated approach toward care delivery.

Independent Healthcare Through Corporate Giants: Amazon, Berkshire Hathaway, and JPMorgan Chase Coalition

In January 2018, Amazon, Berkshire Hathaway, and JPMorgan Chase announced that they would combine their efforts to improve healthcare and lower its cost for the three companies' US employees—more than 900,000 workers in all (Bomey and Weise 2018; Business Wire 2018; Chappell 2018; Snider 2018)—by forming "an independent company that is free from profit-making incentives and constraints" (Business Wire 2018). Executives from each of the three companies were named to lead the initial formation and early planning stages of the new healthcare company, and a CEO search was launched in March 2018 (Business Wire 2018; Chappell 2018; Farr 2018). It was unclear how greatly the three corporate partners would change their employees' existing health coverage as a result of the new plan—whether they would simply help employees find a local doctor, guide employees to online medical advice, or use their influence to negotiate lower prices for drugs and medical procedures.

Although the new healthcare company would serve only the three founding companies' employees, these large corporations were expected to be closely watched so that any successful efforts could serve as a model for other businesses (Snider 2018). Early reactions to the announcement suggested that Amazon's involvement in the new company could make the pharmacy market more competitive, given Amazon's proven ability to lower shipping costs and make delivery more efficient for a variety of other products (Bomey and Weise 2018).

Expansion of Geographic Coverage: Advocate Health Care and Aurora Health Care Merger

In April 2018, Illinois-based Advocate Health Care and Wisconsin-based Aurora Health Care merged to become Advocate Aurora Health, the tenth-largest not-for-profit healthcare system in the United States (Boulton 2018; Schencker 2018). The merger agreement included a single board of directors with equal numbers of directors from each of the two companies; the Advocate and Aurora CEOs serving as co-CEOs of the new company; and dual headquarters retaining the two original headquarters in Downers Grove, Illinois, and Milwaukee, Wisconsin (Boulton 2017, 2018; Burke 2017; Schencker 2018).

Prior to the merger, Advocate Health Care was the largest health system in Illinois and one of the largest healthcare providers in the Midwest, and Aurora Health Care was Wisconsin's largest private employer (Advocate Health Care 2017). The new Advocate Aurora Health operates 27 hospitals as well as several hundred other sites of care and employs about 70,000 people (Advocate Health Care 2017; Boulton 2018; Schencker 2018). The potential advantages of such an increase in size include making full use of advances in information technology, such as analytics, to better manage the care of patients and creating economies of scale for providing increasingly complex care to patients, such as treatments based on patients' genetic makeup (Boulton 2017) as well as improving access to physicians and communication with healthcare providers through services such as telehealth (Schencker 2018). The co-CEOs expressed hope that their merger would not only improve healthcare quality but also slow the ongoing increase in healthcare costs (Boulton 2018).

Vertical Integration: Humana, TPG Capital, and Welsh, Carson, Anderson, and Stowe Acquisition of Kindred Healthcare

In April 2018, the shareholders of Kindred Healthcare, a provider of post-acute care services, agreed to a takeover by national insurer Humana and two private equity firms—TPG Capital and Welsh, Carson, Anderson and Stowe (WCAS)—for $4.1 billion (Sweeney 2018). The acquisition, announced in December 2017, was completed in July 2018 (Gulden 2018;

Livingston 2017; Stankiewicz 2018; Sweeney 2018). The three acquiring companies split off and will jointly operate Kindred at Home (Kindred's provider of home health, hospice, and community care) as a stand-alone company; and TPG Capital and WCAS took over Kindred Hospitals (Kindred's long-term acute care hospitals) and ReHab Care (Kindred's inpatient rehabilitation facilities) to be operated together under the Kindred Healthcare name as a specialty hospital company (Gulden 2018; Livingston 2017; Stankiewicz 2018).

The acquisition of Kindred at Home gives Humana greater control of home health providers that offer the kinds of services needed by about 10 percent of Humana's 3.3 million Medicare Advantage members, which could lead to cost savings for those members and Humana (Gulden 2018). At the time of the acquisition, Humana would own 40 percent of Kindred at Home but have the option to buy out the other 60 percent owned by TPG Capital and WCAS in the future (Gulden 2018; Stankiewicz 2018; Sweeney 2018).

Pharmacy–Insurance Combination: CVS Acquisition of Aetna

CVS is a pharmacy chain with more than 9,700 retail pharmacies across the United States—about 1,100 of them also containing walk-in clinics (Japsen 2018). Aetna is a large insurer, offering health plans for Medicare beneficiaries and serving the employer market. Both firms sponsor Medicare prescription drug plans. CVS paid $69 billion to acquire Aetna in an agreement that was expected to receive the necessary federal and state approval by the end of 2018 (Japsen 2018).

The CVS–Aetna merger joins a health insurance company with healthcare providers—in this case, with retail clinics (Frakt and Garthwaite 2018). By more closely integrating pharmacy benefit management with nondrug coverage, the CVS acquisition of Aetna could benefit consumers, as suggested by studies of Medicare and Medicaid (Dranove and Starc 2017; Lavetti and Simon 2016; Starc and Town 2015). Combining CVS retail clinics with Aetna could improve coordination of care if there were value-increasing investments, which neither company made because they would have financially benefitted only the other firm (Ashwood et al. 2016).

It remains to be seen whether cost savings will materialize, and if so, whether they will they be shared with consumers. It is also unclear whether the coordinated benefits that the combined CVS–Aetna could offer would lead to lower healthcare costs.

Insurer Purchase of Large Doctors Group: UnitedHealth Group and DaVita Medical Group

Following the announcement of the CVS acquisition of Aetna, the large insurance company UnitedHealth Group made a move to buy DaVita Medical Group, a large group of doctors (Abelson 2017; Tech2.org 2018). The acquisition was to be made through UnitedHealth's Optum unit and was expected to pass regulatory review and be completed by the end of 2018 (Seeking Alpha 2018). It would give UnitedHealth control of more than

250 DaVita-operated urgent care clinics and a number of medical practices in California, Florida, and several other states, allowing it to offer consumers a lower-cost alternative to hospital care for some emergency services and certain chronic conditions such as asthma and diabetes (Abelson 2017; Tech2.org 2018).

UnitedHealth had already acquired a chain of outpatient surgical centers in January 2017, and the DaVita purchase was seen by industry observers as an effort to broaden its business model to include direct delivery of medical care (Abelson 2017; Tech2.org 2018). The move was viewed as potentially beneficial to consumers in lowering healthcare costs; however, it could also limit the choice of doctors available in the insured's health plan to those affiliated with UnitedHealth, although the company claimed that Optum currently works with more than 80 health plans (Abelson 2017).

ATTRIBUTES OF HEALTH POLICY DEVELOPMENT IN NONFEDERAL SECTORS

Health policymaking in nonfederal sectors—state and local governments and the private sector—is characterized by several factors:

- The constraints imposed by the broader policy landscape
- The relationship between politics and policy
- The level of public health funding available
- The ways in which the private sector shapes policy direction
- Policy entrepreneurship at the grassroots level

CONSTRAINTS UNDER FEDERAL POLICY

Health policymaking at the state and local levels is limited by broader federal policy. Although regulation is primarily the states' responsibility, federal laws can preempt state legislation. For example, states cannot require firms to offer insurance to their employees because federal law—in the form of the Employee Retirement Income Security Act—would override any attempt by the state to do so.

The private sector is also influenced and constrained by federal regulations, in areas such as practitioner licensing, security and privacy of patient information, and reimbursement. For example, the Medicare and Medicaid programs periodically adjust their *reimbursement methodologies*—the methods by which they calculate how much money to pay providers for services rendered—which has prompted healthcare organizations to make changes in the way services are delivered.

FOR YOUR CONSIDERATION

Traditional Republican and Democratic Stances

The 2016 election cycle highlighted a number of policy positions (known as planks in their platform) favored by each major party. Republicans have traditionally sought "small" government—government that practices limited use of regulation, as opposed to "big," centralized government—and limited taxation and supported business interests, whereas Democrats have historically favored social programs, assistance for vulnerable populations, and a larger tax share from the wealthy than from the middle and lower classes. How do you view these positions in light of the comments made by party leaders during the 2016 presidential and congressional elections as reported by the mainstream media? Do the comments consistently reflect these traditional stances? Why or why not?

RELATIONSHIP BETWEEN POLITICS AND POLICY

Legislation is most likely to pass if the governor and the majority of the legislature carry the same political party affiliation. Similarly, legislation often is stalled or diluted when the policymakers considering it represent different parties (see the For Your Consideration box titled "Traditional Republican and Democratic Stances").

Another link between politics and policy, which applies to all sectors involved in policymaking, is the election cycle. In the time preceding an election, politicians running for reelection often emphasize legislation that is expected to garner immediate results, thus benefiting their reelection bids. Difficult problems that take a long time to solve are often left for future congressional sessions. As a result, many problems facing US residents are cumulative, but the policies meant to address them are *symptomatic*—addressing not the root cause but rather its symptoms—and piecemeal. The underlying problems, left unresolved, tend to worsen over time and exact an even heavier toll on all those affected than an earlier, more comprehensive solution would have.

LEVEL OF PUBLIC HEALTH FUNDING

The US market-oriented economy attracts private entrepreneurs to carry out key functions of healthcare delivery at a profit, leaving the public sector to assume a secondary role when the market alone cannot address all healthcare needs, particularly for members of vulnerable populations who cannot afford expensive care. The resulting healthcare system is functionally fragmented, with little standardization, resulting in the duplication of certain services and inadequacy of others.

Funding for public health in the United States is relatively low. In 2009, of all the money spent on health (nearly $2.5 trillion), only 3.1 percent of it ($77.2 billion) was spent on government *public* health activities (IOM 2012). By comparison, Canada spent 5.5 percent of its total health expenditure on public health in 2005 (Canadian Institute for Health Information 2005). Little public investment is made in health technology, workforce training and recruitment, or facility construction or renovation in the United States. In addition, the fact that spending on public health varies widely across communities raises concerns about whether and how these differences might affect the availability of essential public health services.

SHAPING POLICY DIRECTION

The private sector shapes policy direction more than state and local governments do. As described earlier in this chapter, the topics addressed by private research institutes and the projects funded by private foundations lead to findings that contribute to a better understanding of health problems, their underlying causes, and potential solutions, thus paving the way for policy development. Another way that private research institutes and foundations drive policy is in their evaluations of existing policies, the results of which are often incorporated in policy modifications or new policies.

POLICY ENTREPRENEURSHIP AT THE GRASSROOTS LEVEL

Grassroots efforts by **policy entrepreneurs** involve community stakeholders and may be funded by private foundations. Such efforts are critical to adapting successful experiences to other environments and identifying innovative approaches to solving health-related issues.

Typically, community-based projects stress participation and empowerment; engaging community members in these projects helps the initiative be accepted and helps promote sustainability of the intervention. Community members plan and manage initiatives, and—through community mobilization, skill building, and resource sharing—communities are empowered to identify and meet their own needs, making them stronger advocates for the vulnerable populations within and across their community boundaries.

policy entrepreneurs
Public innovators who, from outside the formal positions of government, introduce, translate, and implement new ideas into public practice.

KEY POINTS

- Although the policymaking process can vary substantially from state to state, states generally apply the same legislative system as the federal government does.
- Local government structures follow the same democratic process for making laws as federal and state legislatures do, except that local legislatures and councils typically have only one legislative chamber.
- The private sector, including private research institutes, foundations, and industry, contributes to health policy development.
- The major attributes of health policymaking in the public nonfederal sector include the constraints imposed by the broader federal policy landscape, influence of politics, availability of funding, level of entrepreneurship at the local level, and lack of integration and coordination among policymaking groups.

CASE STUDY QUESTIONS

CASE STUDY 1

Research the events leading to and following the enactment of the Massachusetts healthcare reform legislation introduced in the case study, and answer the following questions:

1. Why was Massachusetts able to enact state-level healthcare reform whereas most other states were not?
2. What are the positive and negative consequences of the Massachusetts healthcare reform?
3. What consequences would you anticipate if similar reform were enacted nationally?

CASE STUDY 2

Research the prevalence of mental health problems in the United States, and answer the following questions:

1. As mental health becomes a public health issue in the United States and elsewhere, what are the major mental health challenges?
2. What are the determinants of mental health problems in the United States and elsewhere?
3. Using the Connecticut example, how can the state address its mental health challenges from both public health and healthcare perspectives?

FOR DISCUSSION

1. Describe, and provide an example of, the policymaking process at the US state level.
2. Describe, and provide an example of, the policymaking process at the US local level.
3. What are the health policy–related activities of private health research institutes? Of private health foundations?
4. What kinds of public health information and initiatives are contributed by private industry?
5. What impact would the private business sector have on the development of healthcare financing and delivery in the United States?
6. List three characteristics of health policy development in the US state government, local government, and private sectors.

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CHAPTER 4

INTERNATIONAL HEALTH POLICYMAKING

The one who adapts his policy to the times prospers, and likewise the one whose policy clashes with the demands of the times does not.

—Niccolò Machiavelli

Public health service should be as fully organized and as universally incorporated into our governmental system as is public education. The returns are a thousandfold in economic benefits, and infinitely more in reduction of suffering and promotion of human happiness.

—Herbert Hoover

LEARNING OBJECTIVES

After completing this chapter, you should be able to

➤ provide examples of health policymaking at the international level;

➤ describe the functions and policy-related activities of the World Health Organization; and

➤ understand the basic ideas concerning health-related policymaking in Canada, Sweden, and China.

CASE STUDY 1

WHO HEALTHY CITIES INITIATIVE

The World Health Organization (WHO) launched the Healthy Cities (HC) initiative in 1986 with the aim of establishing "health for all" public policies and health promotion programs in local areas (WHO Regional Office in Europe 1997, 5). The Ottawa Charter for Health Promotion adopted that year helped guide the HC initiative in its early stages (WHO 1986). More than 30 years later, more than 5,000 cities worldwide have implemented HC projects (Hu and Kuo 2016). Among notable successes, the HC network in Taiwan has achieved a considerable positive impact and acted as a benchmark model for other participating cities around the world.

As described by Hu and Kuo (2016), the HC program in Taiwan—called Taiwan Alliance for Healthy Cities (TAHC) —was established in 2008 and has actively engaged local governments in health development through a process of political commitment, institutional change, capacity building, partnership-based planning, and innovative projects. The overarching goal of the HC network in Taiwan is to make health a priority on the social, economic, and political agenda of city government with combined resources from industrial, public, academic, civil, and research sectors. Representatives from 23 cities, academic institutions, nongovernment organizations, and private organizations convened in Taiwan to form TAHC and to generate and sign the Protocol for HC. TAHC holds annual meetings and workshops, alternating locations among its member cities. Three commissions within TAHC have specific types of responsibilities: the research and development group (collection, monitoring, and evaluation of city indicators), the events and training group (planning for education and training relevant to HC), and the award evaluation group (planning and selecting awards for HC). Multidimensional indicators are used to assess the population's health in each city and to present information on lifestyles and social and environmental factors that are related to health. Beyond the existing 32 health indicators in the WHO international HC program, TAHC has added 15 more indicators to its program as a tool to evaluate the program's effectiveness in Taiwan. Notably, different cities in Taiwan have adopted different strategies to achieve their HC project goals because they encounter distinct opportunities and challenges. Uniquely, Taiwan integrates the HC program with its Age-Friendly City (AFC) program to simultaneously address its burdens of an aging population and urbanization. A key component of the TAHC program is the platform created to exchange and share the performance of HC and AFC programs with other cities. Specifically, TAHC offers eight performance awards for HC and AFC, based on 16 categories for award applications.

The HC network in Taiwan has resulted in a series of positive achievements. Domestically, the annual HC conference and award ceremonies encourage more cities to participate in the HC projects. At the international level, the success of TAHC has attracted attention in the Asian region. The achievements and innovations of the TAHC are documented so that other HC participants can easily access and learn from them. To help other cities in Asia achieve their HC goals, WHO has been inviting TAHC members to present at its international biannual conference since 2010.

By sharing the progress of their HC and AFC programs, TAHC members have helped other Asian countries resolve many of their current problems. Moreover, TAHC members have been invited to visit the Japanese chapters of HC and presented Taiwan's HC and AFC programs to the Shanghai HC alliance in China. The success of the HC in Taiwan has largely resulted from integration among the public sector, the private sector, and the community (Hu and Kuo 2016; WHO 2016).

CASE STUDY 2

PRIMARY CARE WORKFORCE AROUND THE WORLD

A robust primary care workforce is critical in a diverse global community that faces the challenges of aging populations and epidemiologic transitions. There is a worldwide shortage of primary care physicians and an increased demand for primary care services. In response, the primary care workforce has been diversifying to include a wider range of health professionals such as nurse practitioners, registered nurses, and clinical staff members. Although primary care systems globally face challenges associated with a shrinking workforce and increasing care needs, there are differences in skill mix and organizational structures within and across high-income and low-to-middle-income countries.

A *skill mix* is defined as the combination of posts, grades, or occupations in an organization, or the combination of activities and skills needed for a particular job within an organization. Skill mixes differ by countries, sectors, and health systems. Factors such as resource availability, culture, and demographic makeup may determine the appropriate skill mix (Buchan and Dal Poz 2002).

In high-income countries such as the United Kingdom, the United States, and Canada, primary and community care services face the major challenges of increasing workloads, aging populations, and increasingly complex medical problems (Checkland and Spooner 2015). The numbers and working hours of primary care physicians are decreasing for reasons including, but not limited to, an increase in the proportion of female physicians electing to work fewer hours or part-time and an increase in the number of patients as well as their care demands. In response, most countries have diversified their primary care teams to include nonphysician providers such as nurse practitioners and physician assistants. While nurse practitioners and physician assistants are able to complete at least 60 percent of office-based primary care, owing to low remuneration and high training requirements, the numbers of nurse practitioners and physician assistants working in primary care are still low in many countries (Ginsburg, Taylor, and Barr 2009). It has been suggested that workplace innovations such as shifting tasks from physicians to nonphysician health professionals are necessary to resolve the current challenges of primary care. However, such task shifting necessitates a willingness of physicians to give up tasks and the ability and capacity of nonphysician providers to execute these tasks. In countries with emerging economies such as Brazil and India, workplace innovations such as task shifting have been more easily adopted, partly due to fewer established expectations of professional roles (Freund et al. 2015).

This chapter focuses on health-related policymaking in the international arena. The World Health Organization (WHO), recognized as the leading international health authority, is described, and examples from three countries—Canada, Sweden, and China—illustrate diverse policymaking processes in disparate geographic regions.

THE WORLD HEALTH ORGANIZATION

WHO is composed of the **World Health Assembly**, the Executive Board, and the Secretariat (WHO 2018a). Delegations from WHO's 194 member states make up the World Health Assembly, the decision-making and policymaking body of WHO (WHO 2018a). The Executive Board facilitates the work of the World Health Assembly and advises it on technical issues related to health. The Secretariat is the main implementation body of WHO's policymaking work and includes approximately 8,000 health experts and support staff (WHO 2018d).

World Health Assembly
The decision-making and policymaking body of the World Health Organization (WHO), composed of delegations from all WHO member states.

WHO's FUNCTIONS

WHO has six core functions (WHO 2018a):

1. Provide leadership on critical health issues worldwide, and engage in partnerships where joint action is needed.
2. Shape the research agenda, and stimulate the generation, translation, and sharing of health-related knowledge.
3. Set norms and standards, and promote and monitor their adoption.
4. Articulate ethical and evidence-based policy options.
5. Provide technical support, encourage innovations, and build sustainable institutional capacity.
6. Monitor health issues around the world, and assess trends.

In practice, WHO not only sets international health policy but also coordinates population health programs, such as mass immunization campaigns, emergency response efforts to natural disasters and disease outbreaks, and statistical monitoring of disease prevalence (WHO 2018f). WHO has also made great progress in its reform agenda during the twenty-first century (see, e.g., WHO 2018f, 2018h). Innovative leadership, managerial structures, and systems have resulted in increased effectiveness, efficiency, responsiveness, transparency, and accountability (see also the For Your Consideration box titled "The Impetus for International Healthcare Reform").

FOR YOUR CONSIDERATION

The Impetus for International Healthcare Reform

According to WHO (2008), three major trends are pushing forward the need for international healthcare reform. First, progress has been unequally distributed, with increasing health gaps between and within countries. While morbidity and mortality rates in the aggregate are much better today than in 1978, some countries have advanced enormously in health whereas others have not made similar gains. Second, the nature of health problems has changed due to significant social, demographic, and epidemiological transitions. Globalization, urbanization, and aging of populations have increased the transmission of communicable diseases and the global burden of chronic and noncommunicable diseases. Third, a lack of governance, underresourcing, and fragmentation of health services have led to the unregulated commercialization of healthcare, as in fee-for-service health services, which has contributed to the increased politicization of the right to health and social protection.

WHO has outlined five key elements that are necessary to achieve healthcare reform: (1) universal coverage reforms, (2) service delivery reforms, (3) public policy reforms, (4) leadership reforms, and (5) increased stakeholder participation (WHO 2008).

Universal coverage reforms: An important WHO target for sustained development in worldwide health and well-being is to "achieve universal health coverage," a goal that includes financial risk protection and access to safe, effective, high-quality, and affordable essential health services, medicines, and vaccines (WHO 2018h). WHO strongly supports universal health coverage as a critical method to reduce exclusion and social disparities worldwide.

Service delivery reforms: WHO describes service delivery reforms as a method of "putting people at the center of healthcare, harmonizing mind and body, people and systems" (WHO 2007a). These reforms should optimize a wide array of healthcare services to organize conventional healthcare delivery into people-centered primary care.

Public policy reforms: WHO describes three types of public policies that complement universal coverage and service delivery reforms (WHO 2008):

1. *Systems policies*: Policies that support functional supply and logistics systems
2. *Public health policies*: Policies that address priority health problems of both acute and long-term nature (i.e., public hygiene, disease prevention, nutritional campaigns, epidemic and catastrophe management)
3. *Policies in other sectors*: Policies that can benefit through intersectoral collaboration

Leadership reforms: WHO describes these reforms as replacing disengaged leadership with inclusive, participatory, negotiation-based leadership (WHO 2008).

Increased stakeholder participation: WHO advocates for participation from beyond the public sector, to engage stakeholders that include but are not limited to clinicians, civil society, communities, and researchers (WHO 2008).

WHO Policymaking Process

Proposals for new WHO resolutions or motions can be submitted by any World Health Assembly member state. Except for sessions convened in emergencies and other administrative considerations, proposals for new projects and initiatives can be included on the supplementary agenda of any assembly session. Following a preliminary impact analysis by the WHO director-general, a proposal is referred to the appropriate committee, which examines the proposal and related report at plenary meetings. After passing through the committee, the proposal or resolution is considered for adoption with a vote by the World Health Assembly. Proposals of particular importance, such as the appointment of the director-general and proposals involving other United Nations (UN) agencies (e.g., see the For Your Consideration box titled "Sustainable Development Goals"), require a two-thirds majority vote to be adopted. Most policy implementation is carried out through the WHO Secretariat, which oversees aspects of program design and the logistics of launching programs.

FOR YOUR CONSIDERATION
Sustainable Development Goals

In September 2015, the United Nations General Assembly adopted 17 Sustainable Development Goals (SDGs) by consensus, many relating directly to health. Specifically, SDG 3 seeks to "ensure healthy lives and promote well-being for all at all ages" (UN 2018; WHO 2018h). In shaping the conversation on healthcare reform, WHO has used SDG 3 to frame the healthcare reform agenda and focused on Target 3.8 of SDG 3—achieving universal health coverage (UN 2018; WHO 2018h). The two indicators for this target are (1) coverage of essential health services and (2) the proportion of a country's population with catastrophic spending on health, defined as "large household expenditure on health as a share of total household consumption or income" (WHO and World Bank 2017, vii). WHO has pinpointed the following key challenges to achieving healthcare reform and universal health coverage: data limitations in monitoring health coverage, existing inequalities within and between countries that exacerbate inequalities in health interventions, and lack of financial protection against catastrophic health expenditures (WHO and World Bank 2017).

WHO Health Programs

WHO currently operates programs and projects in more than 150 countries. They range from monitoring chronic diseases such as cancer and heart disease, to conducting eradication efforts for diseases such as leprosy, to combating infectious diseases such as influenza and HIV, to operating initiatives to prevent disease by ensuring access to clean water (WHO 2016, 2018g). Perhaps the most well-known WHO program was the campaign to eradicate smallpox, which came to a successful conclusion in 1979. This effort represents the first and only time thus far that the eradication of a major infectious disease has been achieved (WHO 2007b). In 1988, WHO partnered with four other public and private organizations—Rotary International, the Centers for Disease Control and Prevention, the United Nations Children's Fund, and the Bill and Melinda Gates Foundation—to form the Global Polio Eradication Initiative (GPEI), through which it strives for the same success in eradicating polio worldwide (WHO 2007b; GPEI 2018b). Thirty years after it was established, the GPEI had reduced global polio cases by 99.9 percent, and the paralyzing disease remained endemic in only three countries: Afghanistan, Nigeria, and Pakistan (GPEI 2018a).

One example of an ongoing WHO health program is the WHO Global Task Force on Cholera Control, which in 2017 introduced a "roadmap" with a three-pronged strategy to reduce the number of cholera deaths by 90 percent and eliminate cholera in as many as 20 countries by 2030 (WHO 2018b). The roadmap's three key strategic actions are to (1) detect cholera outbreaks early and respond quickly to contain them, (2) stop transmission of cholera in the small areas most heavily affected by the disease, and (3) provide technical support as well as human and financial resources to assist countries in their local efforts to control cholera (WHO 2018b).

Two key areas of ongoing focus relating to SDG's Target 3.3 are hepatitis and HIV, the virus that in its most advanced form results in AIDS (WHO 2018h). The Global Health Sector Strategy on viral hepatitis in 2016 called for "elimination of viral hepatitis as a major health threat" by 2030, measured as reductions of 90 percent in incidence and 65 percent in deaths (Hutin, Bulterys, and Hirnschall 2018). In 2016, with collaboration among many departments within WHO and across its regional and country offices, 35 countries established national hepatitis action plans (WHO 2018h). To combat HIV, WHO has used a strategy including (1) education to prevent new infections and (2) treatment with antiretroviral therapy (ART) for those who are infected. As a result, between 2000 and 2016, new HIV infections decreased by 39 percent, and HIV-related deaths decreased by about 33 percent (WHO 2018e). Transmission of the virus from an HIV-positive mother to her child during pregnancy, delivery, or breastfeeding has also been substantially reduced through the use of ART, and several countries (Armenia, Belarus, Cuba, and Thailand) have achieved the elimination of mother-to-child HIV transmission as a public health problem (WHO 2018e).

WHO also plays an instrumental role in containing sudden outbreaks of infectious diseases. For example, it helped coordinate the response to the outbreak of SARS (severe acute respiratory syndrome) in 2003 and continues to monitor the incidence of **avian influenza**—or "bird flu"—around the world.

avian influenza
A type-A influenza viral infection in wild or domestic birds. The avian influenza virus can become a public health danger if a change (mutation) allows it to more easily infect humans, and it can potentially start a worldwide epidemic.

WHO's Involvement in Health Policy

WHO is the global leader in formulating health policy. For example, WHO regularly writes and distributes policy reports on major diseases, such as HIV/AIDS, tuberculosis, and malaria. It also issues policy statements in response to disease outbreaks and natural disasters.

However, WHO and its policies and actions have often drawn criticism from various groups (Peabody 1995; Stein 2010). While WHO has increasingly focused its efforts on disease surveillance, many observers believe that the bureaucratic nature of the organization and its perceived slow reaction time undermine its ability to respond in urgent situations (Peabody 1995; Stein 2010). For example, an independent assessment of WHO's response to the **H1N1 (swine) flu** pandemic in 2009, conducted by the Institute of Medicine, concluded that WHO needed improvement in a number of areas (Cohen 2011; Langlois et al. 2016) and included the following points of criticism:

H1N1 (swine) flu
A respiratory disease caused by influenza type-A viruses, first detected in 2009. The new strain of influenza A (H1N1) virus is a mix of swine, human, and avian influenza viruses that is contagious and can cause seasonal flu.

- WHO does not have a standard method to measure the severity of an outbreak.
- WHO was not transparent about the members who served on its Emergency Committee, which led to speculation that they had ties to influenza vaccine–producing pharmaceutical companies.
- WHO had difficulty distributing vaccines in developing countries.

The report recommended that WHO establish an emergency fund for disease outbreaks, have advance agreements in place with pharmaceutical companies to supply vaccines on an as-needed basis, and set up a health emergency corps of personnel to mobilize in the event of an outbreak. Despite those concerns, WHO remains the world's leading policymaker and implementer in addressing health problems around the world.

HEALTH POLICYMAKING IN SELECTED COUNTRIES

Although WHO conducts high-level research, policy analysis, and emergency response, the vast majority of health policy in any country is still made at the national level. This section provides examples from Canada, Sweden, and China to illustrate the diverse political and healthcare systems, health challenges, and policymaking processes that exist around the world.

CANADA

Canada is a parliamentary democracy founded on the British system of government. The king or queen of England is Canada's head of state and is represented by the governor-general of Canada, who carries out formal duties on behalf of the British monarch (OCASI 2016).

The Canadian Parliament has two chambers: a lower chamber called the House of Commons and an upper chamber called the Senate. The House of Commons is the main legislative body (OCASI 2016; Parliament of Canada 2018a). It is composed of elected local representatives called members of Parliament (MPs), who typically belong to one of Canada's five major political parties:

1. Conservative Party
2. Liberal Party
3. New Democratic Party
4. Bloc Québécois
5. Green Party

Canada is divided into electoral districts, or *ridings*, on the basis of population, with one MP elected per riding. The political party with the greatest number of MPs forms the government, and the leader of that party becomes the prime minister, Canada's head of government (OCASI 2016). Elected officials who are not members of the ruling party become the official opposition (OCASI 2016). The Senate acts as a review board for legislation introduced by the House of Commons, and its 105 senators are appointed by the prime minister (OCASI 2016; Parliament of Canada 2018b).

Elected members of the federal and provincial governments can introduce legislation, which is voted on in Parliament or, for regional legislative issues, in the province's Legislative Assembly. The prime minister selects MPs from within the ruling party to form a cabinet. Cabinet ministers take on special responsibility for one or more federal platform issues (e.g., defense, finance, foreign affairs) in addition to representing the members of their electoral riding.

Canada is made up of ten provinces and three territories. Responsibility for such areas as national defense, foreign policy, and international trade rests with the federal government, whereas areas such as healthcare and education are provincial or territorial responsibilities. Large towns and cities also have their own local government, which is responsible for providing services such as police and fire departments and trash collection. See the International Policymaking box titled "Health Policymaking in Canada" for a summary of Canada's health policymaking process.

INTERNATIONAL POLICYMAKING

Health Policymaking in Canada

The health policymaking process in Canada exhibits the following features (Parliament of Canada 2018a, 2018b; Senate Canada 2017):

- The Canadian legislative process is based on the British model. Proposals for new laws or changes to existing laws are referred to as *bills*.
- Bills are usually introduced in the House of Commons; they may also be introduced in the Senate. However, it is the House of Commons rather than the Senate that dominates parliamentary government in Canada.
- After a bill is introduced, it must go through three rounds of readings and reviews, first by the House of Commons and later by the Senate.
- The bill is also sent to a legislative committee to be examined, clause by clause, before the third and final reading. The committee may bring in experts to testify on the contents of the bill before the first parliamentary chamber passes, amends, delays, or defeats the bill.
- If a bill is accepted and passed by both chambers, it is submitted for Royal Assent. In Canada, this approval is given by the governor general on behalf of the queen of England. After receiving Royal Assent, a bill becomes law.

Exhibit 4.1
Canadian Healthcare System Key Statistics (2009–2014 data)

Population	35,544,564 (2014)
GDP per capita (in PPP)	US $50,440
% of GDP spent on healthcare	10.4%
Healthcare spending per capita (in PPP)	US $4,640
Life expectancy at birth, male/female	80/84 years (2014)
Infant mortality rate	4.6 per 1,000 live births
No. of hospital beds per 1,000 people	3

Note: GDP = gross domestic product; PPP = purchasing power parity. No data for 2014 are available on the number of hospital beds per 1,000 people.
Sources: Public Health Agency of Canada (2016a); World Bank (2018).

The Healthcare System

An overview of key statistics related to Canada's healthcare system is shown in exhibit 4.1. The Canadian healthcare system is administered by the provincial and territorial governments and is taxpayer funded, mainly on the provincial level but also through federal taxation by way of the Canada Health Transfer. The 13 provinces and territories must meet the national standards outlined in the Canada Health Act to receive the full amount of federal funding available (Health Canada 2016).

The Canada Health Act stipulates that provinces and territories insure residents for all medically necessary primary and tertiary care provided by physicians and hospitals. Some provinces may provide additional benefits, such as coverage for dental or chiropractic care. Most physicians work in for-profit private practices; however, they bill and are paid through the public insurance system of their respective province or territory on a fee-for-service basis. Many large hospitals are not-for-profit and are associated with a religious group or university.

Health Policymaking

The Canada Health Act, the primary piece of health-related legislation at the federal level, was signed into law in 1984 (Health Canada 2016). The law ensures that all eligible Canadian citizens and residents have access to prepaid health insurance and services. It also provides the legal framework for provincial healthcare plans that receive federal funding.

Specifically, the Canada Health Act sets forth the following tenets:

1. *Public administration:* The healthcare system must be administered publicly and as a not-for-profit operation.
2. *Comprehensive coverage:* The system must provide insurance for all necessary health services.
3. *Universality:* All residents have the right to the same level of care.

4. *Portability:* Insurance must be portable from one province or territory to another.
5. *Accessibility of services:* All insured residents should have reasonable access to healthcare services.

The five listed criteria are considered the pillars of Canada's healthcare system (OECD 2001). However, there have been gradual erosions of the act in the twenty-first century, especially with the use of cannabis. Some researchers believe that the Canada Health Act should be further strengthened and violations punished by imposing fines equitably to protect the country's healthcare system (Norton 2017; Sibbald and Stanbrook 2016).

Key Health Policy Stakeholders

Key stakeholders include the federal government; Health Canada, the federal health department; the provincial governments, which administer the insurance plans; physicians' and nurses' associations and the Canadian Medical Association; industry and trade groups, such as the pharmaceutical industry; and the Canadian public (Boyko 2015; CDM 2018).

None of the political parties of Canada seek to dismantle the universal healthcare system; however, they have differing views on the degree to which it should be privatized. The Conservatives are generally in favor of more **privatization**, whereas Liberal, New Democrat, Bloc Québécois, and Green Party members generally favor less. Some politicians advocate for a two-tier health system, in which consumers can choose between public and private care. The implementation of this framework has become increasingly likely since June 2005, when the Canadian Supreme Court struck down a Quebec law prohibiting residents from buying private insurance that covered services already covered by the public system (Sibbald and Stanbrook 2016).

privatization
The movement of an industry in a country from public to private control or ownership.

Many doctors' and nurses' associations favor the public healthcare system and do not support the privatization of clinics and hospitals. Some, however, believe they would be paid more for their services, if they worked in a private system, than they are currently paid by the public insurance. The Canadian public is generally in favor of the universal healthcare system but, similar to the disagreements between the political parties that represent them, opinions vary on whether the system should remain public and the degree to which the system should become privatized.

Major Health Issues

When prioritizing current health issues, the Public Health Agency of Canada, Health Canada, and the Ministry of Health rely on public policy documents and analytical reports, such as the *Report on the Health of Canadians* (Parliament of Canada 2002), which are developed based on national health surveys conducted by Statistics Canada. Other stakeholders in health policy, such as the Canadian Labor Congress, focus on the broader determinants of health, including unemployment and homelessness, in the context of their priorities.

Those conditions and diseases noted in the report as causing the greatest amount of mortality or morbidity in the population as a whole, in certain geographic areas, or within specific demographic groups are considered high priority for intervention. In addition, the report addresses determinants of health through targeted interventions in the highest-risk communities. This aspect of the reporting reflects the Canadian government's overall focus on preventive health.

Other major areas of focus include the health of the elderly and access to healthcare for those living in rural and remote areas. These priorities directly address two key demographic challenges in Canada: the aging population and the low population density outside of major urban areas. In the twenty-first century, the rapidly growing global burden of noncommunicable diseases affects Canada as well. A 2016 report on the health status of Canadians indicated that the top three health concerns in Canada were cancer, cardiovascular disease, and diabetes (Murray 2017). Specifically, it was estimated that two in five Canadians (40 percent) would develop cancer in their lifetime (Public Health Agency of Canada 2016b). Noncommunicable diseases are also closely linked to aging and thus affect a significant portion of the population (Murray 2017; OECD 2001; Public Health Agency of Canada 2016b).

SWEDEN

Sweden is a constitutional monarchy and parliamentary democracy. Citizens elect 349 members to represent them in the Riksdag, Sweden's legislative assembly. Elections are held every four years. Eight political parties were represented in the Riksdag during the 2014–2018 electoral period. The political party whose members win the most seats in the Riksdag forms the government, which is led by the prime minister. The prime minister, in turn, selects 22 other representatives to become ministers and form the cabinet. The government presents new proposals for legislation and for amendments to existing laws (Government Offices of Sweden 2018; Sveriges Riksdag 2018a, 2018b). The Swedish head of state is the reigning monarch, who has no political powers (*Economist* 2009; Sveriges Riksdag 2018a).

The Swedish Constitution is made up of four fundamental laws:

1. The Institute of Government outlines the functions of the Swedish government and elections.
2. The Act of Succession regulates who inherits the throne of the Swedish monarchy.
3. The Freedom of the Press Act guarantees the people's right to disseminate information.
4. The Fundamental Law on Freedom of Expression gives citizens the right to access government documents.

INTERNATIONAL POLICYMAKING
Health Policymaking in Sweden

The health policymaking process in Sweden is distinguished by the following features (Government Offices of Sweden 2018; Sveriges Riksdag 2018a):

- The Swedish government is responsible for proposing new laws. It must appoint a committee of inquiry to assess the feasibility of a proposed initiative.
- The committee writes a report that is circulated to relevant agencies and the Council on Legislation for consideration.
- After the committee has gauged the feasibility of the proposed law, the government presents a bill to the parliament—known as the Riksdag—which then votes on the bill. If it passes, the bill becomes a new law and is published in the *Swedish Code of Statutes*.

These fundamental laws are prioritized over all other ordinary laws in Sweden (Sveriges Riksdag 2018a). Sweden is also subject to the legislation of the European Union (EU 2018). Some EU laws are automatically adopted by Sweden, and some must pass through a vote in the Riksdag to be formally incorporated. See the International Policymaking box titled “Health Policymaking in Sweden” for a summary of Sweden’s health policymaking process.

Healthcare System

Exhibit 4.2 provides key statistics related to the Swedish healthcare system. Healthcare in Sweden is universal and automatic; it is primarily publicly financed, mainly through a county council income tax paid by individuals (Glenngård 2018). Patients are charged a small fee for services, and the county council pays the remaining costs. The national government sets an annual out-of-pocket ceiling for individuals. Private health insurance, in the form of supplementary coverage, is uncommon but gradually increasing. Individuals who purchase private health insurance typically seek to ensure quick access to an ambulatory care specialist and to avoid waiting lists for elective treatment. In 2016, about 10 percent of all employed individuals aged 15–74 had private insurance (Glenngård 2018).

The national government is responsible for healthcare regulation but plays no role in healthcare delivery; this responsibility lies with county councils and municipal governments. County councils deliver most primary and tertiary care, while municipal governments arrange for elder care, including basic healthcare delivered in the patient’s home or a nursing home (Glenngård 2018).

Exhibit 4.2 Swedish Healthcare System Key Statistics (2009–2014 data)

Population	9,696,110
GDP per capita (in PPP)	US $59,180
% of GDP spent on healthcare	11.9%
Healthcare spending per capita (in PPP)	US $5,218
Life expectancy at birth, male/female	80/84 years
Infant mortality rate	2.4 per 1,000 live births
No. of hospital beds per 1,000 people	no data

Note: GDP = gross domestic product; PPP = purchasing power parity. Life expectancy figures are for 2014.
Sources: Danielsson and Talback (2012); Glenngård (2018); World Bank (2018).

Residents with nonurgent conditions first seek healthcare services from general practitioners (GPs) at primary healthcare centers. Primary healthcare centers offer basic medical and public health services, and the GPs refer patients to a specialized care provider if needed. County and district hospitals provide specialized care, such as dermatology and ophthalmology. Regional hospitals provide highly specialized healthcare services, such as knee replacements, organ transplants, and heart surgery. In addition, highly specialized care often requires advanced technical equipment and is usually located in university hospitals (Glenngård 2018).

Notably, three basic principles apply to all healthcare in Sweden (Glenngård 2018):

1. *Human dignity:* All human beings are equally entitled to dignity and have the same rights regardless of their status in the community.
2. *Need and solidarity:* Those in greatest need take priority in being treated.
3. *Cost-effectiveness:* When a choice is made, there should be a reasonable balance between costs and benefits, with cost measured in relation to improvement in health and quality of life.

Health Policymaking and Key Health Policy Stakeholders

The national, county, and municipal levels of government in Sweden collectively wield influence on healthcare and health policy (Glenngård 2018). As such, they are the primary stakeholders in health policymaking. The various levels of government provide services for the vast majority of the population's healthcare needs. Private health insurers are not common because of the comprehensive public healthcare system. Coverage has been universal since the 1982 Health and Medical Services Acts were enacted to ensure that the health system covers all legal residents in Sweden.

The public is also a major stakeholder in Sweden's healthcare system because it can indirectly influence health policy on the national level and health priorities on the county level through the voting process.

Major Health Issues

Healthcare priorities in Sweden are established by the National Board of Health and Welfare's Health Reports (see, e.g., National Board of Health and Welfare 2013). These reports are based on data collected from a variety of sources: government healthcare inquiries, patient data from public hospitals, literature reviews and existing studies, and national surveys including interviews with and questionnaires administered to target populations. Examples of data sets include the Living Conditions Survey, Household Finances Survey, National Public Health Survey, National Database on Waiting Lists and Wait Times, and Health Care Barometer.

In the 2010 National Public Health Policy Report, 11 objective domains were grouped into three strategic areas developed from a previous Health Report, which identified the most pressing issues facing Sweden in terms of mortality and morbidity in the coming decade. The 2010 goals addressed the following three strategic areas (Linell, Richardson, and Wamala 2013):

1. Good living conditions
2. Health-promoting living environments and lifestyle habits
3. Alcohol, illicit drugs, doping, tobacco, and gambling

About 60 percent of the recommendations in these three strategic areas were adopted within two years after the Public Health Policy Report 2010 was published (Linell, Richardson, and Wamala 2013). In setting priorities, public health researchers consider not only the direct causes of mortality and morbidity but also the determinants of health and the social and economic conditions that may indirectly contribute to an increase in disease burden in certain populations.

Since the report was issued, Sweden has targeted the promotion of smoke-free dining environments and healthy eating habits, achieving an improvement over the 2010 goals in these areas. Many measures and activities have influenced the Swedish people to decrease their use of tobacco (Linell, Richardson, and Wamala 2013). The Swedish government continually monitors access to healthcare and healthcare effectiveness to identify additional areas for improvement. More important, inspiring innovations and reforms are occurring in Sweden.

CHINA

Key statistics for China and its healthcare system are shown in exhibit 4.3. The People's Republic of China operates under a single-party socialist system of government (Lawrence and Martin 2013). The Communist Party of China (CPC) manages the national government

EXHIBIT 4.3
Chinese Healthcare System Key Statistics (2009–2014 data)

Population	1,364,270,000
GDP per capita (in PPP)	US $7,683
% of GDP spent on healthcare	5.5%
Healthcare spending per capita (in PPP)	US $730
No. of doctors per 1,000 people	1.49
Life expectancy at birth, male/female	75/78 years
Infant mortality rate	9.9 per 1,000 live births
No. of hospital beds per 1,000 people	4

Note: GDP = gross domestic product; PPP = purchasing power parity. Data for the number of doctors per 1,000 people are for 2011. No data for 2014 are available on the number of hospital beds per 1,000 people.
Sources: Fang (2018); WHO (2018c).

through the National People's Congress (NPC), which is the main legislative body in China, and through the State Council, which is the executive body of the Chinese government. The president is elected by the NPC, leads the government, and appoints a premier to lead the State Council who, in turn, nominates individuals for the position of vice premier and other ministerial posts. Local people's congresses also take place throughout China.

Although elections are held to select representatives to the NPC and local people's congresses, each candidate for office must be affiliated with the CPC (Lawrence and Martin 2013).

China is governed by a written constitution. In part, it stipulates that the CPC is the sole political party in power, that China will remain a socialist society, and that all power belongs to the people (Lawrence and Martin 2013). See the International Policymaking box titled "Health Policymaking in China" for a summary of China's health policymaking process.

INTERNATIONAL POLICYMAKING
Health Policymaking in China

The health policymaking process in China has the following features (Lawrence and Martin 2013; China Internet Information Center 2018):

- The NPC and its Standing Committee are the main legislative bodies in China. Local people's congresses also draw up legislation on a regional level.
- The Political Bureau of the Central Committee of the Communist Party of China plans legislation in five-year periods.
- Based on the preparations made in this planning stage, bills are introduced to the NPC or Standing Committee. Most bills are introduced by the State Council. Important bills are published for public feedback before being submitted to the NPC for review.
- After bills are submitted for consideration, the president of the NPC and the Council of Chairmen of the Standing Committee decide whether to add the bill to the agenda or to discard it. Bills submitted by the president are automatically considered. The remaining bills on the agenda are debated by the delegates. The Law Committee may make amendments to a bill before a final vote.
- The bill becomes formal law after it passes a majority vote and is signed by the president. The president may not veto a bill once it is passed.

Healthcare System

The laws governing the healthcare system in China are the Fundamental Health Law and the Hygienic Common Law. In 2009, China introduced a universal healthcare system intended to cover 90 percent of the population by 2010 (China Daily 2011). This target was met: Coverage by publicly financed health insurance is near universal—exceeding 95 percent of the population—but the level of coverage varies by type of insurance scheme (Jiang 2015). This reform resulted largely from the expansion of four government insurance schemes: the basic scheme for urban workers, the urban-resident scheme for other urban residents such as children and students, the rural cooperative system for the rural population, and the medical assistance program for the poor. These insurance schemes work by collecting funds from all insured persons, the local government, and employers; pooling the funds; and dispensing them according to health need. The Learning Point box titled "China's Four Insurance Programs" describes the schemes in greater detail.

Healthcare is primarily delivered by local governments. In some communities, large employers such as mining companies may also set up health clinics. Primary care is delivered through local health clinics and small hospitals. Specialized care is provided at regional borough hospitals or larger teaching and research hospitals in urban areas.

LEARNING POINT
China's Four Insurance Programs

Basic insurance scheme: Designed for urban employees, with relatively generous and comprehensive benefit packages. Employees pay premiums and copayments and receive comprehensive care at designated hospitals and providers. Participation is mandatory for employees in urban areas; the population insured under this scheme numbered 283.3 million in 2014 (Mossialos et al. 2016).

Urban-resident scheme: Implemented in 2007 to cover primary and secondary school students who are not covered by the basic insurance scheme. Higher premiums are assessed than for basic insurance. Participation is voluntary at the household level and covered 314.5 million self-employed individuals, children, students, and elderly adults in 2014 (Mossialos et al. 2016). Both urban employment-based and urban resident basic medical insurance are administered by the Ministry of Human Resources and local authorities (Mossialos et al. 2016).

Rural cooperative system: Covers rural residents. Government and local subsidies are typically provided to operate facilities. Benefits are generally low and may only cover catastrophic illness. Not considered a viable insurance scheme by most policy analysts. Participation is also voluntary at the household level and covered a rural population of 736 million—about 99 percent of all rural residents—in 2014 (Mossialos et al. 2016). This system is administered primarily by the National Health and Family Planning Commission and implemented by local authorities (Mossialos et al. 2016).

Medical assistance program: Aims to cover those designated by the government as poor, but eligibility varies widely across regions. Less than 10 percent of the population is eligible for medical assistance coverage (Mossialos et al. 2016).

Health Policymaking

The healthcare reform package of 2009 serves as an example of China's legislative process. China's State Department sets regulations for the healthcare system, and other government departments, such as the State Food and Drug Administration and the Quarantine Bureau, can institute department rules concerning public health.

Key Health Policy Stakeholders

China's national government, including the Ministry of Health (renamed the Commission of Public Health and Family Planning), plays an enormous role in the healthcare system, but it is not the only stakeholder (Ministry of Health, Government of China 2009).

Exhibit 4.4 summarizes the responsibilities and roles, resources, and functions of the following stakeholders:

- The central government
- Relevant ministries
- Local governments
- Hospitals and medical institutions
- Medical staffs
- The pharmaceutical industry
- The public
- Think tanks
- The media

Major Health Issues

China's size and its geographic and socioeconomic variability can stymie efforts to collect comprehensive data about all populations and in all regions. The Chinese Ministry of Health sets priorities by collecting and analyzing data on the conditions that contribute most to morbidity and mortality in the entire country or in specific regions or populations (WHO 2005; Zheng et al. 1998). Some analysis is carried out in conjunction with WHO and other United Nations agencies, such as UNAIDS.

China also has a number of health surveillance systems in place to collect data, such as the Ministry of Health's National Nutritional Surveillance System, the Chinese Center for Disease Control and Prevention, and the National Disease Reporting System, the latter of which was established in 1959 and reports on 37 infectious diseases (Liu et al. 2016; Zhang et al. 2007).

Other areas on which Chinese health policymakers focus are the prevention of infectious disease outbreaks, diabetes, hypertension, cardiovascular disease, and cancers (Fu et al. 2018). More than half of all men in China smoke, posing another long-term public health concern. The size of China's population also fuels government concern over family planning measures; care for the elderly (e.g., mandatory support for elderly by adult family members; subsidies for elderly without children; development of "respect the elderly" housing, similar to the nursing home model in the United States); and the treatment of lifestyle-related chronic diseases, such as diabetes and cardiovascular diseases (Bi et al. 2015; Wang et al. 2017).

Exhibit 4.4
Major Stakeholders in China's Health Policymaking Process

Stakeholders		Resources and roles	Interests	Functions
Government	Central government	The main body in policymaking; plays a leadership role	Social and political interests	Directly responsible for decisions at the national level and overall economic and social policy formulation
	Relevant ministries	The main body in policymaking within jurisdictions	Interests of own department	Directly responsible for policymaking within jurisdictions
	Local governments	Policy interpretation and implementation	Local interests	Directly responsible for the interpretation of central policy and local policymaking; express local opinion to central government
Supply side of healthcare	Hospitals and medical institutions	Market power; have influence and ability to evade administrative power	Government funding, hospital ratings, and market share	Have influence on policymaking by relationship with decision makers and own market reputation
	Medical staff	Have the right to prescribe; hold information superiority	Personal development, income, and professional reputation	Use information superiority and right of prescription
	Pharmaceutical industry	Market power	Profits	Provides funding to research institutions, hires experts and scholars as consultants, and forms coalitions of interest with media and local government
Demand side of healthcare	The public	Has the right to choose medical services	Healthcare quality, fairness, and access to healthcare	Uses media to form public opinion; expresses opinion to decision makers or experts in the research process
Think tanks	Government-affiliated policy advisory body	Provide policy advisory services	Consistent with the interests of their respective ministries	Directly involved in the policy-making process; provide policy advice to decision makers
	Independent research institutions	Provide policy advisory services	Social interests	Provide policy advisory support; submit report to government and releases to the media
Media		Influence public opinion; support different stakeholders	Diverse interests according to policy preferences	Guide public opinion, help form public agenda, and join in various policy networks

KEY POINTS

- ➤ As the world's health authority, WHO acts as a leader and partner on health issues worldwide, sets research priorities and encourages the sharing of health-related knowledge, establishes standards of practice and supports and monitors their adoption, advances policy options founded on ethical and evidence-based principles, lends technical support to health initiatives and contributes to capacity building, and monitors health issues around the world and identifies patterns and trends.
- ➤ The Canada Health Act is the primary piece of health legislation in Canada. It ensures that all eligible Canadian citizens and residents have access to prepaid health insurance and services. It also provides the legal framework for provincial healthcare plans receiving federal funding.
- ➤ The national, county, and municipal levels of government in Sweden collectively wield influence on healthcare and health policy, and they provide services for the vast majority of the population's healthcare needs.
- ➤ China's State Council sets regulations for the healthcare system. Other government departments, such as the Ministry of Health, State Food and Drug Administration, and Quarantine Bureau, can institute department rules for healthcare delivery and public health.

CASE STUDY QUESTIONS

CASE STUDY 1

After researching the origin and evolution of the WHO Healthy Cities initiative, answer the following questions:

1. Why was the Healthy Cities initiative developed?
2. What are the initiative's major objectives? Has it achieved them?
3. What were the ingredients for success for the participants in the Healthy Cities initiative?

CASE STUDY 2

After researching the definition and role of the primary care workforce, answer the following questions:

1. How is *primary care* defined? What are its major components?
2. What roles does primary care play in healthcare delivery and population health?
3. What strategies can be adopted to expand primary care around the world?

For Discussion

1. What are the functions of WHO?
2. How are health policies made at WHO?
3. Cite examples of WHO-sponsored health programs.
4. Answer the following questions for each country profiled in this chapter:
    a. How are health policies made in the country?
    b. What is the primary legislation related to healthcare policy in the country, and what are its main features?
    c. What are the top health issues in the country?
5. Using examples from Canada, Sweden, and China, identify stakeholders and describe their interests in and influence on health policymaking.

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PART III

HEALTH POLICY ISSUES

Part III consists of three chapters that provide examples of health policy issues. Chapter 5 focuses on health policies for US healthcare delivery and financing. Chapter 6 discusses health policy concerns for people with special needs and other vulnerable populations. Chapter 7 illustrates health policy concerns in the international community, including both developed and developing countries.

The broad health policy issues presented in this part of the book should help students understand how health policy is applied in the context of healthcare delivery and other determinants of health. Knowledge of policy applications prepares readers to examine how health policies are studied and evaluated—the focus of part IV.

CHAPTER 5

HEALTH POLICY RELATED TO FINANCING AND DELIVERY

> *Healthcare in our country is too expensive, too complicated. And too many times, the system is downright unfair.*
>
> —George H. W. Bush

> *Nearly a century after Teddy Roosevelt first called for reform, the cost of our health care has weighed down our economy and the conscience of our nation long enough. So let there be no doubt: health care reform cannot wait, it must not wait, and it will not wait another year.*
>
> —Barack Obama

LEARNING OBJECTIVES

After completing this chapter, you should be able to

- ➤ describe how healthcare is financed and delivered in the United States, and
- ➤ provide examples of financing and delivery and discuss related health policy issues.

CASE STUDY 1

THE FEDERALLY FUNDED HEALTH CENTER PROGRAM: PROVIDING ACCESS, OVERCOMING DISPARITIES

The Health Resources and Services Administration (HRSA), a government agency in the US Department of Health and Human Services (HHS), supports access to care for US residents through community-based, patient-directed, federally funded health centers, with patients making up at least 51 percent of board members (HRSA 2011). Health centers have provided accessible and affordable healthcare services to individuals in the most underresourced communities since the 1960s. To be designated as a health center, healthcare organizations must meet the following criteria:

- Be located in or provide services to high-need communities—those the government designates as medically underserved areas or populations
- Provide primary care services and promote access to care exceeding that previously offered through supportive services, such as translation and transportation
- Provide services at fees based on ability to pay

The scope of health center services includes primary care, dental care, and vision care, as well as mental health, substance use disorder, and patient support services (HRSA 2017). Although health centers are not specifically tailored to minorities or the uninsured, a disproportionate number of patients are racial or ethnic minorities; are uninsured; or come from low-income, underserved communities. In 2016, about 62 percent of health center patients were racial or ethnic minorities, and about 24 percent were uninsured (HRSA 2018). Health centers also provide vital services in rural areas, where access to affordable healthcare may be limited. About one-sixth of rural residents used health center services in 2016 (HRSA 2017).

In 2016, the HRSA granted health center status to 1,367 organizations nationwide, serving more than 25 million people (HRSA 2018), including more than 330,000 veterans, at more than 11,000 service delivery sites throughout the United States and its territories (HRSA 2017). Health centers fill a gap in access to critical healthcare for the uninsured by providing high-quality primary care services; delivering cost-effective care; and offering catalysts for local economic development, particularly in underserved communities (HRSA 2017).

CASE STUDY 2

PRECISION MEDICINE

Precision medicine is an approach in prevention and treatment that accounts for individual variability (NIH 2018). The concept has been used before. For example, blood typing has been used since the early twentieth century to guide blood transfusions. Science has driven and improved the broad applications of this concept, depending on financial support and emerging laws and regulations. However, policymaking and regulatory activities related to precision medicine have taken a while to develop since the Human Genome Project was launched in 1990.

The Human Genome Project had the ambitious goal of determining and mapping "the nucleotides in a human haploid reference genome" (Sawicki et al. 1993). Progress in this project has benefited the growing field of precision medicine. Government agencies such as the US Food and Drug Administration (FDA) have issued guidelines for assessing genetic variations in the drug development process, and the National Center for Toxicological Research has studied genetic polymorphisms, individual susceptibility, and drug efficacy, which has helped advance precision medicine (National Research Council 2011). In the late 1990s, several government advisory committees, including the Secretary's Advisory Committee on Genetic Testing, established by HHS, sought to understand the pathway for using genetics more broadly (National Research Council 2011). Their work helped set the regulatory stage for precision medicine.

In April 2003, the Human Genome Project was declared complete, after taking 15 years to sequence the first genome and costing $3 billion (Ashley et al. 2010). Considering the mapping of the human genome and the emerging potential of precision medicine, the FDA issued two guidelines: the 2005 Pharmacogenomic Data Submissions and the 2007 Pharmacogenomic Data Submissions Companion Guidance. These guidelines served as the first policy step toward the real-world application of precision medicine in the drug development and approval process. The 2005 guideline laid the first regulatory foundation for the FDA's evaluation of proposed precision medicine biomarkers, and the 2007 guideline provided specific recommendations (Ashley et al. 2010; National Research Council 2011).

From 2008 to 2014, the FDA and other government entities created or reorganized offices and collaboratives to build regulatory infrastructures, issuing several guidelines to address the expected growth of precision medicine (White House Office of the Press Secretary 2015). In 2013, the FDA launched the Genomic Working Group and published a report, *Paving the Way for Personalized Medicine—FDA's Role in a New Era of Medical Product Development*, to describe the role and responsibilities of the FDA in personalized medicine and to provide a comprehensive overview of precision medicine from scientific and regulatory perspectives (FDA 2013).

In January 2015, President Barack Obama announced the launch of the Precision Medicine Initiative (PMI) during his State of the Union Address. The initiative outlined a broad series of action items, including providing $215 million in funding, and called for the federal government to take on a more significant role in promoting scientific research for precision medicine through the FDA, the National Institutes of Health (NIH), the Department of Veterans Affairs (VA), and the Department of Defense (White House Office of the Press Secretary 2015).

Specifically, the NIH became responsible for a critical element of the PMI: development of a national research cohort program to collect genetic data from more than one million volunteer participants in the United States (White House Office of the Press Secretary 2015). The information would form a database for precision medicine projects, especially for common diseases and conditions, to better understand how diseases occur, predict disease risk, and improve diagnosis and treatment. The PMI also earmarked funds for the National Cancer Institute, part of the NIH, to identify genetic elements in certain cancers and develop better targeted treatments for them (White House Office of the Press Secretary 2015). Intensive efforts in precision medicine have been applied to cancer, based on innovative clinical trials, combination therapies, and knowledge of drug resistance.

The VA also developed the Million Veteran Program (MVP), a national volunteer program that studies how genes influence health. By August 2016, the MVP had voluntarily enrolled 500,000 military veterans and, even though it was only halfway to its goal, had already become the world's largest genomic database (VA 2016). The FDA established a "precisionFDA" initiative to develop open-source methodologies for clinical uses of such databases (White House Office of the Press Secretary 2015). These initiatives represent an unprecedented level of government involvement in precision medicine research and help create a new scientific model that encourages participant engagement, responsible data sharing, and privacy protection.

The American public health system comprises a network of individuals and organizations in both the public and private sectors that work together at federal, state, and local levels (Hyde and Shortell 2012). Public health agencies associated with the federal government, the governments of the 50 US states plus the District of Columbia, and 2,794 local governments and 565 tribal agencies constitute the governmental public health system (Salinsky 2010).

This chapter provides examples of healthcare policies at multiple levels in the United States that affect healthcare financing and delivery, beginning with a summary of their current status to help you appreciate the underlying rationales for healthcare policy in the United States.

FINANCING US HEALTHCARE

Healthcare spending is often described in terms of a country's *national health expenditure* (see the Critical Concept box titled "National Health Expenditures"). The United States, for example, leads the world in national health expenditure; in 2016, national health spending accounted for 17.9 percent of the gross domestic product (GDP)—more than a threefold increase from its 1960 level of 5.2 percent (CMS 2018a; NCHS 2011).

Another way to quantify healthcare spending is average *per capita* (per person) spending, which adjusts the percentage by population size. In the United States, the amount spent on healthcare per capita increased from $146 in 1960 to $10,348 in 2016 (CMS 2018a).

In 2016, of the healthcare dollars being spent in the United States, costs for physician and other professional services (22.7 percent), hospital care (32.4 percent), and prescription drugs and medical products (9.8 percent) accounted for 64.9 percent of total national healthcare expenditures, with the remaining expenditures including nursing home and home health care (7.7 percent); research, structures, and equipment (4.7 percent); public health (2.5 percent); and administration (1.3 percent), among others (CMS 2018a, table 2). The distribution of spending was similar to that for 2011 (CMS 2018a, table 2).

CRITICAL CONCEPT
National Health Expenditures

National health expenditures, also referred to as *national health spending* or *national healthcare costs*, are estimates of annual spending on health services, healthcare supplies, and health-related research and construction activities. Total healthcare expenditures are often compared with total economic consumption, represented by the GDP—a measure of the total value of all goods and services that are produced and consumed during a given calendar year.

Hospitals are the largest source of healthcare spending among institutions. Exhibit 5.1 profiles US hospitals by size and type. The For Your Consideration box titled “Hospital Value-Based Purchasing” describes a program developed by the Centers for Medicare & Medicaid Services (CMS) to link hospital payments to quality of care.

EXHIBIT 5.1
A Profile of US Hospitals, 2016

Total number of US hospitals	**5,534**
Community hospitals	4,840
Federal government hospitals	209
Nonfederal psychiatric hospitals	397
Other hospitals, including nonfederal long-term care hospitals and hospital units within institutions (e.g., prison hospitals, college infirmaries)	88
Total number of staffed beds in US hospitals	**894,574**
Staffed beds in community hospitals	780,272

Source: Data from AHA (2018).

FOR YOUR CONSIDERATION
Hospital Value-Based Purchasing

Under the CMS Hospital Value-Based Purchasing Program, which emphasizes quality of care, acute care hospitals are paid according to quality of care and encouraged to improve quality of care by doing the following (Lee and Kaiser 2016):

- Minimizing adverse events (errors in care that harm patients)
- Applying evidence-based standards and protocols for care that yield the best outcomes for the most patients
- Improving hospital processes and the patient experience
- Increasing transparency of care for consumers
- Recognizing hospitals that provide high-quality care at a lower cost than Medicare

The many contributing factors in the dramatic rise in US healthcare costs include the following:

- An emphasis on curing disease rather than preventing disease and maintaining wellness
- Advances in technology and its extensive use in delivering healthcare
- The inefficiency of a multiple third-party payer system
- An increase in the elderly population and accompanying cases of chronic illness
- Waste and abuse within the system, due in part to geographic variations in practice
- General inflation
- Continuing recovery from the Great Recession (December 2007–June 2009)
- The practice of **defensive medicine**

defensive medicine
The practice of medicine in which the main goal is to avoid malpractice claims, not to ensure good health for the patient or maximum medical efficiency.

Several forms of health insurance have been developed to help patients pay—and allow providers to be paid—for healthcare. These mechanisms fall under two general types: private health insurance and public health insurance.

PRIVATE HEALTH INSURANCE

managed care
A care model characterized by a designated provider network, standardized review and quality improvement measures, an emphasis on preventive rather than acute care, and financial incentives for doctors and patients to reduce use of unnecessary medical care.

Private insurance is an essential source of healthcare coverage for most Americans. Among private insurance options, **managed care** predominates. *Managed care plans* are available through **managed care organizations (MCOs)**, such as health maintenance organizations (HMOs), which tend to be large integrated companies that employ doctors on salary and have a network of providers and sometimes hospitals, and preferred provider organizations (PPOs), which contract with doctors and hospitals to offer patients a preferred provider network for care. (Refer back to chapter 1 for a discussion of HMOs and PPOs.) In exchange for an insurance **premium** and **deductible** from enrollees, MCOs assume financial risk, as well as responsibility, for delivering care to enrollees through provider networks.

Private health insurance is offered by commercial insurance companies such as Aetna and Metropolitan Life; nonprofit organizations such as Blue Cross and Blue Shield associations; self-insured employers; and MCOs, which pay a large portion of healthcare expenses that subscribers incur. Together, they accounted for about 35 percent of the funding sources for medical expenditures nationwide in 2016 (CMS 2018a, table 3).

managed care organizations (MCOs)
Organizations that seek to apply the components of managed care to a population to provide high-quality care at a lower cost than that incurred by fee-for-service care.

premium
The amount an enrollee must pay to join a managed care plan. It serves as a membership fee and is typically adjusted annually.

deductible
The amount an insured patient must pay out of pocket for medical care every year before the insurance plan covers costs.

PUBLIC HEALTH INSURANCE

Public insurance programs are health plans that are financed by the government. Together, these programs account for about 54 percent of funding sources for medical expenditures (CMS 2018a, table 3).

In this system, the government provides benefits to specific eligible individuals by reimbursing providers in the private sector for care given to beneficiaries. The Medicare and Medicaid programs were created under the Social Security Amendments of 1965 and are administered by CMS under HHS. These and other public insurance programs are described in more detail next.

Medicare

The Medicare program provides healthcare coverage to (1) individuals aged 65 or older, (2) people of any age with disabilities who are eligible for Social Security benefits, and (3) individuals with end-stage renal (kidney) disease. The number of Medicare beneficiaries has increased substantially, from 19.1 million in 1966 to 44.1 million in 2007, including 36.9 million elderly and 7.2 million nonelderly individuals, and is expected to reach 61 million by 2020 with the aging of baby boomers (KFF 2018).

Medicare is a four-part program. The parts, labeled using the letters A through D, are described in the following paragraphs (CMS 2018e).

Medicare Part A covers healthcare services received in hospitals, nursing facilities, hospice care, and certain home health care programs. Subscribers do not pay a monthly premium. Part A is financed by mandatory payroll taxes paid by all working individuals.

Medicare beneficiaries who are willing to pay a monthly premium—determined on the basis of income—may also enroll in *Medicare Part B*. This supplemental insurance pays for physician services and for outpatient care that is not covered by Part A. Part A and Part B do not cover certain services and devices, such as vision care, eyeglasses, dentures, and hearing aids. However, Medicare Part B covers Pap tests; mammography; and screening for colorectal cancer, prostate cancer, and glaucoma, as well as influenza and pneumonia vaccinations.

Medicare Part C, known as Medicare Advantage, is an optional private plan that contracts with Medicare and provides all Part A and Part B services, plus additional services as specified by the individual plan. The insurance plan pays participating private health insurers for services received by beneficiaries in exchange for a monthly insurance premium.

Medicare Part D provides coverage for prescription drugs and offers two types of private insurance plans that help pay for brand-name as well as generic prescription drugs purchased at pharmacies listed in the Medicare program.

Medicaid

Medicaid provides healthcare benefits to eligible, low-income, elderly and nonelderly individuals, with separate programs for low-income women and children and people with disabilities. In this joint federal–state program, the federal government provides financial support to states by matching state funding for this program, with federal funding calculated on the basis of states' per capita income (CMS 2018c).

Each state sets its own eligibility criteria and covered services—which must meet a minimum threshold of services required by the federal government—as well as amounts of payments made to providers. Each state also has discretion to establish and define other medically needy categories for Medicaid coverage, which often include individuals living in institutions (e.g., nursing homes, psychiatric facilities) and those receiving care in community-based settings (CMS 2018c).

Children's Health Insurance Program

Children in uninsured families whose income lies within 200 percent of the **federal poverty level (FPL)** are eligible to enroll in the Children's Health Insurance Program (CHIP). This federal program allows states to expand Medicaid eligibility and establish a special child health assistance program by providing additional funds to state Medicaid programs. States can expand the eligibility criteria to cover children younger than 19 years of age in families with incomes exceeding the FPL established for Medicaid eligibility, pregnant women, parents of children enrolled in CHIP, and caretaker relatives (CMS 2018c).

federal poverty level (FPL)
A calculation that reflects federal government guidelines for assessing need from income, based on cost of living (the amount of income needed by families to be self-supportive). Many federal assistance programs use a percentage of FPL as part of their eligibility criteria.

IMPACT OF HEALTHCARE REFORM

The Affordable Care Act (ACA) of 2010 introduced new funding mechanisms in both public and private health insurance. For example, the ACA was expected at the outset to provide financing to increase the proportion of nonelderly legal residents with insurance from about 83 percent to about 94 percent, thus lowering the number of the uninsured nonelderly by 32 million by

2019 (CBO 2010). It also allowed for the expansion of Medicaid coverage (see the Key Point box titled "Medicaid Expansion"), and states that participated in the expansion experienced significant gains in coverage and reductions in uninsured rates (Antonisse et al. 2018). More than 9.2 million people signed up for care on the national exchange in 2017, down by about 400,000 from 2016, but the fate of the ACA remains uncertain under the Trump administration. With the repeal of the individual mandate to purchase healthcare insurance scheduled to take effect in 2019, the Congressional Budget Office (CBO) predicted that about 13 million people would lose their health insurance by 2027 (CBO 2017).

KEY POINT
Medicaid Expansion

The ACA expands Medicaid to cover all non-Medicare-eligible individuals under age 65—including children, pregnant women, parents, and adults without dependent children—whose incomes fall within 133 percent of the federal poverty level (CMS 2018c).

Under the ACA, individuals as well as small businesses have access to qualified, affordable health plans through state health insurance exchanges. Additional features of the ACA also affect funding. (See the Learning Point box titled "Covering the Uninsured" for a more detailed discussion of healthcare reform law and its funding implications.)

LEARNING POINT
Covering the Uninsured

The ACA seeks to reduce the number of uninsured Americans by expanding Medicaid eligibility and offering tax credits for purchasing private insurance. Much of the funding for the ACA comes from the public sector. For example, the ACA includes funding for the creation of health insurance exchanges, expansion of the healthcare workforce (especially primary care), and the addition of community health centers (CBO 2017). Funding mechanisms include the following (CBO 2017): tax credits (e.g., for private insurance and increasing Medicaid eligibility), grants (e.g., community-based prevention, health centers, long-term care, market reform), special programs (e.g., health workforce, maternal and child health, Medicaid and CHIP expansion, Medicare innovation), and taxes (e.g., penalties on corporations, certain medical services deemed luxuries).

US HEALTHCARE DELIVERY

The United States does not have a single, coherent healthcare system; in its place are multiple subsystems of healthcare delivery. Access to care through these subsystems—managed care plans, safety net providers, public health programs, long-term care services, and military-operated healthcare—depends on eligibility factors for each subsystem, as explained in the sections that follow. New models are emerging, however, that may influence the delivery of healthcare, including value-based healthcare and integrated healthcare delivery, each of which is discussed in further detail following the discussion of the existing subsystems.

MANAGED CARE PLANS

Managed care is currently the most prevalent method of healthcare delivery in the United States. Employers and the government purchase health plans for employees through contracts with MCOs, which offer HMO, PPO, and point-of-service (POS) plans, and, more recently, high-deductible health plans (HDHPs).

As reported by the Kaiser Family Foundation (KFF) and the Health Research & Educational Trust (HRET), managed care expanded rapidly over conventional health insurance from 1981 (covering about 5 percent of health insurance subscribers, primarily through HMOs) through 1996 (covering 73 percent of subscribers, through a mix of HMOs, PPOs, and POSs), and by 2017 the transition was nearly complete (covering more than 99 percent of subscribers, through a mix of HMOs, PPOs, POSs, and HDHPs) (KFF and HRET 2017).

Managed care plans provide specific healthcare services depending on the type of plan, paying providers through **capitation** (a fixed fee for each patient), through a **discounted fee-for-service** scheme (whereby providers accept discounted fees in exchange for a guaranteed pool of patients), or a salary such as that paid in some Kaiser HMO plans. Enrollees choose providers from within a specified network, and primary care providers function as **gatekeepers** to manage routine services and referrals for higher-level or specialty care.

capitation
A fixed fee for each patient.

discounted fee-for-service
A fee agreed on between an insurance plan and physicians to provide medical services at a lower cost than is common for the area, in exchange for access to the insurance plan's pool of patients.

gatekeeper
A qualified health professional, usually a primary care physician, who must approve specialist visits before they are covered by an insurance program.

SAFETY NET PROVIDERS

Healthcare services for vulnerable populations uniquely seek to provide medical care and **enabling services** to the poor, the uninsured, racial and ethnic minorities, and immigrants. These services are provided by **safety net providers**, including federally funded health centers (see the first case study at the beginning of this chapter), physicians' offices, and hospital outpatient and emergency departments (see the For Your Consideration box titled "Health Services Provision for Diverse Populations" and the Learning Point box titled "Pennsylvania Rural Health Model"). Health policy for diverse populations is discussed in detail in chapter 6.

enabling services
Services that enhance access to medical care, such as transportation, interpretation, education, and community outreach.

safety net providers
As defined by the Institute of Medicine (IOM 2007), "providers that by mandate or mission organize and deliver a significant level of healthcare and other health-related services to the uninsured, Medicaid, and other vulnerable patients."

FOR YOUR CONSIDERATION
Health Services Provision for Diverse Populations

Despite the public insurance options mentioned so far, members of vulnerable populations often still lack access to safety net providers. One factor is regional variation in the type and level of healthcare services available from providers. Another factor is the mounting pressure on safety net providers from increasing numbers of poor and uninsured people seeking care. In addition, costs for providing uncompensated care—care provided for which no one pays—cannot be transferred to private insurance (e.g., by charging higher fees for privately insured patients for anticipated uncompensated care).

What do you think? Are safety net providers available in your region? How might they provide better care and access to people from diverse populations?

LEARNING POINT
Pennsylvania Rural Health Model

The Pennsylvania Rural Health Model, an alternative payment model created by CMS, aims to improve rural healthcare access and health outcomes while curbing the rise of spending, including Medicare fee-for-service, and helping rural hospitals maintain access to healthcare facilities (CMS 2017).

This model will determine whether modifying care delivery at rural hospitals (including critical access hospitals and acute care hospitals) leads to improvements in health outcomes and quality of care for residents in rural areas of the state, keeps hospital expenditures in check, and helps rural hospitals maintain healthcare access (CMS 2017, 2018b). The model began testing on January 13, 2017, through the Center for Medicare and Medicaid Innovation under the authority of HHS (CMS 2017). Implementation of the model was set to continue through 2023, with performance measured regularly to determine whether specified targets had been met (CMS 2017, 2018b).

PUBLIC HEALTH PROGRAMS

State public health agencies operate numerous programs and services, including the following five most common ones (Shi and Johnson 2014):

1. Preparedness
2. Vital statistics
3. Tobacco prevention and control
4. Public health research laboratories
5. Women, infants, and children (WIC) programs

Local public health agencies also operate programs, generally at the county level. State and local public health agencies form the "backbone" of the US public health system (Salinsky 2010). Agency roles in administrative infrastructure can vary widely, with states and localities organizing their government public health systems in a number of ways, and local health boards ranging widely in function, structure, and authority.

Under the US Constitution, states are granted the power to self-govern, including the role of protecting and promoting population health. Most state health departments are independent, focused solely on public health or with healthcare functions such as Medicaid administration. Some state health departments are part of a larger agency (ASTHO 2014), with functions for services in such areas as public health, behavioral health, and care and assistance. State regulation reflects many of the tensions in US health policy among providers, payers, patients, and institutions caused by structural changes in services and institutions.

activities of daily living (ADLs)
Measure of an individual's functioning that includes six basic activities: eating, bathing, getting dressed, maintaining bowel and bladder continence, using a toilet, and transferring (e.g., getting out of bed or moving into a chair).

instrumental activities of daily living (IADLs)
Measure of an individual's ability to perform activities necessary to live independently in noninstitutional settings, such as driving a car, shopping, preparing meals, and performing light housework.

LONG-TERM CARE SERVICES

Long-term care (LTC) is healthcare that is provided in nursing homes; in skilled nursing, subacute care, and specialized care facilities; by respite care, restorative care, and hospice care agencies; and by noninstitutional, community-based programs such as home health care and adult foster care (Shi and Singh 2018). Most clients of LTC services are elderly people, who typically suffer from chronic conditions as aging increases the probability of developing chronic illnesses and experiencing functional limitations. Functional limitations are measured by **activities of daily living (ADLs)** and **instrumental activities of daily living (IADLs)**. For further information on LTC, see the Learning Point box titled "Key Features of Long-Term Care."

LEARNING POINT
Key Features of Long-Term Care

Individualized, coordinated services
Specific services are provided according to individualized plans. These plans are determined by various factors, such as physical, mental, and emotional conditions; medical and social history; former occupation; and cultural factors (Shi and Singh 2018). As patients' needs change, such as when an acute episode (e.g., stroke, bone fracture, pneumonia) occurs, the LTC provider coordinates care with outpatient settings or hospital inpatient settings, occasionally followed by intensive rehabilitation at a hospital-based transitional care unit or the LTC facility.

Maximized functional independence
LTC aims to enable patients to maintain their maximum possible functional independence and prevent further decline of their abilities by motivating them to perform as many activities by themselves as possible.

Holistic approach, quality of life
Holistic healthcare emphasizes taking into consideration physical and mental needs, as well as social and spiritual preferences, when designing the delivery of care and living environment. The four factors that contribute to quality of life are lifestyle pursuits (personal enrichment through enjoyable activities), living environment (hygiene, furnishings, aesthetic features), clinical palliation (relief from unpleasant symptoms), and human factors (caregiver attitudes and practices, latitude for independency, adequate privacy).

Most nursing home services are paid for by Medicaid; Medicare Part A covers a limited number of services. Private insurance is the least popular funding source for LTC due to its high cost of premiums and limited coverage.

As a result of the recent substantial growth of community-based LTC (e.g., home healthcare, adult day care and foster care, senior centers, home-delivered meals, homemaker and handyman services), institution-based facilities (i.e., nursing homes) have experienced a slight decline in the number of residents (Czaja 2016). However, the growing elderly population will eventually increase demand for institutional LTC (Sullivan and Willis 2018).

Care Delivery for Members of the Military and Their Families

The US military medical care system offers ambulatory care and hospital care services, free of charge, to active-duty military personnel serving in the US Army, Navy, Air Force, Marines, and Coast Guard, as well as in certain uniformed nonmilitary services, including the Public Health Service and the National Oceanographic and Atmospheric Association. It operates through base dispensaries and hospitals, sick bays, first-aid stations, medical stations, and regional military hospitals.

Families and dependents of active-duty or retired military personnel are covered through the military-financed TRICARE program. Retired veterans receive healthcare services through the Veterans Administration healthcare system, which cares for more than 9 million individuals at more than 1,200 sites across the United States, including hospitals, ambulatory clinics, community clinics, nursing homes, and counseling centers, as well as residential care facilities and home health care programs (VHA 2018).

Value-Based Healthcare

Value-based healthcare providers are paid according to patient health outcomes and amount of services delivered, unlike in a fee-for-service or capitated system (Feeley 2016). Value-based care is transforming how providers care for patients. New delivery models emphasize a coordinated care team approach and sharing of patient data to better measure outcomes (see the Learning Point box titled “Patient-Centered Medical Homes”).

The benefits of value-based healthcare include the following (Feeley 2016):

- *Better health outcomes at less cost to patients.* Value-based care models emphasize prevention and prompt recovery, and patients spend less on care as their health improves.
- *Greater provider efficiency and higher patient satisfaction.* Providers spend less time managing chronic disease.

- *Lower payer costs.* Payers experience lower financial risk and burden as a result of improved patient health, fewer insurance claims, and greater efficiency from bundled payments.
- *Supplier price adjustments for improved outcomes.* Suppliers can align products, services, and prices with better outcomes and at lower cost.

The shift from a fee-for-service system to a fee-for-value system is gradual, and as providers increasingly adopt value-based care models, they may experience initial financial losses before reaping long-term cost savings (Lee and Kaiser 2016). However, this shift is considered the best way to reduce costs while optimizing quality of care and health outcomes.

INTEGRATED HEALTHCARE DELIVERY

As states in the United States integrate care with health and social services, this collaborative care involves multiple agents, from patient support systems to providers and practitioners as well as systems, managers, and purchasers. Managed behavioral healthcare organizations (MBHOs) are bringing together primary care and behavioral health professionals, and

LEARNING POINT

Patient-Centered Medical Homes

Value-based healthcare integrates primary care, specialty care, and acute care, often through a healthcare delivery model known as the patient-centered medical home or primary care medical home (PCMH)—a coordinated care approach led by a primary care physician that focuses on the patient as a member of the care team (AHRQ 2018; Compton-Phillips, Bloem, and Singer 2015; NEJM Catalyst 2017). PCMHs share electronic medical records among team providers, thus lessening redundant care and its costs. The PCMH model provides care that is comprehensive, patient-centered, coordinated, accessible, and demonstrably committed to quality and safety (AHRQ 2018).

The PCMH is part of the broader movement toward patient-centered care, which benefits not only patients and their families (e.g., improved health outcomes and higher satisfaction scores) but also providers (e.g., improved morale among clinicians and ancillary staff as well as enhanced reputation of providers among healthcare consumers) and health care systems (e.g., more efficient allocation of resources, reduction of expenses, and increases in financial margins) along the continuum of care (NEJM Catalyst 2017). The PCMH strives to improve the patient experience, health outcomes, and cost with enhanced primary care. Most states already include PCMH in their Medicaid or CHIP coverage.

accountable care organizations (ACOs) and community care organizations are integrating preventive care, primary care, and tertiary care, including specialties such as behavioral health (see the Learning Point box titled "Accountable Care Organizations").

Under Medicaid, more and more states are integrating benefits management—for example, the state of Tennessee contracts with integrated health plans—although MCOs can subcontract benefits management for behavioral health in places where MBHOs also operate.

LEARNING POINT
Accountable Care Organizations

Providers in ACOs, which were established by CMS, work in a coordinated team to deliver the best-quality care to Medicare patients at the lowest cost. Unlike in fee-for-service healthcare, ACOs do not incentivize physicians to order more tests or procedures and take on more patients. As in PCMHs, patients and providers in ACOs make decisions together and there is an emphasis on coordinating care and sharing data among the team.

For example, under the Vermont All-Payer ACO model, created by CMS (2018d), major healthcare payers in the state of Vermont incentivize the value and quality of care, with an emphasis on health outcomes. The Vermont All-Payer ACO lets ACOs in the state join a Medicare ACO initiative and funds coordination of care and collaboration with community providers; Medicaid is also a partner in this model (CMS 2018d).

Implementation of the Vermont All-Payer ACO model began on January 1, 2017, and was scheduled to conclude on December 31, 2022. During this period, CMS is expected to look for improvements in health outcomes, care delivery, and spending across payers that offer ACOs risk-based arrangements based on health outcomes and spending (CMS 2018d).

POLICY ISSUES IN HEALTHCARE FINANCING AND DELIVERY

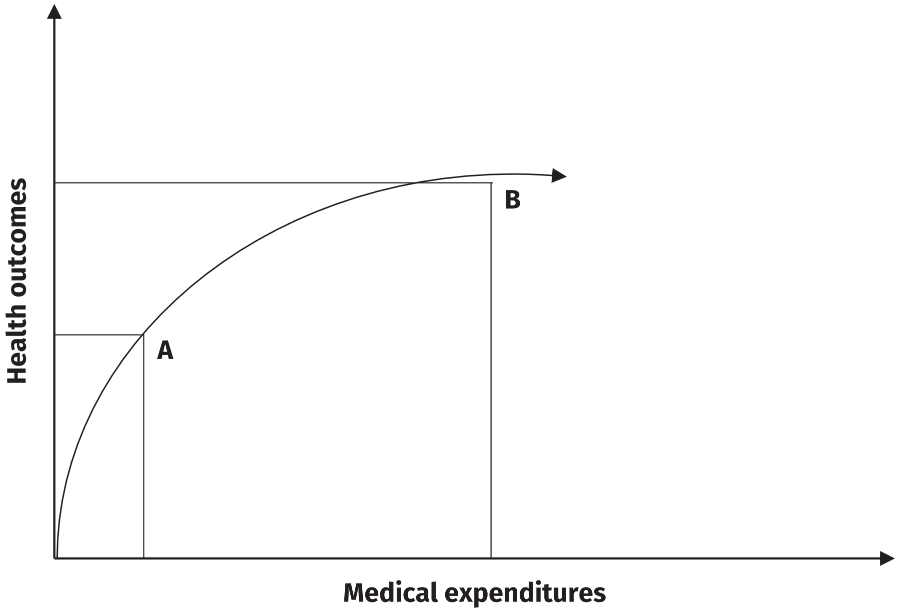
Exhibit 5.2 illustrates the intersection of medical expenditures and health outcomes in the United States. It reveals a relationship between financing and health status that is sometimes regarded as counterintuitive. First, we address the financing policy issues at play in this relationship, and then we discuss delivery issues.

FINANCE

As shown in exhibit 5.2, delivery costs for preventive health and primary care services (the intersection at point A) tend to improve health, whereas delivery costs for disease-focused care, such as secondary and tertiary care (the intersection at point B), do not proportionally improve health status. At a certain point beyond point B (e.g., delivering high-tech treatment for terminal patients), medical care brings minimal health benefits while potentially prolonging suffering and incurring additional costs. Because of this disproportionate relationship, cost containment has become a major health policy priority in the United States.

Regulation-based cost containment is typically achieved through control of supply (number of providers available), price (fees charged for services), and utilization (extent to which services are provided). Countries that operate a national healthcare system are well positioned to contain costs comprehensively by strictly controlling supply and limiting provider payments using global budgets. In contrast, the multipayer system in the United States requires cost control to be implemented sector by sector. The following are two examples of attempts to contain health expenditures through regulation in the United States (IOM 2007):

Exhibit 5.2 Effect of Increased Medical Expenditures on Health Outcomes



- *Health planning*. An example is the implementation of certificate-of-need (CON) statutes at the state level, whereby state government agency approval is required for the construction or expansion of healthcare facilities. (CON did not appear to reduce hospital expenditures on a per patient, per day basis or affect reimbursement rates, offering no incentive for providers and patients to change utilization behavior.)
- *Price controls*. An example is pay for performance (P4P), a Medicare initiative that reimburses providers according to the quality of care they provide. (Although an Institute of Medicine [IOM] study showed that P4P could decrease access and increase disparities in care, the IOM advised Medicare to launch a phased implementation with careful monitoring.)

DELIVERY

Healthcare delivery policy has focused on both the provider and the patient. Provider-related policies target the healthcare workforce, professional accreditation, and antitrust regulations, whereas patient-related policies focus on patient access to care and patient rights.

Workforce

Donelan and colleagues (2010) conducted a survey of leader representatives regarding key stakeholder groups about health workforce policies to examine perceptions on nurse workforce issues. Nurses were found to be essential to the quality and safety of care, and given that nurse shortages were expected to intensify following the passage of healthcare reform, researchers determined that stakeholders should focus on the lack of advocacy and leadership to advance issues of the nurse workforce on the US health agenda and in the media (Beck and Boulton 2016; Donelan et al. 2010). The Critical Concept box titled "Rural Health Professional Shortage" describes workforce shortages of another kind.

Accreditation

To participate in Medicare or Medicaid, healthcare organizations—including hospitals and healthcare systems, critical access hospitals, skilled nursing facilities, portable X-ray service providers, ambulatory surgery centers, and others, as well as suppliers to these

CRITICAL CONCEPT
Rural Health Professional Shortage

MacDowell and colleagues (2010) conducted a national survey of rural hospital CEOs in the United States to study health professional shortages in rural areas. According to analyses from 335 respondents (a response rate of 34.4 percent), 75.4 percent of rural CEOs reported physician shortages, with the top three affected specialties identified as family medicine, general internal medicine, and psychiatric care. Seventy percent of rural CEOs reported shortages of at least two primary care specialties, such as family medicine, general internal medicine, or pediatrics. The four most highly sought-after allied health professionals were registered nurses, physical therapists, pharmacists, and occupational therapists.

In the United States, rural hospital CEOs in states in the region from New England through Virginia reported the highest workforce shortages in all health professions. These findings are consistent with the literature in the researchers' conclusion that (1) physician supply in most rural areas in the United States is inadequate, and (2) there is a shortage of specialty physicians, especially psychiatrists and general surgeons (MacDowell et al. 2010). Similarities in shortages and attributes influencing recruitment across regions indicated the need for substantial, targeted policy and program interventions to develop a workforce of rural health professionals that can meet increased demand for care in the wake of healthcare reform.

The study also identified four factors in recruitment and retention that were significantly correlated with primary care physician shortage: "(1) healthcare is a major part of the local economy; (2) community is a good place for family; (3) doctors are well respected and supported; and (4) people in the community are friendly and supportive of each other" (MacDowell et al. 2010, 1531). The researchers suggest that rural hospital CEOs who seek to improve recruiting should collaborate with community leaders to strengthen public education systems and build a more robust economy to improve the overall quality of life (MacDowell et al. 2010).

organizations—must meet eligibility requirements outlined in federal regulations, including a certification of compliance with CMS **Conditions of Participation**.

Conditions of Participation
Health and safety standards defined by the Centers for Medicare & Medicaid Services (CMS) as the minimum requirements that hospitals and medical centers must meet to serve publicly insured patients.

Healthcare organizations may be accredited by a private accrediting organization, such as The Joint Commission, that has developed standards that meet or exceed Medicare's Conditions of Participation. CMS grants *deeming authority* to accreditors that it considers an appropriate proxy (Joint Commission 2017).

Antitrust

Anticompetitive activities can raise healthcare costs and substantially reduce competition without expanding access to care. The Federal Trade Commission (FTC) may scrutinize these activities, which include the following (Feinstein 2010):

- Mergers and acquisitions of hospitals, clinics, and pharmaceutical companies that reduce competition and access to care
- Price fixing and boycott agreements among healthcare providers to increase the fees they charge healthcare plans without improving the quality of care
- "Pay for delay" drug patent settlements, whereby a drug company that sells a brand-name pharmaceutical on the market pays a competitor to sell a generic version of the drug to delay bringing the lower-cost drug to market

The FTC and the US Department of Justice Antitrust Division provide antitrust guidelines for various types of healthcare arrangements.

Access to Care

The primary goal of health policy concerning access to care is to serve the neediest and most underserved populations. Categories of healthcare services to be included in the necessary level of care, however, are up for debate. Elsewhere in this chapter and throughout the book, we discuss various aspects of access to care that are related to health policy.

Patients' Rights

Patients' rights consist of issues such as informed consent, compliance with Health Insurance Portability and Accountability Act (HIPAA) of 1996 guidelines, and emergency medical treatment.

Informed Consent

The aims of informed consent are to (1) respect and uphold the autonomy of patients and research participants and (2) protect patients and research participants from potential harm

(Jefford and Moore 2008). Fulfilling these aims depends on three primary components: *prerequisites*, including competence (being able to understand and make decisions) and voluntariness; clear and truthful *information*; and free and voluntary *enrollment*, including the opportunity to withdraw consent without affecting the quality of care the patient receives (Bromwich and Rid 2014; Petrini 2010).

HIPAA

HIPAA helps protect patients in the following ways (HHS 2018):

- It protects patients against discrimination from insurers that restrict enrollment or demand unaffordable premiums based on individual health factors, including preexisting medical conditions, previous medical claims, and personal genetic information.
- It lets certain individuals enroll in group health plans or individual health plans after losing employment-based coverage.
- It requires that personal health records be maintained to increase patient access to and ownership over healthcare information by adhering to data security laws and other privacy protection regulations.

EMTALA

The Emergency Medical Treatment and Labor Act (EMTALA) was passed in 1986 to eliminate discriminatory practices by providers and thus increase access to healthcare for the indigent and uninsured. All Medicare-participating hospitals with emergency departments must provide a medical screening examination, stabilization, and further care or a transfer as needed to all patients, regardless of patients' ability to pay. EMTALA also requires hospitals to keep a list of on-call physicians and prohibits hospitals with specialized capabilities or facilities from refusing an appropriate transfer if the hospital can treat the individual (CMS 2010).

KEY POINTS

- Many factors have contributed to the dramatic rise in US healthcare costs, including an emphasis on curing disease instead of maintaining wellness, the inefficiency of a multiple third-party payer system, and an increase in the elderly population and accompanying chronic illness.
- The United States does not have a single, coherent healthcare system but instead consists of multiple subsystems of healthcare delivery. These subsystems include managed care plans, safety net providers, public health programs, long-term care services, and military-operated healthcare.

- As a result of high healthcare costs, cost containment is a major priority for US policymakers through both regulatory (e.g., price controls) and delivery (e.g., promoting accountable, integrated care) approaches.

CASE STUDY QUESTIONS

CASE STUDY 1

Based on your research of the federally funded health center program and its achievements, answer the following questions:

1. What are some examples of recent studies that demonstrate the value of the health center program?
2. Do health centers adequately address the lack of access to care for diverse and vulnerable populations?
3. How can health centers prepare for future challenges?

CASE STUDY 2

Based on your research of the evolution and status of precision medicine, answer the following questions:

1. What is the purpose of precision medicine?
2. What is required to implement precision medicine for both public and private healthcare sectors?
3. How does precision medicine align with the goals of access, quality, and cost?

FOR DISCUSSION

1. Describe healthcare financing in the United States, and list reasons for the country's high healthcare expenditures.
2. What are the major types of private health insurance in the United States? Who are the beneficiaries of these programs?
3. What are the major types of public health insurance in the United States? Who are the beneficiaries of these programs?
4. What are the major subsystems of healthcare delivery in the United States? Why were they developed?
5. What are the critical policy issues in healthcare financing in the United States?
6. Cite examples of price control in healthcare.
7. What are the critical policy issues for healthcare delivery in the United States?
8. What kinds of current healthcare issues involve patients' rights?

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CHAPTER 6

HEALTH POLICY FOR DIVERSE POPULATIONS

The moral test of government is how it treats those who are in the dawn of life . . . the children; those who are in the twilight of life . . . the elderly; and those who are in the shadow of life . . . the sick . . . the needy . . . and the disabled.

—Hubert Humphrey

Millions of our citizens do not now have a full measure of opportunity to achieve and enjoy good health. Millions do not now have protection or security against the economic effects of sickness. The time has arrived for action to help them attain that opportunity and that protection.

—Harry S. Truman

LEARNING OBJECTIVES

After completing this chapter, you should be able to

- define vulnerable populations;
- identify policy issues for racial and ethnic minorities;
- describe policy issues for those with low income;
- highlight policy issues for the uninsured; and
- discuss policy issues for vulnerable subpopulations such as the elderly, people with chronic illness, people with mental illness, women and children, people with disabilities, the homeless, and people with HIV/AIDS.

CASE STUDY 1

THE HEALTH CENTER PROGRAM

Since the 1960s, health centers—nonprofit, community-directed healthcare providers, also known as federally qualified health centers—have provided primary and preventive care services to predominantly low-income, racial or ethnic minority patients in medically underserved areas (HRSA 2017, 2018). In addition to clinical care, health centers provide enabling services such as transportation, translation, and education to facilitate access to care for diverse populations. Health centers coordinate with other community services and are governed by boards made up mainly of health center patients.

Health centers face significant challenges, including the following:

- Persistent economic slowdown
- Shifting demographic trends
- Shifting disease burden
- Increasing complexity of the healthcare delivery system
- Health and healthcare disparities
- Healthcare workforce shortage
- Rapid rate of technological innovation

Yet health centers are making a difference in underserved communities across the United States. As of 2017, nearly 1,400 health centers provided care at more than 11,000 sites throughout all 50 states and several US territories (HRSA 2017). The National Association of Community Health Centers (2018) has chronicled stories of how health centers have provided access to affordable primary healthcare and are saving lives and taxpayer dollars. Following are several examples:

- Center for Family Health (Jackson, Michigan) became a one-stop center for women's health, pediatrics, and related medical services.
- Crescent Community Health Center (Dubuque, Iowa) invested in the implementation of electronic medical records and in patient education.
- Family Health Services (Twin Falls, Idaho) undertook three expansion projects throughout Magic Valley that include medical, behavioral, dental, and pharmacy services.
- Family Practice and Counseling Network (Philadelphia) recruited additional dentists to provide many children with regular dental cleaning before they start school.
- La Clinica Health Care (Medford, Oregon) installed a new ultrasound machine to provide better medical imaging for uninsured and underinsured pregnant women.
- United Neighborhood Health Services (Nashville, Tennessee) became able to serve as a medical home to mothers and children.

- West Cecil Health Center (Cecil County, Maryland) expanded services to include more evening hours.
- Westside Healthcare (northern Delaware) built a new site to expand access to more than 5,000 people.
- Will County Community Health Center (suburban Chicago) acquired a mobile dental van that provides families in the county with dental care.

CASE STUDY 2

MY HEALTH GPS PROGRAM FOR PATIENTS WITH MULTIPLE CHRONIC CONDITIONS

One method of addressing the needs of patients with multiple chronic conditions involves enlisting community health workers, typically members of underserved or indigenous communities who serve as frontline healthcare professionals (Love, Gardner, and Legion 1997). The duties of community health workers range from facilitating access to care and performing outreach to improving healthcare quality and reducing costs (Witmer et al. 1995). The My Health GPS program is one of two state programs requiring community health workers to be part of the care team.

Under the Affordable Care Act of 2010 (Section 2703), states may submit state plan amendments to coordinate care for people enrolled in Medicaid who have chronic conditions using a “whole-person” philosophy and integrating care across the full range of services needed (CMS 2018). In 2017, the District of Columbia Department of Health Care Finance (DHCF) launched My Health GPS, a coordinated care benefit program for Medicaid beneficiaries with multiple chronic conditions enrolled in either fee-for-service or managed care plans (DHCF 2018). The program seeks to improve outcomes and reduce unnecessary hospitalizations and emergency department (ED) visits by integrating an interdisciplinary team led by primary care.

My Health GPS targeted about 25,000 beneficiaries with 3 or more chronic conditions assigned to a provider via an opt-out process (District of Columbia State Innovation Model 2017). Providers under My Health GPS must demonstrate delivery and document all home services, directly provide or subcontract for provision of services, and follow communication protocols with external health partners. Providers are also required to provide patient-centered medical home recognition, certified electronic health records, hospital and ED alerts for enrollees, 24/7 access to clinical advice, and a staffing model of qualified persons or comparable alternatives (District of Columbia State Innovation Model 2017). The preapproved staffing model for My Health GPS includes a health home manager, a nurse care manager, a care coordinator or social worker, a licensed clinical pharmacist, and a peer navigator or community health worker, with an assigned staffing ratio for each role.

Beneficiaries are classified based on the severity of their conditions. Individuals with lower acuity have three or more chronic conditions (Group 1) and are expected to have two 25-minute contacts per month with a care team consisting of a nurse manager, a health home manager, and a community health worker (District of Columbia State Innovation Model 2017).

Those with higher acuity (Group 2) have three or more conditions as well as a qualifying risk score and are expected to have six 40-minute contacts per month with a care team consisting of a nurse manager, a health home manager, a care coordinator, a clinical pharmacist, and a community health worker (District of Columbia State Innovation Model 2017).

Providers are paid on a per-member, per-month (PMPM) basis. To receive the initial payment, providers must (1) inform the beneficiary of this health home benefit, (2) receive consent from the beneficiary, and (3) develop a care plan for the beneficiary. Providers must deliver at least one home health service within a given calendar month to receive a PMPM payment that month. Payments are made directly from the DHCF. Providers were paid $46 PMPM for patients with Group 1 acuity and $137 PMPM for patients in Group 2. During the first quarter of the program (July–September 2017), providers were given a onetime payment incentive of $475.91 per beneficiary for starting a care plan (District of Columbia State Innovation Model 2017).

As of mid-2018, the program had not yet been evaluated, having been implemented for less than a year; however, starting in 2019, providers were to be evaluated for readmissions, preventable inpatient admissions, and avoidable utilization.

This chapter discusses healthcare policies for diverse populations and vulnerable subpopulations of people with special needs. The populations covered in the chapter include racial or ethnic minorities, the uninsured, and individuals with low income. Vulnerable subpopulations include the elderly, people with chronic illness, people with mental illness, women and children, people with disabilities, the homeless, and people with HIV/AIDS.

DEFINING VULNERABILITY

No consensus has been reached on how to define *vulnerability* and *vulnerable populations*. For purposes of our discussion, this chapter defines *vulnerability* as the convergence of health risks. Health risks can manifest in the following categories:

- Physical (e.g., having a fever or other physical symptoms)
- Mental (e.g., feeling depressed)
- Social (e.g., resulting in poor school or job performance)

Because poor health in one dimension can be compounded by poor health in other dimensions, health needs tend to be considerably greater for people with multiple health problems than for those with a single health problem (Hu et al. 2016; Shi and Stevens 2010; Shi et al. 2017). Health risks consist of *predisposing*, *enabling*, and *need* characteristics at the individual and ecological levels (see the Learning Point box titled "Definitions of Health Risk Characteristics").

Vulnerable populations, such as those presented in this chapter, experience a convergence of these health risk factors and, as a result, typically exhibit poorer health status than those without multiple risk factors. The For Your Consideration box titled "Why Should We Care About Vulnerable Populations?" lists and describes compelling reasons to focus national attention on the need to reduce the health and healthcare disparities they experience.

LEARNING POINT
Definitions of Health Risk Characteristics

The following are definitions of the three characteristics of health risks (Andersen 1995):

Predisposing characteristics, which indicate the propensity of individuals to use care services:

- Demographic characteristics (e.g., age, sex, family size)
- Social structure variables (e.g., race or ethnicity, education, occupation)
- Health beliefs (e.g., beliefs about health and the value of healthcare)

Enabling characteristics:

- Resources available to individuals and families for the use of services (e.g., income, insurance coverage)
- Attributes of the surrounding community or region that affect the availability of and access to healthcare services

Need characteristics:

- Specific illnesses or health needs that drive the receipt of healthcare services

HEALTH POLICY ISSUES FOR DIVERSE POPULATIONS

The following sections explore health policy issues for the following types of populations: racial or ethnic minorities, the uninsured, and people with low socioeconomic status (SES).

FOR YOUR CONSIDERATION
Why Should We Care About Vulnerable Populations?

Possible answers to this question include the following:

- Vulnerable populations have significantly greater health needs.
- The prevalence of vulnerability in the United States is increasing.
- Vulnerability is influenced by social forces and therefore should be remedied by them.
- Vulnerability is fundamentally linked with national resources.
- Vulnerability and equity cannot coexist.

What do you think? Are these points valid? Explain your answer.

RACIAL OR ETHNIC MINORITIES

The US Census Bureau (2018) estimates that more than 34 percent of the country's population is made up of racial or ethnic minorities:

Blacks or African Americans	13.3 percent
Hispanics or Latinos	17.8 percent
Asians	5.7 percent
Native Hawaiians and other Pacific Islanders	0.2 percent
American Indians and Alaska Natives	1.3 percent
Identified as two or more races	2.6 percent

Racial and ethnic minorities experience significant problems in accessing high-quality healthcare, leading to disparities in health status as compared with the white, non-Hispanic population.

Healthcare Access

regular source of care (RSC)
A usual place where, or a usual provider from whom, an individual receives healthcare services.

The **regular source of care (RSC)** measure is commonly used to evaluate patient access to care. Research indicates that having an RSC increases the chances of receiving better coordinated care, better treatment for chronic and acute health conditions, fewer delays in care, and access to preventive care. Studies show, however, that members of racial and ethnic minorities are less likely than whites to have an RSC, even when accounting for SES, insurance status, and health conditions (Ailawadhi et al. 2017; Grzywacz, Hussain, and Ragina 2017; Lo et al. 2017; Shi and Stevens 2005). Hispanic adults were the least likely to have an RSC, followed by American Indians and Alaska Natives, African Americans, and Asians. Whites were shown to be the most likely to have an RSC. Similar trends were seen among children from racial and ethnic minority populations compared with children from the white, non-Hispanic population (HHS 2018a, 2018b; Irvin et al. 2018; Tai et al. 2017).

culturally appropriate services
Efforts by healthcare organizations and providers to increase understanding and produce effective interventions for patients by taking into account patients' cultural and linguistic characteristics.

Factors contributing to the lack of an RSC include the following (HHS 2018a):

- Lack of health insurance coverage
- Low family income
- Language other than English spoken in the home

The inability to afford care was reported as the most common reason for Hispanic adults lacking an RSC (Shi and Stevens 2005). Additional factors that limit access to care, especially for Latinos and Asians, include English language barrier, poor geographic proximity to a source of care, and lack of providers offering **culturally appropriate services**.

Healthcare Quality

Racial and ethnic minority patients are more likely to report dissatisfaction with quality of care and patient–provider interactions than white patients are. One reason is that patients from these groups commonly perceive discrimination in quality of treatment. Lack of English language proficiency not only affects access to care for racial or ethnic minorities but also contributes to disparities that racial or ethnic groups experience in receiving high-quality preventive care (Njeru et al. 2018).

Health Status

Racial and ethnic minorities experience disparities in perceived health status, causes of death, and health risk behaviors as compared with non-Hispanic whites. For example, the 2007 National Children's Health Survey showed that Hispanic and African-American children were the least likely to be perceived by their parents as having "excellent" or "good" health, even after adjusting for SES and family demographics (CDC 2017d). Regarding cause of death, among all racial and ethnic groups, African Americans exhibit the highest mortality rates for homicide, stroke and coronary heart disease, and colorectal cancer, as well as the highest morbidity rates for diabetes and HIV/AIDS (CDC 2013, 2017b, 2018c). These causes of death have important implications for healthcare policy because they are preventable through law enforcement, regular screening and early detection, health education, and access to effective medications. As for health risk behaviors, American Indians and Alaska Natives have the highest smoking prevalence (CDC 2013, 2017a; Garrett et al. 2011). Additionally, Asians and Latinos are more likely than whites to live in an area with substandard air quality as compared with the US Environmental Protection Agency standard (Yip et al. 2011).

Programs to Eliminate Racial and Ethnic Disparities

Programs to eliminate racial and ethnic disparities in the United States operate at the federal, state, and local levels of government as well as through private organizations.

Federal Initiatives

The Office of Minority Health (OMH) and the Indian Health Service (IHS), both part of the US Department of Health and Human Services (HHS), are among the federal agencies that address issues related to racial or ethnic minority health. The OMH, according to its mission statement, "is dedicated to improving the health of racial and ethnic minority populations through the development of health policies and programs that will help eliminate health disparities" (OMH 2018). The IHS provides comprehensive health services to federally recognized American Indians and Alaska Natives residing in 12 Indian Health Service Areas across the United States.

State and Local Initiatives

State and local programs work independently to meet the specific needs of minority populations in state, county, and municipal communities. At the same time, state programs often serve as models for federal initiatives. Two examples are Minnesota's Eliminating Health Disparities Initiative and the California Department of Public Health Strategic Plan, both initiated in 2008. They serve large numbers of individuals, and their goals are closely aligned with the determinants of health in *Healthy People 2020* (HHS 2010).

Private Initiatives

One example of private endeavors to eliminate disparities is the Association of Schools of Public Health, which, with the support of the W. K. Kellogg Foundation, promotes health professional involvement in racial and ethnic health disparities research (Horowitz et al. 2000). Another example is the Building Healthy Communities Initiative launched in 2010 by the California Endowment (2018), which seeks to promote long-term improvements in health status in 14 communities with high rates of health disparities through broad investment in social, environmental, and medical interventions, with a primary focus on children and youth.

THE UNINSURED

In 2015, more than 9 percent of the US population lacked health insurance (Shi and Singh 2018). Studies show that people without health insurance face barriers to healthcare access, quality of care, and positive health outcomes (Akinlotan et al. 2017; Garfield and Damico 2012; Kenney et al. 2012; Moonesinghe, Zhu, and Truman 2011; Weissman et al. 2008). Advocates have long urged lawmakers to expand public insurance programs—such as Medicare, Medicaid, and the Children's Health Insurance Program (CHIP)—and have called for the improvement of the quality of care received through these programs.

One primary goal of the Affordable Care Act (ACA) of 2010 was to reduce the number of uninsured Americans. Several provisions in the ACA sought to extend coverage to previously uninsured groups. Examples include the development of health insurance exchanges, which established insurance markets for individuals and small business owners, and the expansion of Medicaid to provide insurance coverage to all individuals and families with an income at or below 133 percent of the federal poverty level (Shi and Singh 2018). In 2013, the year before the major provisions of the ACA took effect, more than 44 million nonelderly people were uninsured, but by 2016, only 27.6 million were uninsured (Foutz et al. 2017). However, after the tax revisions led by President Donald Trump in 2017 eliminated the ACA requirement that all individuals have health insurance, the number of uninsured Americans began to rise again (Beaton 2018; Collins et al. 2018). By March

2018, 4 million fewer working people aged 19–64 had health insurance (Collins et al. 2018). Among lower-income adults in particular, the uninsured rate increased from 20.9 percent in 2016 to 25.7 percent in March 2018 (Collins et al. 2018). If the ACA were to be repealed entirely, as the Trump administration seeks to do—either without replacement or replaced by a plan favored by President Trump—the projected number of uninsured people would rise to about 48 to 49 percent of the population (Statista 2018).

Healthcare Access

Lack of health insurance increases the likelihood of delayed care by increasing the chance that the uninsured individual does not have an RSC. Uninsured children in particular suffer negative consequences. A study on young children aged 0–3 showed that uninsured children had a lower chance of obtaining needed medical care, prescription medications, dental care, and an RSC (Newacheck et al. 2002). Studies have further shown that the type of insurance that patients are covered by affects their rates of ED use and preventable hospitalization. According to several studies, individuals with public insurance are more likely than those with private insurance to use an ED instead of a physician's office as their primary source of care (Gindi, Cohen, and Kirzinger 2012; Meisel et al. 2011; Pukurdpol et al. 2014).

Healthcare Quality

The association between quality of healthcare and type of health insurance has been well documented, as has the impact of insurance status on how many of recommended services an individual receives. One study found that uninsured individuals experienced more deficits in receiving preventive care and less likelihood of receiving care as the uninsured period increased (Garfield and Damico 2012; Foutz et al. 2017; Moonesinghe, Zhu, and Truman 2011; Weissman et al. 2008). This pattern was consistent across most preventive services. Furthermore, poorer access to primary care services among uninsured individuals may result in a greater number of preventable hospitalizations, which are avoidable with timely, quality primary care (Davis et al. 2018; Foutz et al. 2017).

Programs to Eliminate Disparities in Health Insurance

Government and community organizations are at the forefront of the national drive toward universal and more comprehensive health coverage, creating several programs to raise the number of individuals covered by health insurance. Federal programs, such as Medicare, Medicaid, and CHIP, cover nearly 40 percent of the US population. The impact of these programs has been especially noticeable in reducing the number of the uninsured among vulnerable populations.

Many states are expanding Medicaid or CHIP eligibility, and these expansion programs have been credited for improved access to care and health status (Dubay and Kenney

2009; Holahan and Headen 2010; Howell and Kenney 2012; Sommers, Baicker, and Epstein 2012). To assist the remaining uninsured individuals, some states and private organizations have created their own programs for those who cannot afford health insurance but whose income level makes them ineligible for Medicaid or CHIP.

For example, Kentucky is one of a few southern states that have expanded Medicaid under the ACA, extending Medicaid eligibility to many people who are too poor to purchase individual market coverage yet too "rich" to qualify for traditional Medicaid eligibility. Benitez, Creel, and Jennings (2016) found that Medicaid expansion raised accessibility of coverage and affordability of healthcare for populations experiencing financial constraints in using medical care.

In an attempt to improve access to healthcare for all of its people, Minnesota created the Health Care Homes program as part of the state's health reform initiative. The program links primary care with prevention and wellness, self-management, and community services (Minnesota Department of Health 2018). Minnesota has also attempted to provide crucial mental health services through its Medicaid program (see the For Your Consideration box titled "Minnesota's Measuring Adolescent Depression Screening and Treatment in Medicaid").

Because states have broad flexibility in defining their public health role, state-level public health policy throughout the United States varies widely. State governments might pursue any of several strategies in relation to the uninsured (Bowman and Kearney 1988; Brace 1993; Coughlin and Zuckerman 2005; Dye 1966; Erikson, Wright, and McIver 1993; IHPP 1995). First, they may choose to do little regarding uninsurance, enacting few or no reforms and relying on the national government to remedy the problem. Although such inaction is inexpensive in the short run, it provides no assurance that something will be done to mitigate the inadequacy of insurance coverage, as even national policies can be expected to provide, at best, variable solutions to uninsurance across states. Second, states might choose a mix of state-based and market-based reforms to create a balanced policy portfolio. A balanced set of policies might provide some benefits: Relying on state-based policies would ensure that coverage is provided to certain blocs of the population and provide a fallback in the event of rising unemployment, which would lead to a reduction in employment-based coverage. By contrast, market-based policies would limit the state's financial obligations during times of economic prosperity. Third, states may follow purely state-based or purely market-based policy strategies. With a state-based policy portfolio, states assume large financial risk but receive great assurance that citizens will receive coverage through active state intervention. With a market-based policy focus, legislatures may claim credit for both addressing uninsurance and improving the business climate, and the state assumes little financial risk (Glied and Gould 2005; Hall 2000). However, the suitability of this approach is related to the incentives offered to business and the insured. It is one thing for employers to offer insurance benefits, but it is another to make those benefits truly accessible to employees. Passing such policies might address a political imperative to take action while not adequately addressing the uninsurance problem. Alternatively, selling state-based

FOR YOUR CONSIDERATION

Minnesota's Measuring Adolescent Depression Screening and Treatment in Medicaid

Depression among adolescents has demonstrated an increasing trend over time. Major depressive disorder among adolescents increased by 37 percent—from 8.7 percent in 2005 to 11.5 percent in 2014 (Mojtabai, Olfson, and Han 2016). Tasked by 2008 state health reform law, the Minnesota Department of Health established a statewide system of clinical quality measures to apply across coverage types and demographic characteristics (Honsberger and King 2017). In partnership with MN Community Measurement, a nonprofit organization focused on improving quality of healthcare in Minnesota through measurement and public reporting, the Minnesota Statewide Quality Reporting and Measurement System was established. The system requires quality reporting from all physician practices and health centers in the state. The development of these statewide measures was supervised by a committee of providers, health plans, and consumer representatives, who made recommendations and approved measures and reporting policies, and examined issues regarding data collection (Honsberger and King 2017). To address the issue of measuring adolescent depression within the state, the Statewide Quality Reporting and Measurement System developed a specific measure to determine the rate of screening for depression among adolescents in a clinical setting.

To develop a meaningful quality measure, the Statewide Quality Reporting and Measurement System established the denominator of eligible adolescents—people aged 12–17 who received a well visit—and identified a reliable measure of individuals screened. The numerator of eligible adolescents chosen consisted of those who were screened using validated mental health tools in their medical record. To increase the accuracy of the measure, adolescents previously diagnosed with other mental health conditions were excluded (Honsberger and King 2017). Implementation was facilitated by provider support from MN Community Measurement to meet reporting standards via informational webinars, data submission guides, and technical assistance (Honsberger and King 2017). The Minnesota Department of Health Early and Periodic Screening, Diagnostic Treatment provided additional training in mental health screening and services for clinics and providers (Honsberger and King 2017).

After a pilot study in 2013 to test the data-collection process and validate the data, the Statewide Quality Reporting and Measurement Systems launched the statewide measure and collected data for the 2014 measurement year from providers in January 2015 (Honsberger and King 2017). Preliminary results showed that fewer than half of adolescents in the state were screened for depression or other mental health conditions, and approximately 10 percent of those screened were identified as possibly having a mental health condition (Smith and Ghere 2015). Rates of screening for adolescent depression increased in follow-up years (Honsberger and King 2017).

The study showed that Statewide Quality Reporting and Measurement Systems may have a positive influence on preventive care quality measures of importance in public health, such as screening for depression among adolescents.

strategies in the modern era may be politically untenable, even if the ultimate effects were beneficial for providing more broad-based insurance coverage (Holahan and Ghosh 2005).

PEOPLE WITH LOW SOCIOECONOMIC STATUS

SES is defined by several factors, the most common ones being income level, educational level attained, and occupational status. Those with lower SES typically face greater barriers in accessing healthcare than those higher on the SES scale. For people of lower SES who are able to receive care, their overall health status and quality of care are still typically inferior to those for people of higher SES.

Healthcare Access

SES has shown greater impact than race or ethnicity on access to healthcare. According to an analysis of the California Health Interview Survey (Brown et al. 2007), poor adults are more than twice as likely to lack an RSC as their counterparts who are not poor. Those with higher levels of education were more likely to maintain an RSC and to seek care at a doctor's office instead of at community clinics and EDs.

Healthcare Quality

Several studies examined the link between SES and healthcare utilization. Women with lower educational levels were less likely to report receiving Pap tests and mammograms (Monnant 2014), and women with low household income had lower utilization rates for influenza vaccinations, cervical and colon examinations, and bone densitometry (Earle et al. 2003). Regarding SES and healthcare quality, low levels of income and education showed a negative effect on physicians' perceptions of patients, which in turn adversely influenced physicians' selection of treatments and recommendations (Van Ryn and Burke 2000).

Health Status

Low income, low educational level, and low occupational status have long been associated with high health risks, poor health status, and high mortality rates (see, e.g., Cutilli et al. 2018; Singh et al. 2017; Syme and Berkman 1976). Individuals living in poverty were four times more likely to report fair or poor health status than those who were not impoverished (i.e., those with incomes greater than 200 percent of the federal poverty level). Furthermore, the percentage of adults aged 55–64 with functional limitations also increases as income level decreases, with a nearly sixfold difference between the highest and lowest income levels (Minkler, Fuller-Thomson, and Guralnik 2006).

In a study of the relationship between SES and mental health, the Centers for Disease Control and Prevention (CDC) found that high-income individuals were two to three times more likely to report frequent mental distress than were low-income individuals (APA 2005). Low-income adults also showed a high prevalence of health risk behaviors (e.g., physical inactivity, smoking, smoking during pregnancy, short breast-feeding period).

The effect of SES on disparities in mortality rates has also been documented. For example, the 2017 *Health, United States* report showed that infant mortality rates, communicable disease mortality rates, and HIV mortality rates among men are closely associated with educational level (NCHS 2017). A 2011 study found that states with the highest proportions of residents whose incomes were less than 200 percent of the federal poverty level had an *amenable mortality rate* (defined as death "before age 75 from complications of conditions that might be avoided by timely effective care and prevention") twice as high as states with lower poverty rates (Schoenbaum et al. 2011).

Programs to Eliminate Socioeconomic Disparities

Programs to eliminate disparities based on SES in the United States are operated at the federal, state, and local levels of government as well as by private organizations.

Federal Initiatives

Often referred to as the "healthcare safety net," federal programs to address SES disparities have focused on increasing access to care for low-income populations. Federal programs for specific low-income subpopulations include the Public Housing Primary Care program, the Health Care for the Homeless program, and Head Start, which helps disadvantaged preschool-aged children acquire basic math and reading skills. Unlike federal programs that focus on reducing economic and geographic barriers to healthcare, Head Start is the only federal program that invests directly in increasing educational level—an often overlooked contributor to SES disparities in healthcare.

State and Local Initiatives

A notable state program is South Carolina's Welvista program, a public–private nonprofit partnership founded in 1991 that offers free or low-cost primary care, free prescription services, and free pediatric dental care to uninsured low-income people (Welvista 2018). Services are provided by volunteer health professionals, pharmaceutical companies, hospitals, and laboratories, and a number of corporate and community providers are involved (Welvista 2018).

A local initiative for the uninsured is TeleKidcare in Kansas City, Kansas, established through a partnership between the Kansas University Medical Center and a local school district consisting of elementary schools as well as middle and high schools (KansasHealth-Matters 2018). Videoconferencing technology allows providers to conduct physical exams and provide acute care and mental health services to schoolchildren in need of medical assistance.

Private Initiatives

One example of a privately funded program addressing SES disparities is Interact for Health, which awards grants to improve health in Cincinnati, Ohio, and surrounding counties (Interact for Health 2013, 2018).

Another example of addressing SES disparities has to do with employment opportunities provided by the private sector (Thornton et al. 2015). Employment can positively affect health through its provision of resources. In addition, because employers typically provide health insurance, the employed experience better access to health care than the unemployed do. Research indicates that employment and income gains led to increases in life expectancy between the mid-1960s and mid-1970s, and these increases were larger for blacks than for whites and greater for black women than for black men (Kaplan, Ranjit, and Burgard 2008). Research examining employment interventions for women of low SES and for people with severe mental illness suggests that employment interventions can be effective in reducing health disparities in these particularly vulnerable populations (Kneipp, Kairalla, and Sheely 2013; Luciano, Bond, and Drake 2014).

HEALTH POLICY ISSUES FOR VULNERABLE SUBPOPULATIONS

This final section of this chapter takes a closer look at health policy issues for each of the following vulnerable subpopulations: the elderly, people with chronic illness, people with mental illness, women and children, people with disabilities, the homeless, and people with HIV/AIDS.

THE ELDERLY

For the elderly, primary care and health policy concerns broadly revolve around the following:

- Containing costs of care
- Reforming the health delivery system to better serve the growing elderly population
- Improving quality of life as far as possible into old age

Cost Containment

Healthcare costs can be daunting for any American. For the elderly in particular, costs are often prohibitive to seeking care. According to the AARP Public Policy Institute, more than

25 percent of US adults aged 50–64 (who are not yet eligible for Medicare), as well as nearly 40 percent of older adults covered by a public insurance plan (e.g., Medicare, Medicaid), spent a significant amount of their disposable income (at least 10 percent) on healthcare (Smolka, Purvis, and Figueiredo 2009). Costs increased for patients with at least one chronic disease, and especially for many elderly patients, who have a much higher disease burden (with two or more diseases). A Medicare patient with a single chronic health condition sees, on average, four physicians per year (Bodenheimer, Chen, and Bennett 2009). Patients with five or more chronic conditions see, on average, 14 different physicians per year, and a higher number of chronic conditions seems to be related to a higher number of providers seen. After the ACA was implemented, overall US healthcare spending increased further, reaching $3.3 trillion in 2016, with out-of-pocket healthcare costs incurred directly by consumers rising by 3.9 percent—the fastest growth rate since 2007 (Johnson 2017).

Any out-of-pocket healthcare costs for typical elderly individuals is significant, whether covered through public insurance, insured through a private health plan, or paid out of pocket due to lack of insurance. And healthcare costs for the elderly are on the rise, mainly due to higher numbers of chronic diseases per patient in an overall aging population (Bodenheimer, Chen, and Bennett 2009). The number of people aged 85 or older, who have the most multiple chronic conditions, has been projected to grow from 5 million to 21 million from 2005 to 2050, substantially increasing the number of high-cost patients (Bodenheimer, Chen, and Bennett 2009). Most efforts to rein in these expenditures will require major health system reforms.

Quality of Life

According to Bodenheimer, Chen, and Bennett (2009), the most proactive methods to raise the quality of life for the elderly are to provide effective, low-cost preventive treatments designed to lower risk for adverse health outcomes throughout the patient's life. If policies were implemented earlier in life to reduce behavioral risk factors, such as smoking, the rise in chronic diseases might slow, and the resulting lower disease prevalence would improve quality of life (Barile et al. 2015; Bodenheimer, Chen, and Bennett 2009).

The relationship between quality of life and absence of disease may not be absolute. Even with the increase in chronic diseases, many people younger than age 85 experience delays in the onset of limitations and disabilities, in part due to early diagnosis, better treatment, and more effective amelioration of prevalent diseases (Christensen et al. 2009). This finding suggests that a highly functioning health services system is crucial to improving the quality of life for everyone by its potential to help postpone disability.

Service Availability

The availability of assistive technology, specialized facilities, and customized services may be adding further distance between disease and disability, as are indirect changes such as housing, transportation, structural improvements for people with disabilities, women's empowerment, and other social issues (Christensen et al. 2009). Improved funding and coordination of government and private programs to address these issues would simplify the process of obtaining necessary care and improving health outcomes for many elderly patients (Reinhard, Kassner, and Houser 2011).

The ACA and the Elderly

Many experts believe that the current system of healthcare administration in the United States is less than optimal. Issues such as high costs, insufficient focus on prevention, recurring medical mistakes, and a sense of discord among stakeholders are pervasive, especially for the elderly. The ACA attempts to address several of these challenges. One study found that changes in how healthcare providers are paid through Medicare and Medicaid create more incentives to focus on preventive care and coordinate care across providers and facilities while also reducing growth in healthcare spending and providing better value for public payers (Thorpe and Ogden 2010). Reducing hospital readmissions, improving the monitoring of controllable chronic diseases (such as diabetes and hypertension), and helping community health teams coordinate care among physicians and organizations will improve the healthcare delivery system. These modifications are expected to simplify the system, making it more patient centered and better able to serve the changing needs of US patients, particularly the elderly (Bodenheimer, Chen, and Bennett 2009; Thorpe and Ogden 2010).

As the US population ages, it faces unique issues, especially in healthcare cost, treatment coordination, and quality of life, concerns which may move to the forefront of the health policy agenda. Injury prevention is a key area of healthcare gaining increased attention (see the For Your Consideration box titled "Injury Prevention and Control").

FOR YOUR CONSIDERATION
Injury Prevention and Control

Among the various events that can cause injuries are incidents such as car crashes, fires, falls, drownings, poisonings, and assaults. The growing recognition of the costs of injuries to a person and to society and of their predictability and preventability helped promote the development of programs for injury prevention and control in local and international health organizations. For example, The Joint Commission (2015) issued a Sentinel Event Alert on preventing falls and fall-related injuries in healthcare facilities—injuries that can be particularly dangerous for the elderly—and offered an array of suggestions and tools to address this issue across healthcare settings (Joint Commission 2015).

People with Chronic Illness

Chronic diseases are the leading cause of death, disability, and healthcare costs in the United States. According to the CDC, half of all adults have a chronic disease, 70 percent of deaths are associated with chronic diseases, and the majority of healthcare costs are due to treating chronic diseases (Dietz, Douglas, and Brownson 2016).

Chronic conditions are on the rise worldwide. In the United States, the primary care system needs to be overhauled to accommodate the dramatic rise of chronic disease patients, requiring innovation to provide high-quality care and meet their needs (Kimura, DaSilva, and Marshall 2008). Patients with chronic illness in the United States experience less organized care at a higher cost (Schoen et al. 2009; Thorpe and Philyaw 2012). Every year, 86 percent of healthcare costs go toward care for chronic illness and mental health disorders (Schoen et al. 2009; Thorpe and Philyaw 2012).

Uninsured patients who have chronic conditions face a double burden. According to a 2008 study of the National Health and Nutrition Examination Survey, conducted by the CDC National Center for Health Statistics (Wilper et al. 2008), 11.4 million Americans aged 18–65 were living with at least one chronic health condition. According to the study (Wilper et al. 2008), the uninsured faced barriers to care and were more likely not to have visited a health professional (22.6 percent of uninsured vs. 6.2 percent of insured) and not to have a standard care site (26.1 percent vs. 6.2 percent), but if they did have a standard care site, it was more likely to be an ED (7.1 percent vs. 1.1 percent). Failing to receive appropriate, timely primary care can lead to worse health outcomes, which can be especially serious in patients already suffering from a chronic condition.

? FOR YOUR CONSIDERATION
CDC and Chronic Disease Programs

In response to the health and financial burden of chronic diseases, the CDC leads national efforts to prevent and control chronic diseases and their risk factors (e.g., tobacco use, poor nutrition, lack of physical activity, excessive alcohol use) through its National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP). Specifically, NCCDPHP focuses on the following (CDC 2018a):

- Tracking chronic diseases and their risk factors through surveys and research
- Improving environmental strategies to make healthy options easier for people to choose
- Strengthening healthcare systems to deliver prevention services that keep people well and diagnose diseases early
- Connecting clinical services to community programs that help people prevent and manage their chronic diseases

NCCDPHP supports various programs at the national, state, and community levels in the areas of cancer, diabetes, heart disease and stroke, smoking and tobacco use, and chronic diseases, as well as community health, nutrition and physical activity, oral health, population health, and reproductive health (CDC 2018a).

Addressing the Burden of Chronic Disease

The burden of chronic illness is borne both by patients, who experience frustration, high costs, and poor health outcomes, and by the healthcare system, which often cannot provide appropriate, effective, and efficient care. Policy changes with a focus on chronic illness can significantly ease that burden. Programs that test various approaches to chronic care have been introduced in the United States, but none has been accepted on the scale required for major change (Shortell et al. 2009). National policies addressing chronic diseases should take these attempts into account to control cost and improve care for the chronically ill (see the For Your Consideration box titled “CDC and Chronic Disease Programs” and the Learning Point box titled “Combating Chronic Diseases”).

LEARNING POINT
Combating Chronic Diseases

Cancer

National Breast and Cervical Cancer Early Detection Program (NBCCEDP): Breast cancer is the most common cancer among women, and cervical cancer is the leading cause of cancer mortality among women in the United States. Breast cancer screening with a mammogram and cervical cancer screening with a Pap test reduce mortality rates from these cancers (CDC 2014). NBCCEDP has provided timely breast and cervical cancer screening and diagnostic services to low-income, uninsured, and underserved women in more than 11,000 primary care clinics since the early 1990s (DeGroff et al. 2016).

Evidence suggests that NBCCEDP screening for breast cancer has lowered breast cancer mortality among uninsured and underinsured low-income women. However, another study reveals that the US-affiliated Pacific islands face significant barriers to implementing NBCCEDP screening for cervical cancer (Hoerger et al. 2011; Senkomago et al. 2017).

Colorectal Cancer Control Program (CRCCP): In 2015, the CDC provided $23 million in funding to the American Cancer Society, universities, state primary care associations, local health departments, and selected nonprofit organizations to implement the CRCCP over a five-year period. CRCCP grantees partner with health systems and clinics to implement four main evidence-based interventions—patient reminders, provider reminders, provider assessment and feedback, and reducing structural barriers—and other supporting activities (including media, community health workers, patient navigation, and provider education) to increase rates of screening for colorectal cancer (CDC 2018b).

Tangka and colleagues (2017) analyzed the extent to which the CRCCP program model resulted in funding going toward implementation of the interventions recommended by the *Guide to Community Preventive Services*. Their findings revealed that all 29 CRCCP grantees carried out media activities, and more than 90 percent used client reminders, provider assessment feedback, or patient navigation. However, grantees spent one-third of their total budget on broad-based recommendations instead of targeted education on evidence-based strategies by the *Community Guide* (Tangka et al. 2017).

Diabetes

National Diabetes Prevention Program (DPP): Established by the CDC, the DDP is a partnership that brings public and private sectors together to offer evidence-based, affordable interventions in communities to prevent type 2 diabetes. Some of the primary partners include federal agencies, state and local health departments, community organizations, public and private insurers, healthcare professionals, employers, and businesses that focus on wellness. The overarching goal of the DPP is to enable partner organizations to build a workforce that can effectively deliver and implement CDC-recommended programs for lifestyle change through

LEARNING POINT
Combating Chronic Diseases *(continued)*

organizations nationwide, as well as to increase referrals to and participation in the program (CDC 2018e).

Heart Disease and Stroke

Paul Coverdell National Acute Stroke Program: This program was established by the CDC in 2001 to build a high-quality system of care to improve care for patients who have experienced a stroke and to save lives. The stroke system of care aims to improve care and support for patients throughout their journey of care—from the first symptoms of stroke, emergency medical services (EMS), hospital care, and rehabilitation to follow-up with outpatient providers to prevent stroke complications and recurrences. Together, EMS agencies, hospitals, and healthcare organizations collect and analyze data about stroke patients and care, and they share best practices to improve patient care. Through the Coverdell Program, the CDC funds nine state health departments that partner with many hospitals, EMS agencies, healthcare facilities, and community services (CDC 2018f).

Hospitals have been recruited by states since 2007 to join the Paul Coverdell National Acute Stroke Registry Program. By 2012, more than 213,500 patients had been treated and benefited from improved quality of care in more than 300 participating hospitals across the United States (CDC 2015a).

Sodium Reduction in Communities Program (SRCP): Strong scientific evidence has proved the health benefits of reducing dietary sodium intake. SRCP is a national program administered by the CDC's Division for Heart Disease and Stroke Prevention. Grantees in SRCP across the United States partner with local organizations that serve or sell food, such as schools and work sites, to implement strategies for reducing sodium intake as recommended by the Dietary Guidelines for Americans. The CDC funds eight communities to collaborate with food industry partners to make lower-sodium foods more available and accessible, and the CDC monitors and measures their effectiveness (CDC 2018g).

In addition, SRCP has developed several evidence-based toolkits such as *Partnering with Food Service to Reduce Sodium: A Toolkit for Public Health Practitioners* to reduce sodium intake and maximize program impact. Also, award recipients of SRCP, such as the Los Angeles County Department of Public Health and the Philadelphia Department of Health, work at the community level toward meeting SRCP's short-term goal of facilitating environmental changes that make lower-sodium foods more available and accessible as well as its long-term goal of bringing sodium intake levels down to recommended limits (Mugavero et al. 2012; Welsh et al. 2014). Although the CDC has published the official *Sodium Reduction in Communities Program Outcome Evaluation Toolkit*, researchers need to conduct more evaluation studies to assess the outcome and impact of SRCP programs (CDC 2018g).

(continued)

LEARNING POINT
Combating Chronic Diseases *(continued)*

Community Health Programs

National Implementation and Dissemination for Chronic Disease Prevention: This national program supports three community capacity-building awardees (American Heart Association, American Planning Association, and National WIC Association), and two dissemination and training awardees (Association of State and Territorial Directors of Health Promotion and Public Health Education, and Society for Public Health Education). Both types of awardees develop strategies and technical assistance to maximize their collective impact, raise local and national awareness of community health workers, and ensure that the communities they serve can increase their capacity and achieve sustainable improvements even after funding for the program ends (CDC 2017c).

Racial and Ethnic Approaches to Community Health (REACH): To reduce racial and ethnic health disparities in the United States, the CDC initiated REACH as a national program that funds state and local health departments, universities, community-based organizations, and American Indian tribes. The awardees use these funds to plan and implement local, culturally appropriate programs to resolve health issues among such federally classified racial and ethnic groups as African Americans, American Indians, Hispanics/Latinos, Asian Americans, Alaska Natives, and Pacific Islanders. Beyond providing funding, the CDC also offers technical support from experts to the REACH awardees (CDC 2017e).

The REACH program has successfully established community ownership. As a result, various REACH grantees across the United States have initiated local community health programs to address the needs and expectations of their local communities. For example, the Community Asthma Initiative is a program that addresses asthma disparity at Boston Children's Hospital, which reduced hospitalization rates for children by 80 percent, and yielded $1.73 of return on investment per dollar spent a year after the program began. The Medical University of South Carolina launched a Community Diabetes Education Program, which reduced the frequency of amputation and yielded cost savings. The University of Alabama at Birmingham has trained 170 community health advisers to advocate for mammography screening and reached more than 3,000 women, which ultimately reduced the mammography screening disparity significantly, from 18 percent to 3 percent (CDC 2015b).

Tips from Former Smokers: In 2012, the CDC launched the first paid national campaign for tobacco education—Tips from Former Smokers, known more commonly by the shorthand Tips. The Tips campaign profiles real people living with serious health effects from smoking and secondhand smoke exposure. It features compelling stories of former smokers living with smoking-related diseases and disabilities as well as nonsmokers who suffered from exposure to secondhand smoke. With a focus on health issues caused by or associated with smoking and exposure to secondhand smoke, the primary goal of the Tips campaign has

LEARNING POINT
Combating Chronic Diseases *(continued)*

been to raise public awareness of the health damage caused by smoking and exposure to secondhand smoke (CDC 2018h).

Tips has demonstrated significant impact. As of 2017, an estimated 1.83 million smokers had tried to quit smoking, and 104,000 smokers had actually quit smoking. Nonsmokers reported having conversations with family or friends about the harm of smoking and showed an increased knowledge of smoking-related diseases. Smokers who had watched Tips ads showed a greater intention to quit smoking within the next 30 days or next six months, and there was a close relationship between exposure to the ads and intention to quit. More important, since the launch of the Tips campaign, the call volume of national "quitlines" dramatically increased, registering 92.7 percent higher than the two-week baseline period (CDC 2018h).

Some chronic diseases cause chronic pain, which in some cases may be treated with medications containing opioids. However, overdependence on such narcotics can create further problems for patients who become addicted to them (see the Critical Concept box titled "The Opioid Crisis").

PEOPLE WITH MENTAL ILLNESS

Mental health has become an increasingly important public health issue in the United States. Based on the *Diagnostic and Statistical Manual of Mental Health Disorders, Fourth Edition* (DSM-IV) classification system, half of Americans are estimated to be affected by a mental disorder in their lifetime, and a quarter of Americans are affected in any given year (Kessler and Wang 2008). In 2005, 27 percent of those younger than age 65 with Medicare coverage were considered mentally disabled (Goldman, Glied, and Alegria 2008). Mental health disability is rising, and in 2018, about one in five US adults was living with some degree of mental illness (MHA 2018).

These statistics reveal serious health concerns. Poor mental health is associated with increased risk for early mortality, and many mental disorders exhibit an early-age onset that leads to a lifetime of healthcare needs (Goldman, Glied, and Alegria 2008; Kessler et al. 2008). However, in the early twenty-first century, only 41.1 percent of Americans with a DSM-IV-recognized mental disorder were treated for that disorder (Wang, Lane, and Olfson 2005).

In fact, mental health care in the United States has traditionally suffered from **marginalization**. Only recently has the focus on mental health shifted from specialized, inpatient

marginalization
A process in which a person or an idea is pushed aside in favor of another. A marginalized subject typically receives few resources and little attention.

CRITICAL CONCEPT
The Opioid Crisis

Among the greatest drug-related concerns for Americans today is the opioid crisis. Every day, more than 115 Americans die from an overdose of some form of opioid, including prescription pain relievers, heroin, and synthetic opioids (CDC 2018i). According to the CDC, prescription opioid misuse causes the United States an economic loss of $78.5 billion per year, including the actual costs of healthcare, addiction treatment, enforcement of criminal justice, and the opportunity cost of lost productivity (Florence et al. 2016).

In response, several cities, counties, and states have filed lawsuits against pharmaceutical companies over the opioid crisis (Noguchi 2017). Many observers argue that the pharmaceutical industry started and perpetuated the opioid crisis by encouraging the overprescription of pain pills by doctors, leading to higher rates of overuse, abuse, and addiction. An investigation by the *Washington Post* and *60 Minutes* found that the Ensuring Patient Access and Effective Drug Enforcement Act of 2016 removed the authority of the US Drug Enforcement Administration (DEA) to block suspicious narcotic shipments from drug distribution companies, thereby worsening the problem of easy access to drugs (Higham and Bernstein 2017). The investigation also reported that political action committees contributed at least $1.5 million on behalf of the pharmaceutical industry to the 23 lawmakers who sponsored or cosponsored the four versions of the bill (Higham and Bernstein 2017). The DEA and government officials argue, however, that the DEA has effective methods to curb inappropriate narcotic transactions.

treatment options to treatment integrated into the broader healthcare system; a 2012 study found that most mental health patients are identified in the primary care system, and because primary care physicians often report difficulties in obtaining mental health care referrals for their patients, mental health care provided in a primary care setting could improve health outcomes (Kessler 2012). Consistent with this finding, a recent study on veterans' health found that the US Department of Veterans Affairs (VA) Primary Care–Mental Health Integration services increased accessibility to mental health care for primary care VA clinic patients as used in place of non-primary-care-based mental health specialty visits—without increasing acute care use or costs (Leung et al. 2018).

In the course of this shift toward integration into primary care, general practitioners have become far more involved in mental health care than in the past. By the early twenty-first century, 22.8 percent of mental health patients were being treated solely by a general health medical professional, higher than the percentage seen by any type of specialist (Wang, Lane, and Olfson 2005).

This trend, while indicative of better integration of mental health services with general medicine, may also reflect a shortage of specialized mental health professionals. A survey of general practitioners found that 66.8 percent had difficulty obtaining a referral for their patients to any mental health specialist (Cunningham 2009), and another analysis detected unmet patient need for mental health professionals in 96 percent of all counties in the United States (Thomas et al. 2009). Evidence also indicates that the mental health services rendered by general practitioners are of lower quality than those provided by mental health professionals, with only 12.7 percent of general practitioner visits resulting in "treatments that exceeded a minimum threshold of adequacy," compared with 48.3 percent of visits to specialists (Wang, Lane, and Olfson 2005).

This need for increased numbers of mental health professionals may be exacerbated by a major legislative development in mental health care: the passage of federal and state mental health parity laws. On a national level, the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 requires equal coverage in group health insurance plans for mental health and physical health benefits (Cunningham 2009). Several states followed with their own similar policies. Despite these policies, disparities in care between mental and physical health continue, as do disparities between Americans with mental health disorders and those without.

The ACA was expected to expand coverage and thus diminish barriers to adequate mental health care. However, the issues mentioned, if left unexamined and unaddressed, will continue to prevent progress in mental health care delivery in the United States (Bartels, Gill, and Naslund 2015).

WOMEN AND CHILDREN

According to the US Census Bureau (2018), in 2017, 50.8 percent of the US population was female, and nearly 23 percent of the population was aged 17 or younger. Both women and children face unique health issues that deserve policy attention, and maternity and childbirth present yet another set of concerns.

Women

Women's health is an emerging field centered on health issues and concerns that disproportionately affect women. For instance, women tend to live longer, yet also report more physically and mentally unhealthy days each month, and have higher rates of chronic conditions in old age than men (MCHB, HRSA, and HHS 2013; Strobino, Grason, and Minkovitz 2002). Women—especially those who are poor—are less likely to meet minimum physical activity recommendations than men are. Women are also more likely than men to be obese and report more activity limitations (MCHB, HRSA, and HHS 2013; Strobino, Grason, and Minkovitz 2002).

In 2009, 36.6 percent of female-headed households were classified as food-insecure, and 15 percent of all women experienced food insecurity—placing them at increased risk for health problems caused by poor nutrition (MCHB, HRSA, and HHS 2013; Strobino, Grason, and Minkovitz 2002). Of those adults who receive aid through the Supplemental Nutrition Assistance Program (SNAP), 64.4 percent were women (MCHB, HRSA, and HHS 2013; Strobino, Grason, and Minkovitz 2002).

These factors, combined with disparities perpetuated by the limitations of women's traditional roles as caregivers and by economic inequality, call for increased attention to women's health issues.

Children

The health issues faced by children are continuing to rise. For example, chronic conditions in children have increased dramatically in the twenty-first century; in 2007, more than 7 percent of children had a chronic condition that limited their function to perform basic daily activities, as compared with 1.8 percent in 1960 (Perrin, Bloom, and Gortmaker 2007). High-prevalence chronic conditions among children now include obesity (affecting 18 percent of children and adolescents aged 18–25, as compared with 5 percent in the early 1970s), asthma (9 percent of children and adolescents, double the percentage for the 1980s), and attention deficit hyperactivity disorder (ADHD, affecting 6 percent of school-age children), and poverty is associated with an increased risk for many chronic conditions (Perrin, Bloom, and Gortmaker 2007; Wijlaars, Gilbert, and Hardelid 2016). Particularly, conditions such as asthma and ADHD have increased at a disproportionately higher rate among children living in poverty (American Academy of Pediatrics 2016).

As children become greater consumers of medical care, the quality of care they receive increases in importance. A medical record analysis conducted by Mangione-Smith, DeCristofaro, and Setodji (2007) shows that, on average, children seeking medical care received only 46.5 percent of the services recommended or prescribed by a healthcare provider—a reminder that merely expanding access to health services, a primary policy focus for many years, does "not deliver necessary services [and] will not result in optimal outcomes."

Maternity and Childbirth

Pregnancy and childbirth can lead to both temporary and permanent health conditions, including maternal mortality (Misra and Grason 2006). Receiving proper prenatal care is essential for good neonatal health in the United States, but preventive care must be obtained early and continued throughout pregnancy. For example, folate, a substance that helps prevent adverse fetal outcomes such as spina bifida, must be present in adequate levels early on in pregnancy. Thus, women must be able to obtain adequate levels of this nutrient even before conception (Misra and Grason 2006). Considering that 42 percent of the births in the United States in 2008 were reported as unintended, ensuring this level of preventive care is difficult (MCHB, HRSA, and HHS 2010).

Women from racial or ethnic minorities receive prenatal care at lower rates than non-Hispanic white women do (MCHB, HRSA, and HHS 2010). In 2015, 6 percent of pregnant women in the United States received late or no prenatal care (Kids Count Data Center 2018). Pregnant women who received inadequate prenatal care, and lacked education related to the purpose of such care, experienced an increased risk of providing poor nutrition to their unborn baby. In turn, this practice may increase the risk of the child being diagnosed with obesity, asthma, or ADHD. Maternal cigarette smoking during pregnancy is among the most-documented risks for asthma, obesity, and ADHD in children. Alcohol use during pregnancy introduces serious risks as well (Perrin, Bloom, and Gortmaker 2007).

Although considerable progress has been made in improving prenatal care, and thus the health of women and children, these gains have not been evenly distributed. Health disparities between women and children of different ethnic, racial, and socioeconomic groups still exist, and primary care for these groups has great potential for additional improvement.

PEOPLE WITH DISABILITIES

As the US population ages, more people will experience disabilities and need specialized care. The groundbreaking 1991 Institute of Medicine (IOM) report *Disability in America* and the follow-up 1997 IOM report *Enabling America* highlighted disability as a topic of public health action and scientific inquiry (IOM 1991, 1997). IOM predicted substantial growth in the disabled elderly population between 1997 and 2027 (IOM 1997). At the same time, the number of children and young adults facing disability is rising as survival odds increase for once-fatal birth and childhood conditions and as chronic conditions in the young become more common (Iezzoni 2011; Wijlaars, Gilbert, and Hardelid 2016).

Combined, these trends have led to significant, increasing levels of disability in the United States. The World Health Organization estimated that the United States lost 41.372 million **disability-adjusted life years (DALYs)** in 2004 (McKenna et al. 2005). The DALY measure has been used since the mid-1990s to capture the true health burden caused by disability, combining measures of both the years of life lost to disabling conditions and the quality of life lost over the years spent living with a disability (McKenna et al. 2005). DALYs measure the number of life years lost to disability only for people living with disability, yet the effects of disability are also felt by those who care for the disabled and by society as a whole.

disability-adjusted life years (DALYs)
A measure of the loss of healthy life. The DALY measurement is intended to capture the economic, social, and functional realities that a person with a disability faces and the corresponding loss in health status and quality of life.

In addition to the underlying issues of poor socioeconomic, educational, income, and employment outcomes, people with disabilities in the United States encounter a health system characterized by discrimination and barriers to accessing care. Although many years have passed since the Americans with Disabilities Act went into effect in 1990, "inaccessible facilities, equipment, and communication systems still compromise healthcare experiences for individuals with disabilities in the United States. . . . The barriers that disabled patients confront represent quality problems and also heighten patients' sense of stigmatization, disenfranchisement, and demoralization" (Kirschner, Breslin, and Iezzoni 2007).

Although more large-scale research needs to be conducted in this area, studies that have been done so far suggest that far lower rates of preventive care are provided to people with disabilities. According to Iezzoni (2011), only half of women with a severe disability had received a recommended mammogram or Pap test, compared with almost three-quarters of women without any disability who had received a mammogram and more than 80 percent of women without any disability who had received a Pap test. Approximately half of Americans with disabilities are eligible for governmental assistance, such as Medicaid or Medicare, and many more have private coverage. State and federal government spending on individuals with disabilities totaled more than $400 billion in 2008, and patients with disabilities accounted, on average, for almost three times more healthcare expenditures each year than for patients without disabilities (Kirschner, Breslin, and Iezzoni 2007; Livermore, Stapleton, and O'Toole 2011). These expenditures were predicted to only rise, especially after the ACA expanded Medicaid to cover a greater number of Americans with disabilities and prohibited refusal of insurance due to preexisting health conditions in the private market.

THE HOMELESS

Homeless people in the United States are among the most marginalized groups in society; however, their health needs are not marginal. A study published in the first decade of the twenty-first century revealed that up to 3.5 million people each year experience homelessness in the United States, and 700,000 people are classified as homeless on any given night; furthermore, 7 percent of US residents will experience homelessness at least once in their lives (Reid, Vittinghoff, and Kushel 2008). Additionally, many more Americans will face housing instability, a precarious position that, while less drastic than homelessness, predisposes them to several risk factors that can lead to worse health outcomes (Reid, Vittinghoff, and Kushel 2008).

Homeless and housing-unstable people are subject to much higher resource competition than most of the general population, and health issues that others would consider absolutely critical may be sidelined by the homeless in favor of more basic needs such as food and shelter (Kidder et al. 2007). As a result of reduced healthcare, the homeless experience significantly higher rates of morbidity and mortality, greatly reduced access to healthcare (especially preventive services), and, therefore, much higher rates of hospitalization and self-reported poor health than the broader population does (Baggett et al. 2010; Kidder et al. 2007; White et al. 2018).

Several studies have attempted to identify factors that increase ambulatory and preventive care utilization among the homeless. First and foremost, housing situations with greater stability have been shown to increase the amount of healthcare received, especially ambulatory care (Kushel, Vittinghoff, and Haas 2001). The Housing First program was developed in response to these findings, and it realized positive results in reducing ED visits and hospitalizations among the chronically homeless population in several cities, by providing necessary, no-strings-attached housing (Kertesz and Weiner 2009). A recent study revealed that becoming housed is a key facilitator of reduced ED utilization and that efforts to provide housing for homeless adults may also greatly decrease ED use (Moore and Rosenheck 2017).

Another factor, the lack of insurance among the homeless population, was analyzed by Reid, Vittinghoff, and Kushel (2008), who suggested that health outcomes would improve with better insurance options or with options to receive regular care. An earlier study found that health services utilization by the homeless did not increase greatly with either housing stability or insurance coverage alone and, instead, was associated with better community ties and social support. Increased community support was, in turn, correlated with housing stability (Stein et al. 2000).

Overall, homelessness in the United States is a complex and poorly understood issue. Yet ignoring the health problems faced by homeless or housing-insecure people will only exacerbate an already difficult societal situation. Many innovative and comprehensive approaches to improving the health outcomes of the homeless are being developed. The Boston Health Care for the Homeless program, a leading outreach program, works to integrate care across the medical spectrum and to create housing situations that provide continuous services and preventive care (O'Connell et al. 2009). The Homeless Outreach and Proactive Engagement initiative launched in the San Fernando Valley around Los Angeles in 2016 (Walton 2016). The program connects Los Angeles Police Department officers with the city's Sanitation Department, mayor's office, city attorney's office, and the Los Angeles Homeless Services Authority to identify encampments for homeless people and help them transition into permanent housing.

PEOPLE WITH HIV/AIDS

In the relatively short time since the disease was recognized, AIDS has dramatically changed the lives of millions of people, their communities, and the US healthcare system (see the Learning Point box titled "HIV/AIDS in the United States"). Although there have been marked improvements in the prevention and care of HIV and AIDS, more than 35,000 people contract the virus each year (CDC 2018c). At the end of 2015, about 1.1 million people in the United States were living with a diagnosed HIV infection (CDC 2018c). A major factor in the continued high number of transmissions is that 14 to 15 percent of the people infected with HIV do not know that they are HIV-positive (CDC 2018c; KFF 2018b).

Impact on HIV/AIDS Subpopulations

Current health disparities in the United States are also reflected in the trends in AIDS infection. Men who have sex with other men (a category referred to as MSM) constitute only 2 percent of the US population yet accounted for 68 percent of new HIV infections in 2015 (KFF 2018b). Although the proportion of women who are HIV-positive or have AIDS is significantly lower than that of men, the disease has become more prevalent in the female population over time, and research shows that more barriers to care exist for women than for men (KFF 2014). Minorities also carry a disproportionate share of that health burden; African Americans accounted for 43 percent of HIV diagnoses although they comprise only 12 percent of the US population (KFF 2018a). The HIV diagnosis rate for African Americans in 2016 was double the rate for Latinos and eight times higher than for whites (KFF 2018a).

As with other health conditions and diseases, socioeconomic factors also influence the rate of HIV acquisition. Lower SES is associated with higher AIDS mortality, and infection prevalence is higher among Americans with less education, lower incomes, and higher unemployment rates (KFF 2018a; Rubin, Colen, and Link 2010). Even as the demographic profiles of HIV-infected residents have evolved, those living with AIDS still face discrimination, reduced access to care, and other disparities that greatly affect health outcomes.

LEARNING POINT

HIV/AIDS in the United States

HIV is the abbreviation for *human immunodeficiency virus*; the term *AIDS* is derived from *acquired immune deficiency syndrome*. HIV is a retrovirus that infects the human body and, over time, destroys the immune system, leading to AIDS. A person who has AIDS is typically in the final stages of HIV, after the immune system becomes unable to defend itself. HIV is transmitted by having sex without a condom; by sharing syringes, needles, or drug works; and through pregnancy, childbearing, or breast-feeding.

The CDC identified the first AIDS cases in the United States in 1981. Since then, 1.7 million US residents have become infected with HIV, and more than 700,000 have died from AIDS, leaving more than 1.1 million people in the United States living with HIV/AIDS today (CDC 2018c, 2018d; KFF 2018b).

Implications of Advances in Treatment

People infected with HIV/AIDS fare better today than they did at the beginning of the twenty-first century, thanks to the discovery and widespread use of new treatment options, particularly antiretroviral drugs used in combinations of multiple drug classes. These therapies are only effective, however, if administered early and continuously over the course of the infection. For those patients who have access to expert medical care and powerful drug "cocktails," these advances "have transformed HIV/AIDS from a terminal illness to a chronic disease," whereas those with limited means may still face a bleak outcome (Lubinski et al. 2009). The barriers that inhibit HIV-positive people from accessing lifesaving medications are significant; the most important among them is the lifetime health costs associated with the diagnosis. In 2006, the total costs of treating HIV and AIDS per person were estimated to be more than $385,000, of which 73 percent was spent on antiretroviral medications (Schackman et al. 2006). The estimate of lifetime HIV treatment costs was $379,668 (Schackman et al. 2006).

Assuming that an individual has access to these treatments, by 2006, the average patient's life expectancy increased to 24.2 years following diagnosis with HIV or AIDS (as compared with the average expected 6.8 years in 1998), but this greatly expanded life expectancy accounts for much of the rise in treatment costs (Schackman et al. 2006). As discussed next, the federal government pays a substantial portion of these expenses.

Funding

In fiscal year 2017, the US government spent $19.6 billion on HIV-related care and treatment (KFF 2017b). In 2014, Medicare covered about 120,000 people infected with HIV, nearly triple the 42,520 covered in 1997 (KFF 2016b). Medicaid covered 242,000 patients in 2011, a 14 percent increase compared with 212,900 in 2007 (KFF 2016a). The federal government spent nearly $5.8 billion in 2017 for Medicaid HIV activities (KFF 2017b), an amount which is supplemented by state funding. Medicare is the largest federal funder of HIV care and treatment in the United States, followed by Medicaid (KFF 2017b).

Additional funding is provided by the Ryan White HIV/AIDS Program, a federal initiative named after a 13-year-old hemophiliac boy who was diagnosed with AIDS after a blood transfusion in 1984. White gained national fame when he fought for the right to return to school, having been barred from attending because of AIDS (HRSA 2016). The program aims to assist HIV patients who lack sufficient means to obtain treatment by disbursing discretionary funds provided by the US Congress to states, cities, not-for-profit organizations, and healthcare providers. By 2016, this program had become the third-largest source of federal funding for HIV care in the United States, providing about $2.3 billion that year (KFF 2017a, 2017b).

President Trump's budget request for fiscal year 2018 called for decreased funding of HIV/AIDS programs (KFF 2017b).

Policy Initiatives

Two major initiatives in US healthcare policy prior to 2017 showed the potential to lead to improved health outcomes for people with HIV/AIDS. First, President Barack Obama's 2010 National AIDS Strategy for the United States, hailed as "the most comprehensive federal response to the domestic HIV epidemic to date," set three targeted goals for the country to achieve over the next ten years: (1) reduce new HIV infections, (2) increase access to care and improve outcomes, and (3) reduce health disparities for HIV/AIDS (Yehia and Frank 2011).

In 2015, an updated National HIV/AIDS Strategy was released, still with a view toward 2020, which added a fourth goal—to achieve a more coordinated national response to the HIV epidemic (HIV.gov 2017; White House 2015).

Second, accompanying this greater focus on HIV health issues were mandates set forth in the ACA. The ACA raised the income level for Medicaid eligibility and outlawed the denial of coverage due to preexisting health conditions, both of which helped HIV/AIDS patients continue to receive lifesaving healthcare (Dawson and Cates 2017).

Under President Trump, the federal government's willingness to address health disparities for people with HIV/AIDS has appeared uncertain. In addition to his request for reduced funding of HIV/AIDS programs (KFF 2017b), there were indications that Trump's desired changes in federal healthcare programs overall could result in a reduction of coverage through Medicaid and elimination of ACA protections for individuals with preexisting health conditions (Dawson and Cates 2017; Kessler and Kelly 2018; Luhby 2018), both of which would have negative repercussions for people with HIV/AIDS.

KEY POINTS

- Vulnerable subpopulations, such as racial and ethnic minorities, the uninsured, and those with low SES, typically experience a convergence of multiple health risk factors and, consequently, exhibit poorer health status than do other subpopulations.
- For the elderly, concerns about primary care and health policy broadly revolve around containing costs of care, reforming the health system to better serve a growing elderly population, and increasing their quality of life.
- The US primary care system will need to be fundamentally overhauled to accommodate the increase in the number of patients with chronic diseases, requiring new ideas on how best to provide high-quality care and meet the needs of this growing population.
- Although half of all Americans are affected by at least one mental disorder in their lifetime, mental health care in the United States has traditionally been marginalized.

CASE STUDY QUESTIONS

CASE STUDY 1

Based on your own research on health centers, answer the following questions:

1. How would you describe the efficacy of health centers? What are their roles in improving access to care, quality of care, and health outcomes for vulnerable populations?
2. How can health centers cope with the challenges they face?

CASE STUDY 2

Based on your own research on chronic illness, answer the following questions:

1. What are some innovative models of care delivery that target people living with chronic illnesses? How do these models differ from the status quo?

2. The care team approach is often used to provide community-based primary care, particularly to people with chronic illnesses. What is the composition of the team? Why are these individuals essential members of the team?
3. How can low-cost technology be used in community-based primary care for people with chronic illnesses? Provide illustrative examples.

For Discussion

1. Why should health policy focus on vulnerable populations?
2. What health policy issues do racial and ethnic minorities face? Cite examples of programs to eliminate racial and ethnic disparities in healthcare.
3. What health policy issues do uninsured US residents face? Cite examples of programs to eliminate insurance disparities.
4. What is socioeconomic status (SES)?
5. What health policy issues do people with low SES face? Cite examples of programs to eliminate SES disparities.
6. List the health policy issues for each of the following subpopulations:
    a. The elderly
    b. People with chronic illness
    c. People with mental illness
    d. Women and children
    e. People with disabilities
    f. The homeless
    g. People with HIV/AIDS

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CHAPTER 7

INTERNATIONAL HEALTH POLICY ISSUES

Letting a hundred flowers blossom and a hundred schools of thought contend is the policy for promoting the progress of the arts and the sciences and a flourishing culture in our land.

—Mao Zedong

Protecting Health, Saving Lives—Millions at a Time.

—Johns Hopkins Bloomberg School of Public Health

LEARNING OBJECTIVES

After completing this chapter, you should be able to

- describe the critical health policy issues in developed countries,
- discuss the critical health policy issues in developing countries,
- understand how various countries address their health challenges,
- appreciate the common and unique health challenges in an international context, and
- explore emerging and intensifying global health issues.

CASE STUDY 1

CLIMATE CHANGE AND PUBLIC HEALTH

The natural environment has a profound impact on human health, as reflected in the United Nations (UN) Framework Convention on Climate Change (Singh et al. 2011). Climate scientists predict that the world will warm 4°C by 2100, yet the relationship between rising global temperatures and human health is not fully understood. Severe weather events, such as heat waves, earthquakes, floods, hurricanes, and cyclones, pose direct threats to human life and health. Some argue that changing weather patterns have already indirectly affected food yields, water flows, patterns of infectious disease (e.g., the increasing reach of tropical diseases beyond the typical geographic areas of occurrence, changes in the seasonality of certain diseases), and population displacement (Chowdhury, Dey, and Smith 2018; Hundessa et al. 2018; McMichael et al. 2003).

Public health experts are calling for climate change policy interventions that have an immediate, positive impact on population health. For example, policies to encourage reduced meat consumption mitigate the excess intake of saturated fats and remove some methane (a greenhouse gas) from cattle-producing regions (McMichael and Lindgren 2011). Examples such as these and findings from other emerging research show that a public health discussion must be incorporated into the larger climate change discourse.

A public health perspective can unite all actors from disparate sectors behind the common cause of public health and wellness in families, communities, and nations. Reducing inequities not only within but also between countries is crucial to greater climate change resilience and better global health. Neither can be achieved without sustainable development to address fundamental determinants of health such as access to safe water and clean air, food security, strong health systems with good access, and reduced social and economic inequity. Any focus on global health must therefore prioritize sustainable development and climate change (Watts et al. 2015).

By itself, a top-down approach—creating an international agreement, followed by establishing national legislation for individuals and businesses to follow—to addressing climate change is no longer adequate. Organizations and individuals are already taking their own steps to reduce emissions. At the same time, climate change is only one of many factors considered by decision makers, and rarely the one given the highest priority. Adaptation to climate change is clearly also an inadequate response, and current trends in energy production and consumption are driving the world toward a future of great climatic risk.

The most powerful strategy to protect human health from the risks of climate change would be a government mandate of carbon pricing, in ways that strengthen over time until the problem is under control (Boyle 2015). Like tobacco taxation, the policy of carbon pricing would send clear signals to all actors in the system—from producers to users—that the world's economies must shift away from the use of fossil fuels, such as coal—the worst offender in terms of carbon intensity and damage. In addition to direct incentives, the revenues generated from carbon pricing could go toward wide-ranging measures including adaptation; the development of renewable, low-carbon energy sources; and the global diffusion of improved technologies and practices. Carbon pricing thus holds great potential, particularly when carried out as part of a comprehensive policy package. This potential solution, however, still faces political obstacles. The current drivers of economic growth force communities into patterns of energy use that no reframing can change without coordinated realignment of these drivers. And the idea that "others" are to blame and should be the ones to address climate change remains a potent excuse for inadequate action (Vignola, McDaniels, and Scholz 2013). The ideal international agreement would support stronger efforts at all levels in every country. To be effective, any agreement will need not only to set goals but also to identify needs at international and national levels to achieve the goals. Such an agreement may also require a motivation mechanism, such as a "feedback loop," that strengthens national ambitions over time (Marteau, Hollands, and Fletcher 2012).

CASE STUDY 2

PRIMARY CARE AROUND THE WORLD

In 1978, the International Conference on Primary Health Care created the Declaration of Alma-Ata, which underscored not only the necessity of a robust primary healthcare system to sustain a comprehensive national health system but also the importance of establishing healthcare as an essential human right (WHO 1978). Globalization has continued to put pressure on health systems that are under strain to provide services that are high quality, universally accessible, and affordable. There is clear evidence that primary healthcare leads to better health for all and better-functioning healthcare systems.

While global health has improved on aggregate, a number of political, demographic, and epidemiological transitions have increased inequalities in progress within and between countries. These transitions have put a strain on existing healthcare systems, and a focus on primary care as an essential part of healthcare reform is necessary. The World Health Organization (WHO) considers universal healthcare a critical aspect of a move toward reform based on primary care. Since the adoption of the Sustainable Development Goals (SDGs), WHO has framed its advocacy for universal healthcare around Target 3.8 of SDG 3, which focuses on service coverage and financial protection (WHO 2018d, 2018e).

With rising healthcare costs and disorganized systems for financial protection, personal health expenditures now force more than 100 million people into poverty each year. Vast differences in health occur between and within countries and even within individual cities. In reemphasizing primary healthcare, WHO argues that its core principles and approaches are more relevant than ever, a conclusion which several findings support (Van Lerberghe 2008).

Using existing preventive measures more efficiently may reduce the global burden of disease by as much as 70 percent (Van Lerberghe 2008). Tasks performed by specialists may be better managed by general practitioners, family doctors, or nurses. Specialist-oriented care contributes to inefficiency, restricted access to care, and deficiencies in comprehensive care. When healthcare is skewed toward specialist care, a range of protective and preventive care interventions may be lost (WHO 2006). Unequal access to care and disparities in health outcomes are usually worst when health is regarded as a commodity and care is profit driven. Workforce shortages in primary care also pose a significant challenge (as described in Case Study 2, “Primary Care Workforce Around the World,” in chapter 4).

An effective primary healthcare approach protects against many of these problems, emphasizing a holistic view of health in which prevention is as important as cure in a care continuum that extends over the human life span. The primary healthcare approach targets key health determinants in multiple nonhealth sectors, in effect launching an “upstream attack” on threats to health (Van Lerberghe 2008). The main strategy for addressing disparities in healthcare is to shift toward universal health coverage with an emphasis on the values of equity, social justice, and solidarity and the overarching goals of fairness and efficiency in service delivery.

This chapter provides examples of important health policy issues from the international community, using selected countries—both developed and developing—to demonstrate their impact. Students’ exposure to these issues not only helps them understand international health policy applications but also introduces them to **global health** (as defined by Koplan et al. 2009) as a field and **globalization** (as defined by Shi and Singh 2017) as a reality.

global health
A field of study, research, and practice that focuses on improving health and wellness and attaining health equity for all people worldwide.

globalization
Worldwide changes in many aspects of people’s lives driven by the exchange of information across borders and characterized by increased production of goods and services by developing countries and the expanded interdependence of developed and emerging economies.

The advent of globalization, technological advances, and shifting global demographics brings challenges in achieving equitable global health. Although globalization brings conformity in some areas of people’s lives, differences in economic policies, political and legal structures, social and cultural norms, and religious beliefs remain from country to country and region to region, creating additional barriers to the equitable delivery of healthcare (see the For Your Consideration box titled “Worldwide Access to Care”).

FOR YOUR CONSIDERATION
Worldwide Access to Care

According to a 2017 global monitoring report, more than 50 percent of the world’s population does not have access to essential healthcare services, more than 800 million people spend in excess of 10 percent of their household budget on healthcare, and nearly 100 million people experience extreme poverty due to healthcare costs (WHO and World Bank 2017). In today’s world, countries face a fast-growing need for equitable, inclusive, and fair primary healthcare systems.

FOR YOUR CONSIDERATION
Injury Prevention

Several governments around the world have developed national injury-prevention policies, strategies, or plans of action (WHO 2018f). Although these instruments vary in nature and scope, they help guide a country's efforts to prevent injury-related death and disability. WHO suggests that responsibility be assigned for all stages of implementation and that these injury-prevention policies or action plans be developed in a collaborative way, involving both government and nongovernment participants. Some policies are developed by and for a single sector (such as health, transport, justice, or education), but ideally they should be developed across multiple sectors. WHO also recommends that policymakers and planners take into account at an early stage the human and financial requirements that will be necessary for their policies' implementation.

The greater ease of travel and communications has not only diminished barriers between countries but has also ushered in new concerns of disease transmission and other global health threats. Recently considered a problem predominantly afflicting the developing world, infectious diseases have become a concern for all countries as global trade, tourism, international relations, and migration facilitate the spread of disease. Another issue of global concern is injury prevention, particularly when injuries are the result of violence in the country (see the For Your Consideration box titled "Injury Prevention"). The United Nations (UN) works with several constituent organizations on global health initiatives; in addition, WHO coordinates some health activities between countries and surveillance of global health concerns. These organizations, and policymakers around the world, face varied problems and tough decisions regarding global health.

This chapter begins by discussing issues shared by many industrialized countries. Japan, Denmark, Canada, and South Korea are profiled in terms of their major health issues and the solutions they have proposed to address these issues. Next, the chapter discusses both common and unique challenges faced by developing nations. The variety of unique issues confronted by emerging economies is demonstrated in discussions of China, Ukraine, Nigeria, and Colombia. The chapter also includes several Global Health Impact boxes to

GLOBAL HEALTH IMPACT
Migration

The UN Department of Economic and Social Affairs estimates that 3.1 percent of the world's people live outside of their country of origin (International Organization for Migration 2017). In addition, many people are *internally displaced*, meaning that they have been forced from their homes but remain within the country's boundaries.

People migrate for a variety of reasons, including to take advantage of economic opportunities, in reaction to political instability, and to avoid conflict. Two aspects of migrant health must be addressed. The first is the public health threat inherent in the migratory movement

GLOBAL HEALTH IMPACT
Migration *(continued)*

of people. Infectious disease concerns exist in all phases of such a journey, and the ease with which people and products can move around the world directly corresponds to the rapidity with which a disease threat may spread.

The second issue concerns the health needs of individual migrants after they reach their destination. In many countries, the health system restricts migrants' access to healthcare or does not provide culturally appropriate care, leading to poor health outcomes (International Organization for Migration 2017).

Australia, in which one-fourth of the population was born elsewhere, has a well-developed system of healthcare delivery for migrants (*Bulletin of the World Health Organization* 2008). In contrast, Spain has only just begun to consider the health concerns and integration issues of migrants (International Organization for Migration 2017). Migrant health issues will grow as people continue to move around the world to find work or to escape undesirable conditions.

illustrate issues that could affect global health in the future, challenging policymakers to rethink their approaches to public health (see, for example, the one titled "Migration").

HEALTH POLICY ISSUES IN DEVELOPED COUNTRIES

Some health policy issues are unique to advanced economies. Most developed nations have controlled the spread of communicable diseases through well-established public health infrastructures and effective sanitation services (although the threat of importation of communicable disease from uncontrolled regions is a concern caused by globalization and increased travel and trade). However, their health systems are strained by an aging population and widespread chronic diseases.

COMMON POLICY ISSUES

All industrialized nations with established healthcare systems struggle to adapt these systems to meet changing needs. They must maintain an adequate, well-trained workforce and integrate new technologies while keeping costs at a manageable level.

Researchers first found that healthcare spending was rising among the Organisation for Economic Co-operation and Development (OECD) countries in the 1970s; a 2009 study confirmed the continuation of this trend by showing that OECD countries spent an average of 9.5 percent of their gross domestic product (GDP) on health, compared with an average of 5.3 percent in the 1970s (OECD 2011).

Policymakers in industrialized countries constantly seek ways to achieve sustainable growth and allocate adequate funding to ensure fiscal and population health. To meet the challenge of cost control, many countries have experimented with alternative methods of paying for and delivering health services. For example:

- The Australian healthcare system provides universal access to a comprehensive range of services, largely publicly funded through general taxation. Australia has a federal system of government, with a national (Commonwealth) government and six states and two territories. At the time of federation, health remained the responsibility of the states. However, the Commonwealth government holds the greatest power to raise revenue, so states rely on financial transfers from the Commonwealth to support their health systems. This setup makes the Australian healthcare system a complex division of responsibilities and roles across levels of government (Duckett and Willcox 2015).
- The Canadian provinces and territories have primary responsibility for organizing and delivering health services and educating, accrediting, and licensing healthcare providers. Generally, these regional health authorities are responsible for the funding and delivery of hospital, community, and long-term care, and mental and public health services. Some jurisdictions have consolidated a number of these authorities. Healthcare providers are almost entirely private (Hutchison et al. 2011).
- The Danish government consolidated health services administration, decision making, and services provision (Andersen and Jensen 2010).
- Israel placed its health system budget under the jurisdiction of the Ministry of Finance rather than the health ministry as in most other countries (Ministry of Finance, State of Israel 2017). The relationship is intended to help control spending: The Ministry of Finance sets the level at which it will fund the national health insurance after estimating the amount that will be collected from cost-sharing provisions (Ministry of Finance, State of Israel 2016).
- Italy decentralized the authority of the Servizio Sanitaris Nazionale as a way to control federal health spending (Tediosi, Gabriele, and Longo 2009).
- The Japanese government regulates almost all aspects of the universal public health insurance system. The national government sets the fee schedule by developing consensus among stakeholders; gives subsidies to local governments, insurers, and providers to implement its policies; and establishes and enforces detailed regulations for insurers and providers (Ikeda 2004).
- New Zealand replaced its former healthcare model with one called the Primary Health Care Strategy, which increased public funding of preventive and public

health activities, encouraged general practitioners to form nongovernmental primary health organizations, and changed payments from fee-for-service to capitated fees paid to primary health organizations (Cumming and Mays 2011).

- In the United Kingdom, the National Health Service (NHS) provides healthcare, including hospital and physician services and prescription drugs, to all of its residents. Under the terms of the NHS Health and Social Care Act 2012, the day-to-day responsibility for running the NHS rests with NHS England, formerly known as the NHS Commissioning Board (Bevan and Hood 2006; Department of Health and Social Care 2012).

Each of these countries faced similar problems and shared the goals of providing low-cost healthcare while achieving positive health outcomes. Yet, they developed different solutions, each of which took into account the particular country's level of political will and societal values.

In addition to experimenting with health system structure, some countries have developed mechanisms for determining suitable treatment methods in the hope of reducing pharmaceutical expenditures without negatively affecting health outcomes (Clement et al. 2009). Australia, the United Kingdom, Canada, and other countries have governmental agencies that evaluate the cost-effectiveness of certain pharmaceutical products by analyzing cost and comparative effectiveness evidence to make national coverage decisions. Australia has taken this measure a step further by often delaying the recommendation of drugs for use until the price is negotiated to a level low enough to be deemed cost-effective (Clement et al. 2009).

Some cost-reduction policies aim to directly improve health outcomes. For example, the United Kingdom has set up a physician payment model called **pay for performance**, under which physicians treat patients following disease-based **clinical practice guidelines**. The guidelines are drawn from **evidence-based medicine** and are designed to reflect the best path to achieving high-quality healthcare and strong patient outcomes. Not all experts agree that evidence-based care is the best mode of service delivery. Researchers assert that because patients experience diseases differently, treatment should be patient centered rather than disease centered (Prey et al. 2014; Starfield and Mangin 2010). Still, this example illustrates that most governments struggle to ensure that the money allocated for health systems is used to deliver the best possible health outcomes and high-quality care. In fact, France codified quality assurance—a medical practice supported by the government—in its creation of the National Agency for the Development of Medical Evaluation in 1990 and the Hospital Act in 1991, which made quality-of-care assessment mandatory. In 2004, a newer agency called the Agency for Accreditation and Evaluation of Health Care was given responsibility for these activities (Legido-Quigley et al. 2008).

Other countries have imposed varying levels of **cost sharing**, the amount of which depends on income, on their residents in an attempt to reduce government expenditures while ensuring adequate care for society's poorest inhabitants. Ireland introduced a three-tiered

pay for performance
Payment-related incentives often used by insurance companies or government payers to reward healthcare providers, such as physicians and hospitals, for meeting preestablished performance measures for quality and efficiency.

clinical practice guidelines
Systematically developed protocols (statements) used to assist healthcare providers in making appropriate healthcare and clinical decisions regarding specific conditions or circumstances.

evidence-based medicine
Using the best available evidence acquired through the scientific method to guide clinical decision making.

cost sharing
The obligation of patients to pay for a portion of the healthcare services they receive. Cost sharing is typically used as an incentive to avoid excessive or unnecessary utilization. However, it may also deter appropriate utilization.

payment system to address health equity issues. Those in the bottom tier (corresponding to the lowest-income residents) receive free health services, the middle-tier population shares some costs, and those in the highest tier overwhelmingly opt out of public insurance and buy private health insurance. Rather than providing equitable access to health services, however, this system created increased inequality in access (Smith and Normand 2011).

These examples illustrate that an individual's income and sociodemographic status are among the most important predictors of unmet healthcare needs; that is, disparity is a multifaceted issue that extends far beyond the health system (Bryant, Leaver, and Dunn 2009; Chen et al. 2018). To determine the best solutions to meet these challenges, each country's government must clarify its values and priorities with regard to health equity and cost sharing. As the burden of chronic disease increases in industrialized countries, disease prevention is promoted as a way to improve public health and reduce healthcare costs. Obesity is a preventable risk factor associated with many chronic diseases, such as cardiovascular disease, diabetes, cancer, and premature death. The treatment, management, and health complications associated with these chronic diseases generate high healthcare expenditures (Guy et al. 2017; Sassi 2010). Therefore, some countries are taking a public health approach to addressing obesity by encouraging lifestyle changes. Nordic countries have placed taxes on unhealthy foods in the hope of steering consumers to healthier choices. However, the obesity epidemic is not merely a result of an individual's food choices; it also reflects broad changes that have occurred in the everyday lives of people in the modern world compared with preindustrial times. As such, some governments are considering new transportation and urban planning policies, among other programs, to improve health and decrease obesity rates.

UNDERLYING FACTORS

Several factors affect healthcare costs in developed countries, including the impact of aging populations and technological progress, as previously discussed. Country GDP, the participation of women in the labor force, and public budgetary values are also important variables that influence cost trends (Lavigne, Brown, and Matzke 2017; Pammolli, Riccaboni, and Magazzini 2012). For instance:

- As a country's total income rises, so do healthcare expenditures.
- As an increasing number of women enter the workforce, caregiver responsibilities shift from the private sphere to the public sphere.
- Countries tend to spend more money on those social goods most valued by society, which may be related to healthcare or its associated products and services.

UNIQUE POLICY ISSUES, BY SELECTED COUNTRY

Maintaining a healthy population should be a high priority for any nation, just as cost control should be. Taking these two priorities into consideration, countries have approached the creation and implementation of health system administration, quality, and access policies in different ways. We discuss Japan, Denmark, Canada, and South Korea to illustrate unique health policy issues addressed by developed nations.

Japan

Japan adopted universal health insurance coverage in 1961. Since that time, its model has served as a blueprint for other counties to build a successful low-cost, high-quality, and highly equitable health system. However, the Japanese system is reaching a critical crossroads. The population has been rapidly aging since the late twentieth century (currently, more than 20 percent of the population is aged 65 or older), which has enormous implications for the cost of healthcare. At the same time, the government cannot rely on increasing tax revenues to pay for the health system because population growth and, consequently, economic growth are stagnant (Shibuya et al. 2011). In response to these challenges, the Japanese government has introduced innovative ways to slow spending.

In 2000, the government instituted its Long-Term Care Insurance (LTCI) program to care for the country's aging population. The goal of LTCI is to provide long-term care services to adults aged 66 or older at the institutional and community levels and to ease financial and emotional burdens for both the patient and the patient's caregivers (Tsutsui and Maramatsu 2007). To pay for LTCI, Japan set aside a portion of general tax revenues and levied a new tax on adults aged 41 or older.

Compared with other industrialized countries, Japan has made few formal efforts to ensure healthcare quality. While healthcare payment is under tight control, healthcare delivery is not; providers within the system are free to deliver care as they see fit. They are reimbursed on the basis of diagnosis–procedure combination categorization, thus diluting healthcare quality data that would be available under a fee-for-service payment system; monitoring fee-for-service data is the primary way providers can be held accountable. Although its health outcomes are comparable to those of other countries, Japan has no accountability mechanism in place, such as the pay-for-performance model in the United Kingdom and the quality assurance law in France. As Japan's health system continues to undergo reform, structural measures of quality assurance might eventually be considered (Hashimoto et al. 2011).

Out of total health expenditures, 80.5 percent were financed through the public sector through the universal Statutory Health Insurance System in 2009 (Matsuda 2018; OECD 2011). Insurance premiums accounted for about half of the total health expenditure and are determined on a per capita, per-household, income-related, and asset-related basis. Employer-based insurers levy premiums on employee wages, and employers pay half of these employee premiums. The rates of such plans vary from 3 percent to 10 percent of wages, while rates are about 10 percent of income for employees of small- and medium-sized employers, who are insured by the Japan Health Insurance Association (Matsuda 2018; OECD 2011). Rates also vary among municipalities, albeit to a lesser degree. Government employees are covered by their own system of insurers (known as Mutual Aid Societies), as are some groups of professionals (e.g., physicians in private practice). Government subsidies, funded from the general budget, are provided mainly to Citizens Health Insurance insurers, Health Insurance for the Old-Old (a federal program) insurers, and, to a lesser extent, small-business employer-based insurers. There are also cross-subsidies from Citizens Health Insurance and employer-based insurance to Health Insurance for the Old-Old, and between Citizens Health Insurance and employer-based insurance (Ikegami and Anderson 2012).

In 2012, the federal government revised its health promotion objectives, known as Health Japan 21, and made reduction of health disparities a general goal. Its objectives include a target for reducing disparities in healthy life expectancies and cancer treatment delivery between prefectures; the government gives subsidies to prefectures to develop cancer care centers (Ueno 2013).

One emerging trend has been to promote evidence-based policymaking. For example, the current process through which the Central Social Insurance Medical Council revises the national fee schedule has been criticized for a lack of transparency and for vulnerability to potential abuses and conflicts of interest. Introduction of economic evaluation methods into health technology assessments, although highly controversial, has been increasingly discussed. Policymakers have also stressed the importance of prevention and wellness in reducing healthcare costs. Current priorities in prevention include reducing smoking and reducing the incidence of cardiovascular disease, diabetes mellitus, and hyperlipidemia. Since 2008, statutory health insurers have been responsible for delivering annual health checks to beneficiaries aged 40–74 (Matsuda 2018). Policy tools for improving quality and efficiency, such as comparable quality indicators, are being developed. As an early victim of bioterrorism, Japan also has had to consider security threats posed by the deliberate release of infectious diseases and address this issue in its policies and laws (Sugishima 2003; see also the Global Health Impact box titled "Bioterrorism, Global Health Security, and Surveillance").

Despite a lack of quality standards, Japan's long-standing health system has achieved successes that other developed countries are still striving toward. All of the measures described here were adopted to maintain good health outcomes and quality of life at low cost to both consumers and the government, making it a model worthy of consideration by other developed nations.

Denmark

The Danish parliament passed major legislation in 2007 to reorganize and consolidate the country's governmental structure; 215 local municipalities were condensed to 98, and 13 counties were reduced to 5 regions. The health system underwent a similar recentralization.

GLOBAL HEALTH IMPACT

Bioterrorism, Global Health Security, and Surveillance

A notorious example of bioterrorism is the 1995 attack in a Tokyo subway, where a domestic terrorist group released a chemical weapon called sarin. Sarin is a nerve agent that can paralyze muscles needed for breathing; in the Tokyo subway attack, 13 people were killed and 50 were severely injured. Also in the twentieth century, Iraq and the former Soviet Union were found to have military bioweapons programs (Khan et al. 2000). Scientists in the United States and the Netherlands exposed the possibility of disease-related bioterrorism when they created a highly contagious strain of avian flu in late 2011 (Novossiolova, Minehata, and Dando 2012).

The 2014 Ebola virus outbreak in West Africa was of unprecedented scale and impact and brought attention to global health security—its definition and role in programs and policy. For example, the government sought to strengthen its core public health capacities to meet the International Health Regulations, and experts sought to define global health security concerns. The lessons learned from the Ebola outbreak can serve to inform better global health governance. Once viewed merely as a protection from the pandemic spread of infectious diseases, health security demands greater collective action to ensure "access to safe and effective health services, products, and technologies" for the health security of all individuals (Heymann et al. 2015). This more inclusive definition recognizes that collective health security derives from individual health security, and it compels an adequate global response to provide all people worldwide with access to essential healthcare services (Heymann et al. 2015).

Health policy to counter bioterrorism should focus on preparedness efforts, as with natural disasters and pandemics, and plans that are put in place must be carefully and thoroughly executed. Local jurisdictions can also take measures to reduce their vulnerability to bioterrorism by assessing their infrastructures and environment, health system capacity, and emergency response teams and procedures. International cooperation is required on a far larger scale to establish better disease surveillance systems, laws and policies that strengthen health systems, and preventive measures against violent conflicts to make the world a healthier and safer place for all people.

Key areas in need of improvement had been identified in hospital future planning and current efficiency, primary care coordination, and public health prevention (Andersen and Jensen 2010). Denmark has one of the lowest life expectancies and highest cancer mortality rates in the European Union (Economist Intelligence Unit 2011; OECD 2016). The population is also getting older, and as a result, the chronic disease burden is increasingly cumbersome (OECD 2016).

Denmark's 2007 health reform legislation, called the Health Act, included several measures to address the country's pressing health policy concerns. To improve coordination of care, Danish officials put into effect a series of regulations (Andersen and Jensen 2010):

- Regional health authorities were charged with creating patient rehabilitation plans for hospital discharge.
- General practitioners were asked to participate in coordination-of-care strategies by reporting patient data in a shared database.
- The newly formed regions were required to plan hospital systems whereby all hospitals are expected to provide an array of basic, frequently needed services, accounting for about 90 percent of hospital services; one hospital per region is to provide specialized services; and a few hospitals in the country will perform a limited number of highly specialized services.

These initiatives are meant to work together to provide coordinated and high-quality care for all Danish patients, whether they have an acute condition or a chronic disease.

The 2007 reform aimed to centralize hospital care administration to enhance the coordination of delivery and improve quality and efficiency. The five regions established under the reform are reorganizing their hospital systems, closing or merging small hospitals, and building new hospital infrastructure, at a total cost of 40 billion Danish kroner, or about US$7.2 billion (Rigsrevisionen 2013). Reorganization of acute care with stronger prehospital services and larger specialized emergency departments is an important aspect of this new structure. The Danish Health and Medicines Authority has also issued new guidelines for the localization of specialized treatments and departments; generally, these guidelines support centralization. The structural reform also introduced municipal cost sharing (about 20 percent of the cost of treatment) for hospital services to encourage municipalities to emphasize disease prevention and health promotion. Mandatory agreements between municipalities and regions are also intended to promote collaboration. These agreements are formalized at least once during each four-year election term for municipal and regional councils, and they must be approved by the Danish Health and Medicines Authority (Rigsrevisionen 2013).

Apart from the government, semi-independent organizations also play a governance role. The Danish Healthcare Quality Program (known by its Danish abbreviation, DDKM) consists primarily of medical professionals and works to develop extensive accreditation standards to improve quality across all healthcare sectors. The DKKM is developed, planned, and managed by the Danish Institute for Quality and Accreditation in Healthcare (known by its Danish abbreviation, IKAS), a board that comprises representatives from the Danish Health and Medicines Authority, the Danish regions, and the Ministry of Health. The International Society for Quality in Healthcare, in turn, oversees both the DDKM and the IKAS. The DDKM has now been implemented in all hospitals and is being introduced in primary care and pharmacies. It aims to include all healthcare delivery organizations, and it applies both organizational and clinical standards. The core of the program is a system of accreditation based on annual self-assessment and external evaluation (every third year) by a professional accreditation body. The self-assessment involves reporting of performance against national input, process, and outcome standards, which allows comparison over time and between organizations. The external evaluation considers the self-assessment when determining the status of providers' overall quality improvement activities and opportunities. Quality data for a number of treatment areas are captured in clinical databases and published online. The data are used for a variety of purposes, including patients' choice of hospitals and the management of hospital quality (EU 2011).

The implementation of Danish health reform is well under way, but it is progressing at a sluggish pace. Successful implementation seems to depend on the goals of the dominant political party in each region. Yet to be seen is how political and ideological tensions—such as those present in most countries—will affect the end result of the Danish health reform (Andersen and Jensen 2010).

Canada

Canada's health policy issues are different from those of Japan and Denmark. Its population is not aging as rapidly as Japan's, and, unlike Denmark, its provincial decentralization of the healthcare system has been stable since the late twentieth century. However, Canada faces problems related to paying for healthcare and an increasing public health burden from preventable diseases.

Based on OECD (2011) data, Canada spends a greater percentage of its GDP, and more per capita, on healthcare than many industrialized countries do (but less than Germany, Denmark, and the United States spend). In the twenty-first century, the country has taken steps to control healthcare spending at all levels of government. For example, the Common Drug Review process was introduced in 2003 to assess the safety, clinical effectiveness, and cost-effectiveness of new drugs presented by pharmaceutical companies and to provide recommendations regarding eligibility for public reimbursement to all participating drug plans (CADTH 2018). In this way, Canada seeks to promote the use of the most effective and least expensive pharmaceuticals.

Canada's drug plans, which are administered separately from general health services plans, attempt to use cost-sharing mechanisms to control public expenditures. For example, the province of British Columbia implemented the policy Fair PharmaCare in May 2003. It is an income-based benefits program with three main goals: (1) to keep government spending low while (2) providing access to all necessary medication (3) in a way that is equitable for people of all income levels. Analyses show that decreases in public pharmaceutical funding would work against stated policy goals and that federal money infused into the states is key to access and equity (Morgan et al. 2006).

Canada's struggle to achieve equity in medication access and affordability reflects its larger struggle with health disparities. The life expectancy at birth of an aboriginal man living on a reserve (67 years) is nine years less than that of a man in the general population (76 years); aboriginal status and socioeconomic status are the biggest contributors to health inequities in Canada, with disadvantaged populations having increased infant mortality rates, risky health behaviors (e.g., smoking), infectious disease, and chronic disease (Health Council of Canada 2011). These disparities are primarily attributable to differences in access to resources and opportunities (Farmer, Peressini, and Lawrence 2017; Frohlich, Ross, and Richmond 2006; Rocheleau et al. 2017). As with the public health agencies of other countries grappling with similar issues, research findings about Canadian health issues are slowly being translated into programs and policies designed to reduce health disparities.

According to the Canadian Institute for Health Information (CIHI 2012a), private health insurance covers about two-thirds of the 23 million people who make up the Canadian population. In 2010, it accounted for approximately 12 percent of total health spending (CIHI 2012a). Private health insurance covers services such as vision and dental care, prescription drugs, rehabilitation services, home care, and private rooms in hospitals (which are not covered by public programs). Out-of-pocket payments made by private households accounted for about 15 percent of total health expenditures in 2010 (OECD 2011). According to CIHI (2012a), the main services sought with out-of-pocket spending in 2010 were dental care (20 percent), nonhospital institutions (mainly long-term care homes) (20 percent), prescription drugs (17 percent), vision care (12 percent), and over-the-counter medications (10 percent). In 2011, approximately 85 percent of premiums for private health plans were paid through group contracts with employers, unions, or other organizations (CLHIA 2018). Supplementary private insurance to provide faster access to publicly funded physician and hospital services was not available. Providers set their own fees for services covered by private insurance, and each insurer sets its own reimbursement level (e.g., based on the lowest fee among representative providers in a particular geographic area).

In 2010, of the 69,699 total doctors in Canada, about half were family doctors and half were specialists (CIHI 2011). Primary care physicians largely act as gatekeepers for further care. Most physicians are in private practices and are remunerated on a fee-for-service basis, although an increasing number of family doctors receive alternative forms of public payment such as capitation, salary, and blended funding. For 2010–2011, fee-for-service payments made up 50 percent of payments to family physicians in Ontario, compared with 70 percent in Quebec and 86 percent in British Columbia (CIHI 2012b).

South Korea

South Korea adopted universal health insurance coverage in 1989. Since then, it has worked to improve the health system, but with minimal success. Although the country has achieved admirable gains in health outcomes (e.g., increased life expectancies), the health system is plagued with several problems, including the following:

- The healthcare benefits that citizens enjoy are still limited compared with those of other developed countries.
- The public sector has little involvement in healthcare delivery.

- Costs are rapidly rising.
- Some insurance plans are in financial distress.

These problems are caused by a diverse set of factors and will likely take significant effort over many years to resolve (Moon and Shin 2007).

From 1989 to 2000, South Koreans were covered under a multi-insurance fund that included about 370 insurers. The National Health Insurance Act, enacted in 2000, integrated these multiple insurers into a single insurer and established the Health Insurance Review and Assessment Service (HIRA) to review medical fees and assess the quality of healthcare services provided to those who are insured (HIRA 2018a, 2018b). The government instituted the National Health Insurance Corporation (NHIC) in 2000 under the Ministry of Health, Welfare, and Family Affairs (MIHWAF). South Korea is currently working to increase health insurance benefits, which is particularly difficult because of the variety of sources that fund the NHIC, including the public sector, out-of-pocket payments, private financing, and voluntary and charitable contributions (Ahn et al. 2015; Chun et al. 2009).

In South Korea, under the Medical Law, only authorized healthcare professionals—doctors, dentists, nurses, oriental medicine doctors, and midwives who are licensed by MIHWAF—can provide health services. Nurse's aides, acupuncturists, and massage therapists are considered "quasi-medical professionals." Based on OECD health data, there were 91,400 physicians, 23,114 dentists, 16,663 traditional oriental medicine doctors, 57,176 pharmacists, 8,587 midwives, and 235,687 nurses in South Korea in 2007 (Moon and Shin 2007). To address the high utilization of physician and medical technology services, South Korea piloted a diagnosis-related group financing mechanism with promising results (Moon and Shin 2007).

A major problem concerning healthcare resources in South Korea is regional disparities in medical services. Due to medical profit maximization strategies, most private medical facilities are located in urban areas, as are 92.1 percent of physicians, 90.8 percent of hospital beds, and 79.7 percent of the population (National Health Insurance Corporation 2018).

South Korea is becoming an aging society faster than any other country in the world. Along with the increase in the elderly population, there has been a rise in medical expenditures for chronic degenerative diseases, which has become a great social burden. The South Korean government is trying to reduce the financial burden, especially for younger people, with comprehensive healthcare reform. The MIHWAF is also taking various measures to care for the elderly, such as expanding healthcare facilities and introducing Long-Term Care Insurance Program (National Health Insurance Corporation 2018).

HEALTH POLICY ISSUES IN DEVELOPING COUNTRIES

The health policy issues of developing countries are, in many ways, fundamentally distinct from those of developed countries. Developing countries face a range of health problems, from communicable, highly contagious diseases to incipient, invisible problems that manifest from exposure to polluted environments. These nations must address the drivers of preventable morbidity and mortality to improve health outcomes and, relatedly, increase economic growth and development.

In this section, we discuss the policy issues shared by developing countries, including the communicable and noncommunicable diseases that cause the highest burden of disease. Because developing nations rely heavily on international governing bodies to provide assistance regarding health concerns, we also outline the types of policy actions these international agencies take to address these concerns. Finally, as with the selected developed countries, we delve into the particular problems faced by selected developing countries—China, Ukraine, Nigeria, and Colombia.

COMMON POLICY ISSUES

Distinct policy issues and risk factors related to both **communicable diseases** and **noncommunicable diseases** are common problems in developing countries. Communicable diseases include acute diarrheal disease, sexually transmitted diseases, HIV/AIDS, tuberculosis (TB), malaria and other tropical diseases, and other infectious diseases, particularly when they spread quickly and become a worldwide threat (see the Global Health Impact box titled "Pandemics: SARS, H1N1, Avian Flu, and Zika"). Noncommunicable diseases—illnesses not traditionally seen in abundance in developing nations, such as cancer, cardiovascular disease, diabetes, chronic pulmonary disease, and mental illness—are becoming increasingly

communicable diseases
Illnesses caused by organisms such as bacteria, viruses, fungi, and parasites. Communicable diseases, also called *infectious diseases*, may be transmitted by one infected person to another, from an animal to a human, or from an inanimate object to an individual, depending on the disease.

noncommunicable diseases
Noninfectious medical conditions or illnesses, typically of long duration and slow progression.

GLOBAL HEALTH IMPACT
Pandemics: SARS, H1N1, Avian Flu, and Zika

A single businessman traveling from the Guangdong province of China through Hong Kong and on to Hanoi, Vietnam, brought severe acute respiratory syndrome (SARS) to global attention. He, and the doctor who diagnosed him, died of the disease while it was spreading rapidly throughout Asia, and later to 24 other countries worldwide (*A.D.A.M. Medical Encyclopedia* 2018). The story of SARS illustrates the negative impact of globalization and migration and the ease with which a highly contagious disease can spread worldwide and cause a pandemic (Shi and Singh 2017).

Threats of widespread illness from H1N1 (swine) influenza and West Nile virus evolved in similar fashion, and avian flu is the next major infectious disease to watch, according to observers (CDC 2017b; Pompe et al. 2005). Typically, only people who had worked in close contact with infected birds are known to have been infected with avian flu. However, it is a highly deadly influenza virus, and if it were to mutate and become easily transmitted from human to human, serious consequences would follow.

GLOBAL HEALTH IMPACT

Pandemics: SARS, H1N1, Avian Flu, and Zika *(continued)*

The Zika virus is a growing public health concern. As documented by Flahault and colleagues (2016), the Zika virus is found in parts of Africa, was reported in Southeast Asia, and is rising in the Americas and Caribbean. Since it was first detected in Brazil in 2015, it has become a major public health challenge in the Americas. Although the virus can cause mild illness (characterized by conjunctivitis, fever, rash, and joint pain), many affected countries also reported neurological and autoimmune complications potentially related to the Zika virus, including more cases of Guillain-Barré syndrome and birth defects such as microcephaly. Aware of the growing body of evidence suggesting an association between infection by the Zika virus and the development of neurological disorders, including adverse pregnancy outcomes, WHO established a framework to systematically assess for a causal relationship based on three types of clinical outcomes: (1) autoimmune disorders, including Guillain-Barré syndrome; (2) acute central nervous system disorders, including myelitis; and (3) congenital anomalies, including microcephaly (Flahault et al. 2016).

In efforts to thwart pandemics, worldwide reporting and surveillance systems have been developed and are improving, but many countries lack critical laboratory infrastructure and access to vaccines and antiviral medications. Any country that has not already done so should establish emergency preparedness plans that account for social distancing, travel, health system processes, and mass vaccination procedures.

common in developing countries and come with a different set of health policy considerations (George et al. 2017; Walker et al. 2018).

A common theme among these diseases is the economic depression that accompanies the high incidence of disease and the paradoxical need for large economic inputs (capital, labor, and innovation) to prevent the transmission and onset of disease, which places low-income, developing countries at a particular disadvantage in solving these public health problems.

The way to address health policy issues in developing countries is increasingly envisioned as a stewardship of trust and legitimacy between a government and its people for improving the welfare of a population. Health policy today involves multiple actors and increasingly involved global and international agencies. Increased investment in the context of the Millennium Development Goals (a UN effort to improve health and healthcare around the world) is also placing greater attention on good national and international governance (WHO 2008). This approach has demonstrated benefits for the specific diseases being addressed, yet it threatens other programs and the capacity of local authorities to meet broad health needs. National governments in developing countries should set clear priorities on the basis of health needs and infrastructure capacity as well as on sound ethical guidance that will help achieve maximum improvement in health for minimum expenditure.

Comprehensive national health accounting is an important policy tool to track health spending from all sources. Performance assessment can support policymaking in monitoring and evaluating progress toward critical outcomes and the efficiency of the health system in a way that allows comparison over time and across systems. Particular attention is being given to financing healthcare for the more than 1.3 billion people in rural poverty and workers in the informal sector in developing countries who have no financial protection against catastrophic costs of healthcare (González-Block et al. 2009).

Success with these and other efforts will depend on solving the multiple challenges facing the health workforce. Relying on a public–private mix of services to address health infrastructure raises the question of the capacity of government to develop contracts, set prices, and monitor and supervise private providers. It is not always easy to reconcile efficiency with equity in health policy. Equity should be a primary concern for sustainable policymaking, and tools are available to measure how greatly national investments benefit the poor and needy. In many respects, health policy in developing countries is all about the encouragement of innovation and the scaling up of lifesaving technologies and systems (see the Global Health Impact box titled "Technology and Innovation"). Access to knowledge and technology has accounted for a high proportion of the decline in mortality rates. New

GLOBAL HEALTH IMPACT
Technology and Innovation

The advancement of information technology, and of clinical technology in particular, has greatly altered how healthcare is delivered. Examples of these technological innovations in healthcare include health informatics, mHealth, electronic medical records, telemedicine, and virtual physician visits. Medical innovations have also brought safer surgical and imaging procedures; genetic testing and gene therapy; and therapeutic uses for vaccines to treat diseases such as cancer and HIV/AIDS.

As with any area of technological innovation, the positive aspects of clinical technology are accompanied by a number of challenges. The development of useful medical technologies often comes at a very high cost, which may make it difficult for poorer countries to bring technological innovations to their populations. In addition, technological advances in processes can threaten the privacy of individuals and patient confidentiality because of increased access to medical records.

The US Department of Health and Human Services, in its Global Health Initiatives statements, has described the need for the government to strengthen regulatory systems and to monitor the safety of the medical products, food, and feed that enter the United States through global manufacturing and supply chains (HHS 2013). Another approach to addressing the challenges brought by technology is for the health department of a country to assess community needs and ensure that appropriate medical devices and technologies reach people in need in a cost-effective manner.

strategies for organizing health research systems can contribute to making evidence-based policy a reality in developing countries (González-Block et al. 2009).

The term *universal health coverage* is gaining popularity among countries that have not yet attained it. A majority of the world's developing countries plan to implement universal health coverage to protect vulnerable citizens who cannot afford healthcare services and thus may incur catastrophic expenses as individuals and families. If a nation can provide universal health coverage, it can bring all of its citizens under the provision of equal and high-quality care. However, implementation of universal health coverage is not an easy task. Good governance and a sustainable health financing system are fundamental to establishing universal health coverage in developing countries (Zaman and Hossain 2017).

Communicable Diseases

Acute diarrheal disease and other diseases attributable to poor water sanitation (e.g., acute respiratory disease, some tropical diseases) account for about 10 percent of the global burden of disease. Nearly 1.7 million deaths each year are attributable to acute diarrheal disease; about 95 percent of these deaths occur in children aged four or younger in developing countries (Van Minh and Hung 2011). Worldwide, at least 2 billion people lack access to a clean water supply—one of the most important preventive measures that can be taken to lower mortality rates (WHO 2018b).

The UN has recognized this type of disease as a global public health problem. In its Millennium Development Goal (MDG) 7.C, the UN stated that it aims to "halve, by 2015, the proportion of the population without sustainable access to safe drinking water and basic sanitation" toward ensuring environmental sustainability (UN 2010). Cost–benefit analyses suggest that achieving this MDG could result in a total worldwide economic benefit of $38 billion annually (Van Minh and Hung 2011). Some countries have accepted the challenge, but, as the UN has noted, "disparities in urban and rural sanitation remain daunting" (UN 2010). These challenges were illustrated by the cholera epidemic in Haiti following the devastating earthquake there in 2010, which showed that poor sanitation and resulting diseases can shut down entire industries (Haiti Libre 2010). By 2018, at least 2 billion people worldwide still were using a drinking water source contaminated with feces (WHO 2018b).

The MDG also addresses HIV/AIDS, TB (which often accompanies AIDS), malaria, and other major diseases in MDG 6 (UN 2010), as the burden of these diseases is felt more strongly in developing countries. At the same time, some global health experts argue that the attention given to HIV/AIDS prevention and treatment diverts resources from more basic public health and health system needs (Wu, Roychowdhury, and Khan 2017; Yu et al. 2008).

Noncommunicable Diseases

Much has been written about the devastating effects of communicable diseases, as well as their prevention and treatment modalities (on HIV/AIDS, see, e.g., Bongaarts and Over

2010; Potts et al. 2008; Sambo and Kirigia 2011; Stanecki et al. 2010; UN 2010; Weiss et al. 2008; and on TB and other infectious diseases, see Avert 2018b; Kirwan 2009; WHO 2018a). However, noncommunicable diseases are beginning to have an equally disruptive impact on developing countries (Islam et al. 2014; see also the Global Health Impact box titled "Noncommunicable Diseases"). In these nations, 80 percent of deaths related to noncommunicable diseases occur before the age of 60—the age at which people tend to reach their peak economic productivity, therefore reducing economic growth and progress in the country.

GLOBAL HEALTH IMPACT

Noncommunicable Diseases

The global rise in noncommunicable and chronic diseases is one of the greatest current challenges faced by all countries, whether they are developed, emerging, or developing. In September 2011, WHO Director-General Dr. Margaret Chan discussed noncommunicable disease in her address to the General Assembly (UN 2010):

> The worldwide increase of non-communicable diseases is a slow-motion disaster, as most of these diseases develop over time, but unhealthy lifestyles that feed these diseases are spreading with a stunning speed and sweep. I can understand why some developing countries are being taken by surprise by the onslaught of these diseases. Their initial burden was greatest in affluent societies.

Noncommunicable diseases were once considered to be confined to wealthy people and wealthy nations. That paradigm is shifting as the burden of noncommunicable and chronic diseases, and associated risk factors, is now being felt worldwide. A fundamental shift is also being seen in the United States and other developed countries as community wellness and preventive care are increasingly viewed as a vital part of controlling and reducing chronic disease prevalence in their populations (Bauer et al. 2014; Navarro et al. 2007). In general, noncommunicable diseases are quickly becoming the leading cause of death worldwide and have been associated with nearly 70 percent of all global mortalities (Bauer et al. 2014; Navarro et al. 2007). Although not currently the largest cause of mortality in sub-Saharan Africa, deaths from noncommunicable diseases in the region are projected to surpass deaths from maternal, perinatal, and nutrition-related diseases by 2030 (Bauer et al. 2014; Navarro et al. 2007).

The risk factors associated with many noncommunicable diseases are well documented in the scientific literature. Risky behaviors such as tobacco use, alcohol abuse, unhealthy diet habits, and physical inactivity have been linked to cancers, cardiovascular diseases, chronic respiratory diseases, and diabetes. Lifestyles in developing nations are changing to include these behaviors, sometimes as a consequence of development, such as the emergence in low- and middle-income countries of supermarkets—the largest providers of processed foods

GLOBAL HEALTH IMPACT
Noncommunicable Diseases *(continued)*

that are high in fat, sugar, and sodium and low in nutritional value (Vancampfort, Stubbs, and Koyanagi 2017; Wagner and Brath 2012). The health-related costs of development are stunning: In 2005, the estimated national economic losses from heart disease, stroke, and diabetes were (in US dollars) $18 billion in China, $11 billion in the Russian Federation, $9 billion in India, and $3 billion in Brazil (WHO 2006).

Researchers working in developing countries have produced a robust literature on the epidemiology of noncommunicable diseases in most regions of the world (except for sub-Saharan Africa, but see Dalal et al. [2011]). Evidence suggests that public health policymakers have several policy tools by which to address noncommunicable diseases and their risk factors. Yet such policies are not well defined at the national or global levels, even though science and medicine have enhanced our understanding of the determinants of chronic disease. Observers note that the most effective policies are long-term, collaborative approaches that engage both the public and private sectors. For example, WHO has deemed "best buy" interventions to be cost-effective in reducing disability-adjusted life years associated with noncommunicable diseases. Examples of such interventions include raising tobacco taxes, restricting access to alcohol, providing primary care diet counseling, promoting healthy living and physical activity in mass media, and offering vaccination programs (Dalal et al. 2011).

The consequences of failing to stem noncommunicable diseases are enormous. In developed countries, where clinical chronic care is currently available, the increasing burden of disease will place increasingly greater strains on the health financing system. In developing countries, where clinical chronic care is less available and more people go undiagnosed, primary prevention is essential to saving lives and improving life expectancies (Alaofè et al. 2017). Policymakers at all levels, as well as other stakeholders, have the power to reshape this intensifying public health issue.

Mental illnesses are a group of noncommunicable diseases responsible for about 13 percent of the global burden of disease. Mental illnesses in particular do not generally attract international health policy attention. Neuropsychiatric disorders that affect people in developing countries include unipolar depressive disorder, bipolar disorder, schizophrenia, epilepsy, substance abuse disorders, dementia, anxiety disorders, mental retardation, and some neurological disorders (Patel 2007). Those who experience mental illness often endure many years of living with a disability. In addition, the societal costs of mental disorders, such as the impact on families, social services, and the criminal justice system, are significant and essentially immeasurable.

Globally, most people in need of mental health care lack access to high-quality mental health services. Stigma, insufficient human resources, fragmented service delivery models, and lack of research capacity for implementation and policy change contribute to the mental health treatment gap. The global mental health landscape has transformed since 1990 with the raised visibility of the disease burden of mental health and substance-use disorders. Mental health disorders comprise 7.4 percent of disability-adjusted life years and 22.7 percent of years lived with disability worldwide (Baingana et al. 2015). The main contributors are depression and dysthymia, which account for 9.6 percent of all mental health disorders; anxiety, which accounts for 3.5 percent; and schizophrenia, substance-use disorders, and bipolar disorder, which together account for about 2.0 percent (Baingana et al. 2015). According to Baingana and colleagues (2015), alcohol and substance-use disorders are the second-leading cause of mental health disorders in most of the developing world, especially for southern Africa (drug use) and Eastern Europe (alcohol). The global prevalence of mental health and substance-use disorders is predicted to rise in coming years, with the most dramatic increase expected in low- and middle-income countries as a result of longer life expectancy, population growth, and underresourced healthcare. For example, the associated health burden of alcohol and substance misuse is predicted to increase by 130 percent in sub-Saharan Africa by 2050 as a result of population growth and aging (Baingana et al. 2015). Untreated mental health disorders are associated with a high burden on the economy. Yet commonly used health metrics do not reflect the additional social burdens of living with mental illness. Pervasive stigma and human rights violations increase the suffering associated with these disorders and exacerbate the social vulnerabilities of people with mental illnesses (Baingana et al. 2015).

People who are poor, less educated, or experiencing acute financial strain are at a greater risk for mental illness than are those who are financially secure and educated. In turn, those who suffer from mental illness are likely to remain impoverished due to lost wages or the cost of medical care. Mental health disorders can be effectively treated, but policymakers in developing nations face enormous challenges in legislating and financing effective interventions; the average government mental health spending (in US currency) in 2016 was a mere two cents per person per year in low-income countries and $1.05 per person per year in lower-middle-income countries, as compared with $2.62 per person per year in upper-middle-income countries and a whopping $80.24 per person per year in high-income countries (WHO 2018c). People in developing countries experience similarly huge disparities in their access to mental health professionals (including psychiatrists, other medical doctors, psychologists, social workers, nurses, and other paid workers working in mental health). In 2016, low-income countries had an average workforce of 1.6 mental health professionals for every 100,000 people, and lower-middle-income countries had an average workforce of 6.2, as compared with 20.6 in upper-middle-income countries and 71.7 in high-income countries (WHO 2018c).

To help countries identify gaps in their existing mental health system and address any deficiencies with system-level policy changes, WHO developed the WHO Assessment Instrument for Mental Health Systems (WHO-AIMS), which evaluates countries across several domains (e.g., policy/legislative framework, existing mental health services) to present a broad picture of their mental health provision capabilities (WHO 2009). Nearly 40 low-income and lower-middle-income countries have used WHO-AIMS, and the resulting data reports are available through WHO (2009, 2018g). As additional countries implement WHO-AIMS, policymakers can comprehend the state of their country's mental health services and policy as a whole, which will enable them to make better policy decisions that can lead to improvement.

Weak Health Infrastructure

The lack of a sound health system infrastructure affects care for all diseases and impedes access to essential health services. At the beginning of the twenty-first century, governments in developing countries generally spent about 5 percent of their total budget on health (Nambiar et al. 2007); in contrast, the average developed country spent more than 10 percent of its GDP on health, according to OECD data. Low government spending leads to extremely low quality of care and creates long waiting times, constant shortages of essential drugs and supplies, and inadequacy of staff training. In addition, out-of-pocket expenses can prohibit residents of developing countries from seeking care.

Modern Environmental Hazards

In the developing world, substances such as mercury, lead, pesticides, asbestos, air toxins, and hazardous waste are commonly released into the environment by unregulated mining operations (e.g., mining for gold ore), soap product and paint manufacturers, gasoline producers, agricultural operations, emissions from automobiles, and industrial waste disposal. Such toxins are associated with a host of complicated health problems, including nerve or nerve tissue damage, birth defects, and hormone dysfunction—problems that the health systems of many developing countries are ill equipped to handle.

These and other modern environmental health hazards are emerging in a health environment that is already overwhelmed by poverty, malnutrition, and communicable and chronic diseases. With the understanding that governments in developing nations must take swift preventive measures, the United Nations Environment Program has made headway with its Partnership for Clean Fuels and Vehicles initiative for removing lead from gasoline and sulfur from diesel fuel. Other initiatives aim to reduce or control stockpiles of harmful pesticides, introduce cleaner methods of gold mining (which is strongly associated with mercury poisoning), and initiate substance monitoring programs for manufacturing and other operations.

Most of this work has been performed by nongovernmental organizations, with less substantive action taken by national governments. Going forward, policymakers must take a population-level approach toward addressing modern environmental health hazards to reduce the burden of preventable ill health and premature mortalities (Nweke and Sanders 2009).

UNDERLYING FACTORS

These health-related challenges raise the question of how to use health policy to strengthen health systems and public health infrastructure in developing countries. Industrialized countries are seeking ways to provide aid to developing nations that will help their overwhelmed ministries of health. The *sectorwide approach*, which focuses on centralizing public health leadership, improving health sector management, and increasing coordination, is one such method that has had some success.

In recognition of the fact that good governance is essential for an effective health system and overall development, WHO devised a method for assessing health system governance. This framework allows researchers to assess public health problems with health system leadership and governance at the policy and operational levels and to suggest improvements. Using the WHO method allows motivated governments to effectively promote and protect population health (Siddiqi et al. 2009).

Addressing noncommunicable diseases requires that health policies be designed to work together at various levels of government. For example, one policy might impose taxes to deter people from smoking cigarettes, and other policies might ensure that people who need it can access care for chronic obstructive pulmonary disease.

UNIQUE POLICY ISSUES IN SELECTED COUNTRIES

Many blanket statements have been made about health issues in developing countries, but it is essential to recognize the great diversity between and within countries when considering health issues and health policies. China, for example, has a huge land mass and a diverse population of urban and rural dwellers. This situation poses health policy challenges that are unique to that country. Each country is dealing with a particular set of factors that largely determine what health issues are pertinent and what policy solutions are feasible in that particular country. In the following sections, we examine the unique situations of four developing countries: China, Ukraine, Nigeria, and Colombia. The small nation of Singapore is also highlighted; see the For Your Consideration box titled "Singapore's Healthcare Delivery."

China

With more than 1.4 billion people, China has one of the largest populations in the world (Worldometers 2018). The country has experienced overwhelming transformations since the late twentieth century, which have dramatically affected population health.

Prior to 1978, the Chinese government headed up extensive public health improvements, leading to lower infant and maternal mortality rates, greater life expectancies, and improved quality of water and sanitation. The associated policy decisions emphasized disease prevention and community involvement, reflecting an approach to health rooted in basic public health principles (Gong, Walker, and Shi 2007).

FOR YOUR CONSIDERATION

Singapore's Healthcare Delivery

Singapore has one of the most successful healthcare systems in the world, based on its efficiency in financing and the positive results it has achieved in community health outcomes. The Singaporean government combines the ideas of individual responsibility and government control in a financing system of federal subsidies for primary care, hospital services, pharmaceuticals, and individual savings accounts (Bai et al. 2018; Brookings Institution 2018). In 1983, the government established a National Health Plan, which detailed plans for the infrastructure for the next 20 years, together with the idea of individual savings accounts, called Medisave. The restructuring of public-sector hospitals in 1985 started merging the business and financial sectors into healthcare services to provide higher-quality services and more efficient financing. In 2002, the government promulgated the ElderShield plan to help the elderly and people with severe disabilities in particular.

Singapore provides all citizens with universal healthcare coverage, funded by a combination of federal subsidies, financing schemes, and individual savings, all administered nationally. Capital expenditures for healthcare are calculated at the national level in the federal budget. In the first tier of financial protection, the government subsidizes up to 80 percent of the total bill in public hospitals and primary care polyclinics. Subsidies of up to 80 percent are also provided for bills in government-funded intermediate and long-term care institutions. This coverage is funded by a network of savings and insurance programs known as the "3Ms" (Medisave, MediShield, and Medifund) to help individuals and families pay for their care. Together, these programs play a critical role in maintaining the health and welfare of all Singaporeans.

A major change in China occurred in 1978, when it moved from a communism-based to a capitalism-based market economy. This shift brought many positive developments as well as a number of challenges to China's health system:

- Overall spending on healthcare has rapidly increased, while government funding for public health institutions has steadily fallen (Gong, Walker, and Shi 2007; Nofri 2015).
- Rates of noncommunicable diseases and health disparities are on the rise (Hu, Liu, and Willett 2011; Zhu et al. 2017).
- The cost of healthcare has become prohibitively expensive for many people, particularly those living in rural areas (Hu, Liu, and Willett 2011).

In response to these emerging issues and to create a solid health policy framework for the coming years, in 2008 the Chinese government passed the Healthy China 2020 act to address healthcare equity and accessibility through five mandates that correspond to major health problems identified by the Chinese Ministry of Health (Chen 2009; Hu et al. 2011; Ling et al. 2011):

1. Health insurance must be expanded to cover 90 percent of the population.
2. A national drug system must be established to meet basic pharmaceutical needs.
3. Grassroots-level improvement of medical care and public health must occur.
4. Basic public health services, including preventive health, must expand.
5. Hospital reform must be instituted to abate the health system's increasing tendency to commercialize.

The development of a "Healthy China" is central to the Chinese government's agenda for health and development. President Xi Jinping has placed health at the center of the country's entire policymaking operations, and China's leaders have made health a national political priority with the approval of the Healthy China 2030 Planning Outline by the Central Party Committee and the State Council (Tan, Zhang, and Shao 2018).

Through advanced technologies and an improved health insurance system, China hopes to achieve health equity for its people by 2030. Significant steps have already been taken toward that end. In 2009, China embarked on a major national health system reform (Nofri 2015), aiming to extend care to those residing beyond its prosperous urban centers. At the beginning of the twenty-first century, less than one-third of the population had access to health insurance. Now nearly 100 percent do (Tan, Zhang, and Shao 2018). China has provided its huge population a healthcare safety net that protects its people from becoming impoverished by the costs of healthcare (Tan, Zhang, and Shao 2018).

Still, China faces many health challenges. They include increasing rates of cancer; higher incidence of cardiovascular disease linked to such lifestyle factors as smoking; and demographic trends such as an aging population (Nofri 2015; Tan, Zhang, and Shao 2018). These challenges cannot be met sustainably in a health system that relies solely on hospitals. Therefore, a key component of Healthy China is the promotion of healthy lifestyle behaviors and physical fitness, including through the development of the Healthy Cities program, to emphasize prevention over treatment. One of the most important steps toward a Healthy China is a national smoke-free law, which would have a significant impact on the prevention of many associated noncommunicable diseases.

According to Tan, Zhang, and Shao (2018), to better protect people's basic right to health, a series of plans have been implemented, including the Healthy China 2030 Planning Outline, the National Fitness Program (2016–2020), the Thirteenth Five-Year Plan for Medical and Health Service Development, and the Plan for Deepening Reform of the Medical and Healthcare System During the Thirteenth Five-Year Plan Period (2016–2020).

The Chinese government has set a "three-step" goal: (1) establishment of a sound basic medical and healthcare system with distinctly Chinese characteristics covering both urban and rural residents, such that its main health indicators would place China in the forefront of the rankings of high- and middle-income countries by 2020; (2) improvement of the health-promotion system such that its main health indicators would be in the ranks of those of high-income countries by 2030; and (3) existence of a healthy China that conforms to the requirements of a modern socialist country by 2050 (Tan, Zhang, and Shao 2018).

Ukraine

Over the five years following the fall of the former Soviet Union in 1991, Ukraine faced—and continues to battle—several debilitating public health issues. The population is plagued by epidemics of HIV and TB, which are interrelated: In 2015, 22 percent of tested TB patients were HIV-positive (CDC 2017a). In addition, cardiovascular disease, the leading cause of mortality in the country, is highly prevalent among the population, partly because of high rates of smoking and alcohol consumption.

Inconsistencies in public health legislation and implementation, resulting from an unstable parliament, create a difficult political environment in which to address these challenges and improve health (Lekhan, Rudiy, and Shevchenko 2015). For example, the Global Fund for AIDS, Tuberculosis, and Malaria initially granted $98 million to the Ukrainian government to respond to the combined AIDS/TB epidemic; however, the Global Fund switched its grantee to community organizations instead because the government was not transparent with the use of funds (Hurley 2010). As a result, local community organizations now provide most HIV/AIDS prevention and treatment services in Ukraine, with funding from the Global Fund (Hurley 2010).

Poor development and implementation of policies distinguish Ukraine's TB control from that of the rest of Europe. For example, TB infections are often transmitted through the prison system, but postincarceration treatment plans are not coordinated before prisoners' release. Furthermore, many ex-prisoners do not adhere to medication plans and transmit the disease to the public, as evidenced by higher-than-average TB infection rates in areas surrounding prisons. In addition, Ukraine lacks a centralized TB monitoring system, and most regional TB recording and reporting systems do not meet WHO recommended standards (Atun and Olynik 2008).

Policies aimed at reducing the burden of noncommunicable disease in Ukraine have been more successful—the tobacco excise tax is one example. Estimates from 2005 suggest that 66 percent of men and 20 percent of women smoked cigarettes (Ross, Stoklosa, and Krasovsky 2011). Following the lead of other countries that adopted tax policy reform in response to high rates of disease, premature death, and lost productivity, Ukraine implemented excise taxes on tobacco in 2009 and 2010. These taxes significantly reduced tobacco consumption, illustrating that tobacco use is price sensitive (Ross, Stoklosa, and Krasovsky

2011). By 2015, cigarette smoking rates had fallen to about 49 percent among men and 14 percent for women (Tobacco Atlas 2018).

From 2006 to 2012, the average life expectancy in Ukraine increased, even with little progress in policy implementation. During the 2010s, armed conflict created a new, large-scale humanitarian crisis in Ukraine, and the health system proved ill equipped to cope with it. Even before the turmoil that led to this crisis, the Ukrainian health system was weak and far from equitable. Pilot reforms initiated in 2010, which aimed to reorient the system toward a primary care focus, were still in early stages, and scale-up was delayed indefinitely (Lekhan, Rudiy, and Shevchenko 2015). In many respects, as Lekhan, Rudiy, and Shevchenko (2015) observed, the pilot reforms showed that change is possible in the system, although a lack of meaningful reform since independence from the Soviet Union meant that many inefficiencies were deeply entrenched. In October 2017, the Ukrainian Parliament approved a bill that made major changes to the country's healthcare system effective January 1, 2018, including the establishment of a National Health Care Agency and a financing model similar to that of the United Kingdom (Raczkiewycz 2017). However, the country's political instability made successful implementation of the approved changes uncertain.

As Lekhan, Rudiy, and Shevchenko (2015) contend, successful implementation of the health system reforms requires both political will and popular consensus, including community and health worker engagement in the reform and belief in its benefits. Perhaps most important, changes to a health system need policy windows. For example, although economic crises can spur focused efforts to make health systems more efficient, a policy environment of political, social, and economic turmoil can push health systems concerns far down the policy agenda. The successful implementation of health systems reform requires a certain degree of stability, but stabilizing such conditions is beyond the control of the health sector.

Nigeria

Nigeria's health issues are all-encompassing, ranging from communicable diseases, such as HIV/AIDS, TB, rare tropical diseases, and even poliomyelitis (polio), to noncommunicable diseases, such as cardiovascular disease and the effects of modern environmental health hazards. Each of these health problems has been inefficiently managed by the Nigerian government and exacerbated by a weak health system, little health financing, and loss of health professionals through emigration (FMTalk360 2016; GPEI 2018).

Two key health issues set Nigeria apart from other sub-Saharan nations with otherwise similar health problems. First, Nigeria is the only African country (and one of only three countries in the world, the other two being Afghanistan and Pakistan) to have failed to ever eliminate polio (GPEI 2018). Efforts implemented by the Global Polio Eradication Initiative (GPEI) beginning in 2009 greatly reduced the total number of cases, to the point that the country went for two years with no new cases of polio detected. However, in July 2016, one type of wild poliomyelitis reemerged, triggering a GPEI response in which nearly 58 million children were vaccinated to help prevent further outbreaks (GPEI 2018; WHO 2016).

Second, Nigeria has encountered particular difficulty implementing key components of standard disease control protocol in combating HIV/AIDS. In 2016, only about 30 percent of the 3.2 million people living with HIV in Nigeria were receiving antiretroviral therapy, and the death rate from AIDS was about 148,000 people per year (Avert 2018a). The rate of mother-to-child transmission remains high—at 22 percent in 2016—and Nigeria accounts for nearly 27 percent of all the mother-to-child transmission cases in the world (Avert 2018a).

Several types of barriers impede Nigeria's ability to effectively address the HIV/AIDS epidemic, including the following (Avert 2018a):

- Cultural practices that increase HIV vulnerability among the general population (e.g., female genital mutilation, marriage of young girls to much older men, encouragement of men to have multiple female sexual partners, low levels of condom use) as well as the social stigma of being known as HIV-positive, which inhibits testing
- Strict laws against homosexuality (punishable by up to 14 years in prison) that discourage men who have sex with men from seeking treatment; laws against sex work (punishable by two years in prison) that make sex workers reluctant to disclose their occupation to healthcare workers during provision of healthcare services
- Lack of sites for HIV testing and treatment for those willing to seek it
- Low levels of funding by the Nigerian government to address the epidemic, exacerbated by gender inequality, with less than 1 percent of government spending on HIV allocated for women despite the fact that 58 percent of the people living with HIV are women

Closely related to the challenges in addressing the HIV/AIDS epidemic is the dramatic rise in Nigeria of TB, which is a common coinfection that can develop in people living with HIV and has likewise reached an epidemic level (Avert 2018a, 2018b). Multidrug-resistant strains of TB in Nigeria increased by 30 percent between 2015 and 2016, making the disease even harder to treat effectively (Avert 2018a).

Unavailability of modern equipment and obsoleteness of existing equipment is a major issue with the Nigerian healthcare system. Lack of proper or properly functioning equipment has been identified as a root cause of incorrect diagnoses and is reportedly a key reason foreign medical trips remain the only option for affluent Nigerians or patients in dire need of a correct diagnosis (see the Global Health Impact box titled "Medical Tourism"). Stories of medical errors and how they have accounted for avoidable deaths in some Nigerian medical facilities have also been reported, further contributing to Nigerians' discomfort with seeking medical care in their own country (FMTalk360 2016).

GLOBAL HEALTH IMPACT

Medical Tourism

Medical tourism is an international phenomenon by which people travel to another country for medical services. Travel often occurs on a regional level, and most procedures are elective (e.g., weight loss surgery, cosmetic surgery, dental care, fertility treatment). For example, Americans travel to Mexican border towns for dental procedures that are very expensive in the United States (*IMTJ* 2012) and seek affordable healthcare procedures, such as knee and hip replacements and cardiac surgery, outside of the country. Some countries are known to specialize in the provision of medical tourism procedures, including gender reassignment surgery in Thailand and cell transplants in China (Aizura 2010; Alleman et al. 2011; Song 2010).

Major US medical schools have partnered with other countries to set up tertiary and referral hospitals that provide higher-level care and procedures. These ventures can control costs for private insurers and improve the standards of care for those seeking care abroad. Joint Commission International has accredited more than 600 hospitals and certified hundreds of other specialty facilities and programs worldwide (JCI 2018). People also travel to the United States to receive healthcare at leading institutions, such as the University of Texas MD Andersen Cancer Center in Houston; Mayo Clinic in Rochester, Minnesota; and Jackson Memorial Hospital in Miami.

Since 2003, the government of Thailand has attempted to make its country a global center for medical tourism through the Center of Excellent Health Care of Asia initiative. It has held international road shows and allowed tax exemptions for investment in new health facilities to target medical tourists and recruit patients. In 2011, revenues from medical tourists generated the equivalent of an estimated 0.4 percent of Thailand's GDP (Noree, Hanefeld, and Smith 2016). Despite such financial benefits, there is concern about the impact of medical tourism on equity in care, especially in areas with weak health systems and limited resources that may be diverted toward caring for patients from abroad (Noree, Hanefeld, and Smith 2016).

Facilitators of medical tourism have established an industry focused on connecting people with medical services abroad. However, several challenges have arisen with this emerging field. Reports have surfaced of complications after surgeries that could have been avoided if proper quality standards had been followed, underscoring the need for uniform standards of care across various settings, such as those used by Joint Commission International. Public health concerns also can be an issue for medical tourists, as they may become *vectors* (able to spread infectious agents) or victims of multidrug-resistant bacteria—a threat whenever physicians are unprincipled in their use of antimicrobial medications (Cusumano et al. 2017; Rogers, Aminzadeh, and Paterson 2011). Critics cite ethical issues regarding the use of the healthcare workforce and resources for medical tourism that takes away resources from the basic local medical needs of the country's citizens. Another concern is the current lack of regulation and oversight of the providers of medical tourism; ethical issues have been raised concerning patients traveling after being given very limited information and foreign patients purchasing organs or surrogacy services from local populations in low- and middle-income countries (Noree, Hanefeld, and Smith 2016). As the medical tourism market continues to develop and become established, these and numerous other issues will need to be addressed.

Despite these difficulties, the prospects for improving global health policies are promising. The 2011 presidential election in Nigeria was deemed by some experts as the most legitimate and transparent election the country ever held. The National Assembly passed the National Health Bill in May 2011, placing health at the top of the national agenda with an emphasis on ensuring basic access to health services for all citizens, retaining trained health professionals, and holding the government accountable for complete implementation of the bill's mandates (*Lancet* 2011). With widespread support from health professionals and the general public as well as a demonstrated commitment to health by the Nigerian president, the bill was signed into law on October 31, 2014, and became known as the National Health Act (Enabulele and Enabulele 2016). A study in December 2015, however, found that although most health professionals were aware of the National Health Act and viewed it favorably, nearly 74 percent of them showed poor knowledge of it (Enabulele and Enabulele 2016), signaling a need for further education on the provisions of the act.

In 2016, the Nigerian Sovereign Investment Authority (NSIA), along with the country's Ministry of Health, agreed to modernize and expand healthcare services with the involvement of the private sector. They aimed to build the capacity of specialist hospitals and diagnostic centers to ensure that they can provide advanced medical care. Ten memorandums of cooperation had already been signed between the NSIA, Ministry of Health, and various healthcare facilities in the country's six geopolitical zones, with six of them in advanced stages. Although Nigeria's National Health Insurance Scheme (NHIS), introduced in 1999, aims for universal coverage, penetration remains low. In 2016, less than 5 percent of the population was enrolled in the NHIS, and an estimated 120 million people lacked health insurance (Oxford Business Group 2018). Stakeholders in the insurance sector—such as the NHIS and health maintenance organizations—also called for legislators to make it mandatory for employers with more than ten employees to provide them with health insurance (Oxford Business Group 2018).

Colombia

Colombia faces challenging public health issues that are deeply rooted in an ongoing conflict and urban–rural disparities.

Insurance Scheme

Colombia's health disparities are evident in examinations of its universal health insurance system. Law 100 was approved in 1993, granting all citizens the right to health insurance with an essential benefits package, regardless of ability to pay. By 2009, about 80 percent of Colombians were covered under one of two health insurance schemes—the Contributory Regime (CR) or the Subsidized Regime (SR). The CR covers those who work and earn more than a set minimum level of pay, and the SR covers those who are considered poor, as determined by a means test. The SR offers a meager benefits package compared with that for the CR; for example, the SR offers only basic primary care services and coverage for catastrophic costs, whereas the CR offers comprehensive coverage. Critics say that the managed care model used by insurers covering both CR and SR limits access to care, restricts utilization, and has changed public providers' behaviors to suit a competitive market scheme—all resulting in increased health disparities (Vargas et al. 2010). Meanwhile, proponents argue that this universal health insurance approach improved on the previous model covering SR subscribers by increasing access and reducing catastrophic health spending (Giedion and Uribe 2009). Although the government plans to implement policies to reach 100 percent insurance coverage of the population, no concurrent strategy is in place to address the great disparities inherent in this insurance scheme.

Vector-Borne Diseases

Colombia is also working to prevent and treat **vector-borne communicable diseases**, which are still prevalent and dangerous across about 20 percent of the country's land area (Castillo-Riquelme et al. 2008). Vector-borne diseases include malaria, Chagas disease, and dengue fever, which are preventable with the proper insecticide treatment measures. However, prevention measures are not executed in a systematic, efficient way in Colombia (Castillo-Riquelme et al. 2008), and the bulk of the money allocated to vector-borne diseases is spent on treatment several years after contraction.

vector-borne communicable diseases Diseases spread to humans by another species, often an arthropod (e.g., insect).

For example, sufferers of Chagas disease, which is typically transmitted by an insect, usually do not present with symptoms for at least a decade after exposure, and when symptoms do manifest, they often resemble other general cardiac illnesses (Cucunubá et al. 2017). Significant amounts of money, at levels that far surpass prevention efforts, are needlessly spent on diagnostic testing for and treatment of cardiomyopathy (deterioration of the heart muscle) and congestive heart failure (Castillo-Riquelme et al. 2008; Cucunubá et al. 2017). The government pays the majority of costs under Law 100, which grants universal health insurance coverage, but those with Chagas do not experience a positive health outcome (Castillo-Riquelme et al. 2008; Cucunubá et al. 2017). A comprehensive study by Cucunubá and colleagues (2017) concluded that a "a firm commitment from all levels of government and a coordinated, collaborative global response from international organizations and other stakeholders" are needed to successfully address the issues associated with Chagas disease in Colombia.

Colombia has had some success in its efforts to prevent vector-borne diseases, however. In 2013, it became the first country in the world to eliminate onchocirciassis (river blindness), an infection caused by a parasite, as verified by WHO (Cucunubá et al. 2017; Nicholls et al. 2018).

Violence

Colombia is among the leading Latin American countries in homicides, fueled by gang activity, civil strife, and general civil disobedience exacerbated by alcohol consumption. The murder rate in 2012 was 30.8 homicides per 100,000 people, compared with the US rate of 4.7 per 100,000 (UNODC 2013).

Law enforcement policies are in place to tackle gangs and paramilitary forces, and municipalities address the "culture of violence" through social outreach and restrictive policies that mitigate the effects of alcohol use (Ceaser 2007). For example, between 2004 and 2008, the government of Cali enacted three policies dictating the availability of alcohol. Studies showed that when alcohol sales were stopped earlier in the night, homicide rates dropped significantly (Sánchez et al. 2011). To further reduce the homicide rate, Colombia must address underlying social factors leading to multiple types of violence.

Overall, Colombia's health policy issues reflect larger societal problems. Tropical diseases, health inequities, and violence must be curbed in conjunction with broader social and economic policies. The Colombian government under Alvaro Uribe, president from 2002 to 2010, began to address these issues (especially those related to violence), and his successor, Juan Manuel Santos, has followed suit.

Healthcare Reform

In 2015, Colombia underwent an economic recovery and transitioned toward an improved healthcare system, enacting important health-sector legislation, such as the Statutory Health Act (Act 1751) in basic welfare law and the National Development Plan (Act 1753), which builds on the General System of Social Security in Health and emphasizes key healthcare topics such as health system equity, access, quality, timeliness, trust, legitimacy, and sustainability. The revised health system includes features such as an integrated healthcare policy; an integrated healthcare model that comprises primary healthcare, a family and community healthcare focus, risk management, and a differential approach; further development of the Ten-Year Public Health Plan (2012–2021) in the country's regions; creation of a unit to administer system resources; and strengthening of the pharmaceutical policy that was implemented in 2012. The Colombian government made peace with the armed rebel group Revolutionary Armed Forces of Colombia (known by its Spanish initials, FARC) in 2017 and in early 2018 was pursuing talks with another rebel group, the National Liberation Army (known by its Spanish initials, ELN), in a continuing effort to bring an end to Colombia's ongoing civil strife (Charles 2018). As a result of the FARC talks, Colombia established a public health and postconflict policy jointly coordinated by the Ministry of Health and the Ministry for Post-Conflict. It also created a program for psychosocial and integrated care for victims of armed conflict, which guarantees the right to health and restoration of physical, mental, and psychosocial conditions according to relief and rehabilitation measures in the Victims Act (Charles 2018).

All Colombians have access to the same services as well as financial protection from excessive healthcare spending. Patient out-of-pocket expenses make up 14 percent of all health spending—one of the lowest proportions in Latin America and lower than the OECD average of 19 percent (OECD 2011).

In Colombia, the informality of the labor market presents a significant challenge to raising health system revenues. About half of the total health system funding comes from *contributory sources* (employer and employee payroll contributions). It has proven difficult to substantially increase this component of funding due to the size of the **informal labor market**: about 60 percent of the workforce. Informality narrows the contributory and tax bases and creates financial hurdles in all public sectors. These financial issues are exacerbated in the health sector, however, because of the Constitutional Court's requirement to expand the range of services in the SR and make them equal to the CR.

informal labor market
A workforce made up of people who engage in productive activities that are not taxed or registered by the government.

Healthcare providers in Colombia tend to be largely concentrated in densely populated areas, with a notable increase in the number of private providers in those areas since the beginning of the twenty-first century. In contrast, people living in remote and rural provinces have very little choice of provider, even for simple outpatient care. Providers in these areas tend to be public providers and often struggle with issues such as high operational costs and difficulties in attracting and maintaining an adequate number of health professionals, which is likely to affect the quality of care provided.

Although unmet healthcare needs and visit waiting times have been significantly reduced, health insurers in Colombia have not yet transformed into effective, efficient purchasers of healthcare services. Payments to providers should reward quality of care and good health outcomes, rather than volume of services provided (Charles 2018).

KEY POINTS

- Although most developed nations have controlled the spread of communicable diseases, their health systems are strained by an aging population and widespread chronic disease. They must maintain an adequate, well-trained workforce of health professionals and integrate innovative technologies while keeping healthcare costs at a manageable level.
- Several factors affect rising healthcare costs in developed countries, including aging populations, rapid technological progress, the participation of women in the labor force, and public funding for healthcare.
- Developing countries experience a range of public health problems, from communicable, contagious diseases to incipient, invisible health effects from exposure to pollution. These nations must address the drivers of preventable morbidity and mortality if they are to increase economic growth.
- The lack of a sound health system infrastructure in most developing countries affects the spread of all diseases and impedes access to essential health services. Further, low government spending leads to low quality of care and creates long waiting times, constant shortages of essential drugs and supplies, and lack of trained staff.

CASE STUDY QUESTIONS

CASE STUDY 1

Based on your own research on climate change and its impact on public health, answer the following questions:

1. Why is addressing climate change important for public health?
2. What health policies and public health strategies could mitigate the effects of climate change?

CASE STUDY 2

Based on your own research of the global primary care workforce, answer the following questions:

1. Why is there a shortage of primary care providers worldwide?
2. What strategies might nation states adopt to expand their countries' primary care workforce?

FOR DISCUSSION

1. What are the primary health policy issues in developed countries? In developing countries?
2. What are the specific health challenges in Japan?
3. What has Denmark's health reform accomplished?
4. What is Canada's health policy agenda?
5. What are the public health challenges facing South Korea?
6. What goals is China's Healthy China 2020 attempting to accomplish?
7. What are the public health challenges faced by Ukraine?
8. What are the public health issues of Nigeria?
9. What factors do Colombia's health policies target?

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PART IV

HEALTH POLICY RESEARCH

Part IV of this book consists of three chapters that describe how policy issues can be studied and analyzed. Chapter 8, "Overview of Health Policy Research," provides an introduction to the field of health policy research, including definitions and general characteristics. Chapter 9, "Health Policy Research Methods," illustrates some commonly used methods—both quantitative and qualitative—for conducting health policy research. Chapter 10, "An Example of Health Policy Research," concludes the book with an example of an application of health policy research. The introductory and illustrative materials presented in this part may stimulate students to delve further into health policy research at an advanced level. We include health policy research in an introductory health policy book because, ultimately, solid health policy hinges on solid evidence, and well-conducted research is a means to sort out the relevant evidence.

CHAPTER 8

OVERVIEW OF HEALTH POLICY RESEARCH

Honesty is the best policy.

—Benjamin Franklin

The advancement and diffusion of knowledge is the only guardian of true liberty.

—James Madison

LEARNING OBJECTIVES

After completing this chapter, you should be able to

- define and understand the characteristics of health policy research,
- describe the process as applied to health policy research,
- discuss how to communicate findings from health policy research, and
- appreciate the challenges in implementing findings from research to health policy application.

CASE STUDY 1

THE RAND HEALTH INSURANCE EXPERIMENT

The RAND Health Insurance Experiment was one of the largest and most comprehensive health policy studies carried out in the United States. The Health Insurance Experiment was a randomized experiment conducted between 1971 and 1986; a total of 2,750 families, including more than 7,700 individuals aged 64 or younger, were chosen from six sites across the country to participate (RAND Health 2018). The study answered two questions regarding the financing of healthcare:

1. If medical care were free, how much more would patients use?
2. Are patient health outcomes affected by the cost of medical care?

The study subjects were randomly assigned to one of five types of health insurance plans:

- Free care
- 25 percent coinsurance
- 50 percent coinsurance
- 95 percent coinsurance
- A health maintenance organization (HMO) that provided care free of charge

The key findings of the study, as noted by Brook and colleagues (2006), were the following:

- Patients who had to contribute toward the cost of medical care used fewer services than did those who received services free of charge.
- Coinsurance equally reduced patient utilization of highly effective and less effective medical care.
- The quality of medical care was not significantly affected by coinsurance.
- Overall, coinsurance was not shown to negatively affect patients' health; however, medical care provided free of charge brought about improvements in hypertension, dental and vision health, and other serious conditions. This difference was found to be the greatest among patients with poor health and low income.

The study's findings provided input for policymaking related to restructuring private insurance and strengthening managed care.

CASE STUDY 2

IDAHO'S PREVENTIVE HEALTH ASSISTANCE PROGRAM

Providing incentives for positive health behaviors is one approach that can lead patients to use preventive services, including vaccinations, screening, and other single-visit health outcomes (Kane, Johnson, and Town 2004; Sutherland and Christianson 2008). Idaho was one of the first states to implement changes to its Medicaid program under the 2005 Deficit Reduction Act (PL 109-171) in 2006 (Kenney and Pelletier 2010). Through its Children's Health Insurance Plan (CHIP), or the Idaho Health Plan for Children, the state added a preventive health benefit in 2007. The Preventive Health Assistance (PHA) program offers incentives to encourage wellness activities (such as use of preventive children's care) and healthy behaviors (such as weight management through diet and exercise). The children's wellness benefit promotes the timely and appropriate wellness visits and immunizations for children in accordance with guidelines issued by the American Academy of Pediatrics.

Beginning in January 2007, Idaho's PHA program began to reward parents of children who received up-to-date well-child care by paying for delinquent premiums (Kenney and Pelletier 2010). Although in the initial nine months of implementation additional points could be issued as vouchers for car seats, bicycle helmets, or sports equipment, eventually points were used exclusively to offset premiums—current and delinquent. A key to the success of the PHA program was the early support of the Idaho Legislature.

Idaho's PHA program has been highlighted as an example of the successful use of incentives to promote health behaviors among patients (Barth and Greene 2007; Blumenthal et al. 2013). Data from Idaho Medicaid officials indicate that loss of coverage due to failure to pay premiums decreased from a range between 15 and 20 percent before the PHA benefits began to less than 1 percent in 2009 (Kenney and Pelletier 2010). As reported by Blumenthal and colleagues (2013), a quasi-experimental study of the program compared the outcomes of children with CHIP (who paid a monthly insurance premium) to children with Medicaid (who did not pay a monthly insurance premium). The following two Healthcare Effectiveness Data and Information Set measures were considered in the assessment of completion of recommended guidelines:

1. Well-child visits in the third, fourth, fifth, and sixth years of life
2. Adolescent well care visits for patients aged 12 or older

Follow-up years were compared with the baseline period, before any cost sharing or incentive policies started. As reported by Barth and Greene (2007), in the first year, well-child visits increased among CHIP children who paid a $10 premium by 36 percent and among CHIP children with a $15 premium by 49 percent; in the second year, well-child visits increased for CHIP children with $10 premiums (118 percent increase) and $15 premiums (75 percent increase) as well as children with Medicaid (13 percent increase). On the other hand, the success of the weight management plan was less conclusive. Despite providing Medicaid beneficiaries nearly $160,000 in incentive payments, less than 1 percent of Idaho Medicaid enrollees were participating in the weight management program (Blumenthal et al. 2013).

Now that we have a basic understanding of the policymaking process and major health issues in the United States and elsewhere, we continue with an overview of the field of health policy research (HPR), which contributes significantly to policy development and improvement. In this chapter, HPR is defined and its unique characteristics highlighted. The process of HPR is then summarized, followed by a discussion on how to communicate findings from HPR. The chapter concludes by underscoring the challenges in implementing HPR.

DEFINING HEALTH POLICY RESEARCH

Health policy research is the process of scientific investigation that applies various health-related and social science methodologies to formulate and evaluate health policies (WHO 2005). The goal of HPR is to improve the health of populations through needs assessment, policy and program development, implementation, and evaluation.

Harrison (2001) identifies the following aspects of the policy process that researchers actively investigate:

- How issues come to be seen and defined as problems
- How some issues reach policy agendas and others do not
- How policies and decisions are made, and why proposed options are rejected
- The normative and explanatory theories espoused by researchers
- The impact that implementation attempts have on the policy itself
- Why certain policies survive whereas others are abandoned
- The factors that contribute to successful interventions

policy research
A rigorous, systematic process of scientific investigation that is used to formulate and evaluate policies.

policy analysis
A systematic approach by which to assess problems and guide decision making, based on existing information, often with limited information and time constraints.

Although this book does not make the distinction (i.e., the two terms are used interchangeably), *health policy research* is technically different from *health policy analysis*: Although both disciplines address a particular health problem, **policy research** tends to be conducted in a rigorous and systematic fashion, whereas **policy analysis** is time sensitive and relies on existing and current information.

In the second edition of the classic text *A Practical Guide to Policy Analysis*, Bardach (2005, 13) elaborates on the multiple roles and tasks of policy analysts:

> Policy analysts help in planning, budgeting, program evaluation, program design, program management, public relations, and other functions. They work alone, in teams, and in loose networks that cut across organizations. They work in the public, nonprofit, and for-profit spheres. Although their work is ideally distinguished by transparency of method and interpretation, the analysts themselves may explicitly bring to their jobs the values and passions of advocacy groups as well as "neutral" civil servants. The professional networks in which they work may contain—in most cases, do contain—professionals drawn from law, engineering, accounting, and so on and in those settings the policy-analytic point of view has to struggle for the right to counter—or better yet, synthesize—the viewpoints of the other professionals. Although policy-analytic work products typically involve written reports, they may also include briefings, slide presentations, magazine articles, and television interviews. The recipients of these products may be broad and diffuse audiences as well as narrowly construed paying clients or employers.

As Bardach describes, the work of policy analysts informs the decision making of, and guides program implementation for, policymakers and professionals in other fields. Policy analysts often follow a five-step framework to assess problems, as described in the classic work by Stokey and Zeckhauser (1978): (1) establishing the context and goals for a particular issue, (2) identifying alternative approaches to addressing the issue, (3) evaluating alternatives and predicting the consequences, (4) valuing the outcomes, and (5) making a choice.

Health policy analysis is performed by a wide array of researchers and research organizations, including academics, government officials, think tanks, and consulting firms, each yielding different types of policy analysis products. For example, academic researchers tend to produce scholarly articles or policy analysis books for publication; government officials write policy memos or briefs to inform policymakers; and think tanks and consulting firms issue reports tailored to the needs of particular clients. For example, the not-for-profit think tank RAND Corporation (the same company that sponsored the research described in Case Study 1) released a report on the diffusion of health information technology (HIT) in 2005 (Taylor et al. 2005). In this study, RAND performed classic policy analysis by summarizing the current state of HIT adoption by the US healthcare system, identifying factors predicting its adoption, determining policy alternatives to improve HIT diffusion, discussing the alternatives, and making policy recommendations regarding HIT (Taylor et al. 2005).

CHARACTERISTICS OF HEALTH POLICY RESEARCH

HPR can be characterized by five main attributes: its nature as an applied field, its ethics framework, the multidisciplinary input it enjoys, its basis in science, and its focus on population.

Applied Field

HPR is an applied field in which objectives are largely determined by priorities within health systems and concerns of society. To illustrate this point, the pioneering researcher Anderson (1985, 237) wrote, "Research in the field of health services has generally stemmed not from curiosity, but from a need to have facts on which to base organization, administration, and legislation and this search for facts has been frankly for public policy purposes, to provide a factual basis for a given policy."

HPR aims to address problems related to specific populations (e.g., pregnant women, the elderly, migrants) and to enhance health interventions at local, national, and international levels. Findings from HPR are used by clinicians, healthcare administrators, and formulators of healthcare policy, and researchers must often frame findings in a way that will be useful for various stakeholders.

The objectives of researchers and policymakers are not always complementary. This view is echoed in the early twentieth-century work of Lavis and colleagues (2002), who used organizing frameworks from three disciplines—organizational behavior and management research, knowledge utilization, and political science research—to study the role of HPR in public policy formulation in Canada. They found that interactions between researchers and policymakers can affect the amount of influence research has on policymaking.

For example, small-scale, content-driven policies (e.g., HIV prenatal testing, needs-based funding formulas) appeared to be particularly amenable to recommendations from research findings, but larger-scale policy decisions (e.g., broad healthcare financing schemes) seemed less affected because of various conflicting and influential political factors.

FOR YOUR CONSIDERATION

The Michigan Maternal Infant Health Program

The Michigan Department of Health and Human Services evaluates the Maternal Infant Health Program (MIHP) using multiple strategies, including administrative data analyses, certification reviews to ensure consistent fidelity to the program model, and an independent, evidence-based evaluation conducted by Michigan State University (MSU) research partners (MDHHS 2018). Because MIHP is a population-based program, a randomized trial is not feasible (i.e., all Medicaid-insured pregnant women are eligible for the program). Instead, MSU researchers use a quasi-experimental design. They created matched comparison groups with baseline equivalence on a variety of characteristics. Subjects enrolled in MIHP were matched to nonparticipants based on similar characteristics.

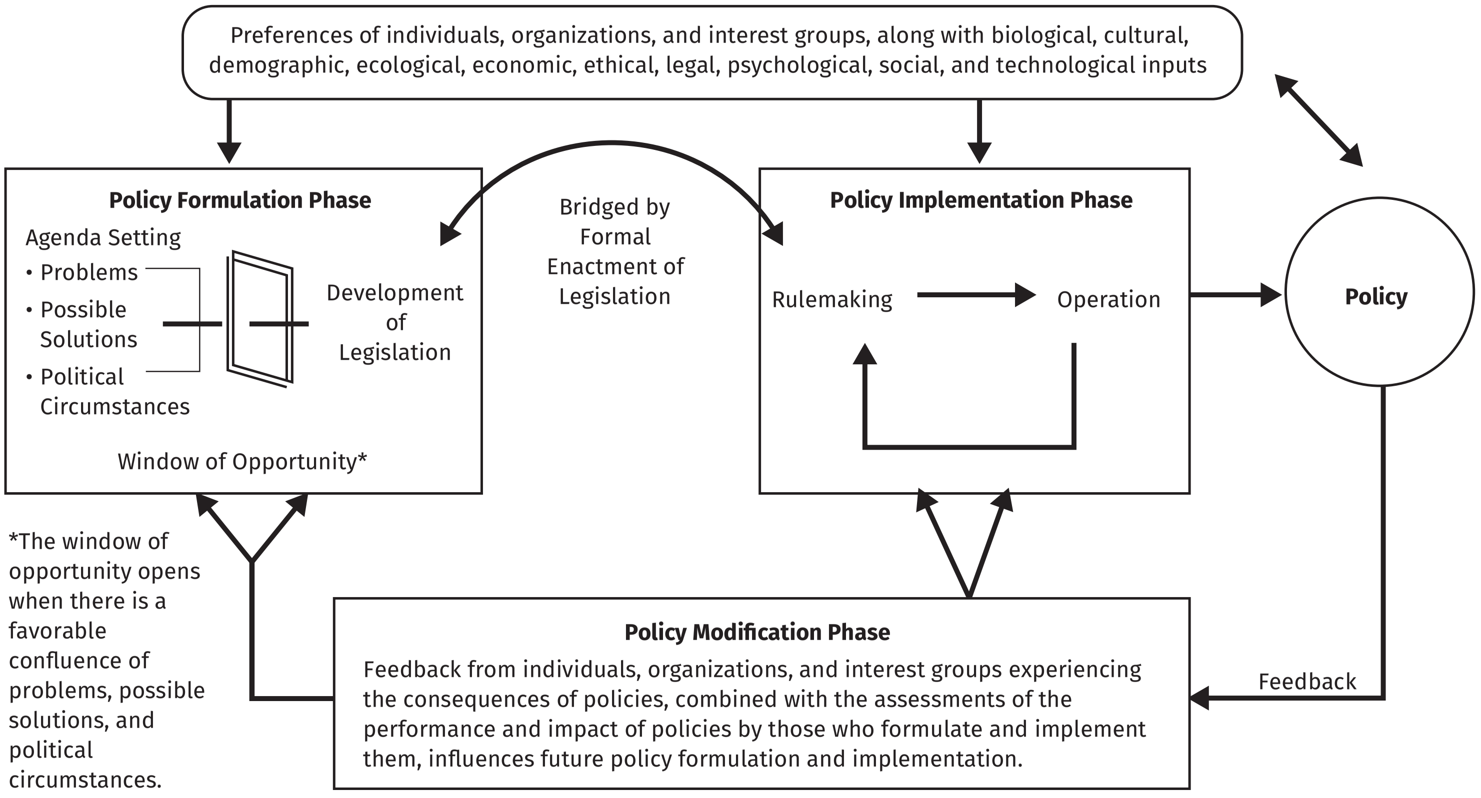
MIHP has been shown to reduce the risk of adverse birth outcomes in Medicaid-insured women, with benefits especially noted for African-American women who are at higher risk for adverse outcomes.

The practical application and problem-solving orientation of HPR must remain balanced with theory-driven standards. Theory and systematic methodologies provide the framework within which healthcare problems are modeled. Health policy researchers should ensure that their techniques and the findings they uncover are generalizable beyond specific populations or settings to properly assess the quality of research and corresponding findings. For an example of a program that uses multiple research strategies, see the For Your Consideration box titled "The Michigan Maternal Infant Health Program."

Exhibit 8.1 shows the policymaking process as developed by Longest (2016). Health policy research and analysis may occur at several points

Exhibit 8.1

A Model of the Public Policymaking Process in the United States



*The window of opportunity opens when there is a favorable confluence of problems, possible solutions, and political circumstances.

Source: Longest (2016). Reprinted with permission from Health Administration Press, Chicago. © 2016 Health Administration Press. www.ache.org/hap.cfm.

throughout the policy process. For example, HPR often comes into play as the life of a policy begins—at the policy formulation stage, during which problems and possible solutions are evaluated against the current political and social climate. Researchers may investigate successful (or failed) policies to inform policymakers or offer suggestions for the direction of future efforts. As mentioned in earlier chapters, for a policy to be fully developed, there must be a window of opportunity, which is determined by the current landscape of social, economic, political, ethical, and legal factors. Regardless of the amount and quality of evidence gathered by researchers, this window of opportunity must be present for successful acceptance and implementation.

After a policy is implemented and appropriate regulatory rules are in place for it to function, policy researchers may conduct evaluations to assess whether the policy and associated programs are meeting objectives and the needs of target populations. Policy researchers may also compare the current policy's performance against existing or past efforts.

On the basis of findings from policy researchers or of feedback from individuals, organizations, or interest groups, a policy may enter the *policy modification* stage, during which it is further evaluated and assessed for impact. Thus, the policy process is a feedback cycle that is constantly informed by policy research.

Framework of Ethics

Ethical standards dictate the proper conduct of research, including accommodation of the interests of its human research subjects. Health policy analysts must consider all relevant ethical issues when developing research plans to ensure the safety and rights of study participants. The organization that sponsors the research typically has an **institutional review board (IRB)**, whose responsibility is to review the study design before the research begins to ensure that researchers have thoroughly considered all ethical implications of their work and to consider potential legal implications if ethical negligence were to occur.

institutional review board (IRB)
A committee that examines the ethical implications of research to protect study subjects from physical or psychological harm.

For example, study designs should not place participants at risk for potential physical or psychological harm. Researchers must seek voluntary participation and disclose any associated risks. Ethical standards for research are particularly important to follow when dealing with "captive audiences," such as students or prisoners.

Throughout the duration of the study, the privacy of subjects should be protected through anonymity (i.e., participants remain anonymous throughout the study, even to the researchers) or confidentiality (i.e., identifying information is not made available to anyone who is not directly involved in the study).

An important ethical consideration for health policy researchers is to avoid succumbing to the prior beliefs of either the sponsors or the users, especially when the users may influence the career pathways of the researchers. Providing selected evidence to justify their previously held beliefs could gain researchers a short-term advantage but would eventually tarnish the researchers' reputations and, more seriously, undermine the policy that the research is supposed to enlighten.

Multidisciplinary Approach

HPR incorporates a wide variety of biological and social sciences in its approach to finding the best solutions to complex health-related problems—particularly disciplines used in problem solving and public decision making, as described in a seminal paper by Bice (1980). In fact, many health policy researchers are trained in social science disciplines, including sociology, economics, law, psychology, and political science, and they often incorporate the theories and methods from these areas when addressing health policy concerns.

Knowledge from the biological sciences is often applied in the beginning stages of policy analysis, during which an existing health issue or program must be analyzed. As described in a seminal work by the Institute of Medicine (IOM 1979), the biological sciences include the study of biological determinants, risk factors, and consequences of health processes—as well as methods and techniques to characterize such phenomena—to contribute to the understanding of human populations. Examples of research that involves the biological sciences include the study of the prevalence or incidence of a given condition and the genetic makeup of a certain population (Mozaffarian 2016; Norton et al. 2016).

In the social sciences, health policy researchers benefit from knowledge of *demography*, or population studies. Facts about population size, composition, and growth rates are needed for the early stages of program planning. Mapping technologies can be particularly helpful for health policy researchers (Chambers, Chenoweth, and Neumann 2016). For example, using data on hospital patients and estimates of population size, local health researchers can compute hospital discharge rates for their local geographic or service areas. Such information might be used to guide funding decisions and allocation of resources to areas of need.

Economics is another area of expertise from the social sciences that is critical to health policy research, particularly with regard to cost–benefit and cost-effectiveness analyses of healthcare interventions (Neumann et al. 2016). Findings from health economics–related research enable decision makers to best allocate limited resources.

Finally, the behavioral sciences are crucial to HPR, drawing from epidemiological studies that identify behavioral determinants of illness or risk factors, such as diet and smoking habits, and examining the social and psychological components of these determinants (Koon, Hawkins, and Mayhew 2016).

Although many biomedical and social science disciplines are incorporated into HPR, true multidisciplinary research is uncommon. Researchers from diverse fields do not often collaborate when conducting health-related research that could affect policy. For example, economic theory and methodologies have been used in research on prospective payment systems to assess the systems' impact on hospital cost containment, but knowledge that is often closely related—such as research from the behavioral sciences about patient characteristics or research from population studies on the community—is not usually considered. Such fragmentation of knowledge and disciplines restricts the impact that research toward problem solving and decision making can have on policy solutions.

Scientific Basis

Theories from the social sciences and methodologies used in empirical research can provide guidance for HPR and include problem conceptualization, data collection, analysis, and interpretation. Incorporating scientific methodologies can also help health policy researchers maintain objectivity about their work.

Although such methods could be useful to health policy researchers, the application of scientific principles is often constrained due in part to the complex nature of health-related problems. HPR often examines specific settings and populations; thus, findings from a particular study are not always generalizable. For example, the policy decisions that apply to healthcare delivery in rural areas are usually drastically different from those that emerge in urban areas in terms of access issues and financing (Humphreys et al. 2009).

The types of data available often impose limitations on HPR, which must rely on information from existing population surveys, records, and documents as well as direct observation. Seeking information beyond these sources is usually outside the scope of the study design because it can be an expensive and time-consuming activity. For example, health policy researchers studying the effect of technological advances on healthcare spending among cancer patients may be limited to the data contained in the annual series of national healthcare expenditure estimates produced by the Centers for Medicare & Medicaid Services (i.e., annual healthcare expenditures by type of service and source of funding)(CMS 2018); reports from the National Health Care Survey (i.e., national estimates of the prevalence of illness and the use of various health services)(NCHS 2011); or the Medical Expenditure Panel Survey (Stagnitti and Carper 2014), which could be outdated or not fully applicable to the researchers' populations of interest.

The gold standard for scientific research is the randomized controlled trial, in which research subjects are randomly assigned to an experimental group or a control group. However, this experimental design is often incompatible with HPR because researchers must consider determinants of health and environmental factors beyond those captured under strict experimental conditions. Ethical standards of HPR do not allow experimental research on humans. Furthermore, the effects of bias introduced into study results because of the inability to control outside influences can skew findings. To address these concerns, health policy researchers typically use quasi-experimental designs, cohort studies, longitudinal analyses, survey analyses, and multidisciplinary approaches (discussed later in this book).

Population Focus

HPR differs from other health-related research in that it focuses on healthcare solutions for the population rather than for the individual. In contrast, clinical research primarily focuses on the efficacy of the preventive, diagnostic, and therapeutic services applied to individual patients (IOM 1979). In addition, biomedical research is largely concerned with the conditions, processes, and mechanisms of health and illness at the biological level within the human body (Frenk 1993).

Epidemiological research investigates questions at the population level, focusing on frequency distribution and determinants of health and disease among populations. In other words, epidemiological research begins with a specific condition and studies its various determinants. Bioepidemiology, clinical epidemiology, decision analysis, and technology assessment are some examples of disciplines that are similar to HPR in that they also deal with connections and interfaces among the major types of health-related research.

THE PROCESS OF HEALTH POLICY RESEARCH

HPR or analysis can be undertaken in a number of ways. The most widely used approach is a rationalist model (see exhibit 8.2), similar to the five-step framework outlined earlier in this chapter, in which problem definition leads to the identification and evaluation of alternatives followed by policy implementation. (Chapter 9 provides a more detailed discussion of this approach.)

A more formal approach to conducting HPR is presented in exhibit 8.3, which displays the steps involved in systematically conducting health policy research. This approach is similar to that followed when conducting health science–related research. Exhibit 8.4 breaks down these steps into their critical elements. Although the sequencing is not fixed, the stages are interdependent, and some stages must be conducted before others are initiated.

EXHIBIT 8.2
The Process of Health Policy Analysis Under the Rationalist Model

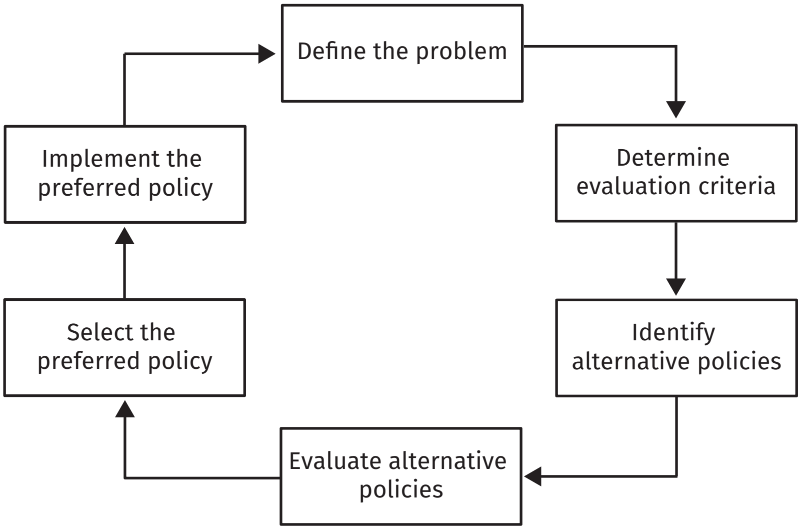
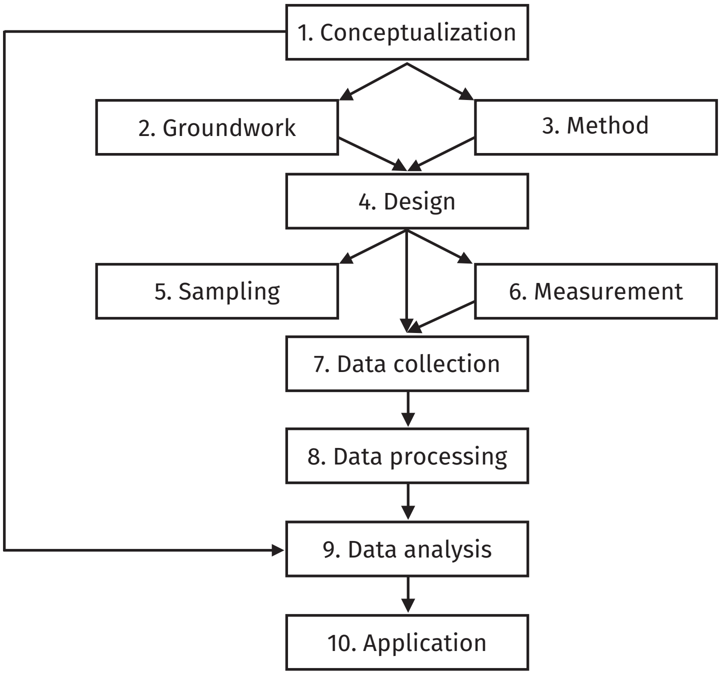


Exhibit 8.3
Steps in Conducting Health Policy Research



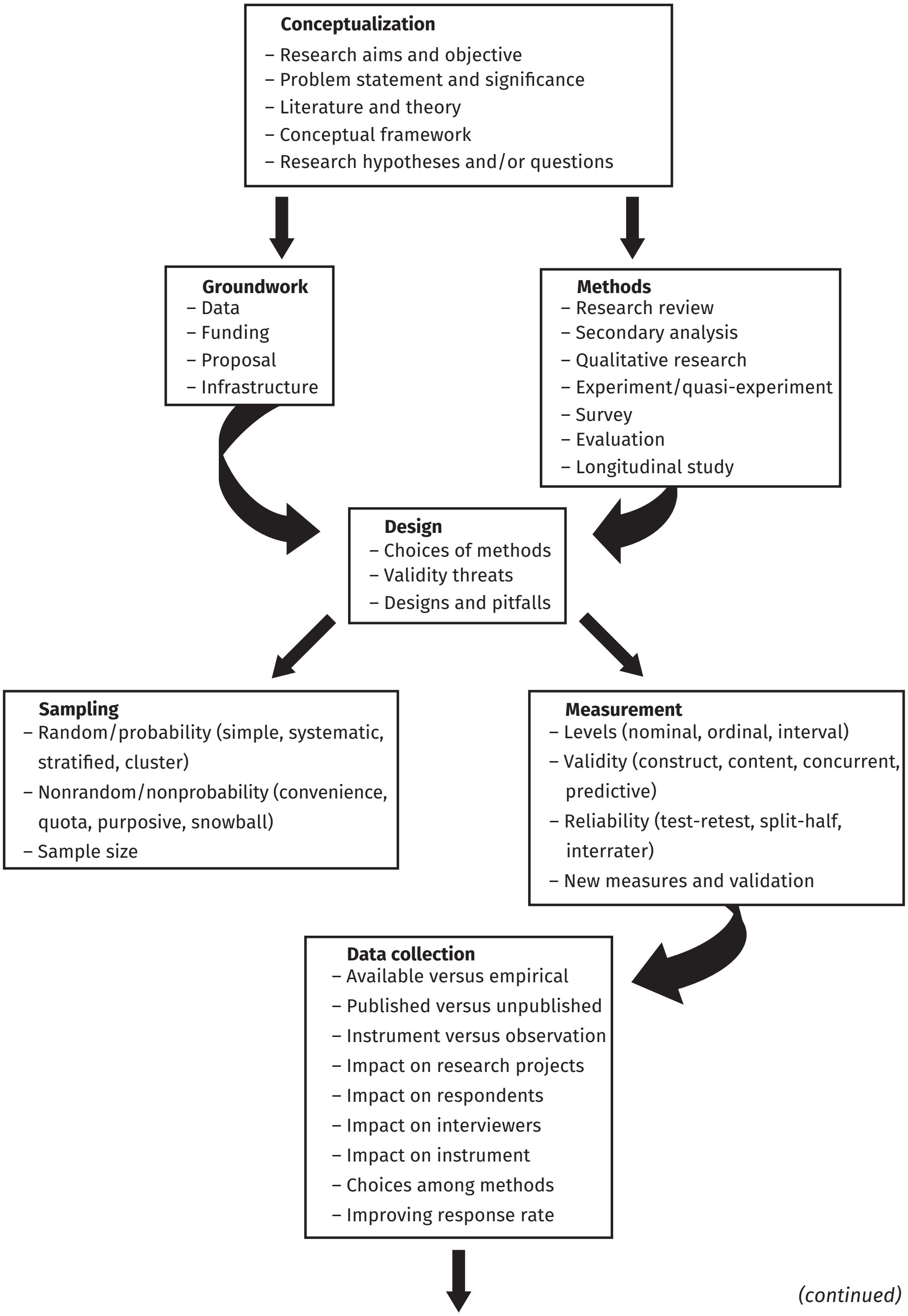
For example, an adequate hypothesis cannot be formulated without a proper understanding of the underlying subject matter. Similarly, the early steps of the research process must be executed properly to achieve a successful study. Writing an untestable hypothesis and securing an inadequate sample are two examples of execution errors that prevent successful completion of a study.

CONCEPTUALIZATION

The conceptualization stage of the research process requires the researcher to understand the general purpose of the research, determine the specific research topic, identify theories and literature relevant to the topic, specify the meaning of the concepts and variables to be studied, and formulate general hypotheses or research questions. Research hypotheses differ from research questions in that hypotheses suggest relationships between the variables.

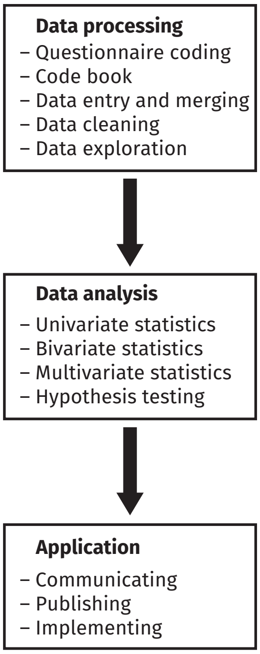
Theoretical research generally involves the testing of hypotheses developed from theories that are intellectually interesting to the researcher, whereas research questions typically arise from current social problems. Applied policy research focused on current social problems generally specifies its purpose through research questions. Hypotheses may be formulated if current knowledge (from theories and evidence) indicates an anticipated direction of the relationships among the variables of interest.

Exhibit 8.4
Key Elements of the Research Process Steps



(continued)

Exhibit 8.4
Key Elements of the Research Process Steps *(continued)*



conceptual framework
A preliminary model of the problem under study that depicts relationships among critical variables of interest and between variables and concepts of interest.

The conceptualization phase completes the development of a **conceptual framework**, which is a preliminary model of the problem under study that depicts relationships among critical variables of interest and between variables and concepts of interest. This phase, which is founded in literature and existing theory, helps researchers synthesize and guide the course of research and its subsequent analysis.

Conducting literature review is a critical step within the conceptualization component. Literature review informs researchers about the current state of the study on the topic as well as the existing limitations in the body of research. Findings from literature review can be used to direct research efforts to areas that need to be explored or to those with conflicting results.

In addition to helping researchers narrow and refine a topic, literature review facilitates the identification of theories and provides guidance in the formulation of hypotheses to be tested. As a result, researchers do not need to confine themselves to the generally accepted practices of their discipline when searching for relevant theories. They can either extend existing theories in the literature or use alternative approaches and theories to stimulate their research and generate more thorough findings than they might otherwise.

Another benefit of literature review is that it helps researchers identify relevant study and control variables to be included in the analysis. Exhibit 8.5 illustrates this process. The initial topic of interest is represented by the variable Y, and researchers are interested in

Exhibit 8.5
Looking for Variables Through Literature Review

Researcher's initial area of interest:

$? \longrightarrow Y$

Researcher's initial focus of study:

$X \longrightarrow Y$

Researcher's refined focus after performing systematic literature review:

$X\text{s}, Z\text{s} \longrightarrow Y\text{s}$

finding out the causes of *Y*. The variable *X* is identified as a potential cause on the basis of the researchers' experience or the observed evidence; however, researchers have limited experience with *Y* and thus are unable to consider all potential causes of *Y*. Literature review helps identify not only the potential causes (i.e., variable *X*s) but also other potential factors (variable *Z*s). Furthermore, literature review may suggest different dimensions of the topic (variable *Y*s). In short, literature review enables researchers to operationalize abstract concepts—a prerequisite for empirical research.

Literature review also suggests pertinent research design, procedures, and analyses by indicating how other researchers have addressed a given topic. Researchers may use a previous investigator's method, revise the research design, or even replicate an earlier study. (See the Learning Point box titled "Conducting a Systematic Literature Review" for a summary description of the systematic research literature review process.)

LEARNING POINT
Conducting a Systematic Literature Review

1. **Identify the Topic**
   The choice of a topic for review is influenced by the interests of the policy community. A topic is probably not suitable for independent review unless sufficient research activity already surrounds it.

2. **Prepare a Coding Sheet**
   After the topic is identified and refined, a coding sheet should be constructed to collect relevant information from articles to be reviewed. A coding sheet enables the researcher to collect all needed information during the first reading. The preparation of a coding sheet is even useful for reviewing a small number of studies because the information collected will assist the investigator in analyzing and reporting those studies.

(continued)

LEARNING POINT

Conducting a Systematic Literature Review *(continued)*

The information to be collected in the coding sheet should be determined on the basis of the preliminary review and the strategy to be adopted in analyzing and synthesizing studies. Generally, any information that may be analyzed and used in the review should be collected at the time of the review, because it is better to collect too much information than to have to reread the published studies.

The general categories of information related to empirical research in which an investigator is likely to be interested include a study's background, design, measurement, and outcome characteristics.

In the background category, the source indicates the media or information channel from which a study is retrieved.

In the design category, the general categorization as presented may not be sufficient to generate information. Researchers may then include additional design characteristics (e.g., whether restrictions were placed on the types of individuals sampled in the original study, when and where the study was conducted, whether time series or longitudinal designs were used).

In the measurement category, investigators may document the use of particular scales, available instruments, and specific features of the analytic models (e.g., number of variables used, types of measures implemented for the same construct, tests of interaction terms and nonlinearity).

In the outcome category, if more quantitative analysis is envisioned, precise statistical information related to study results may be recorded. Examples include means, standard deviations, sample sizes for each comparison group (to be used for effect size calculation), association between variables (e.g., correlation coefficient), values of inferential test statistics (e.g., c^2, t ratio, F ratio), and the strength of an F ratio (e.g., regression, R^2).

It bears reemphasizing that the construction of a coding sheet is the result of, rather than a prelude to, preliminary review. The development of a coding sheet forces researchers to think ahead about the review and analysis strategy and to be precise in their approach to gathering the information.

3. **Search Research Publications**

   Five major sources of literature are available for reviewers to retrieve: (1) books; (2) journals, including professional journals, published newsletters, magazines, and newspapers; (3) theses, including doctoral, master's, and bachelor's degree theses; (4) unpublished work, including monographs, technical reports, grant proposals, conference papers, personal manuscripts, and other unpublished materials; and (5) the internet, including institutional and individual websites.

LEARNING POINT
Conducting a Systematic Literature Review *(continued)*

4. **Synthesize Research Publications**
   The relationship between synthesizing and coding studies is a close one. Before studies can be synthesized, they need to be properly coded. The proper coding of studies relies on knowledge about how the studies will eventually be analyzed and synthesized. Thus, although analysis and synthesis are performed much later in the literature review process, the strategy needs to be delineated before the coding sheet is designed.

   Synthesizing research entails categorizing a series of related studies, analyzing and interpreting their findings, and summarizing those findings into unified statements about the topic being reviewed.

Policy-oriented reviews summarize current knowledge of a topic to draw out the policy implications of study findings. Such reviews require knowledge of the major policy issues and debates and common research expertise. (See the For Your Consideration box titled "Steps in Synthesizing Policy Research Studies" for a way to make the findings relevant to your work.)

FOR YOUR CONSIDERATION
Steps in Synthesizing Policy Research Studies

1. Compile an inventory of public policies that might address the health problem under study.
2. Determine the policy that will be the focus of your synthesis.
3. Detail the sequence of effects that you expect will link the policy to the problem.
4. Synthesize data on the impact of this policy in areas of previous implementation (e.g., effectiveness, unintended effects, effects related to equity) and on related issues (e.g., cost, feasibility, acceptability).
5. Consider the data drawn from the literature review in terms of the present context under study.

Source: Adapted from NCCHPP (2010).

GROUNDWORK

In the groundwork stage, the researcher identifies relevant data sources, explores potential funding, develops a research plan or proposal by which to obtain funding, and makes organizational and administrative preparations to carry out the research.

Choosing a data source for policy research can be a difficult endeavor; policy-related evidence is not as clearly available as evidence from experimental research in the life sciences. For example, a researcher planning to investigate the effects of tobacco control policies might need to examine economic data on tobacco taxes as well as health outcome information from local healthcare systems. Those engaged in policy research often use a range of data types, including quantitative, qualitative, experimental, and descriptive data. Although it is difficult to fully assess the quality of data sources that might be used for policy research, investigators should weigh the positive and negative factors associated with using each relevant data source.

METHODS

After completing the groundwork stage, the researcher must choose the appropriate research methods with which to conduct the study. Many methods are available for researchers undertaking policy analyses, such as research review (e.g., meta-analysis), secondary analysis (e.g., research analysis of administrative records), qualitative research (e.g., focus group, in-depth interview, case study), survey methods (e.g., longitudinal study), experimental methods, and evaluation research. Each method has its own strengths and weaknesses, and the best strategy often is a combination of methods.

There are three categories of research methods: exploratory, descriptive, and explanatory. The appropriate application of the research method varies according to these categories. Researchers should carefully consider the field of supporting evidence, research questions, population of interest, and funding and administrative resources prior to choosing one or more methods.

Exploratory research methods are used to learn more about a little-known topic or to test new research methods. Examples of exploratory research include qualitative efforts, such as case studies or focus groups, observations, and interviews. Although it is among the least expensive research methods (due, in part, to the frequent use of small sample sizes), exploratory research is also considered the least rigorous, and findings may not be generalizable to other contexts or research questions. However, exploratory research has been increasingly used in the scientific field as a methodology through which to provide context-rich information that can inform further, more rigorous research study design.

Descriptive research methods are used to investigate study characteristics among subjects; one example is the administration and analysis of survey data. Although descriptive research methods are considered more rigorous than exploratory methods, they can be expensive to conduct because they often require large sample sizes.

The final type of research method, *explanatory research*, includes experimental studies—considered the gold standard among research study methods—as well as case control studies and longitudinal research. These methods are among the most rigorous in design, and thus their findings have the greatest level of generalizability compared with other research methods. Explanatory research can be expensive, however, requiring large sample sizes and complex statistical analysis.

DESIGN

After the research problem has been identified, the researcher develops an overall framework for investigation. Research design addresses the planning of scientific inquiry by anticipating subsequent stages of the research project, including choosing the research method; identifying the unit of analysis and the variables to be measured; establishing procedures for data collection; and devising an analysis strategy. Potential implementation strategies must also be considered because much of the value of HPR lies in using research to bring effective and targeted programs and resources to populations in need (Atkins and Kupersmith 2011; Xiu-xia et al. 2015). Problems that arise in the future would necessitate changes to the research plan.

SAMPLING

In the sampling stage, the researcher must clearly define the population of interest in the study. It is not feasible to study every individual in the population; thus, a sample must be taken to draw conclusions about that population.

Four types of sampling methods—often referred to as *probability sample designs* because each subject in a **sampling frame** has a known probability of being selected for the sample—incorporate varying degrees of **random selection**:

1. *Simple random sampling* is the most basic method, in which every subject in the sampling frame has an equal probability of being selected.
2. *Systematic sampling* is a bit more complicated. Every *k*th subject from the sampling frame is selected, with the interval between selected subjects (*k*) having been determined by the researcher (e.g., every fifth subject is selected from the sampling frame).
3. *Cluster sampling* involves the distribution of subjects in the sampling frame into **heterogeneous** groupings called *clusters*, which are then randomly selected to

sampling frame
The population from which a sample is selected.

random selection
Methods by which subjects from a sampling frame are chosen to create a representative sample, such that each subject has a known probability of being selected and the selection process is not biased against any particular individual in the sample.

heterogeneous
Consisting of different types; a term used to describe a sample or a population composed of subjects that have dissimilar characteristics.

comprise a sample of clusters. Cluster sampling can be a cost-effective way to conduct research over a broad geographic area.

4. *Stratified sampling* is similar to cluster sampling in that subjects from the sampling frame are divided into groups; however, these groups (known as *strata*) are **homogeneous**. Simple random sampling is used within each of the chosen strata to select a final sample. Stratified sampling is used to ensure that the sample is representative of the population about which a researcher hopes to draw inferences in terms of characteristics of interest.

homogeneous
Consisting of the same type; a term used to describe a sample or a population composed of subjects that have similar characteristics.

See exhibit 8.6 for an evaluation of probability sampling designs.

A number of nonprobability sampling methods are also available, such as convenience sampling, quota sampling, purposive sampling, and snowball sampling. The probability of subject selection in a sample is unknown when these methods are used. Although nonprobability sampling methods can be less expensive to employ than probability sampling methods, nonprobability methods cannot be used to make inferences about a population and are subject to research bias.

measurement validity
The extent to which the measurement tool accurately measures the intended concepts.

measurement reliability
The extent to which results are similar if the measurement tool is reapplied in a consistent way.

MEASUREMENT

The measurement, or operationalization, stage involves devising measures that link concepts of interest to empirically observable events or variables. The **measurement validity** and **measurement reliability** should also be ascertained. Because survey research is frequently

EXHIBIT 8.6
Trade-Offs of Commonly Used Random Sampling Methods

	Simple random sampling	Systematic sampling	Cluster sampling	Stratified sampling
Precise	Highest	Moderate	Lowest	Highest
Able to capture groups of interest	No	No	Yes	Yes
Cost-efficient	No	No	Yes	Yes
Requires knowledge of population in advance	No	No	Yes	Yes
Allows for disproportionate sampling	No	No	Yes	Yes
Involves complex data analysis	No	No	Yes	Yes

used, health policy researchers should be knowledgeable of the general guidelines and specific techniques for writing survey questionnaire instruments.

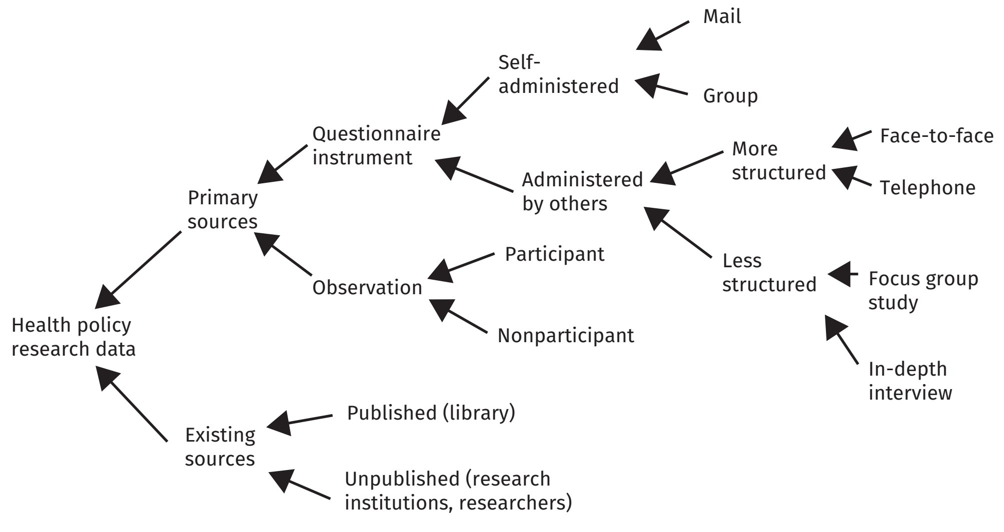
DATA COLLECTION

Data for HPR can come from a variety of sources, typically categorized as *primary sources* and *existing sources* (see exhibit 8.7). The research method chosen often influences the method used for data collection. Two commonly used primary data-collection tools are interviews and administration of questionnaires. Primary data are collected by researchers for the purpose of their specific study, so primary data tend to be more relevant and hence more valid than existing data. Researchers can design the questions they use to gather primary data specifically according to the study objectives, whereas existing data from another study may not contain all of the information desired for analysis. However, existing, or secondary, data are widely used in HPR because they tend to be more generalizable and are more efficient in terms of saving time and cost than primary data.

DATA PROCESSING

Generally, data in their raw format are difficult to analyze and interpret. Before data can be interpreted, the researcher must transform or process the data into a format that can be

EXHIBIT 8.7
Health Policy Research Data Sources



analyzed. For example, the data may need to be converted into numerical values or "cleaned" to identify data-entry errors. In addition, the researcher may need to identify missing data and account for them.

DATA ANALYSIS

After the raw data have been processed, they are ready for analysis. The researcher employs statistical procedures to manipulate the processed data and draw conclusions about the study population.

APPLICATION

The final stage of research deals with the interpretation and use of research. Applying research findings to scientific theory and policy formulation can be the most satisfying step in the research process (see detailed discussion in the next sections). Researchers should also provide recommendations for further research on the subject and outline limitations that may be avoidable in future studies.

COMMUNICATING HEALTH POLICY RESEARCH

The way in which evidence is disseminated depends on the intended audience. Potential audiences may be divided into three groups: the research community, stakeholders (e.g., funders, policymakers), and the public. The research community includes scientists or others who share similar research interests. Stakeholders are those who provide funding or have a key role in implementing research findings. The public is the population at large affected by the findings of the research who are neither researchers nor stakeholders. Investigators should adapt and tailor their communications to specific audiences to maximize comprehension and acceptance.

RESEARCH COMMUNITY

When the intended audience is part of the research community, certain assumptions can be made about prior knowledge. Research findings may be summarized, rather than explained in great detail, and technical terms may be used. Researchers must also be as transparent as possible, clearly explaining methods and the reasons behind them. Transparency is even more important regarding studies that employ modeling because the findings that a researcher chooses to include or omit in a study can have an enormous impact on the results (Padula, McQueen, and Pronovost 2017; Søgaard and Lindholt 2011).

The most common way of communicating results to the scientific community is by publishing an article on the research in a peer-reviewed scientific journal. Prior to submitting a paper for publication, researchers should be aware of the manuscript preparation guidelines of the journal in question. Because it often takes months from the time of submission for an article to be published, researchers often seek out other ways to publicize research findings.

Professional conferences are another common way to present findings. Professional associations generally hold annual conferences that offer members the opportunity to present their research. Conferences are an excellent outlet because it is often much easier to get a paper selected for a conference than to have an article accepted by a journal for publication and because results can be presented sooner than in a journal. Conferences also enable the researcher to receive comments, suggestions, and criticisms that may be useful for later submission of a research article to a journal. However, certain journals prohibit content from being released prior to publication, and researchers may need to show what they have presented when submitting articles for review.

Working papers and monographs are a third way in which results can be presented to the research community. The implication of calling a document a "working paper" is that a journal article is in progress. A working paper is typically circulated among those with the same research interests, with an implicit request for comments and suggestions. Because professional reputations are not at stake when distributing a working paper, tentative analyses and interpretations can be included. Similar to working papers, which are preludes to journal articles, monographs are drafted in preparation for writing books. Monographs are usually written for large, complex projects and may also be circulated among peers for suggestions.

STAKEHOLDERS

When stakeholders are the intended audience, investigators cannot assume any prior knowledge of the research subject and terminology. Stakeholders include funders or sponsors, people affected by the research results, and primary users of the research results. It is important to consider how to best translate research findings for these distinct kinds of stakeholders (Fontaine et al. 2018; Milstein, Wetterhall, and CDC Evaluation Working Group 1999; Montague et al. 2016).

A research proposal is often the first point of contact a researcher has with the sponsor or funders. A research proposal is written by the investigator to convince a potential sponsor of the investigator's qualifications for performing research and to answer questions that are important to a sponsor or funder.

Perhaps the most common means of communicating with stakeholders is through technical reports required by funders and sponsors. Reports often serve the additional purpose of informing policymakers, administrators, and other groups interested in study results. The report should directly address the questions posed by sponsors or funders and be consistent with the intended use and audience of the research. If applicable, it also may summarize the ways in which the research has advanced scientific knowledge.

Stakeholders such as sponsors and policymakers may also be invited to symposia where the research and its implications for decision makers are discussed. Symposia provide a forum where the research and its importance to the stakeholders can be fleshed out.

PUBLIC

When the intended audience is the general public, investigators can rely on the mass media to publicize significant research findings. In this instance, presentations to the press should avoid technical language and clearly explain any key terms or concepts. No assumptions should be made about the audience's existing knowledge of the research topic.

Fact sheets and issue briefs are other ways to synthesize and communicate research findings to the public. Many government and private research agencies regularly disseminate summaries of major studies or analyses this way. For example, the Henry J. Kaiser Family Foundation has produced periodic issue briefs and fact sheets on such topics as healthcare disparities, global health policy, Medicaid, Medicare, the uninsured, private insurance, and women's health policy (KFF 2018).

Researchers must expend more effort to educate the public on HPR. With improved dissemination of research results, members of the public may take more notice of healthcare findings and implement policy research into their healthcare decision making.

In some cases, the use of *community-based participatory research*—a partnership approach that equitably involves community members, local organizations, and researchers in all aspects of the research, and in which all partners contribute expertise and share decision making and ownership—can lead to the dissemination of research to the public, as noted in the classic work by Israel and colleagues (1998). For example, a study of the cardiovascular risks among Mexican Americans living along the Mexico–United States border not only collected data on the cardiovascular risks of the population but also informed these subjects of the study results through the community-based researchers (Balcazar et al. 2009). Another study showed that public libraries could be an important avenue in community-based participatory research to reduce the burden of cancer in medically underserved communities (Rapkin et al. 2017).

For researchers conducting studies in the field of health services, the ultimate challenge is to see their findings through to implementation in policy decisions. Because of the applied nature of HPR, a major goal is to apply disciplinary knowledge to solve current and emerging health-related problems. The synthesis and dissemination of HPR have played, and continue to play, an important role in health policy formulation (Ginzberg 1991; Price et al. 2016). Historically, HPR influenced early health policy formulation, implementation, and clinical practice with respect to HIV/AIDS-related illness and primary care (AHRQ 1990; National Center for Health Services Research and Health Care Technology Assessment 1985).

IMPLEMENTING HEALTH POLICY RESEARCH

The impact of HPR on health policy has increased over time. For example, research identifying large gaps in access to healthcare has compelled the formulation of policies aimed at healthcare reform to reduce these gaps. The Robert Wood Johnson Foundation's Covering Kids and Families (CKF) initiative represents an elegant integration of HPR and practice (Morgan, Ellis, and Gifford 2005). The CKF initiative aimed to improve states' reenrollment processes for children and families covered by Medicaid and CHIP. An evaluation of the initiative found that it had a positive impact on reenrollment in 45 states and allowed states that have succeeded in improving their reenrollment processes to advise struggling states (Morgan, Ellis, and Gifford 2005). Workplace health promotions based on research evidence have also been proven successful (see the For Your Consideration box titled "Evidence-Based Workplace Health Promotions").

FOR YOUR CONSIDERATION
Evidence-Based Workplace Health Promotions

Based on a benchmark study in workplace health promotion supported by the Robert Wood Johnson Foundation, the Promoting Healthy Workplaces project (Institute for Health and Productivity Studies 2016; Kent et al. 2016), the following characteristics of best and promising practices in workplace health promotion programs are summarized:

- They create and sustain a *culture of health* (a physically and socially supportive environment and active employee involvement).
- They apply *strategic communications* (effective strategic communications are designed to educate and motivate employees and build trust).
- They set goals with reasonable expectations.
- They have leadership commitment.
- Their program design is employee driven (i.e., tailored to employees' needs and wants, includes employee ownership).
- They feature "smart" incentives, especially intrinsic motivation—the key for health behavior changes.
- They include screening and triage programs.
- They measure program impact by leveraging available administrative data.

(continued)

FOR YOUR CONSIDERATION

Evidence-Based Workplace Health Promotions *(continued)*

Following are two examples of successful workplace health promotion programs based on research evidence.

Johnson & Johnson

Johnson & Johnson is a large multinational corporation active in more than 60 countries and is regarded as a pioneer in developing health promotion programs. Johnson & Johnson introduced its first workplace health promotion program in 1979, and the program has continued to evolve up to today because of its demonstrated positive effects. For example, Johnson & Johnson experienced average annual growth in total healthcare spending that was 3.7 percent lower than that of comparable large companies. Average annual per employee savings were $565 in 2009 dollars, producing a return on investment of $1.88 to $3.92 saved for every dollar spent on the program (Carls et al. 2011; Henke et al. 2011; Ozminkowski et al. 2002).

The key success factor was that the organization provided various health promotion programs (e.g., biometric screening; healthy coaching; on-site pharmacy, health clinic, and fitness center) to meet employees' diverse needs and interests. Making these programs convenient helped employees make healthy choices more easily. Leadership communicated consistent messages to support full integration of health into the way the organization operated. The program had a strong system to measure and evaluate its effects, through internal self-assessment annually as well as external evaluation every three years (Institute for Health and Productivity Studies 2016).

Next Jump

As reported by the Institute for Health and Productivity Studies (2016), Next Jump is a small e-commerce company in New York City with about 200 employees. It developed a workplace wellness program internally with direct feedback from employees (i.e., without hiring outside vendors), thus giving them a sense of engagement and ownership throughout the process. Leadership support was another key factor in the success of the program; the company's CEO was directly involved and committed to creating a healthy company culture. At the time the program began, Next Jump had no on-site fitness center, so the CEO brought in trainers to conduct fitness classes in the company's conference room. After the company's own fitness center was built, the CEO routinely attended fitness classes there with the employees. Next Jump also restructured the physical environment to encourage consumption of healthy food. Although the small company lacked a cafeteria, it created a healthful food environment by replacing candy jars with fresh fruit and nuts, and management stocked the on-site refrigerator with free healthy snacks, such as yogurt. The company also set up specific but attainable health promotion goals for employees. Specifically, employees at Next Jump were encouraged to work out twice a week for 20 minutes each time. More than 90 percent of the employees met this goal (Institute for Health and Productivity Studies 2016).

Research is often dismissed or improperly reflected in policy efforts, leaving investigators frustrated. The remainder of this section identifies barriers to the implementation of research in policy and some ways to overcome these barriers.

RELEVANCE

Sometimes, a scientifically significant study may not have immediate or obvious policy significance. Further investigation may be necessary to make such a study more relevant from both a clinical and a health policy perspective. Studies that translate scientific discoveries into practical (i.e., clinical) applications are termed *translational research* (see the Learning Point box titled "Phases of Translational Research").

TYPE OF STUDY

Adoption of research findings by policymakers and practitioners is also influenced by the type of study conducted. Research with a clinical focus is typically adopted more quickly than that focused on organization because of the importance that evidence plays in clinical practice. Research related to organization is often slowly adopted because organizational

LEARNING POINT
Phases of Translational Research

The phases of translational research are summarized as follows (Gannon 2014):

T0 Research: Basic biomedical research, including preclinical and animal studies, not including interventions with human subjects

T1 Research: From basic biomedical to humans, including Phase 1 clinical trials, and focused on new methods of diagnosis, treatment, and prevention in highly controlled settings

T2 Research: From basic biomedical to patients, including Phase 2 and 3 clinical trials, and controlled studies leading to clinical application and evidence-based guidelines

T3 Research: From controlled clinical trials to clinical practice, including comparative effectiveness research, postmarketing studies, clinical outcomes research, health services, and dissemination and implementation research

T4 Research: From clinical practice to communities, including population-level outcomes research; monitoring of morbidity, mortality, benefits, and risks; and impacts of policy and change practices require more time to change. An emphasis on quality improvement within an organization will often speed up an organization's propensity to change.

Research focusing on a national health problem or need takes much longer to influence policy. Often, national policies are formulated through political processes in which stakeholders strongly advocate for their own interests. In this context, research is merely one form of advocacy that competes with other influencers for the attention of policymakers.

PRIORITIES

A potential conflict exists between policy priorities and research priorities. Decision makers, who choose a course of action in response to a given health problem, are generally concerned with the most pressing and current issues. Researchers, who are generally at liberty to choose their research focus, often study problems that do not align with the concerns of decision makers, which can limit the reach of useful HPR.

Increasing the frequency of meetings between investigators and decision makers would facilitate the communication process and, in turn, enhance the applicability of research. One way to achieve this increase is by ensuring the presence of decision makers in the governing or consultative bodies of research institutions. Their access to the institutions may more easily bring their needs to the attention of researchers as possible projects.

Community-based participatory research, in which academics partner with community leaders who have direct knowledge of community health issues, is becoming increasingly important (Greenhalgh et al. 2016; O'Brien and Whitaker 2011). The practicality of this type of research is enhanced by including not only decision makers but also stakeholders and community leaders as contributors to the study (Israel et al. 1998; Rapkin et al. 2017).

TIMETABLE

Another potential area of conflict between decision makers and investigators is their respective expectations regarding the research timetable. Decision makers facing a pressing problem expect research results immediately. Researchers, on the other hand, are concerned with the validity of the study design and findings and often require more time than decision makers are willing to give them to collect and analyze the evidence and complete the research.

This discrepancy can be reduced by involving decision makers in the research planning phase so that more-realistic expectations are set. This gap can also be bridged by producing a series of progress reports outlining intermediate results from the study. During data collection, the participation of respondents and their characteristics can be summarized and reported. Also, immediately after data collection, descriptive summaries can be shared with decision makers before in-depth analyses are conducted.

COMMUNICATION

To enhance the comprehension by decision makers about study findings, research results must be expressed accurately without using technical terms. Investigators are trained to communicate results with specific scientific terms, in part to adhere to scientific journal guidelines, but decision makers often have trouble understanding study design descriptions or statistics used in data analysis. Researchers should help decision makers reach a clear understanding of results by providing them with nontechnical reports that avoid scientific language. The technical details such as methodology and definitions of terms can be included in an attached appendix.

SCOPE

Differences between policy scope and research scope constitute another barrier to the implementation of research findings. Because of the inherent complexity of social problems, decision makers require research to provide broad, integrated results that account for all dimensions of the problem. To deliver such results, investigators must overcome their tendency to focus on a well-defined subject and provide broad results instead.

Researchers must be knowledgeable about the context of the problems under investigation so that an integrated project that takes into account all important policy issues can be designed. Effective research will include an analysis that reflects the multiple interests in both the political system and the healthcare system.

VALUES

Researchers and decision makers often place different values on research. Investigators may desire publication in a prestigious scientific journal, whereas decision makers are focused on the applicability of the research to problem solving. Decision makers should, at a minimum, value the contribution that scientific inquiry has made toward improved decision making and understand the criteria for judging quality research. In turn, the scientific community must accept that excellence in research is defined not only as scientific knowledge but also as application for health policies and problem solving.

Because of the role that funding agencies play in the research process, they can often serve as intermediaries between policymakers and researchers. Funding agencies take into account the importance of political needs while balancing a desire to gain advances in science. In short, funding agencies often shape the direction of policy and science by accommodating the values of both the policymakers and the researchers (Braun 1998; Tsey et al. 2016).

LEADERSHIP

Although investigators may provide valid and practical research, leadership is required to transfer HPR into politically acceptable policy. The development and implementation of policy depend on the initiatives taken by decision makers across all levels of society. For example, leaders must promote local ownership of the clinical effectiveness agenda among clinicians and managers, make better use of the skills and expertise available in higher education organizations, increase understanding of the mechanisms that encourage the adoption of new interventions, and facilitate organizational receptivity of new research (Harvey et al. 2011).

RAPPORT

Researchers and decision makers operate interdependently. Decision makers rely on investigators to assist them in making sound and legitimate decisions on the basis of scientific evidence. Researchers need decision makers to help identify research problems, obtain funding, gain access to research sites and subjects, and implement findings. By cooperating, decision makers and researchers increase the potential impact of HPR on policymaking.

SKILLS

Although researchers may possess some background in related disciplines, such as medicine, public health, and political science, they must be competent in six specific skill areas. These six skill areas are relevant to each stage of HPR and include knowledge of subject matter, methodology, statistics, statistical application software, writing, and public relations—each of which is described briefly in the sections that follow. If investigators lack any of these skills, proper steps must be taken to ensure that a member of the research team is able to compensate for the lack of expertise. Many of these skills can be acquired in the classroom, but proficiency in research can be achieved only through experience in the field of HPR.

Subject Matter

The most important research skill is subject knowledge. In-depth knowledge of the subject matter, research data, instruments, funding sources, and survey design is critical to the conceptualization, groundwork, and measurement steps in HPR. For example, conceptualization requires an investigator to clearly understand the topic and purpose of the research, relevant theories and literature, and the process of formulating hypotheses and research questions.

Methodology

The second critical research skill is a command of general research methods. Without a clear understanding of the general approaches to research, the investigator will be unable to select the appropriate research method, study design, sampling model, and type of data collection.

Statistics

The third important research skill is statistical knowledge. This skill is particularly critical in the data analysis, design, sampling, and measurement phases of research. Knowledge of the choice and appropriate application of statistical procedures enable the investigator to conduct research independently.

Statistical Application Software

The fourth research skill—knowledge of statistical application software—is especially critical for analyses of large data sets. This skill is particularly useful in the data processing and analysis stages of HPR.

Writing

The ability to write well is a fifth critical research skill. Whether drafting proposals for funding or reports for scientific publication, investigators must properly convey their research goals and specific findings. In many cases, they can follow established formats (e.g., research proposals, journal articles). However, the ability to write concise and clear text is extremely valuable in producing reports.

Public Relations

The sixth and final skill is public relations, which is particularly useful in the groundwork, data-collection, and application stages of research, as well as for project management. Excellent "people skills" are essential in acquiring potential funds for a study, obtaining access to research sites and subjects, and collaborating successfully with decision makers for policy formulation.

KEY POINTS

- HPR can be characterized by five main attributes: its nature as an applied field, its ethics framework, the multidisciplinary input it enjoys, its basis in science, and its focus on population.

- Formal approaches to HPR typically include ten steps: conceptualization, groundwork, methods, design, sampling, measurement, data collection, data processing, data analysis, and application.
- HPR findings should be communicated to the research community, stakeholders, and the public.
- Numerous barriers constrain the implementation of research in policy. However, researchers and decision makers should operate interdependently.

CASE STUDY QUESTIONS

CASE STUDY 1

On the basis of your research of the RAND Health Insurance Experiment, answer the following questions:

1. How does the RAND study illustrate the characteristics of HPR?
2. What specific contributions did the RAND study make to health policies regarding health insurance?

CASE STUDY 2

In conducting an evaluation study such as this case study, answer the following questions:

1. What kinds of variables must be collected both before and after the intervention?
2. How can one design evaluation studies to address real-life constraints while adhering to scientific rigor at the same time?

FOR DISCUSSION

1. Define HPR. What is the difference between HPR and health policy analysis?
2. What are some differences and trade-offs between the sampling methods commonly used in HPR?
3. What distinguishes reliability of measurements from validity of measurements?
4. What six skills are needed to become a health policy researcher? Why are these particular skills so important?

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CHAPTER 9

HEALTH POLICY RESEARCH METHODS

Facts, and facts alone, are the foundation of science. . . . When one devotes oneself to experimental research it is in order to augment the sum of known facts, or to discover their mutual relations.

—François Magendie

It is by a thorough knowledge of the whole subject that [people] are enabled to judge correctly of the past and to give a proper direction to the future.

—James Monroe

Learning Objectives

After completing this chapter, you should be able to

- appreciate commonly used methods for health policy research,
- discuss experimental research,
- understand survey research,
- describe the process of conducting evaluation research,
- differentiate between cost–benefit analyses and cost-effectiveness analyses, and
- appreciate qualitative research methods.

CASE STUDY 1

HEALTH CENTERS AND THE FIGHT AGAINST HEALTH DISPARITIES IN THE UNITED STATES

The United States has experienced a long history of inequality among its citizens. From civil rights violations and suffrage restrictions, which only began to be resolved in the mid-twentieth century, to the widening income gap between the poor and rich into the early twenty-first century, inequality continues to pervade many aspects of modern life, including education, employment, housing, healthcare, and other means for fulfilling life necessities. Those most deeply affected are groups delineated by race or ethnicity, socioeconomic status, immigration status, culture and language, gender, and sexual orientation (Shi, Lee, Haile, et al. 2017; Shi and Stevens 2010). Perhaps the most persistent manifestation of inequality has been the ongoing and, in some cases, growing disparity in health and well-being across these social divisions. Today, it is not unusual to see major health differences between whites and racial or ethnic minorities such as African Americans and Latinos, between the wealthy and the poor, and between the insured and the uninsured. Although the United States spends by far the highest per capita amount on healthcare in the world (OECD 2017, 132–33), it ranks in the middle of the pack in international comparisons of quality of care and health status (Macinko, Starfield, and Shi 2003; OECD 2017, 28, 22; Reinhardt, Hussey, and Anderson 2002).

Recognizing the inefficiencies and injustices created by health disparities, the US Department of Health and Human Services (HHS), through its decennial *Healthy People* publication, has sought to eliminate these disparities (HHS 2010). Similarly, the Institute of Medicine (IOM) published landmark reports in the early twenty-first century, including *Crossing the Quality Chasm* (IOM 2001) and *Unequal Treatment* (IOM 2003), to increase awareness of these issues. Research on the various domains of primary care (accessibility, continuity, comprehensiveness, and coordination) showed that high-quality primary care can reduce the adverse impact of income and racial or ethnic inequality on health (Gaston et al. 2001; Hu et al. 2016; Shi, Stevens, and Politzer 2007; Starfield and Shi 2007). In response to these findings, the federal government launched the health center model as a primary care approach to improving health equity.

The health center model features community, migrant, homeless, and public housing health centers, collectively known as *federally qualified health centers*. They are not-for-profit, community-directed healthcare providers that offer primary and preventive care to predominantly low-income, underserved urban and rural communities, including homeless people, agricultural workers, residents of public housing, and veterans. Health centers are governed by boards composed of at least 51 percent (a majority) health center patients, and these centers have served as a crucial component of the nation's safety net system since the 1980s (HRSA 2017; Hu et al. 2018; Lefkowitz 2007; Nath et al. 2016; Sardell 1988; Shi, Lee, Chung, et al. 2017; Thompson et al. 2018). Today, there are nearly 1,400 health centers operating more than 10,000 service delivery sites in the United States and its territories (HRSA 2017).

In addition to clinical care, health centers provide enabling services, such as transportation, case management, and health education, to facilitate access to care for vulnerable populations (HRSA 2017). As of 2016, nearly 26 million people nationwide (about 15 million more than in 2001) relied on a federally qualified health center for primary healthcare services, including more than 330,000 veterans as well as about 33 percent of people living in poverty, 10 percent of children aged 17 or younger, and nearly 17 percent of rural residents in the United States (HRSA 2017).

Numerous studies have demonstrated that health centers improved access and delivered high-quality, cost-effective care (Frick and Regan 2001; Hadley and Cunningham 2004; Hadley, Cunningham, and Hargraves 2006; Landon et al. 2007; O'Malley et al. 2005; Politzer et al. 2003; Proser 2005; Shi and Stevens 2010; Shi, Stevens, and Politzer 2007; Shin, Markus, and Rosenbaum 2006; Vanderpool et al. 2016). In addition, a number of studies found that patient outcomes and quality of care in health centers were comparable to or better than those in the private sector (Falik et al. 2006; Hicks et al. 2006; Shin et al. 2008; Ulmer et al. 2000). Studies have also been conducted to examine whether health centers were able to overcome health disparities—that is, to narrow the differences in healthcare access, quality, and outcomes across racial, ethnic, and socioeconomic population groups—and have revealed mixed findings so far (Goldman et al. 2015; HRSA 2017).

CASE STUDY 2

VERMONT'S ACCOUNTABLE COMMUNITIES FOR HEALTH LEARNING LAB

The Centers for Medicare & Medicaid Services (CMS) presented the Accountable Health Communities Model as a strategy that "addresses a critical gap between clinical care and community services in the current healthcare delivery system by testing whether systematically identifying and addressing the health-related social needs of Medicare and Medicaid beneficiaries through screening, referral, and community navigation services will impact healthcare costs and reduce healthcare utilization" (CMS 2018).

The Vermont Accountable Communities Model sought to align programs and strategies related to integrated care and services for individuals with prevention efforts throughout the community to improve health outcomes. This effort was carried out in two phases. First, the Accountable Communities for Health (ACH) were defined and core elements were identified through research. Second, the Vermont ACH convened multidisciplinary teams from across the state to explore implementation and community capacity building through the ACH Peer Learning Lab (State of Vermont Health Care Innovation Project 2018a). Using in-person and distance learning methods, the Peer Learning Lab aided participants in increasing their capacity and readiness across nine core elements: (1) mission, (2) multisectoral partnership, (3) integrator organization, (4) governance, (5) data and indicators, (6) strategy and implementation,

(7) community member engagement, (8) communications, and (9) sustainable financing. Findings and lessons learned from the Peer Learning Lab will help inform future state decision making, including infrastructural and resource concerns on multiple levels (State of Vermont Health Care Innovation Project 2017b, 2018b).

The Public Health Institute's (PHI) Survey Research Group and Population Health Innovation Lab collaborated to conduct a formative evaluation of the Vermont ACH Peer Learning Lab project. Ten ACH sites throughout Vermont participated in the Peer Learning Labs (State of Vermont Health Care Innovation Project 2017a). Evaluation measures were collected before and after project completion via web-based, self-administered surveys to assess changes in participants' understanding, ability, and readiness after participating in the Peer Learning Labs (State of Vermont Health Care Innovation Project 2017a).

In postassessment surveys, most respondents agreed that the Peer Learning Labs helped improve their understanding and readiness to implement eight of the nine core elements—all except sustainable financing, for which the findings were mixed (State of Vermont Health Care Innovation Project 2017a). Evaluators also reported that sentiments of confidence and trust in other members and confidence in the ability to achieve goals increased among respondents (State of Vermont Health Care Innovation Project 2017a). Thus, the Peer Learning Lab approach seemed to be an effective strategy for implementing an accountable community for health among Vermont's ACH sites.

Following an overview of health policy research (HPR) in chapter 8, this chapter illustrates methods commonly used in HPR. Examples of both quantitative and qualitative methods are provided.

Quantitative Methods

Quantitative methods in HPR include experimental or quasi-experimental research, survey research, evaluation research, cost–benefit analysis, and cost-effectiveness analysis.

Experimental Research

Since the mid-twentieth century, the purpose of experimental research has been to study causal relationships between independent and dependent variables—by testing hypotheses under predefined intervention settings to either establish a direct link between two factors or measure the magnitude of their association (Broota 1989; Cochran 1957; Kirk 2013). The Learning Point box titled "Causal Relationship" provides the definition and characteristics of causal relationships.

LEARNING POINT
Causal Relationship

An association between variables must have the three following characteristics to be considered a causal relationship:

1. *Statistical association*. Two variables must have a statistically significant relationship, or correlation, for causality to be present.
2. *Sequence of influence*. A clear temporal sequence must exist between the two variables to determine a cause–effect relationship. The causal factor must occur first, before the effect.
3. *Nonspuriousness*. A change in one variable results in a change in another regardless of the actions of other variables. Nonspuriousness can occur when an association or a correlation between variables cannot be explained by any variable other than the two variables of interest.

Essential Elements of Experimental Research

The ultimate goal of experimental research is to enable inferences to be drawn between the independent and dependent variables in particular intervention conditions. Key components of experimental research include (1) experimental and control groups, (2) randomization, (3) pretesting and posttesting, and (4) application of the intervention.

Experimental and Control Groups

The *experimental group* includes those individuals who receive the intervention, while the *control group* includes those who do not receive the intervention (or who receive an alternative form of intervention, such as the status quo).

The main purposes of a control group are to assess the true impact of the service or intervention being studied and to account for possible effects on the outcome from participation in the experimental intervention. In social science experiments, control groups are also used to account for factors or events occurring outside the experimental setting. In this case, both experimental and control groups are subject to the effects of outside events, but the control group helps account for potential biases and determine the true effects of the experiment. Although, ideally, subjects within the control group should be as similar as possible to those in the experimental group in all key characteristics except receipt of the experimental intervention, in reality the degree of similarity varies between groups. As defined by pioneering researchers Fitz-Gibbon and Morris (1987), control groups are either *true control groups* (made equivalent by random assignment, generally ensuring a nonbiased distribution of the various characteristics) or *comparison groups* (nonequivalent in terms of assignment—i.e., assigned in a nonrandom way).

Randomization

Randomization refers to the allocation of a set of subjects to either an experimental or a control group by means of some procedure that is not biased against any individuals in the set. Under the ideal randomization method, each subject has an equal chance of being assigned to either group.

In a pure experimental design, random sampling (as described in chapter 8) is used to select a representative number of study subjects from a target population to ensure that study results are generalizable to the population. Randomization procedures are then used to allocate each member of the sample to the experimental group or the control group, thereby ensuring internal validity of the study. Randomization also eliminates potential bias from self-selection, taking into account that people who volunteer for a study likely differ from those not choosing to volunteer. Randomization is the most effective way to eliminate alternative explanations of an intervention effect, because it helps account for a variety of characteristics (including those not explicitly captured in the study itself) that may otherwise influence study results.

Pre- and Posttesting

Experimental and control groups are typically tested or observed before (pretest) and after (posttest) the intervention at identical points in time, as explained in the classic work by Fitz-Gibbon and Morris (1987). Pretest and posttest results are then compared to assess the impact of the intervention. In the simplest experimental design, a single pretest measurement is taken prior to the subjects' exposure to an intervention and a single posttest measurement is taken following the intervention.

Researchers may make additional observations while the intervention is taking place to measure the impact of the intervention over time. Similarly, a series of measurements or tests may be conducted after a program concludes to measure the long-term impact—called a *time series test* if measurements are taken at equal time intervals before and after the program. Often, a time series test can eliminate the need for a control group because results from pretests may project the outcome without the intervention.

independent variable
The variable representing the treatment, characteristic, exposure, or other intervention that is being examined to determine its effect on the dependent variable.

dependent variable
The variable that is examined to determine whether its observed value changes when the independent variable is present or when exposed to the independent variable.

Application of the Intervention

The main **independent variable** in an experiment typically takes the form of the experimental stimulus, or intervention, that is either present or absent. It is essential that both the independent variable and **dependent variable** be operationally defined for the purpose of the experiment. Examples of common interventions include taking a new therapeutic drug, undergoing a new treatment procedure, becoming eligible for a new service, or responding to a questionnaire that might influence behavior.

Types of Experiments

In the sections that follow, we discuss four types of experiments in which interventions may be applied: (1) laboratory (or controlled) experiments, (2) field experiments, (3) natural experiments, and (4) simulations.

Laboratory Experiments

Laboratory experiments are conducted in artificial settings in which researchers have full control over the random assignment of subjects to treatment and control groups and the application of the intervention. This is the ideal type of scientific experiment; however, laboratory experiments are rarely used in HPR because the ability to randomly assign subjects is limited and the manipulation of interventions by social, economic, or health-related factors causes practical and ethical concerns.

Field Experiments

Health policy studies often employ field experiments, which are conducted outside of laboratories in natural, real-life settings. For example, researchers may study the triage system in emergency departments of urban hospitals, unobtrusively making experimental observations of the normal activities of subjects. Field experiments have high external validity, usually yield generalizable results, and are particularly suitable for applied research focusing on problem solving, because they enable the researcher to gain insight into how complex problems unfold in the real word.

A major weakness of field experiments is the limited control the researcher has over experimental conditions (as compared with complete control in laboratory experiments). Furthermore, because random assignment to study groups may not be possible due to ethical considerations or subject preferences, systematic differences may result between control and experimental groups in participant characteristics and levels of exposure to independent variables and other environmental factors. For an example of a field experiment, see the Research from the Field box titled "Experimental Research: Field Experiment."

Randomization of participants to an experimental or a control group, application of an intervention, and observation of outcomes in a real-world setting are key features of field experiments. Because they examine the real-world impact of an intervention, field experiments are critical to HPR.

RESEARCH FROM THE FIELD

Experimental Research: Field Experiment

HealthPlus, a not-for-profit organization that provides HMO coverage for Michigan residents and employers, initiated a program in 2008 that gave members online access to performance and quality reports on their plan physicians. To examine how effectively the reports helped members select high-quality physicians, researchers from RAND Corporation conducted a randomized controlled field experiment of new enrollees (Martino et al. 2012).

In 2009 and 2010, the researchers randomly assigned new HealthPlus enrollees to either the experimental group or the control group. Each week, the researchers randomized batches of participants who had yet to select a primary care physician, using an adapted coin-flip technique. Participants in the control group were not encouraged to view the online reports, while participants in the experimental group were encouraged to do so. The encouragement—the intervention in this experiment—included a letter from the plan's chief medical officer outlining the importance of the reports and a follow-up phone call. The encouragement intervention was associated with members' selection of higher-rated physicians, indicating that encouragement is a feasible intervention for increasing access to physician data and possibly also quality of physician chosen, although missing data in the reports limited their effectiveness (Martino et al. 2012).

Natural Experiments

Natural experiments are characterized by a complete lack of control over experimental conditions, as compared with field experiments, which retain some level of artificiality (i.e., experiments occur purely for research purposes) and in which researchers have control over the random allocation of subjects to treatment or control groups. In studies such as those assessing the effects of lack of access to care on health status, researchers must often rely on truly naturally occurring events in which different levels of exposure exist.

Simulations

Stokey and Zeckhauser (1978) first defined *simulation*, or *modeling*, as a special type of experiment that does not require subjects or a true intervention. Simulations are dynamic models that operate over a specified period to demonstrate the structure of the system of interest and the effects on system components when one or more of those components are altered. It is a powerful method that enables researchers to artificially observe what a world exhibiting the study factors of interest might look like as it moves into the future, giving users the opportunity to intervene and attempt to make improvements to system performance (Dooley 2002).

The major advantages of simulations are their high economic feasibility (compared with other types of experiments), ability to magnify the visibility of a phenomenon, ability to control and manipulate conditions, and availability as a safe alternative to experimentation that may be dangerous or unethical (Fone et al. 2003). The major downside to simulations is their artificiality. The possibility always exists that a simulation is inaccurate or incomplete and that conclusions garnered from a working model are not applicable to the phenomena of interest. Simulation is thus more useful when a significant amount of empirical knowledge is already available because a model is only as good as its assumptions.

As this discussion demonstrates, trade-offs are inherent in each experimental technique, and in certain situations, a combination of modeling and real-life experiments is necessary. For example, simulation can illuminate the effects of a program's intervention by allowing greater control over certain factors, but field experiments can reveal the degree to which the actual environment may alter the intervention. Policymakers can benefit from using both modeling and studies conducted in the field when examining certain topics of interest (Chen et al. 2009).

Perhaps the best-known health policy experiment is the RAND Health Insurance Experiment. See the discussion of RAND in chapter 3, in the "Private Health Foundations" section, and the first case study presented in chapter 8 on the Health Insurance Experiment for more detailed information about the organization and this experiment. For another recent health policy experiment, see the For Your Consideration box titled "An Example of Experimental Research."

FOR YOUR CONSIDERATION
An Example of Experimental Research

Mobile applications have been increasingly used as crucial tools to deliver health interventions. The purpose of a study by Mummah and colleagues (2017) was to investigate the efficacy of a mobile app, termed the Vegethon Mobile App (which primarily includes goal setting and self-monitoring of vegetable consumption), in increasing daily vegetable consumption among a large sample of overweight adults attempting to maintain weight loss.

The study group consisted of 135 overweight adults living in Stanford, California, who were aged 18–50 and had a body mass index in the range of 28–40 kg/m^2 but were nondiabetic and nonhypertensive and had no cancer or heart, kidney, or liver disease. These subjects were recruited from a 12-month weight loss trial and randomly assigned to either the Vegethon Mobile App group of 68 or a wait-listed control group (told to expect an eight-week delay for the app) of 67. The random assignment procedure ensured that the two groups were similar to each other prior to the Vegethon intervention. Specifically, a researcher who had no contact with participants assigned them to each group using a random, computer-generated allocation

FOR YOUR CONSIDERATION
An Example of Experimental Research *(continued)*

sequence, and communication with the participants was performed by a research assistant who was not informed of their group assignment nor involved in data collection and analysis. The study participants were also not told whether they were in the intervention or control group.

The primary measure was intended to gauge the effect of the app intervention on participants' overall vegetable consumption, using an adapted Harvard Food Frequency Questionnaire. The secondary measure was intended to capture subjects' recall of the number of daily vegetable servings they consumed during the previous 24 hours, through questioning by interviewers who were unaware of which group the subjects had been assigned to, using the Nutrition Data System for Research. The Vegethon app usability and satisfaction were examined using a 21-item questionnaire that was built into the system software. Statistical analyses were conducted using linear regression models to assess the main effect of the app and to investigate the influences of possible effect moderators.

The study findings indicated that daily vegetable consumption was significantly greater in the intervention group than in the control group for both primary and secondary measures. Specifically, the participants who had received the Vegethon app consumed an average of two more servings of vegetables per day than members of the control group did when measured by the Food Frequency Questionnaire. The app users reported consuming an average of one more serving on a daily basis than the control group members did when measured by the 24-hour dietary recall interviews. The study also suggested that baseline vegetable consumption significantly moderated the impact of the intervention in that effects increased as baseline vegetable consumption increased. The Mummah group's study findings implied that theory-based mobile interventions might be an affordable, scalable, and effective approach to support dietary behavior changes among overweight adults.

QUASI-EXPERIMENTAL RESEARCH

Although randomization is crucial for valid experimental results, in many situations (as in HPR), it is not always feasible for practical and ethical reasons. For example, people may object to being randomly assigned to interventions that will significantly affect their lives. In addition, withholding certain interventions from a control group may be deemed unethical. To avoid these issues, researchers may employ quasi-experimental research methods. Quasi-experimental research is similar to controlled laboratory experiments in that researchers are concerned with the effect of a treatment or intervention but do not randomly assign participants to treatment groups. (See the For Your Consideration box titled "An Example of Quasi-Experimental Research" for further insight into this research method.)

FOR YOUR CONSIDERATION
An Example of Quasi-Experimental Research

The Massachusetts 2006 healthcare reform was hailed as a model for the Affordable Care Act for attaining near-universal insurance coverage while increasing access to care. Its effect on population health was less clear. The quasi-experimental research conducted by Sommers, Long, and Baicker (2014) aimed to determine whether the Massachusetts reform was associated with changes in all-cause mortality and deaths from causes amenable to healthcare.

The researchers compared mortality rates before and after the reform in Massachusetts, looking at changes in mortality rates for adults aged 20–64 in Massachusetts from 2001 to 2005 (prereform) and 2007 to 2010 (postreform) versus changes in a propensity score–defined control group of adults in other states. The researchers used all-cause mortality data in age-, sex-, and race-specific cells (n = 146,825) from the Centers for Disease Control and Prevention's Compressed Mortality File (Sommers, Long, and Baicker 2014). Mortalities from causes amenable to healthcare, insurance, access to care, and self-reported health served as secondary outcomes.

The researchers found that the Massachusetts healthcare reform was associated with a significant decrease in all-cause mortality (2.9 percent; $p = 0.003$, or an absolute decrease of 8.2 deaths per 100,000 adults) and in deaths from causes amenable to healthcare (4.5 percent; $p < 0.001$). The decreases were more significant in counties with lower household incomes and higher uninsured rates before the reform. There were also significant increases in insurance coverage, access to care, and self-reported health. The number needed to treat was 830 adults obtaining health insurance to prevent one more death per year. In summary, the healthcare reform in Massachusetts was associated with significant decreases in all-cause mortalities and deaths from causes amenable to healthcare (Sommers, Long, and Baicker 2014).

matching
The process of ensuring equal representation among experimental and control groups by matching participants or proportions of participants on the basis of selected characteristics.

Because quasi-experimental studies lack the element of random assignment essential to true experimentation (Rossi, Lipsey, and Freeman 2004), researchers must use other methods to ensure some level of comparability between study groups, such as propensity score matching (Austin 2011). **Matching** is a strategy commonly used for the nonrandom assignment of subjects to study groups. Under this approach, researchers attempt to create a control group that is as similar as possible to the experimental group by controlling for one or more major characteristics of the two groups. For example, if demographics are important, researchers select control group subjects on the basis of how their demographic characteristics compare to the experimental group. As a result, the average demographic characteristics of the experimental group (e.g., age, gender, racial composition) are comparable to those of the control group. Characteristics should only be matched if they are expected to affect the outcome of the intervention (if not taken into account in the study design).

Matching ensures some level of similarity between characteristics of the experimental and control groups, other than the intervention, and helps yield more valid findings than would be obtainable from unmatched groups.

Stratified random sampling is a similar strategy that combines elements of matching and randomization and may be employed in studies where the sample size is small and the population is heterogeneous. From a target population, researchers first create **strata** of study subjects who are similar in the characteristics to be matched. Next, subjects are chosen from each of the strata and randomly assigned to the study groups.

stratified random sampling
A random selection of individual subjects from sampling frame subgroups, where each subgroup is made up of individuals who share a characteristic of interest.

strata
Levels into which a population or a sample is divided on the basis of selected characteristics.

SURVEY RESEARCH

The administration of surveys is the most common method of data collection (Houser and Bokovoy 2006; Miller and Brewer 2003) and is used extensively both inside and outside the scientific community for various purposes (Bailer and Lanphier 1978; Dillman and Smyth 2014; Fowler 2014; Miller and Salkind 2002; Singleton and Straits 2017). Its application is also widespread among health policy researchers. Those conducting qualitative research (e.g., case studies, which are discussed later in this chapter) may integrate a survey component into the data-collection process. Researchers conducting experimental research commonly use surveys to collect additional information on the impact of an intervention. Similarly, survey findings are often used in evaluation research to fully assess a program's impact.

Survey research is defined as (1) the use of a systematic method to collect data directly from respondents that are of interest to researchers and (2) the subsequent analysis of the data using quantitative methods. It aims to measure the distribution of certain characteristics or results among a study sample to provide a detailed description of the population.

Survey administration is popular with researchers because it enables a wide range of topics to be covered. It may be used to discover factual information, such as use of healthcare services and their spending, or to ascertain beliefs, opinions, or values, such as satisfaction with care experience and treatment outcome. When properly constructed, surveys can help researchers explore factors associated with a phenomenon of interest and later test a specific hypothesis.

Typically, survey research consists of the following characteristics (Fowler 2014; Miller and Salkind 2002; Singleton and Straits 2017):

- Large and randomly chosen samples
- Systematic instruments
- Quantitative analysis

A large sample of respondents that is randomly chosen from the population of interest produces survey findings that are more representative and generalizable than results from small, nonrandom groups. Survey research uses a systematic questionnaire or interview guide to ask questions of respondents. Questions are carefully considered and written beforehand, and they are asked in the same order for all respondents. Interviewers are trained to present questions with exactly the same wording and in the same manner. Standardization of surveys and their administration is of utmost importance because it enhances data reliability by minimizing measurement error. These principles are illustrated in the For Your Consideration box titled "An Example of Survey Research."

FOR YOUR CONSIDERATION
An Example of Survey Research

The dual aims of this study presented by Bosch and colleagues (2017) were (1) to assess the association between intimate partner violence (IPV) and health risk factors, health behaviors, and poor mental health and (2) to examine potential moderators of the relationship between IPV and health risk factors or health behaviors by using secondary data from the 2005 Behavioral Risk Factor Surveillance System (BRFSS) survey data for the state of Missouri.

The BRFSS is a cross-sectional survey collected via telephone by the Centers for Disease Control and Prevention (CDC) at the state level, which collects data about noninstitutionalized adults aged 19 or older regarding their health behaviors, health conditions, and use of preventive services. The BRFSS includes a core questionnaire for every state but also optional questions (such as questions on IPV). BRFSS data for 2005 were selected for this study because it was the year in which IPV questions were investigated in Missouri. Demographics, IPV, health risk factors, poor mental health, and health-compromising behaviors (including physical inactivity, binge drinking, and cigarette smoking) for 3,110 female respondents aged 18–89 from the 2005 BRFSS were included in this secondary data analysis. In terms of statistical analysis, chi-square analyses were performed to explore the relationship between IPV and demographic indicators, health risk factors, and health behaviors; and logistic regression analyses were conducted to assess the association between IPV and health risk factors, health behaviors, and mental health, adjusted for demographics.

The study results revealed that women with a history of IPV were significantly more likely than women without a history of IPV ($p < .05$) to be overweight or obese, smokers, and binge drinkers, and to report poor mental health. The study also found that demographic variables moderated the association between IPV and obesity, smoking, high blood pressure, and high cholesterol. Women with a history of IPV were usually younger, divorced, and more often unable to work, and those who were unable to work were significantly more likely to be obese and diagnosed with high blood pressure and high cholesterol. These study results implied that clinics, community health centers, and other healthcare settings should provide women who have a history of IPV with appropriate resources to reduce the health-related consequences of IPV.

Survey Types

Surveys may be *cross-sectional* (capturing one point in time) or *longitudinal* (providing a series of observations over a period of time). The **cross-sectional survey** is by far the most commonly used survey design. In a cross-sectional survey, data from a composite representation of respondents that reflect a target population are acquired within a short period.

cross-sectional survey
A descriptive research method used to examine characteristics of a population within a short time frame.

The cross-sectional survey method has two major limitations. First, data collected using these surveys do not reveal causal relationships because the data are acquired within a short and limited period. Second, the risk of bias is inherent in study results because the quality of cross-sectional survey data depends on the accuracy with which individuals recall information.

One example of a cross-sectional survey is the Community Health Center User Survey, conducted by the Bureau of Primary Health Care (BPHC) of the Health Resources and Services Administration. The Community Health Center User Survey collected information on demographics and health status, healthcare utilization, and quality of services received among patients who visit community health centers. All health centers that received BPHC funding and provided primary care at the time the Community Health Center User Survey was administered were included in the survey's sampling frame. The content and sampling strategy of the survey produced a nationally representative snapshot of health centers' characteristics and those of the patients they served.

A **longitudinal survey** follows a single sample, or another similar sample with repeated (at least two) surveys over a specified period. Data may be collected at predetermined intervals (e.g., at three, six, and nine months over a one-year period) or continuously (e.g., monthly over two years). Longitudinal surveys often are initiated when cross-sectional surveys or other sources of data reveal new trends. They enable researchers to investigate questions about causes and consequences associated with the data of interest and form stronger inferences about causal direction, potentially providing a basis that can substantiate theory.

longitudinal survey
A survey administered to the same sample or similar samples at repeated intervals over a predetermined length of time.

The use of longitudinal surveys is limited by two factors. First, they are relatively expensive to conduct (due to the need for repeated follow-up), and continual implementation requires long-term funding and a secure organizational base from which the researchers can operate. Second, they are prone to **attrition**—the loss of subjects who drop out of the study at some point during the study period. The difficulty with following individuals over time is that the researcher is often left with a smaller subgroup at the completion of the study than at its onset. This subgroup may not be representative of the full population, threatening the validity of the study conclusions. Because of the expense associated with conducting longitudinal surveys, many are designed to be multipurpose, asking a variety of questions related to other topics in addition to a core set of questions addressing the topic of interest.

attrition
Loss of participants during a study that measures outcomes over time.

The two major types of longitudinal surveys are trend studies and panel studies. A **trend study** includes a series of cross-sectional surveys used to collect data on the same items within randomly selected samples of a single population. Trend studies can also take on the appearance of cohort studies when the impact of an intervention or program on a

trend study
A series of cross-sectional studies examining how a characteristic or set of characteristics changes over time through repeated sampling from the overall population.

group is to be studied. A *cohort* is a group of individuals who experience the same significant event within a specified period or who share some major characteristic. See the Research from the Field box titled "Survey Research: Longitudinal Survey, Trend Study" for an example of a trend study.

RESEARCH FROM THE FIELD

Survey Research: Longitudinal Survey, Trend Study

Beginning in 2006, a trend study type of longitudinal survey of clinician attitudes toward the implementation, use, and impact of electronic health record (EHR) systems was administered to a network of health centers participating in Atrius Health, a multicenter group practice (El-Kareh et al. 2009). The objective of the longitudinal study was to examine whether clinician attitudes toward the use of EHR would change over time. Clinicians, nurse practitioners, and physician assistants practicing at selected health centers that were implementing EHR systems were included in this study. Cross-sectional surveys measuring perceptions of the EHR system were administered to all participants 1 month following EHR implementation and then again at 3, 6, and 12 months following implementation. All participants experienced the same intervention (EHR implementation) and were repeatedly surveyed on the same measures to determine changes over the course of one year.

Most national health surveys sponsored by the federal government are trend studies. One example is the National Health Interview Survey, conducted by the National Center for Health Statistics, which is an annual survey of the US noninstitutionalized population that includes detailed questions on health conditions, doctor visits, hospital stays, and personal characteristics. Analyses of data from the National Health Interview Survey have informed policy decisions on health insurance mandates and programs to increase access to care for vulnerable populations.

A **panel study** follows a representative sample of the group of interest over time by administering a series of surveys. Whereas trend studies focus on variables and their changes over time, panel studies focus on individuals and how they change over time. For example, the Medical Expenditure Panel Survey, conducted by the Agency for Healthcare Research and Quality and the National Center for Health Statistics, is a well-known panel study used to collect information on the financing and utilization of medical services in the United States. The Medical Expenditure Panel Survey consists of three major components: the Household Component (which collects medical expenditure data at the personal and household levels), the Medical Provider Component (which surveys medical providers and pharmacies identified by household respondents), and the Insurance Component (which collects data on health insurance plans obtained through employers in both the public and private sectors).

panel study
A study in which data are collected repeatedly over time within the same sample selected from the overall population to examine how individuals change over time.

EVALUATION RESEARCH

Evaluation research is most often used in HPR for needs assessment; program planning, monitoring, and improvement; and policy implementation (Ammerman, Smith, and Calancie 2014). When researchers apply evaluation research to program monitoring and improvement, they are usually interested in assessing the effectiveness of the program in terms of its implementation, components, participation, cost-effectiveness, and areas for improvement. In contrast to program monitoring and improvement, which assess a program in one particular setting, evaluation research performed for policy implementation is intended to assess how well a policy can be applied to other settings (Bissell, Lee, and Freeman 2011). Investigators who engage in evaluation research are typically interested in studying organizational cultures, target populations, resources, financing, or effects on communities.

Evaluation research is most useful when resource constraints exist and the need arises to prioritize problem areas and select those programs that can most effectively and efficiently address health or social problems.

It is also a key methodology by which to fulfill funding requirements. For example, evaluation of health programs and policies is often required to receive funding (CDC 1999), and to that end the Government Performance and Results Act of 1993 mandates that federal agencies set performance goals and measure results. Private sources of funding routinely require performance evaluations as well.

Evaluation research is a form of systematic, applied research conducted to assess programs and policies or their components (Rossi, Lipsey, and Freeman 2004). When used in HPR, evaluation is performed on a particular product (e.g., therapeutic drug), service (e.g., family planning), or health or social problem (e.g., lack of access to healthcare) to study policy or program components, operation, overall impact, or generalizability to other settings and populations.

A hallmark of evaluation research is the objectivity with which it is performed. Typically, an outside investigator who has no involvement in the implementation of the program or policy is charged with conducting an evaluation through the following steps:

1. Determine the scope of evaluation.
2. Become acquainted with the program.
3. Choose the methodology for evaluation.
4. Collect the data.
5. Analyze the data.
6. Report findings.

Often, working with the program or policy sponsor and staff, an investigator delineates the general purpose of the evaluation, specific components to be assessed, goals and objectives of the evaluation, study design, and evaluation budget. In addition, an investigator may outline the respective roles of researchers and staff in conducting the evaluation and delegate the responsibility for distributing evaluation results to an appropriate research team member (Nelson et al. 2011).

When choosing a study design for evaluation research, both quantitative and qualitative methods may be used, depending on the goals of the evaluation. Quantitative approaches (e.g., administering surveys, extracting information from administrative records) are used to measure, summarize, and analyze outcomes or effects and to generalize program or policy results to a population. Qualitative approaches (e.g., conducting focus groups) can offer another dimension through which to get context-rich and in-depth understanding of a program or policy, uncover nuances that may not be captured by quantitative data methods, or identify unanticipated outcomes (Brownson et al. 2010; Tolley et al. 2016).

Whether using one or both of these approaches, the following measures are typically examined:

- Participant characteristics
- Characteristics of the program structure or context that might affect the intervention (e.g., staff characteristics, organizational setting, environmental impact)
- Characteristics of program implementation or processes (e.g., types of intervention, activities, staffing, resources)
- Characteristics of program outcomes, both long-term and short-term (e.g., measures of program goals and objectives, including health status, condition, knowledge, satisfaction, behavior changes, and unanticipated outcomes—positive and negative)
- Costs and benefits associated with the program and outcomes

Types of Evaluation Research

The main types of evaluation research are needs assessment, process evaluation, and outcome evaluation (Brownson et al. 2010; Patton 2002; Rossi, Lipsey, and Freeman 2004).

Needs Assessment

The purposes of a needs assessment are to identify areas of weakness or deficiency (i.e., needs) in a program that can be remedied and to anticipate future conditions to which a program might need to adjust (Huber et al. 2015).

Needs assessments can be performed at the individual, organization, or community level (Brownson et al. 2010; Huber et al. 2015). Data for a needs assessment can be obtained from a variety of sources and are used to identify and prioritize problems and determine which outcomes to pursue.

In an organizational needs assessment, investigators focus on the key components of a program to identify any problems, such as the absence or inadequacy of necessary services, a lack of efficiency, or the delivery of ineffective or superfluous services. Investigators must also carefully consider the effects of proposed solutions on compatibility with program objectives, staff, clients, and finances. Ultimately, it is the responsibility of the investigator, working with evaluation sponsors and program staff, to account for the consequences of alternative solutions and select the one that offers the greatest net benefit.

A community needs assessment is more expansive than an organizational needs assessment in terms of the scope of issues that must be considered. Investigators must examine the social, medical, and health characteristics of the population and understand its relationship with the community's health system. When conducting a community needs assessment of vulnerable populations, common problems include gaps between services and needs, a lack of knowledge of programs on the part of providers and patients, a lack of coordination between health entities and providers, poor patient education, and inappropriate distribution of necessary services.

RESEARCH FROM THE FIELD

Evaluation Research: Community Needs Assessment

Following the World Trade Center terrorist attacks on September 11, 2001, a community needs assessment was done to assess the health status and use of mental health services by New York City residents (Boscarino, Adams, and Figley 2004). To collect data, the researchers conducted a telephone survey of 2,368 adults selected through the use of random-digit dialing. Participants were asked a series of questions measuring service utilization, medication usage, mental health status, and general health status. Researchers also asked participants a series of questions regarding their demographic background and social support networks. By examining participants' demographic, social, and health characteristics, the researchers were able to identify gaps in service use among resident subpopulations.

Community needs assessments can be especially useful for policymakers. One example is an assessment conducted in Louisiana in 2004. Researchers investigated tobacco use among ninth-grade students in south-central Louisiana by surveying more than 4,800 students about their tobacco habits (Johnson et al. 2004). The study team confirmed self-reported survey results by collecting saliva samples from a subset of students. According to the study, more than half of all the participating students reported smoking a cigarette at some point; additionally, researchers were able to identify which racial or ethnic groups contained students most likely to smoke and what types of social relationships and attitudes were associated with smoking. The results from this community needs assessment provided state lawmakers with real-world evidence to guide tobacco-control efforts, focusing on policies and funding of programs targeted toward smoking prevention and cessation among youth. See the Research from the Field box titled "Evaluation Research: Community Needs Assessment" for another example.

Process Evaluation

The purpose of a process evaluation is to monitor and improve ongoing program delivery or policies. A process evaluation usually considers the components that are essential to the implementation and success of a program. For example, it may be used to assess operations by studying the staffing structure, budget, critical activities and services, and administration of a program. It may also be used to ensure that resources are being allocated in the proper and most efficient way or that a program is compliant with legal and regulatory requirements (Rossi, Lipsey, and Freeman 2004; Moore et al. 2015).

The researchers Rossi, Lipsey, and Freeman (2004) noted the abilities of process evaluation to

- help investigators assess the efficiency with which program administrators carry out their day-to-day activities and identify ways to enhance the efficiency;
- help investigators identify unexpected problems with program implementation;
- provide evidence to funders, sponsors, and other stakeholders that a program is being implemented according to predetermined goals and objectives;
- help researchers monitor costs and resource expenditures associated with a program—information that can be crucial for conducting cost–benefit analyses; and
- serve as a prerequisite for planning and conducting an outcome evaluation of a program or policy.

Outcome Evaluation

The purpose of an outcome evaluation is to examine the impact and effectiveness of a service, program, or policy in order to inform its planning and implementation (Kozica et al. 2015; Lee et al. 2018). Program results are compared with either the status quo or an alternative program with similar goals. To complete an outcome evaluation, a researcher must address many aspects of a program by understanding how its goals and objectives are measured, how its essential components are related to achieving those goals, and how its level of success in accomplishing its intended results can be measured. With this information, the program can be compared with an alternative. After changes that may lead to increased attainment of goals and objectives are identified, a final decision can be made on whether to continue, expand, or modify a program.

Common outcome measures seen in the public health literature include health status, health-related behaviors, performance (e.g., smoking cessation), and effectiveness (e.g., participants' satisfaction on completion of a program). Measures of health outcomes can include short-term outcomes such as attitudes, knowledge, and beliefs; intermediate outcomes such as health-related behavior and access to care; and long-term outcomes such as mortality and morbidity as well as physical function, mental well-being, and other aspects of quality (Lee et al. 2018).

A variety of structured instruments are available for assessing many dimensions of health status, such as measures for general health, pain, social health, and quality of life. These instruments are listed in the Research from the Field box titled "Health Status Dimensions Assessment Instruments."

Outcomes research at the patient level, also known as **medical outcomes research** or *effectiveness research*, has grown in importance with the increases in therapeutic options available to patients, their healthcare costs, and the need for healthcare reform. This research typically focuses on the most prevalent or costly medical conditions for which more cost-effective alternative clinical strategies or pathways may be available. As explained in a classic paper by Guadagnoli and McNeil (1994), at the patient level, outcomes research involves linking positive and negative outcomes to the type of care (e.g., drug therapies, surgical procedures, diagnostic care, preventive care, rehabilitative care) received by a variety of patients with a particular condition to identify what treatment works best for which patients.

RESEARCH FROM THE FIELD

Health Status Dimensions Assessment Instruments

The following are examples of assessment instruments used to determine a variety of health status dimensions, along with the names of these instruments' creators. See the reference citations that accompany each assessment for more information.

- Four Single Items of Well-Being: Andrews and Grandall (1976)
- McGill Pain Questionnaire: Melzack (1983)
- Medical Outcomes Study: Riesenberg and Glass (1989); Tarlov et al. (1989)
- Nottingham Health Profile: Hunt and McEwen (1980); Hunt, McEwan, and McKenna (1985)
- Quality of Life Index: Spitzer, Dobson, and Hall (1981)
- Sickness Impact Profile: Bergner et al. (1976, 1981)
- Social Health Battery: Williams, Ware, and Donald (1981)

Both the public and private sectors are interested in outcomes research focusing on measuring health-related outcomes and their predictors. In both sectors, payers are responsible for controlling spending and helping to improve quality of care. This responsibility can be fulfilled in part by allocating resources to treatments that are known to be effective, making outcomes research invaluable to both policymakers and payers.

medical outcomes research
Research that examines the comparative effectiveness of available treatments for a patient with specified characteristics.

Results from outcome evaluations can also enable sponsors to decide whether to continue, expand, or reduce the scope of programs or policies by providing information on the financial implications of the alternative clinical strategies.

Such studies are key drivers in the continued support and funding of the nation's health center network (see the first case study at the beginning of this chapter). Community health centers receive a significant portion of their operating budget from the federal government, and outcome evaluations have shown that these health centers provide high-quality, cost-efficient primary and preventive healthcare (Falik et al. 2006; Jones, Zur, and Elam 2016; O'Malley et al. 2005; Shin, Markus, and Rosenbaum 2006; Stevens 2016). In addition, outcome evaluations have shown that expansion of the health center network is a promising strategy for reducing racial and ethnic disparities in health and healthcare (Earnshaw et al. 2013; Greene and Dawson 2016; Marino et al. 2016; Shi and Collins 2007; Shi, Tsai, and Collins 2009; Shi et al. 2004).

Strengths and Weaknesses of Evaluation Research

The major strength of evaluation research is its potential for making an impact on policy. Findings from evaluation research can lead to improved design and implementation of health programs and interventions in public health. Evaluation research offers practical and tangible evidence for policymakers and other decision makers to act on.

Evaluation research can, however, suffer from selection bias and differential attrition rates (i.e., subjects drop out of each study group at varying rates) due to an inability to randomly assign subjects to study groups. In addition, results from evaluation studies often have limited generalizability—that is, the success of a particular program or policy may not be guaranteed in other environments or settings. Finally, time constraints, financial constraints, and an unfavorable political climate are limitations that can affect the scope and depth of program evaluation.

The For Your Consideration box titled "Two Examples of Evaluation Research" illustrates some strengths and limitations of this type of research.

FOR YOUR CONSIDERATION

Two Examples of Evaluation Research

Outcomes Research

Evidence indicates that health promotion programs can help people with disabilities better manage their secondary health conditions. However, access to those programs is limited for people who are unemployed or people with disabilities who live in rural areas. The Health Plans to Employment (HPE) program consists of low-cost interventions that can be remotely delivered to people with disabilities through electronic means. The purpose of a research study by Ipsen and colleagues (2014) was to assess the comparative effectiveness of three variations of the HPE program that were given to a Factsheet group (to receive a series of four electronic fact sheets), an HPE group (to receive access to an online interactive health promotion website), and an HPE+MI group (to receive the online health promotion website access plus two motivational interviewing calls) for improving health in a sample of vocational rehabilitation (VR) consumers.

Study participants were recruited from two state VR agencies in Washington and North Carolina. The agency personnel mailed recruitment postcards to 600 randomly selected consumers who were aged 21–65 and had a primary physical disability. The postcards asked about their interest in this internet-based health promotion program and outlined inclusion criteria; thus, participants all volunteered to be in the study. Among the 142 participants from Washington and 80 participants from North Carolina, each person was randomly assigned to one of the three groups (Factsheet, HPE, or HPE+MI). Data on health and health behavior outcomes were collected before the three interventions began and again at two, four, and six months into the interventions. The primary outcomes variables included the Sum of Secondary Conditions Surveillance Instrument measures of the prevalence and severity of 32 secondary health conditions (e.g., fatigue, weight, depression, urinary tract infection); the Behavioral Risk Factor Surveillance System Health-Related Quality of Life Module measures of the prevalence

FOR YOUR CONSIDERATION
Two Examples of Evaluation Research *(continued)*

of health problems; and the Health Promoting Lifestyle Profile II measures of the six dimensions of lifestyle behavior (e.g., physical activity, nutrition, interpersonal relations). Data were analyzed using repeated measures analysis of variance to compare changes over time.

Contrary to the researchers' hypothesis, the study results did not find differences between the Factsheet, HPE, and HPE+MI groups based on intervention intensity. Participants in all groups experienced statistically significant reductions in secondary health conditions ($p < .001$) and health-related quality of life symptom days ($p < .004$) and significant improvements in health-related behaviors ($p < .017$) over six months.

Policy Analysis

As presented in a study by Kehler and Hahn (2016), Kentucky has had one of the highest smoking rates of all states in the United States. Particularly, exposure to secondhand smoke (SHS) has led to significant public health and financial burdens (smoking-related illness and smoking-attributed productivity cost) on Kentucky. Evidence showed that comprehensive smoke-free laws are the most effective approach to fully protect people from exposure to SHS. In 2010, the comprehensive smoke-free legislation that bans smoking in public places and employment settings was introduced in the Kentucky House of Representatives. However, the comprehensive smoke-free bill named HB145 in 2015 (similar to bills filed in the previous four years) failed to receive a hearing in the Kentucky Senate after passing the House with amendments that significantly weakened it. Kehler and Hahn conducted a policy analysis of HB145.

The researchers used Kingdon's three streams model for agenda setting (see, e.g., Kingdon 2011) to guide the analysis of the legislation and to illustrate how and why HB145 failed to pass into law. The Kingdon model consists of three independent streams: problems (which come to the attention of the government and public attention), policies (policy communities develop alternatives and policy proposals), and politics. Specifically, the Kehler and Hahn (2016) study focused on the leadership team, the context of partisanship, and the supporting and opposing business and organizations of the smoke-free legislation. In the problem stream, the researchers evaluated the components of indicators and focus events, feedback, and problem definition. In the policy stream, the researchers examined the criteria of policy communities, survival criteria, the short list of ideas, available alternative, fiscal impact, and unintended consequences. In the politics stream, the factors of state mood, organized forces, consensus building, and coupling were assessed in analyzing the failure of HB145.

The policy analysis found that smoke-free legislation in Kentucky obtained public support and was feasible, but policymakers were divided on whether the issue should be determined at the state level or by the individual business owners. The failure of HB145 was strongly associated with partisanship, fragmentation of advocacy groups when amendments were made to the bill, lack of political negotiation and compromise, and conflict of values (Kehler and Hahn 2016).

Key Health Services Evaluation Studies

Examples of important evaluation research for the health services abound in the literature. One of the most notable is the Women's Health Initiative, which evaluated the health risks and benefits of hormone replacement therapy (HRT) for postmenopausal women (Writing Group for the Women's Health Initiative 2002). For decades, HRT was routinely prescribed to this population to help prevent coronary heart disease, despite the lack of evidence of its long-term effects. Beginning in 1993, the Women's Health Initiative conducted a rigorous randomized controlled trial that enrolled more than 16,000 women to assess the associations between HRT and coronary heart disease, breast cancer, stroke, pulmonary embolism, endometrial cancer, colorectal cancer, and hip fracture. After approximately five years of follow-up study, the trial was abruptly halted in response to the finding that women using HRT experienced unacceptably high rates of invasive breast cancer.

COST–BENEFIT ANALYSIS AND COST-EFFECTIVENESS ANALYSIS

Cost–benefit analysis (CBA) and cost-effectiveness analysis (CEA) are methods used to analyze or ascertain the efficiency and impact of programs. These analyses, each of which is a type of **efficiency analysis**, are particularly useful when evaluating policies or programs and when considering alternative programs. The following paragraphs provide definitions of CBA and CEA (Rossi, Lipsey, and Freeman 2004), and exhibit 9.1 compares the methods on the basis of key characteristics.

efficiency analysis
Thorough examination of the overall direct and indirect costs and benefits of an intervention; can be used to compare interventions or programs that have similar goals.

CBA is a type of efficiency analysis in which a program's benefits are compared with its costs (direct and indirect) in monetary terms. The benefits and costs may be projected into the future, or the future benefits and costs may be discounted to convert them into their present values.

CEA is a type of efficiency analysis in which a program's benefits are compared with its costs, but only the costs of the program are monetized. Program benefits in CEA are expressed in outcome units, such as the quality-adjusted life year, which measures quality or desirability of a health state for the duration of survival (Haddix, Teutsch, and Corso 2003). CEA is often used to compare the efficiency of programs that share similar goals and outcome measures.

Because both CBA and CEA provide insight on efficiency levels of programs, these analyses are both crucial for decisions related to planning, implementing, continuing, and expanding health programs. Resource constraints force program directors to measure programs' effectiveness to determine whether they should be continued. See the Research from the Field box titled "Cost-Effectiveness Research" for an example of research using CEA.

QUALITATIVE METHODS

Qualitative research can serve as a critical complement or an alternative to quantitative research. It is particularly useful as an exploratory study method when little is known about

EXHIBIT 9.1
Comparisons Between Cost–Benefit Analysis (CBA) and Cost-Effectiveness Analysis (CEA)

Steps	Considerations	CBA	CEA
Specify the accounting perspectives to influence what items are chosen and how items are valued	Decide whether to consider costs and benefits from the perspective of program participants, the program sponsor/funder, or society as a whole	√	
Identify costs and benefits	Include all relevant cost and benefit components to ensure valid results	√	√
Measure costs and benefits (in terms of a common monetary unit) and specify measurement method	Consider opportunity costs (to reflect alternative ways that resources can be used) and externalities (unintended spillover consequences)	√	√
Value costs and benefits; compare total program costs to total program benefits	May employ discounting, a technique used to reduce costs and benefits that are spread out over time to their present or future values	√	√
Assess effectiveness of the program and compare results to similar programs	Measure program benefits in terms of whether the program reached its substantive goals		√

Sources: Adapted from Blaney (1988); Drummond et al. (2015); Patrick (1993); Pearce (1981); Rossi, Lipsey, and Freeman (2004); Rowland (1995); Stokey and Zeckhauser (1978); Svensson and Hultkranz (2017); VA (1989); Veney and Kaluzny (2005).

RESEARCH FROM THE FIELD

Cost-Effectiveness Research

The Health Disparities Collaborative (HDC) is a program that was initiated by the BPHC to improve the quality of care for chronically ill patients receiving primary care services at Health Resources and Services Administration (HRSA) health centers. Various HDCs have been established to focus on specific chronic conditions. To examine the efficiency of the Diabetes HDC, researchers conducted a cost-effectiveness study of the program, using data collected between 1998 and 2002 on 80 randomly chosen patients with diabetes from selected health centers (Huang et al. 2007). The data included information on patient demographics and receipt of services as well as clinical information. Using these data and a simulation model, the researchers determined the resulting *quality-adjusted life years* (QALYs) and the costs associated with the patients' treatments. The QALYs and costs were then compared to determine the cost-effectiveness of care received through the Diabetes HDC.

a program or its outcomes. In contrast to quantitative research, in which numbers represent the bulk of an analysis, qualitative research focuses on observations and analyses made from concepts identified in open-ended responses and statements from participants.

The goal of qualitative research is to gain individual accounts of actions, knowledge, thoughts, and feelings. The focus of qualitative research is not to generalize findings to predict future events but, rather, to provide context-rich information and gain in-depth understanding of a particular research problem (Petty, Thomson, and Stew 2012a, 2012b). Researchers attempt to understand the perspective of a program insider by capturing the participants' view of reality and their perceived experiences. By examining the program from this perspective, qualitative researchers hope to gain insight into a complicated event or problem.

TYPES OF QUALITATIVE RESEARCH

Many types of qualitative methods are used in research (Isaacs 2014). In fact, a number of terms are commonly applied to qualitative research methodological approaches (Patton 2002). For example, qualitative research is often referred to as *field research* because it often takes place in a natural social setting to allow researchers to directly and closely interact with subjects and situations under study.

The three most widely used qualitative approaches are participant observation, in-depth interview (including focus groups), and case study (Babbie 2006; Patton 2002; Petty, Thomson, and Stew 2012a; Singleton and Straits 2017; Yin 2003).

Participant Observation

Direct participation and close observation are critical methodologies by which to understand a program, enabling researchers to go beyond the selective perceptions of others and experience a program firsthand. Qualitative observation differs from other forms of scientific observation, because it takes place in a natural setting (rather than a controlled setting or laboratory) and requires the researchers to be physically present for direct observation (rather than participating in an indirect capacity, such as through a survey). Participant observation generally involves fieldwork, which allows the researchers to experience the lives of the people they are studying as much as possible.

Often referred to as *observational research*, participant observation allows researchers to become part of the group or setting of interest. Participation can either be *open*, with investigators making known their role as researchers, or *disguised*, with only group leaders or the heads of organizations being made aware that the observation is taking place. The selection of open versus disguised participation depends on whether the knowledge that an observer is present would be expected to significantly alter the usual behavior of the participants.

As participants, researchers pay close attention to the physical, sociocultural, and human environment; formal and informal interactions; and unplanned activities surrounding the topic under study. By directly observing activities and operations within the research setting, researchers gain a better understanding of the context and process of the study environment.

In-Depth Interview

An in-depth interview can take one of three forms: (1) the informal conversational interview; (2) the general interview guide approach, or semistructured interview; or (3) the standardized open-ended interview, or structured interview (Patton 2002).

All kinds of interviews extend along a continuum of structuredness, from highly unstructured to highly structured. The **informal conversational interview** is the least structured of the three types. Often occurring during the course of fieldwork, informal conversational interviews do not include specific predetermined questions or presentation of general topics. The interaction is organic, allowing researchers to spontaneously generate questions depending on the flow of conversation.

The **general interview guide approach or semistructured interview** is in the middle of the structuredness continuum—more structured than the informal conversational interview but less structured than the standardized open-ended interview or structured interview in that it allows the researcher some flexibility while conducting the interview. Under this methodology, a researcher follows an outline listing the issues to be explored during the interview; however, the interviewer's approach to raising the issues is unstructured, and the questions asked are open-ended and vary in length. The outline ensures that no major issues are omitted. The general interview guide approach or semistructured interview often yields new findings that may determine subsequent interview questions. It also allows the interviewers full control over what they seek from the interview but not excessive control of the interview flow.

The **standardized open-ended interview or structured interview** is the most structured of the three in-depth interview types—at the opposite end of the spectrum from the informal conversational interview. The interviewer follows a set of explicit instructions and uses a questionnaire that contains a set of carefully worded and ordered questions. Each respondent is asked the same set of questions in the same sequence. Although the standardized open-ended interview or structured interview affords the researcher less flexibility and spontaneity than the other two types, it minimizes variation in the questions asked and thus reduces the potential bias introduced by the interview process.

In-depth interviews may be conducted with an individual or a group of individuals. The latter is often referred to as a focus group study or, simply, **focus group**. Focus groups are conducted to gather in-depth knowledge about individuals' attitudes, perceptions, and opinions regarding a specific topic (Clow and James 2014). A focus group typically consists of 8 to 12 people who are brought together to engage in a guided discussion of a topic (e.g., see the For Your Consideration box titled "An Example of Qualitative Research: Focus Group"). Participants are selected on the basis of their experience with the topic rather than through the use of probability sampling methods, as in experimental and quasi-experimental research.

informal conversational interview
A face-to-face in-depth interview, conducted in person during observational studies, that does not adhere to a prescribed set of questions.

general interview guide approach or semistructured interview
A method of conducting an in-depth interview that provides an outline of issues that the interviewer must explore but allows the interviewer flexibility with regard to the type and order of questions asked.

standardized open-ended interview or structured interview
An in-depth interview that is conducted by a researcher asking each respondent the same set of predetermined open-ended questions, recited verbatim in a specified order.

focus group
A small group (8–12 people) whose reactions to a given topic are studied to provide an in-depth understanding of the topic.

FOR YOUR CONSIDERATION

An Example of Qualitative Research: Focus Group

The college or university years represent a critical period for potential unhealthy lifestyle changes in eating behaviors among students. The purpose of this study conducted by Deliens and colleagues (2014) was to explore which factors influenced the eating behavior of Belgian university students, using a qualitative research design centered on focus groups.

Participants were asked to complete a questionnaire beforehand about their demographics, height, weight, and perceived health. Then, based on a semistructured interview guide, five focus group discussions were conducted with 36 university students ranging in age from about 18 to 22 and coming from a variety of academic disciplines. The students were asked to share their thoughts and ideas for health promotion and interventions to counter unhealthy eating behaviors. The focus group moderator (interviewer) also asked additional side questions about these topics, with flexibility to encourage open discussions and more in-depth answers.

During subsequent data analysis, the students' statements were examined for recurrent themes, which were grouped by coding (content analysis) into general concepts (subcategories) and then into main categories. To ensure reliability, two rounds of analyses of the data were carried out independently by two researchers, and disagreements were discussed with two other researchers until consensus was reached.

Students reported that they were influenced by individual factors, social networks, the physical environment, and society in making their food choices. Furthermore, these influences on the students' eating behavior seemed to be moderated by university characteristics, including residency, student societies, campus lifestyle, and exams. Recommended actions for university administrators and researchers included the following:

- Providing students with information and advice to enhance healthy food choices and preparation
- Encouraging students' self-discipline and self-control
- Helping students develop effective time-management skills
- Enhancing students' social support
- Changing the campus food environment by offering healthful foods at lower prices than unhealthful food and by stocking vending machines with more healthful products

This was the first European study to examine the perceived determinants of eating behavior in university students and to collect ideas and recommendations for healthful eating interventions in a university setting. University characteristics influenced the effect of individual and social environmental determinants on students' eating behavior. These findings should be considered when designing multilevel intervention programs to improve healthful eating behaviors in university students.

Conducting a focus group can be an efficient way to gather information that would be difficult to capture through a survey or an individual interview, because a focus group establishes a context for the perspectives of its members and allows researchers to assess whether these perspectives are consistent among the target population. Focus groups are often used to assess outreach efforts of programs and policies, such as health insurance coverage programs aimed at vulnerable populations (Jones et al. 2016). In addition, data obtained through focus groups are useful to inform future quantitative research, such as questionnaire development.

The use of in-depth interviews offers several advantages, including flexibility in how and where an interview is conducted, high validity in interview responses, and low costs (Patton 2002). However, in-depth interviews also have several limitations. Time limits may affect the number of questions asked or issues explored. The less structured formats of the informal conversational interview, the general interview approach or semistructured interview, and the focus group give the researcher minimal control of the group and lead to discussion of irrelevant issues more frequently than when using more-structured methods. Furthermore, data from in-depth interviews can be a challenge to analyze, because the process of conducting and transcribing the interview demands considerable time and intensive training for the interviewers and requires that the investigator remain objective and record the participant's statements with high accuracy to reduce bias (i.e., avoid asking leading questions). See the Research from the Field box titled "Qualitative Research: In-Depth Interviews" for two examples of in-depth interviews.

RESEARCH FROM THE FIELD

Qualitative Research: In-Depth Interviews

Two examples of qualitative research using in-depth interviews are provided here. The first study assessed the capabilities of community health centers (CHCs) in responding to emergency and disaster situations. Researchers conducted a series of focus groups between 2006 and 2007 with CHC staff in New York City (Ablah et al. 2008). Participants were not randomly chosen but instead recruited from among center administrators and medical director members of the Community Health Care Association of the New York State Emergency Preparedness Advisory Committee. They were then assigned to one of three focus groups of 6 to 12 participants each. A predeveloped script of questions was used to direct the conversation toward discussion of New York CHCs' competency in responding to emergency situations and the use of or further need for emergency preparedness training. This method enabled the researchers to gain an

(continued)

RESEARCH FROM THE FIELD
Qualitative Research: In-Depth Interviews *(continued)*

in-depth understanding of the capacity of multiple CHCs and collect information to inform future programming and training.

The second study assessed US older adults' experiences and perspectives of the overuse of healthcare. Researchers conducted focus groups in Baltimore senior centers in 2016. Participants were not randomly selected but instead recruited from among residents aged 66 or older at selected senior centers through flyers soliciting volunteers, using purposive sampling to include those who were representative in race and socioeconomic status. Five focus groups consisting of six to nine participants each were conducted in four senior centers. A predetermined brief questionnaire helped direct the conversation toward discussion of participants' experiences and perceptions, consequences, and factors of healthcare overuse. This method helped researchers to gain an in-depth understanding of healthcare overuse by older adults in the United States and to collect information that informed the construction of a framework to understand and reduce such overuse.

Case Study

A *case study* is an empirical inquiry that draws on multiple sources of data to study a real-world organization or phenomenon (Yin 2003). A case study typically takes place in a single social setting, such as an organization, a community, or an association. Case studies can be especially valuable when the researcher is trying to distinguish between environments, as they can provide rich detail for an in-depth, comprehensive understanding of programs.

The case study method is flexible and diverse; the type and quantity of data collected and analyzed can vary greatly. Researchers typically rely on several methods of data collection, including administrative record analysis, in-depth interviews, structured surveys, and participant observation. Multiple data sources enable researchers to obtain a more complete understanding of issues than a single data source does, which makes case studies useful in both qualitative and quantitative research.

The ways that researchers define *cases* are as diverse as the potential data sources for a case study. Types of cases may include a person, an event, a program, a critical incident, or a community.

During a case study of an individual, interviews are typically conducted over an extended period to obtain detailed accounts of a personal history. Individual case studies are commonly used to study ethnic or cultural groups with distinctive experiences. In addition to the individual's account, interviews of family and friends and observations of relevant settings or events can provide an enhanced picture of an individual's history.

In contrast, case studies that focus on a social entity or group seek to describe certain aspects of community life. For example, a community case study can provide a detailed account of a community's organization and needs for assessing a community-based healthcare network.

A case study may also be conducted for organizations or institutions, such as health services organizations, schools, or regulatory agencies (see the For Your Consideration box titled "Example of Qualitative Research: Case Study" to learn how this research method was used for a governmental public health system). For example, a case study of a health insurance organization may assess its impact on cost and quality of care, while a case study of a political interest group can help measure its influence on health policies.

QUALITATIVE STUDY DESIGN

Similar to quantitative methods, qualitative research should begin with a review of literature and background information so that researchers become familiar with the relevant

FOR YOUR CONSIDERATION

An Example of Qualitative Research: Case Study

According to Jacobson and colleagues (2015), the local health department workforce in the United States decreased by nearly 19 percent from 2008 to 2010. In response, the governmental public health system developed an innovative strategy called Public Health Entrepreneurship (PHE), which applied entrepreneurial skills to supplement public funds with other revenues from other sources. The Jacobson group's study examined the feasibility and desirability of PHE in governmental public health efforts.

The researchers used multisite qualitative case design for their study. Semistructured interviews were conducted at 32 local health departments in 18 states across the United States. Specifically, the respondents included chief health officers and senior management staff, other public health representatives, health authorities, and members of national health organizations. The local health departments were identified through literature review, consultation with experts, and examination of survey data from the National Association of County and City Health Officials. Further sampling identified additional entrepreneurial programs or individuals' contacts. Narrative and descriptive analyses were performed to compare the interview data and documentary evidence across sites.

Generally, respondents identified three PHE practices: strategic planning, operational efficiency, and generation of revenue. Most respondents reported that clinical services were the strongest revenue-generating opportunity; traditional public health services provided inconsistent revenue sources and therefore only limited entrepreneurial opportunities. Some major barriers facing PHE consisted of strict civil service rules, a risk-averse culture, and the primary concern that movement toward profit-oriented PHE strategies would compromise core public health values. These barriers would need to be overcome for PHE to succeed.

population, setting, and issues in a field study. Investigators must also ensure that they can obtain the desired level of access to the study participants and research setting of interest. In qualitative research, investigators often work closely with program administrators and other staff, who are crucial to facilitating access to study participants.

The primary difference between quantitative research and qualitative research is that in the latter, investigators do not attempt to manipulate the research setting. Qualitative study—and thus qualitative study design—depends on the changing nature of the setting. In many cases, the design is not finalized until the major issue of study and potential opportunities and obstacles are identified.

The following paragraphs describe a number of design considerations unique to qualitative study, including the unit of analysis, preliminary sampling procedures, the role of researchers, ethical implications, data collection, and analysis strategy.

Unit of Analysis

In qualitative research, the unit of analysis selected depends on the research goals for the study. Units of analysis may include individuals; groups; incidents or longer-term actions, such as events and activities; or the research setting itself. The unit of analysis in turn determines the researcher's strategies for data collection, analysis, and reporting.

Preliminary Sampling Procedures

The sites and subjects from which the qualitative research investigator can select a sample are typically determined by their availability and accessibility. Researchers must rely on alternatives to probability sampling to choose a sample that is as representative as possible of the population. One such method is **purposive sampling or quota sampling**, which is used to ensure that a small sample of individuals or entities is similar to its target population in terms of important characteristics. For example, for qualitative research of statewide hospital conditions, limitations on funding and other resources may only allow for a few sites to be included. A purposive sampling technique may help researchers choose hospitals that share certain characteristics with average hospitals in the state, such as an urban or rural location, socioeconomic status of the patients in the community, or size. Thus, the use of purposive sampling improves the generalizability of the qualitative research results.

purposive sampling or quota sampling
A nonprobability sampling technique whereby the investigator selects the study sample from among accessible sites or participants to establish proportions of characteristics in the sample that are similar to the proportions found in the population.

Other commonly used qualitative sampling methods are time sampling, typical case sampling, extreme (deviant) case sampling, intensity sampling, and stratified purposeful sampling (Patton 2002). *Time sampling* is based on sampling time periods (e.g., months of the year) or units of time (e.g., hours of the day) and is used when activities are believed to vary significantly from one period to the next. *Typical case sampling* enables the researcher to compile a profile of one or more typical cases to determine the major characteristics of the study. In contrast, *extreme (deviant) case sampling* focuses on atypical cases, providing examples of unusual or extreme situations. *Intensity sampling* uses the most information-rich cases to provide researchers with detailed accounts of events or situations. *Stratified purposeful sampling* combines typical and extreme case sampling to produce samples that fall along an entire spectrum of characteristics.

Role of Researchers

The role of investigators and the degree to which they reveal themselves during the study must be clearly defined during the preliminary stages of a study. The researcher's role may range from solely observation (i.e., the investigator simply watches events) to full participation (i.e., the investigator interacts with the study participants as a member of the group).

Ethical Implications

Ethical considerations are extremely important when designing and implementing qualitative research. Potential risks—such as bodily harm, side effects, legal liabilities, and ostracism by colleagues—must all be taken into account. (Refer back to the discussion in chapter 8 on the ethical framework of HPR.)

Data Collection

In general, qualitative researchers rely on multiple sources of evidence to address a range of issues related to a topic and to validate study findings. As previously described, the most commonly used methods of data collection are observations, interviews, and case studies.

To properly collect data, researchers must be familiar with administering interviews. Even during informal conversational interviews, certain protocols must be followed. Prior to the interview, the interviewer must have a general understanding of the topic and issues under study as well as the type of information being sought. During the interview, the investigator must maintain neutrality by avoiding asking leading questions or expressing personal opinions. Finally, the interviewer must listen to complete, detailed answers while understanding that the interview setting may influence those answers.

Technology is becoming increasingly useful in the data-collection process, which has important implications for qualitative research. First, a larger amount of data for future analysis can be collected by technological means than can be gained manually, allowing for a more comprehensive qualitative study (Peacock et al. 2011). Technology can also facilitate the participation of program staff and support future evaluation efforts.

Analysis Strategy

Through descriptions, field notes, and coding schemes, researchers must not only produce detailed descriptions of subjects' perspectives through anecdotes, examples, and quotes but also further organize these descriptions into a comprehensible framework for analysis.

Descriptions may be organized by the periods and processes they cover, the level of importance to the study, the extent to which they focus on critical events, or the category they fall in within the major unit of analysis.

Researchers are also responsible for explaining and interpreting the participants' actions, activities, and beliefs described and assigning significance to the results, themes, and concepts identified as possible components of grounded theories.

The frequent review and editing of field notes is one way to facilitate subsequent data analysis. The coding can begin with a small segment of data (e.g., interview or observational notes) for which the researcher identifies each unique response, theme, or concept. Coding strategies act as a foundation for analyzing the next segment of data and can be refined with a better understanding of the data. When new categories no longer present themselves during data collection, the researcher can develop instructions for coding. After this step, all of the data should be recoded using the same coding instructions and framework.

Although an exhaustive overview of the approaches for analyzing qualitative data is beyond the scope of this book, two central methods—constant comparative analysis and narrative analysis—are described in the sections that follow.

Constant Comparative Analysis

Glaser and Strauss (1967) first developed the process of constant comparative analysis in their seminal text *The Discovery of Grounded Theory*. The constant comparative process involves comparing pieces of data (e.g., an interview or a statement) to understand the relationships between the distinct pieces of data (Thorne 2000). This method enables the researcher to identify similarities and differences across data sets and develop theories about relationships and patterns that emerge from the data. The use of constant comparative analysis produces an enhanced understanding of a human phenomenon within a specific context, enabling the researcher to develop theories about basic social processes and factors that may account for variation in people's experiences of these processes (Heidari et al. 2016; Thorne 2000).

One example of this type of analysis is a study conducted at the Washington Diabetes Care Center in Seattle by researchers who used constant comparative methods to explore issues of trust and collaboration in the healthcare setting (Ciechanowski and Katon 2006). First, 27 diabetic patients completed a self-reported measurement of "attachment style," which captured the level of trust patients felt toward the healthcare system. The set of patient responses was used to obtain a wide range of attachment styles among the group, allowing for comparisons within the group. Researchers then interviewed the patients, asking questions about their experiences within the healthcare setting and interactions with providers. By comparing the interview results of patients with varying levels of attachment style, the investigators were able to develop theories about how patients with particular levels of trust in the healthcare system could be better served.

Narrative Analysis

Narrative analysis is a process that involves the generation, interpretation, and representation of people's stories (Thorne 2000). Narrative analysis as a method of qualitative research is distinguished by its ability to "highlight the uniqueness of each human action and event rather than their common properties" (Chase 2005, 657). In contrast to constant comparative analysis, which aims to identify similarities across groups, narrative analysis aims to identify patterns and themes within each individual narrative. Thus, rather than create generalizations, the goal of narrative research is to emphasize the uniqueness of each particular narrative and to place it into a broader frame (Chase 2005).

In HPR, narrative analysis can help improve understanding in specific areas such as patients' personal experiences with disease. For instance, noting the small amount of literature that addressed living with lupus (a chronic autoimmune disease) at that time, one researcher conducted a narrative analysis using interview data from lupus patients (Mendelson 2006). Seven women with lupus participated in three interviews, conducted one month apart, and maintained a daily symptom journal. Interviews were also conducted with 23 additional women. Using narrative analysis, the researcher identified patterns and themes within each narrative and noted many overlapping themes across the narratives, such as feelings of uncertainty, a shifting sense of identity, and experiences of financial stress related to living with lupus. This type of research is important in shaping programs and funding therapies both in and beyond the healthcare setting.

ENSURING RIGOR IN QUALITATIVE RESEARCH

In the late twentieth century, Devers (1999) and Bowling (1997) cited several criteria for ensuring the rigor and quality of qualitative research. The research question, theoretical framework, process methods, and context should be clearly defined. The research study design should reflect the researcher's understanding of the implications of choosing a particular sample. Similarly, researchers must choose an appropriate sample size that will ensure that useful information is collected, while avoiding the saturation point, at which similar ideas are repeated by study participants. In fact, qualitative researchers have called for a more rigorous definition of *saturation*, as this concept has been invoked to justify small samples with inadequate data for explanation (Charmaz 2006).

Data-collection methods, data types and sources, and data-analysis methods must also be described and justified. Ideally, an independent investigator should be able to replicate the data collection and analysis in a study to produce the same or similar results. The validity and reliability of qualitative research can also be improved through *triangulation* methods, in which several quantitative and qualitative methods are used together to investigate the same research topic. Other strategies for enhancing the rigor of qualitative research include searching for evidence that may disprove the results, archiving the data, and conducting a peer review.

Finally, researchers must carefully consider the information they and their colleagues present in a final report and how that information may be interpreted by sponsors and other stakeholders. For example, presenting adequate amounts of raw data (e.g., transcripts of interviews) in the final report supports the researcher's claim that interpretations of the data are based on evidence rather than subjective impressions.

KEY POINTS

- Quantitative methods in health policy research include experimental or quasi-experimental research, survey research, evaluation research, and cost–benefit analysis and cost-effectiveness analysis.
- The main difference between experimental and quasi-experimental research is that in the latter, there is no random assignment of participants to treatment groups; thus, researchers must use other methods to ensure that the study groups are comparable.
- Survey research is a popular approach to studying health policy. It provides a systematic way to capture data from a large sample.
- Evaluation in health policy research allows researchers to objectively assess policy or program components, operations, or impacts associated with a particular product, service, or problem.
- Qualitative research is performed to capture and categorize observations and thoughts into cohesive themes and concepts; the most widely used types are participant observation, the in-depth interview, and the case study.

CASE STUDY QUESTIONS

CASE STUDY 1

On the basis of your research of health centers and the fight against health disparities, answer the following questions:

1. What prompted the establishment of health centers in the United States?
2. What services do health centers provide to address health disparities?

CASE STUDY 2

On the basis of your research of Vermont's Accountable Communities for Health Learning Lab, answer the following questions:

1. For what purposes was the Vermont Accountable Communities Model established?
2. What are the core elements that were shown to improve through the Peer Learning Lab?

CASE STUDY ASSIGNMENT

Using one quantitative and one qualitative health policy research method described in this chapter, design a study to examine whether health centers are able to reduce or eliminate health disparities (i.e., differences in access, quality, and health outcomes) across racial or ethnic and socioeconomic subpopulations.

FOR DISCUSSION

1. What methods are commonly used in health policy research?
2. What are the conditions for a causal relationship?
3. What are some types of experimental research and situations in which such methods are most appropriately used?
4. What is survey research?
5. What is the difference between a cross-sectional survey and a longitudinal survey?
6. What is a panel study?
7. What is evaluation research?
8. How would you differentiate among needs assessments, process evaluations, and outcome evaluations?
9. What are the differences between cost–benefit analysis and cost-effectiveness analysis?
10. What methods are commonly used in qualitative research?
11. Through what process is a qualitative study designed?
12. How can rigor in conducting qualitative research be enhanced?

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CHAPTER 10

AN EXAMPLE OF HEALTH POLICY RESEARCH

by Sarika Rane Parasuraman

Research serves to make building stones out of stumbling blocks.

—Arthur D. Little

Without action, almost 400 million people will die from chronic diseases in the next 10 years. Many of these deaths will occur prematurely, affecting families, communities and countries alike.

—Dr. Catherine Le Galès-Camus, Assistant Director-General for Noncommunicable
Diseases and Mental Health, World Health Organization

LEARNING OBJECTIVES

After completing this chapter, you should be able to

- appreciate how health policy research is conducted,
- discuss the determinants of a health problem,
- identify a policy intervention to address the health problem,
- assess the policy intervention, and
- propose next steps in addressing the health problem.

This chapter presents an example of how policy analysis may be applied. It reproduces an actual qualifying examination completed by a student of the Johns Hopkins University Department of Health Policy and Management in 2006. The exam requires students to choose a current public health problem and conduct a policy analysis of it. In the course of the analysis, students must present the determinants of a health problem, identify a policy intervention to address it, assess that intervention, and propose next steps in solving the health problem.

The example is presented as follows: First, the exam questions posed to the student are provided, followed by the sample exam submission. This sample policy analysis was provided by Sarika Rane Parasuraman, a graduate student at the time of the exam's completion, and is used with permission (adapted for editorial style and with additional citations of some supporting sources published since 2006). The health problem she selected was obesity.

QUESTIONS FOR POLICY ANALYSIS

1. Briefly define the nature and scope of the public health problem chosen. Then discuss the most important individual, sociocultural, political, and economic determinants of the problem. Select what you consider to be the most important determinant or combination of determinants of the problem, and defend your choice.
2. Identify one policy intervention (e.g., changes to service delivery, prevention initiative, legislation, regulation, litigation strategy) that has been used or proposed to address the public health problem you chose. Draw from the literature, when possible, to assess the appropriateness, comprehensiveness, and effectiveness of the intervention.
3. For the sample intervention, also discuss the political and economic feasibility of implementing the policy. If considerable resources are needed to implement the program, identify the source (e.g., new taxes, fees, fines, redirected current resources).
4. For the intervention you selected, provide a summary review of previous evaluations, if available. Then you may either describe and critique an existing evaluation or suggest your own evaluation. In either case, articulate the study design, key measures, type of statistical model for your key outcome measure(s), generalizability, and notable strengths and weaknesses. Your answer should include a discussion of the strengths and weaknesses of the evaluation, including its appropriateness, the reliability and validity of key measures used, and an assessment of any threats to the validity of the findings. Be realistic in developing your evaluation plan. Do not assume unlimited resources, and be mindful of standards for ethical research with human subjects.

5. On the basis of your discussion above, propose and discuss the next steps needed in the realms of research, interventions, and policy to address the problem. Of the next steps you identify, select which, in your view, is the most important next step, and justify your choice.

POLICY ANALYSIS: RESPONSES TO EXAM QUESTIONS

QUESTION 1

Introduction

Obesity in the United States is one of the most significant public health problems facing the population. The Centers for Disease Control and Prevention (CDC) estimates that more than 36 percent of adults (aged 20 or older) living in the United States are currently considered obese, with a body mass index (BMI) of 30 or higher—a figure that has steadily risen since the late twentieth century (Ogden et al. 2014). The statistics describing children and adolescents are even more shocking. Since the late 1990s, the proportions of youth aged 6–11 and aged 12–19 who exceeded a "normal" weight had nearly doubled and tripled, respectively (Hedley et al. 2004). Although the prevalence rate has slowed in its ascent, an estimated 17 percent of children and adolescents are "overweight" (BMI for age at 95th percentile or higher)—a figure many experts consider an underestimate (Hedley et al. 2004; Ogden et al. 2016). For the purposes of this paper, *obese* or *obesity* is used to denote all overweight conditions in adults and youth.

Researchers estimate that obesity is responsible for nearly 300,000 deaths per year; this figure will likely grow as obesity prevalence continues to rise in the population (Allison et al. 1999). Obesity could soon exceed tobacco to become the leading cause of preventable morbidity and mortality in the United States (IOM 2012; Sturm and Wells 2001) and may be responsible for reversing the trend of improvements in disability among elderly Americans that began in the late twentieth century (Sturm, Ringel, and Andreyeva 2004). Nutrition, physical activity, and obesity are among the 26 leading health indicators identified by *Healthy People 2020* (HHS 2010), which reinforces the significance of obesity as a public health problem (see exhibit 10.1). Obesity is also a major risk factor for, and has been linked to, the leading causes of death and disability among Americans, including heart disease, certain cancers (particularly colon and breast cancer), stroke, diabetes, hypertension, sleep apnea, pulmonary dysfunction, osteoporosis, hypercholesterolemia, and asthma (Biener and Decker 2018; Bray 2004; National Task Force on the Prevention and Treatment of Obesity 2000; NIH 2013). Obesity experienced prior to adulthood is a significant predictor for these conditions into adulthood (Baba et al. 2007; Freedman et al. 1999; Gurnani, Birken, and Hamilton 2015; Lawlor et al. 2006; Manson et al. 2004; Yanovski and Yanovski 2003). Childhood obesity also has social and economic consequences later in life, particularly for women. One study found that women who were overweight during youth experienced low educational attainment, were less likely to be married, and had higher poverty rates

(Gortmaker et al. 1993). Obese individuals are more likely to suffer the burden of disability throughout life in terms of fewer years free from limitations in their activities of daily living (Peeters et al. 2004). In fact, obesity is a major factor in the rising economic burden on the nation's healthcare system—estimated costs in the United States total approximately $190.2 billion in annual direct and indirect obesity-related medical expenditures (Biener and Decker 2018; Daviglus 2005).

Exhibit 10.1
Healthy People 2020 Objectives Related to Nutrition and Weight Status in Youth

Healthier Food Access

- NWS-1: Increase the number of states with nutrition standards for foods and beverages provided to preschool-aged children in childcare.
- NWS-2: Increase the proportion of schools that offer nutritious foods and beverages outside of school meals.
- NWS-3: Increase the number of states that have state-level policies that incentivize food retail outlets to provide foods that are encouraged by the Dietary Guidelines for Americans.
- NWS-4: (Developmental) Increase the proportion of Americans who have access to a food retail outlet that sells a variety of foods that are encouraged by the Dietary Guidelines for Americans.

Healthcare and Workplace Settings

- NWS-5: Increase the proportion of primary care physicians who regularly measure the BMI of their patients.
- NWS-6: Increase the proportion of physician office visits that include counseling or education related to nutrition or weight.

Weight Status

- NWS-10: Reduce the proportion of children and adolescents who are considered obese.
- NWS-11: (Developmental) Prevent inappropriate weight gain in youth and adults.

Food and Nutrient Consumption

- NWS-14: Increase the contribution of fruits to the diets of the population aged 2 or older.
- NWS-15: Increase the variety and contribution of vegetables to the diets of the population aged 2 or older.
- NWS-16: Increase the contribution of whole grains to the diets of the population aged 2 or older.
- NWS-17: Reduce consumption of calories from solid fats and added sugars in the population aged 2 or older.
- NWS-18: Reduce consumption of saturated fat in the population aged 2 or older.
- NWS-19: Reduce consumption of sodium in the population aged 2 or older.
- NWS-20: Increase consumption of calcium in the population aged 2 or older.

Exhibit 10.1 Healthy People 2020 Objectives Related to Nutrition and Weight Status in Youth *(continued)*

Physical Activity

- PA-3: Increase the proportion of adolescents who meet current federal physical activity guidelines for aerobic physical activity and for muscle-strengthening activity.
- PA-4: Increase the proportion of the nation's public and private schools that require daily physical education for all students.
- PA-5: Increase the proportion of adolescents who participate in daily school physical education.
- PA-6: Increase regularly scheduled elementary school recess in the United States.
- PA-7: Increase the proportion of school districts that require or recommend elementary school recess for an appropriate period of time.
- PA-8: Increase the proportion of children and adolescents who do not exceed recommended limits for screen time.
- PA-9: Increase the number of states with licensing regulations for physical activity provided in childcare.
- PA-10: Increase the proportion of the nation's public and private schools that provide access to their physical activity spaces and facilities for all persons outside of normal school hours (that is, before and after the school day, on weekends, and during summer and other vacations).
- PA-11: Increase the proportion of physician office visits that include counseling or education related to physical activity.
- PA-13: Increase the proportion of trips made by walking.
- PA-14: Increase the proportion of trips made by bicycling.
- PA-15: (Developmental) Increase legislative policies for the built environment that enhance access to and availability of physical activity opportunities.

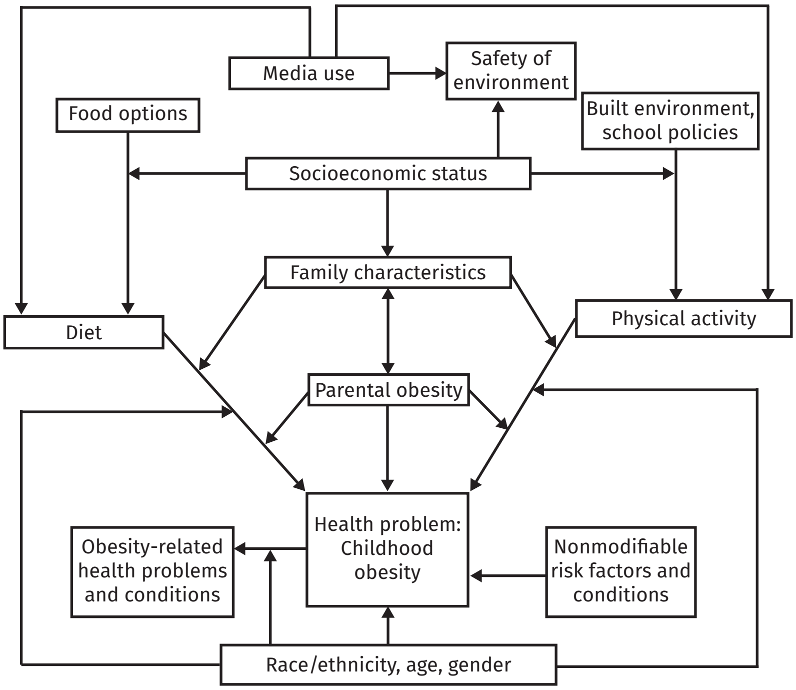
Source: HHS (2010).

Perhaps the most alarming trends are of those conditions newly incident among youth that are traditionally associated with adulthood; for example, pediatricians now report higher incidences of asthma, hypertension, and type 2 diabetes in patients (Din-Dzietham et al. 2007; Luma and Spiotta 2006; Veugelers and Fitzgerald 2005). Obese children and adolescents also experience lower health-related quality of life than their non-overweight counterparts in the form of poor school performance, lower social functioning, poor emotional health, and depression (Sjoberg, Nilsson, and Leppert 2005; Swallen et al. 2005; Williams et al. 2005), although there is some conflicting evidence regarding these associations (Williams et al. 2005). Obesity is a psychosocial, medical, and economic threat to youth, which establishes it (specifically childhood obesity) as a significant public health problem that must be addressed.

Determinants of Obesity

The determinants attributed to childhood obesity are multifactorial and complex. A conceptual framework (exhibit 10.2) has been developed that helps categorize determinants as proximate (biological, demographic, behavioral), midlevel distal (home, neighborhood, school), and macrolevel distal (social, political, economic). Some evidence suggests nonmodifiable causes of obesity that include genetic susceptibility, endocrine disorders, maternal diabetes, and high birth weight (Farooqi and O'Rahilly 2006; Han, Lawlor, and Kim 2010; Mello, Rimm, and Studdert 2003; Plourde 2006). Having one or both parents who are obese is a strong and proven risk factor for childhood obesity and can be considered a proximate and distal determinant (Whitaker et al. 1997). The roles of age, gender, and race or ethnicity on obesity are more consistently proven at the population level, although the exact causal mechanisms are not completely understood (Han, Lawlor, and Kim 2010; Hedley et al. 2004). The prevalence figures between males and females slightly differ. Although in recent years only males have exhibited a significant increase in obesity prevalence, females are more likely to suffer extreme obesity (Manson et al. 2004; Ogden et al. 2016). Significant differences in obesity prevalence by race or ethnicity have persisted over the years. In general, obesity is more prevalent among males and females in minority groups, but gender acts as a modifier of the relationship between race or ethnicity and obesity (Freedman et al. 2006; Ogden et al. 2016).

Exhibit 10.2
Conceptual Model of Proximate and Distal Determinants of Childhood Obesity



Note: Proximate determinants = race/ethnicity, age, gender, unmodifiable risk factors and conditions, diet, physical activity, family characteristics, parental obesity, and media use. Midlevel distal determinants = safety of environment, built environment, and food options. Macrolevel distal determinants = socioeconomic status and school policies.

Proximate determinants also include behaviors, habits, and other lifestyle choices of the individual. Experts generally agree that childhood obesity mostly results from caloric intake in excess of physical activity; as previously shown, this relationship is confounded by nonmodifiable determinants. Thus, the two major behavioral determinants of childhood obesity are physical activity and dietary choices. Both factors are included in the top health indicators identified in *Healthy People 2020* (HHS 2010) and are the focus of a call to action by the US surgeon general (HHS 2001). Just 22 percent of youth aged 6–19 achieve the recommended amount of moderate-to-vigorous physical activity as recommended (National Physical Activity Plan Alliance 2016). Although about 50 percent are enrolled in physical education classes in schools, less than 30 percent regularly attend these classes (Grunbaum et al. 2004). Inadequate physical activity is an undisputed determinant linked to requisite energy expenditure, childhood obesity, and the development of obesity-related health conditions (Duke, Huhman, and Heitzler 2003; Grunbaum et al. 2004; HHS 2001; Plourde 2006; Schneider 2000). Similarly, an unhealthy diet is a proven determinant of childhood obesity (HHS 2001; Mello, Rimm, and Studdert 2003; Schneider 2000), although evidence is mixed regarding whether childhood obesity is due to excessive fat intake or excessive carbohydrate intake (Plourde 2006; Whitaker et al. 1997). One study found a dose–response relationship between the consumption of sugar-sweetened drinks and BMI in children and adolescents (Ludwig, Peterson, and Gortmaker 2001). Although consumption of fruits and vegetables has improved in the twenty-first century, most youth do not consume the CDC's recommended amount of fruits and vegetables (Grunbaum et al. 2004; Kim et al. 2014). Both age and gender are modifying determinants between the aforementioned behavioral choices. Males are more likely to regularly engage in vigorous or moderate physical activity; in contrast, females are more likely to engage in risky behaviors aimed at trying to lose or keep from gaining weight (Grunbaum et al. 2004). The role of media use, particularly screen time and television viewing, has been shown to be a determinant of obesity in children by some researchers (Dietz and Gortmaker 1985; Epstein et al. 2008), yet others have failed to prove such associations (Burdette and Whitaker 2005). Some researchers have proven an association between television use and sedentary lifestyles, reduced intake of fruits and vegetables, and reduced participation in organized sports (Boynton-Jarrett et al. 2003; Dietz and Gortmaker 1985; Robinson 2001). One early study found a dose–response relationship whereby incrementally decreasing television viewing was associated with decreasing BMI in youth (Dietz and Gortmaker 1985). A link between food choices and marketing of high-calorie food and beverages to youth on television has been posited, but little empirical evidence has emerged to support it. Finally, one study showed parental obesity to be a modifier between television use and obesity (Vandewater and Huang 2006), while another showed neighborhood safety to be significantly linked to television use but not directly to obesity (Burdette and Whitaker 2005).

Midlevel distal determinants include home, neighborhood, and school environments. The home environment includes family characteristics such as emotional well-being, marital status, and cognitive stimulation. One study quantified these home environment characteristics into one standardized measure and showed that low-scoring youth were at greater risk of developing obesity than their high-scoring counterparts (Strauss and Knight 1999). Parental obesity is a relevant determinant in this category as well (recall that it was also categorized as a personal characteristic due to a possible heritable trait of obesity). Parental obesity can interact with family characteristics (e.g., marital status, emotional well-being in the home) and can also modify the behaviors of children by influencing lifestyle choices (Whitaker et al. 1997). Neighborhood characteristics are broad and include walkability, the presence of recreational facilities, number of mobility options, food choices (markets or fast-food restaurants), and other traits of the built environment (Sallis et al. 2018). Neighborhood safety has been previously discussed, with an unproven direct link to inactivity (Burdette and Whitaker 2005). All have been linked to either sedentary lifestyles (Gordon-Larsen et al. 2006; Merchant et al. 2007; Nelson 2006) or unhealthy diets (Merchant et al. 2007; Nelson 2006; Nielsen 2002; Strauss and Knight 1999) in children, although the causal link to obesity is precarious (Merchant et al. 2007; Nelson 2006). Finally, school policies have been linked to an increasing prevalence of childhood obesity, most notably loosening standards for foods served in school cafeterias, the presence of vending machines that offer snacks and drinks with little nutritional value, and physical education requirements that are either not required or unenforced (Trust for America's Health 2005). To date, no federal laws mandate either physical education or school nutrition requirements, and state mandates vary.

Finally, macrolevel distal determinants affect childhood obesity and include socioeconomic status (SES) as measured by income, education, and occupation. The relationship between SES and obesity is complex, and an inverse relationship between SES and BMI has been empirically determined in a number of studies (Janssen et al. 2006; Marmot and Wilkinson 2006; Stunkard and Sorenson 1993). SES and the behavioral risk factors of sedentary lifestyle, unhealthy diet, and inadequate physical activity have also been linked. However, the status of SES as a direct predictor of obesity in any of these cases is intuitively questionable (Adler and Ostrove 1999; Janssen et al. 2006; Marmot and Wilkinson 2006). Experts have attempted to consolidate these factors to state that SES is likely an important modifying determinant affecting the link between home or neighborhood environment and behavioral or lifestyle determinants (Janssen et al. 2006; Marmot and Wilkinson 2006; Stunkard and Sorenson 1993). For example, SES could affect access to recreational facilities or various food options. Finally, SES is significantly associated with both family characteristics and neighborhood safety (Boynton-Jarrett et al. 2003; Gordon-Larsen et al. 2006).

Most Significant Determinant of Obesity

It is clear that behavioral and lifestyle choices of youth are the most important determinants of childhood obesity. Direct causal links between physical activity, diet, and childhood obesity have been consistently proven in the literature. Moreover, a dose–response relationship exists between physical activity and BMI; moderate physical activity results in lower BMI and a decrease in risk factor status for several obesity-related conditions, and this effect is stronger after consistent vigorous physical activity. Studies also show that lifestyle habits begun during youth are likely to be continued into adulthood (Rhodes, MacDonald, and McKay 2006). Although the interaction of several more distal determinants is linked to the aforementioned primary relationships (acting to facilitate, inhibit, or confound the relationships), their association is complex and likely affected by a host of additional confounding or mediating determinants that are beyond the scope of this paper. In this regard, the literature can be considered limited.

A final reason that inadequate physical activity and unhealthy diets may be considered major determinants of childhood obesity is that they are highly actionable. As previously mentioned, many lifestyle habits begun in childhood are continued into adulthood. Primary prevention interventions that address these two determinants and affect the decision-making process of youth could have the most profound impact on reducing the prevalence of childhood obesity, regardless of intervening factors or barriers that may exist in the environment (Daviglus 2005; Nelson 2006). Recognizing that activity and diet directly affect childhood obesity, the federal government has deemed them important, actionable health areas (HHS 2010) and centerpieces of major policy objectives to reduce obesity among children and adolescents (HHS 2001).

QUESTION 2

Selection of the Intervention

A hallmark of public health practice is the planning and implementation of interventions aimed at preventing a health problem. The Question 1 analysis shows that childhood obesity is a complex problem, and the major (and most actionable) determinants are those categorized as behaviors or lifestyle choices. Evidence reveals direct relationships between inadequate physical activity and unhealthy diets and childhood obesity. Because habits established during youth are likely to continue into adulthood (Rhodes, MacDonald, and McKay 2006), interventions for the primary prevention of obesity that seek to alter these risky behaviors and encourage youth to make positive and healthy lifestyle choices are most appropriate for addressing the major determinants of childhood obesity (Schneider 2000). In fact, evidence suggests that interventions aimed at behavioral modification may be more effective with youth than with adults (Yanovski and Yanovski 2003).

Schools are an ideal setting in which to administer primary obesity prevention interventions. An estimated 58 million children and adolescents attend more than 98,000 schools throughout the year (US Census Bureau 2017), so school-based interventions can reach a wide array of students. Randomized controlled trials that evaluate interventions have found that health education administered in schools can reduce risky behaviors among students, such as smoking, alcohol use, and substance abuse—behaviors that are clear determinants of adult chronic diseases (Fisher et al. 2007). Dietary and activity habits can be potentially risky behaviors established during school-age years (Edmunds, Waters, and Elliot 2001). Studies have underscored the potential strength of coordinated health education approaches to address childhood obesity in schools (HHS 2001; Nelson 2006; Veugelers and Fitzgerald 2005).

Clearly, childhood obesity is a salient issue, and schools are ideal settings for health education interventions; however, current results from school-based interventions are mixed. Most only show modest behavioral modifications and uneven results with regard to obesity and BMI levels. This paper considered only programs shown to be partially effective (exhibit 10.3); Planet Health is currently one of the most effective examples of such a program.

Exhibit 10.3
School-Based Interventions Considered in Addition to Planet Health

Child and Adolescent Trial for Cardiovascular Health (CATCH)
As described by Luepker et al. (1996), CATCH was a comprehensive, three-year, school-based health behavior intervention targeted toward elementary school students and aimed at the primary prevention of cardiovascular disease. Program components encompassed the elementary school environment, classroom curricula, and home programs. The pilot incorporated the program through 56 intervention schools (with 40 control schools), involving more than 5,000 ethnically diverse third, fourth, and fifth graders in California, Louisiana, Minnesota, and Texas. Although the program appeared to somewhat improve the behaviors of students and lower cardiovascular risk, it did not significantly affect obesity.

Wellness, Academics & You (WAY)
As reported by Spiegel (2006), WAY is a multidisciplinary, elementary school–based intervention focused on fourth and fifth graders. The pilot was conducted in four states (Delaware, Florida, Kansas, and North Carolina) and comprised more than 1,000 students in 16 schools. WAY aims to reduce obesity and its concomitant diseases as well as improve academic performance. The program incorporates health content in the existing academic curriculum through rigorous and extensive modules led by teachers. It also includes activities that involve parents and families. The main areas of intended impact are obesity, fruit/vegetable consumption, and physical activity. The program showed significant changes in students' BMI and healthy food consumption, although its rigorous nature and costs are challenges to widespread implementation.

Pathways
As described by Sharma (2006), Pathways is a two-year school-based intervention aimed at American Indian elementary school students in third through fifth grades. The program's aim is to develop and implement an intervention to prevent obesity, promote healthy eating behaviors, and increase physical activity. It incorporates a classroom curriculum, encourages physical activity, instituted food preparation and service modifications, and includes an extensive family support component. To date, the intervention has produced significant changes in students' attitudes and behaviors but no significant changes related to obesity. Furthermore, because the program's components are specific to the needs and background of American Indians, its widespread implementation and generalizability are limited.

Planet Health is a unique and ideal intervention to examine, mainly because it incorporates comprehensive health education into the standard academic curriculum. The program was applied to a broad sample of schools and among students of all demographic backgrounds. It also includes a component targeted to reducing television viewing among youth—a study outcome that had not been examined by other researchers or evaluators at the time of the pilot program. Thus, Planet Health addresses the two major determinants of childhood obesity, physical activity and diet, plus the third determinant of television viewing, which, while more distal, is likely an important secondary, modifiable behavior and risk factor for obesity in youth that is worth incorporating into health education programs (Katz et al. 2005).

Description of the Intervention

Planet Health is an interdisciplinary program that is school based, incorporating health education into the regular, existing academic curriculum. Planet Health was developed through the Harvard Prevention Research Center on Nutrition and Physical Activity and was originally supported by the National Institute of Child Health and Human Development in 1995 as a pilot program in ten Boston public middle schools among sixth and seventh graders. After the initial success of the program, Boston Public Schools partnered with Planet Health researchers in 2002 to expand the pilot to 12 additional Boston middle schools. Further success of the program caught the interest of state decision makers, and in 2004, BlueCross BlueShield of Massachusetts partnered with Planet Health to implement the program statewide, expanding it to include after-school programs. At the time of this writing, 48 states and 20 countries have demonstrated interest in learning more about the program (Franks et al. 2007). The main goal of the program is to lower the prevalence of obesity among middle-school students and is largely based on social cognitive theory (Gortmaker et al. 1999). The objectives of Planet Health are as follows: (1) reduce television viewing time (i.e., decrease sedentary behavior), (2) decrease consumption of unhealthy food choices, (3) increase consumption of healthy food choices, and (4) increase physical activity.

The program includes teacher training, as teachers in schools administer the program; classroom lessons in math, science, language arts, and social studies; a "media-reduction campaign"; physical education units; and wellness sessions for teachers. Classroom sessions are delivered over two years (the time duration a typical child spends attending a Boston public middle school). Sixteen sessions per year are conducted during 30- or 45-minute class periods. The time duration for teacher training is typically two to three hours. Planet Health program materials can be ordered through the program's website (Harvard T. H. Chan School of Public Health 2018).

Analysis of the Intervention

It is important to first consider the appropriateness of Planet Health. The program focuses on four behavioral objectives in physical activity and diet. Health education is incorporated into

32 regular classroom lessons. Additionally, teachers lead 30 physical education "microunits" with activity and inactivity themes. Thus, Planet Health is consistent with the primary determinants identified in Question 1. The intervention also addresses television viewing with a two-week lesson entitled "Power Down," which focuses on reducing TV use to increase activity time. Planet Health is based on social cognitive theory, a framework that models behavior change as resulting from dynamics between psychosocial factors and individual characteristics (Glanz, Rimer, and Lewis 2002). The program encourages students to work together in the modeling and practice of decision making and gives them confidence to perform behaviors with reinforcement by peers and teachers, the power of self-determination by imparting cognitive skills to alter risky behaviors, and time for self-reflection of new behaviors (Glanz, Rimer, and Lewis 2002; Gortmaker et al. 1999).

Planet Health is also appropriate when considering the participants' demographics. First, research has shown that poor eating habits, sedentary lifestyles, and even binge eating and dieting are solidified during middle childhood (Edmunds, Waters, and Elliott 2001; Tanofsky-Kraff et al. 2006). These findings indicate that the initiation of Planet Health in middle schools serves an appropriate target population of students. Furthermore, Planet Health meets standards upheld by the Massachusetts Curriculum Framework; because the program is interwoven with the standard academic curriculums, it is grade appropriate and accounts for the varying competency levels of children during middle childhood (Gortmaker et al. 1999). Studies suggest that sustained results from school-based obesity programs often originate from those focused on preadolescents, which is one potential weakness of Planet Health (although the program is being expanded to fourth and fifth graders in Massachusetts). A further weakness of the program is its lack of gender specificity. Statistics suggest that young females have different personal attitudes and sociocultural pressures than young males regarding body image and self-esteem (Grunbaum et al. 2004); the broad-based approach of Planet Health may not address such gender differences. Similarly, Planet Health does not contain educational components that are specific to minority groups who have differing levels of obesity risk (Ogden et al. 2016). Finally, a strength of Planet Health is its even application throughout most school populations, which contain both overweight students and students with normal BMI. The premise for this application lies in social cognitive theory, which espouses a population-based approach (combined with an individual approach) to effect change. Obesity, particularly among youth, often results in stigmatization and low self-esteem (Latner, Stunkard, and Wilson 2005), but Planet Health's approach avoids such stigmatization.

An assessment of Planet Health's comprehensiveness overlaps with the appropriateness analysis in terms of the target population's characteristics (i.e., age, gender, and race or ethnicity) and the breadth of obesity-related determinants it addresses. To that end, two weaknesses exist. First, the program does not attempt to address socioeconomic determinants of obesity. SES is a complex and distal determinant; the efficacy of actionable strategies that alter its relationship with obesity is tenuous. However, the literature does suggest the utility of school-based interventions prioritized for low-SES youth (Veugelers and Fitzgerald 2005). Furthermore, parental involvement in obesity interventions can greatly enhance the effectiveness and sustainability of behaviors, including activity levels and television viewing (Vandewater and Huang 2006; Yanovski and Yanovski 2003). The framework outlined in Question 1 identifies the moderating role of family (under family characteristics) in the relationships between physical activity, diet, and obesity. Several voluntary Planet Health lessons provide opportunities for parents and family members to participate. A strength of Planet Health with regard to comprehensiveness is its strategy of incorporating health education into existing academic frameworks. Additionally, the entire school and all teachers are actively involved in designing and implementing Planet Health into the curriculum. Thus, Planet Health is comprehensive in that it imparts a holistic, pedagogical approach to obesity-related health education within the target setting of schools that is widely recommended (Brener et al. 2006; HHS 2001, 2010).

To date, credible evaluations of Planet Health that report the program as effective in achieving its objectives and goals are limited. The most widely cited evaluation was conducted by program researchers during the pilot program from 1995 to 1997 (Gortmaker et al. 1999). It was a randomized controlled trial evaluating the curriculum and outcomes of the Planet Health program in ten Boston public middle schools. Students participated in the full Planet Health curriculum and were evaluated using BMI measurements, body assessments, and a food and activity survey. The evaluation found that only the amount of television viewing was reduced in both boys and girls of the intervention schools (versus control schools). The following significant outcomes were shown *only* among girls in the intervention schools: decrease in obesity prevalence, increase in consumption of fruits or vegetables, and reduction in dietary energy intake. There were no significant outcome differences among males. This evaluation is unique because it was randomized, involved a broad base of study participants, and assessed behaviors (a somewhat subjective measure) and BMI (an objective measure). Thus, this evaluation is the most useful to analyze.

A three-year diffusion analysis of this benchmark evaluation to investigate its feasibility, acceptability, and sustainability was conducted among six Boston public middle schools (Wiecha et al. 2004). During the evaluation, teachers attended training workshops on Planet Health and received instruction from trained program professionals. A majority of teachers found the curriculum to be acceptable and indicated that they would continue to use it in classrooms. Additionally, more than 90 percent found the curriculum effective and an asset to school curricula. A major weakness of this evaluation was its descriptive nature and small sample size, which prevented statistically significant assertions or power assurances. The study also depended on teacher self-report, which may have resulted in overestimates. Finally, the generalizability of the methods is questionable.

Finally, a small, two-year outcome evaluation of Planet Health was conducted in an Indiana middle school among seventh and eighth graders (Bai et al. 2006). The Planet Health curriculum was implemented in the intervention school and no intervention was administered to the control school. The School Physical Activity and Nutrition questionnaire was administered by the researchers conducting the program evaluation to students during pre- and postintervention periods in both schools. The evaluation reported a significant decrease among all students in fat and soda intake and reduced television viewing; however, no significant change was seen in fruit or vegetable consumption or physical activity promotion. This evaluation is weakened by its small size and scope (involving only two middle schools). Furthermore, the full reliance on a self-report questionnaire by students only allows analysis of behavioral change, rather than the associated health outcome of obesity.

QUESTION 3
Organization and Financing of the Intervention

Planet Health was originally funded with grants from the National Institutes of Health (NIH) and CDC Prevention Research Centers and a monetary gift from the Harvard School of Public Health (Glanz, Rimer, and Lewis 2002). This funding helped develop the Planet Health curriculum, implement the program as a pilot, and support the subsequent benchmark randomized controlled trial study. In 2002, the US Department of Education's Physical Education for Progress grant program funded a diffusion study to assess the feasibility and sustainability of the program. Results showed the Planet Health curriculum to be effective and positively viewed by teachers. Independent funding supported further efforts to expand and sustain the program in Boston schools (Glanz, Rimer, and Lewis 2002). In 2004, BlueCross BlueShield of Massachusetts announced that it would provide $3 million over four years to Massachusetts middle schools to implement and expand Planet Health programs.

The US federal government is committed to supporting initiatives aimed at childhood obesity (HHS 2001, 2010; IOM 2012; National Task Force on the Prevention and Treatment of Obesity 2000). Several agencies provide avenues for obtaining funding, including the departments of Agriculture, Health and Human Services, and Education; CDC; and NIH. Federal support for obesity prevention, in the form of "chronic disease funding" and "prevention and public health," is largely distributed through state grants from the CDC National Center for Chronic Disease Prevention and Health Promotion.

Federal agencies often partner with public and private organizations to support obesity initiatives, as in the case of Planet Health and its grant from BlueCross BlueShield. Such collaborations allow different stakeholders to become engaged in the program and provide promising sources of funding for schools to implement Planet Health. Initial implementation of Planet Health's pilots was successful in assessing positive outcomes, suggesting that schools may not face onerous barriers in obtaining such funding. The fact that more than 5,000 copies of the program's textbook have been purchased by 48 states and 20 countries speaks to the large-scale implementation possibilities (Harvard T. H. Chan School of Public Health 2018).

Economic Feasibility

It is important to consider the economic feasibility of implementing Planet Health in a school or school system. Avenues to obtain federal support exist, particularly considering that the program's efficacy and effectiveness have been proven through evidence-based techniques. States face rising healthcare costs partly due to a rising prevalence of obesity and its concomitant conditions; more than 25 percent of growth in total US healthcare spending over a 15-year period was estimated to be attributable to obesity (Finkelstein, Fiebelkorn, and Wang 2003). An increased prevalence of childhood obesity could have profound implications on future state healthcare spending because obese individuals incur higher medical costs and have decreased quality of life compared with their nonobese counterparts (Thorpe et al. 2004). Hospital costs associated with obesity have risen nearly threefold since the 1990s for youth aged 6–17 years and are largely borne by states or private insurers (Wang and Dietz 2002). These figures, while staggering, do not include intangible costs such as school absenteeism or missed days of work. Clearly, states could benefit on many levels from widespread implementation of Planet Health in schools to reduce the burden of obesity among youth and the state's future population.

Programs and policies instituted by states are not always implemented to an equal or appropriate degree by schools. Physical education requirements and school nutrition mandates are two such programs for several reasons. Schools throughout a state often serve diverse populations with a variety of backgrounds and needs. Schools in the inner city or a rural locale may serve children of lower SES, minority students, and others who are prone to risky behaviors. Furthermore, such schools may be unable to allocate limited budgets to implementing Planet Health, purchasing didactic materials for the program, or paying for teacher training and time away from the classroom. Finally, schools may worry that funding to support activities beyond the initial program implementation would be unstable and difficult to obtain.

In 2003, independent researchers conducted a cost–benefit analysis of the first randomized pilot of Planet Health (Wang et al. 2003). To date, this analysis is the only one to formally evaluate a health promotion program aimed at reducing obesity. Its strength is that it considers the benefits of Planet Health from a population perspective rather than on an individual level. The outcomes assessed were cases of adulthood obesity prevented and quality-adjusted life years saved. Tangible program costs were assessed. Due to the seamless coordination of Planet Health with existing academic curricula, additional classroom costs (monetary costs and time) are minimal. The requisite curriculum book is priced at about $45 [in 2007; $68 in 2018] and includes lesson plans, micro units, the Power Down campaign, and the FitCheck self-assessment tool (Human Kinetics 2018). Wang and colleagues (2003) estimated that the program cost per student per year was $14; the program could save approximately $1.20 in medical costs and lost wages for every $1 spent. Given that states and schools have finite monetary resources, the preceding economic analysis shows that implementing Planet Health would be an "effective use of available resources and should be included in [school] portfolios" (Wang et al. 2003). However, during times of tight budgets, weak academic performance standards, or economic downturns, schools may not choose to prioritize health education or accept the relatively low program costs. Planet Health must be in part financially supported at the district, county, or state level.

Administrative Feasibility

An assessment of administrative feasibility naturally follows economic feasibility. Schools have varying levels of curriculum competencies and may face challenges in implementing Planet Health—particularly if they have little prior experience with interdisciplinary curricula or substandard existing academic curricula (Gortmaker et al. 1999). Teachers can incorporate Planet Health components in a piecemeal fashion or teach lessons in varying degrees of detail, but these approaches may compromise program efficacy. Teachers also vary in teaching competencies, and the average training time may be insufficient for those needing additional support. A strength of the program is that teachers are responsible for program implementation and administration, and they tailor Planet Health materials to their schools and classrooms. However, if the school itself is experiencing overall staffing shortages, administration of Planet Health could be threatened. The cost of teacher training is mostly a onetime cost, as teachers could pass on material and knowledge as soon as they were properly trained and knowledgeable—and could volunteer if they believe it has a positive effect on students (Wiecha et al. 2004). Planet Health requires every participating teacher to use the program book (Human Kinetics 2018), but schools may not be willing or able to purchase many books. However, one book can be purchased and shared between teachers or school districts, with the only cost being the copying of materials. The technological requirements are minimal (a computer or an overhead projector for presentations during teacher training) for Planet Health and could be borrowed. Finally, because the program is diffused over the course of two years, it is not overly burdensome to deliver or administer.

Some administrative burden is placed on the human resources component associated with Planet Health. Teachers may not have the time to undergo training, although the time is designed to be minimal (an average of two to three hours). They must also spend time incorporating Planet Health components into their regular academic lessons (on the other hand, this could allow for creative adaptations). Teachers also have the option of self-training, although key components of teacher training are group activities, discussion, and expert training. They may be reluctant to participate in the voluntary program. A stipend was provided to teachers throughout the pilot program; however, schools may not be able to provide such monetary incentives even with additional funding from outside sources. School administrators could explore nonmonetary incentives to offer (e.g., the optional wellness program). Overall, Planet Health has a moderately high level of administrative feasibility and allows schools to try creative or collaborative solutions to the aforementioned challenges they may face.

Political Feasibility

A final analysis of political feasibility is critical before overall feasibility and implementation can be judged. The political environment is generally supportive of programs aimed to reduce childhood obesity. First, the American public believes obesity to be a serious health concern facing children and adolescents. A recent nationally representative survey suggests that a majority of Americans ascribe responsibility to schools with regard to addressing obesity; most also believe that it is the government's responsibility to help support health promotion programs aimed at obesity (Evans 2005). Further, the program is socially acceptable because it incurs minimal costs to the public and offers proven benefits (Lakdawalla, Goldman, and Shang 2005). Additional supportive stakeholders include teachers and other school administrators, community groups, family members, advocacy agencies, community healthcare providers, and private and public insurers. The cost-effectiveness of Planet Health's broad and local implementation was previously outlined, but it becomes even more striking when considered against the backdrop of costs to the federal healthcare system, which will escalate because the deleterious effects of obesity will soon eclipse those from smoking and problem drinking (Lakdawalla, Goldman, and Shang 2005; Sturm 2002). Planet Health implementation could reduce costs to the federal government and taxpayers.

Several federal agencies already support initiatives targeting childhood obesity. Some federal lawmakers have championed the issue and pushed it onto Congress's agenda with the introduction of various pieces of legislation; such bills offer comprehensive approaches to prevention but have been slow to garner attention. State-level policies are similarly slow to develop. A critical point is thus revealed: Planet Health, which is evidence based, generally feasible in its implementation and delivery, cost-effective, and socially acceptable, presents a unique alternative that is palatable to a wide range of stakeholders. This point demonstrates the unique role of what Kingdon (2011) terms *specialists*—hidden participants in the generation of policy or program alternatives who are often responsible for unique yet grounded ideas. Lawmakers may view policies structured in a similar manner as Planet Health to be characterized as "client politics"—politically attractive to lawmakers on both sides of the aisle, large in scope, having one or more clear and measured objectives, and targeting a group deemed deserving (Oliver 2006). The ultimate political success of Planet Health lies in the formation of coalition groups comprising a wide array of stakeholders; such collaborations would increase buy-in to the program, enable the generation of creative strategies and solutions that are personalized to the community's needs, and encourage program sustainability.

QUESTION 4

Selection of the Evaluation

For one main reason, few outcome evaluations of Planet Health exist. As outlined in Question 3, conducting outcome evaluations is a challenge for many schools with limited human and financial resources or expertise. One evaluation was a diffusion analysis aimed at evaluating feasibility, acceptability, and sustainability of Planet Health. The descriptive study used a relatively small sample size (Wiecha et al. 2004). Another evaluation was performed between two Indiana middle schools using a quasi-experimental design but was small in sample size and collected data completely through self-report questionnaires from students (Bai et al. 2006).

The evaluation chosen avoids many of these weaknesses (Gortmaker et al. 1999). When it was conducted, little evidence showed a causal link between program objectives, target behaviors, and obesity. In addition, few studies had been conducted on school-based interventions for broad populations of adolescents (such studies were mostly on obese or high-risk individuals). The evaluation used a population deemed demographically and ethnically diverse. Its objective was to evaluate the impact of Planet Health on obesity among boys and girls in grades 6–8. Completion of this evaluation produced a benchmark that is widely used in the implementation of Planet Health and related programs.

Study Design

As shown in exhibit 10.4, this evaluation employed a randomized pretest–posttest control group experimental design (Gliner and Morgan 2000). At the start in 1995, schools were matched by town, or school size and ethnic composition, after which ten schools from four communities were randomly assigned as either intervention or control schools. The Planet Health curriculum was administered to students whose school enrollments in grades 6 or 7 began in fall 1995. Intervention school students received two years of Planet Health teaching within schools. In contrast, control schools did not receive the Planet Health curriculum—they only received the standard health education and/or existing physical education classes.

Exhibit 10.4
Study Design of Planet Health

Randomized experimental design: Pretest–posttest control design

Assignment	Group	Fall 1995 (pretest)	I.V.	Spring 1997 (posttest)
R	E:	O_1	X	O_3
R	C:	O_2	~X	O_4

Key
I.V. = Active independent variable
R = Random
E: = Experimental/intervention group
C: = Control or comparison group
O = Observation/measurement (anthropometric and behavioral assessments)
X = Intervention (Planet Health)
~X = Control or other treatment

Baseline data were collected in fall 1995 and follow-up data were collected in spring 1997. Planet Health didactic materials were provided to each teacher in the intervention schools, and the curriculum was applied during teacher trainings, classroom lessons, and other activities.

Study Population

The target or theoretical population from which researchers hoped to generalize results included all male and female students in grades 6–8. Researchers recruited schools to participate, choosing them on the basis of their willingness to implement the classroom or physical education curriculum, understanding of possible random assignment to a control or intervention group, and having an ethnically diverse student body. A cluster sampling technique was employed—schools were first matched in a nonrandom way and later randomly assigned to a study group. The selected sample had divided ten schools into an intervention group ($NI = 5$) and a control group ($NC = 5$). Students within each school (cluster) were not randomized. The study sample was an appropriate target for the intervention.

This study met ethical considerations to ensure protection of study participants and was approved by the Committee on Human Subjects at the Harvard School of Public Health. Five schools used active informed consent, which required parents to return a consent form indicating whether they wanted the child to participate. The other five schools used passive consent; parents had to sign and return a form only if they did *not* want their child to participate. Forms originally written in English were also translated into seven other languages to accommodate the schools' multiethnic compositions.

Researchers collected baseline data from 1,560 students after considering exclusion criteria; sample size calculations for precision were not performed. Students were excluded if they had transferred schools during 1995, attended special education classes, or were in a grade that would not have been expected for their age (either skipped a grade or were held back). Baseline analysis showed that the intervention and control students were similar in terms of gender, age, and ethnic composition.

Key Measures

Several types of variables and measures were used in this analysis (see exhibit 10.5 for variable analysis and measure assessment). The active independent variable was the Planet Health intervention. Attribute independent variables were assessed by program staff and included age, sex, and race or ethnicity. Dependent variables included BMI (as a function of height and weight), triceps skinfold (TSF), amount of television and video viewing, moderate or vigorous physical activity levels, intake of fruits and vegetables, proportion of energy from total fat versus saturated fat, and total energy intake. Several measures were used to assess these variables, including assessment by program staff and student self-report on a food and activity survey.

Exhibit 10.5
Key Variables and Measures

Category of variable	Variables	Levels of measures	Data collection (instruments, etc.)	Instrument and measure assessment
(1) Attribute independent variables	Age (years)	Continuous	Calculated by program staff on the basis of birthdate and date of baseline examination.	Generally reliable; in cases of missing birthdate, data from the Food and Activity Survey were used (questionable reliability).
	Sex (M/F)	Dichotomous, categorical	Classified by program staff during baseline examination.	Reliable; in cases of missing data, data from school records were obtained.
	Race/ethnicity (white, African American, Hispanic, Asian/Pacific Islander, other)	Nominal, categorical	Reported by students; based on responses to baseline surveys.	Generally reliable, although weakened because of reliance on self-reporting and student discretion.
(2) Active independent variable	Planet Health intervention	N/A	N/A	Not available at time of evaluation.
(3) Dependent variables	BMI (kg/m2)*	Continuous	Height and weight were obtained by program staff. Height was measured using a Shorr stadiometer; weight was measured using a calibrated electronic scale.	The electronic scale for measuring weight was calibrated using a standard test. It is unclear whether the instrument used to measure height was calibrated.
	TSF (mm)	Continuous	Program staff measured TSF using Holtain calipers.	Measurements of TSF were performed twice to ensure precision. When measurements differed substantially, an average measure was calculated.
	Television and video viewing (hours/day)	Continuous	Students answered 11 questions pertaining to a television and video measure.	The study cited high test-retest reliability of youth self-reports for television viewing.
	Moderate and vigorous physical activity levels (hours/day)	Continuous	Students answered 16 questions on a youth activity questionnaire.	The questionnaire was excerpted from a larger survey that had been proven reliable and valid in adults only.

Exhibit 10.5
Key Variables and Measures *(continued)*

(3) Dependent variables *(continued)*	Intake of fruits and vegetables (servings/day)	Continuous	Students answered questions on a youth food frequency questionnaire.	The questionnaire was excerpted from a larger survey that had been validated for use in ethnically and socio-economically diverse populations. It is unclear whether validation occurred only among children.
	Proportion of energy from fat and saturated fat (%)	Continuous		
	Total energy intake (kJ/day)	Continuous		
	Dieting to lose weight (%)	Continuous	Students answered questions on the Food and Activity Survey related to these measures.	These questions were adapted from the Youth Risk Behavior Surveillance Survey (YRBSS), which is widely recognized and used among youth. The measures used in the YRBSS have been shown to be associated with obesity in youth (Grunbaum et al. 2004).
	Exercising to lose weight (%)	Continuous		
	Vomiting/taking laxatives to lose weight (%)	Continuous		
	Taking diet pills to lose weight (%)	Continuous		

BMI = body mass index; TSF = triceps skinfold

*BMI has high specificity but low sensitivity for identifying adolescents who are overweight or obese. BMI has a high degree of correlation with laboratory measures of body fat composition but may differ by age, sex, and race or ethnicity. The use of BMI alone is also weak because it does not account for an individual's body frame size (Freedman et al. 2006).

The main outcome measure was obesity, defined as a "BMI and TSF measure greater than or equal to the 85th percentile of age- and sex-specific reference data" (Gortmaker et al. 1999). Researchers cited limitations in previous obesity assessment using solely BMI or TSF (refer back to exhibit 10.5) and chose to use this definition to ensure methodological soundness. Baseline data to assess demographics, anthropometry, and diet and activity were collected in fall 1995 from students in both intervention and control schools. Follow-up data on anthropometry and diet and activity were collected in spring 1997 from students in both intervention and control schools.

Analytic Strategy

Researchers employed the generalized estimating equation regression method (Zeger and Liang 1986) to adjust for individual-level confounders within clusters (schools) and account for correlations between responses within schools. The generalized estimating equation is an appropriate regression model to use because it works well in analyses of multivariate, longitudinal data; assumes independence of between-cluster responses; assumes that a correlation pattern exists within cluster responses; and can control for the matched-pair design of this study. Researchers also accounted for school matching by including indicator variables in the regression analysis to represent randomization pairs. A further strength of the strategy used by Zeger and Liang (1986) was that it accounted for differences between boys and girls—running separate regressions by gender. The following variables were controlled for in the regression models: race or ethnicity, age, BMI, TSF, intervention status, and randomization pair indicators.

Regression analyses were run not only to predict changes in behavioral measures but also to assess to what level the intervention could be attributed to significant changes in behavior. Neither power calculations to ensure sufficient ability to detect statistical change nor α and β levels were reported in the analysis.

Threats to Internal Validity

The randomized design granted a high degree of internal validity to this study, which helped ensure that any observed outcomes were actually due to the active independent variables. Researchers controlled for most threats to internal validity by ensuring equivalence of intervention and control schools through their particular sampling methods and assessment of baseline characteristics. Regarding instrumentation, steps were taken for all measures to ensure measurement validity and reliability, through proper calibration of instruments or objective survey results assessment (i.e., Scantron). Randomization averted threats from regression—groups were similar throughout the study and did not appear to have extreme characteristics at the outset—and selection bias in this study. (An additional note: Neither schools nor students self-selected into either group.) Attrition initially appeared to be a threat. At baseline, the participation rate of students was 65 percent; rates were lower at follow-up due to school transfers, school absences during data-collection times, or refusal to participate. However, participation rates at test points were similar between intervention and control schools, suggesting that any effects from attrition are likely to be controlled in the study.

Because this was a field-based design, particularly one being conducted in schools, researchers had a low level of control over extraneous variables in the students' environment (Gliner and Morgan 2000). Although Planet Health's ultimate goal is to enable adolescents to make healthy choices in any scenario, the lack of control for such factors in the analysis threatened internal validity. As an example, a major advocacy group could have launched a nationwide campaign aimed at reducing child obesity during this study's time frame, rendering any significant results solely attributed to Planet Health questionable. Finally, the use of self-report on dietary intake and physical activity is a major threat to validity. Students could have overestimated their actual behaviors to show themselves in a positive light or simply reported results that they thought researchers would want to see. These self-report responses also have questionable reliability due to the young age of study participants—a measurement error that could have biased outcome measures.

Threats to External Validity

External validity refers to the generalizability of the study. Study populations were determined to be a good representation of adolescents across the country; because the actual sample was a good representation of the theoretical target population, a high level of population external validity exists (Gliner and Morgan 2000). A high degree of ecological external validity also exists, as a "natural" setting for Planet Health was used (Gliner and Morgan 2000). External validity was threatened by reactive or situational effects of testing. Students' awareness of learning from the Planet Health program may have been heightened during the study time—particularly after their baseline characteristics were gathered and the food and activity survey was administered. Their responsiveness may also have changed after taking the pretest—this change could have occurred in both the intervention and control groups. Finally, threats from multiple treatments were small but may have existed. Although additional interventions were not administered in the schools, health promotion campaigns could have existed in the community or at parents' workplaces. Such situations could have biased the results of the study to make them less generalizable to the general population. A final source of bias could have been inherent in the researchers' initial active recruitment of the ten schools. Researchers sought schools that had experience with multidisciplinary curricula and whose academic standards were at least minimally being met with adequate resources. These schools also received financial assistance. Such assistance may not exist in many other schools; thus, results may be tempered if Planet Health is applied in other settings.

Appropriateness of the Evaluation

Overall, the use of a randomized design for this evaluation strengthened the design and validity of the study. Randomization reduced bias and ensured equivalence among control and intervention schools; the initial matching of school pairs only served to enhance sampling efficiency and did not appear to affect outcomes. The main outcome measure was a reliable and valid indicator of obesity change because it incorporated both BMI and TSF measures. Furthermore, although the behavioral measures were assessed via self-report, they were compiled using valid and reliable survey instruments. The large sample populations taking the surveys overcame any inaccuracies of survey results. Possible confounding characteristics of the obesity–behavior relationship were controlled by both randomization and sampling as well as within regression analyses. When considering recommended program evaluation standards (CDC 1999), this Planet Health evaluation scored high—having great utility (properly served the needs of participants), good feasibility (practicality), high propriety (fair application of the intervention to students along appropriate ethical protocols), and high accuracy (addressed every hypothesis and research question it posited). It showed that Planet Health achieved many of its goals and objectives. Thus, although the generalizability of Planet Health was moderate, both the program and proper evaluations must continue to occur. Such evaluations will increase knowledge about the reliability and validity of program measures and continue to build an evidence base for Planet Health.

QUESTION 5

Consideration of the Intervention

As shown, Planet Health is a school-based primary prevention program that uniquely addresses childhood obesity by weaving health education through a school's academic curriculum. It addresses the major proximate and most actionable determinants of obesity (physical activity and diet) through comprehensive classroom lessons. Planet Health also incorporates the theory that television viewing among youth is an important and actionable determinant of obesity with the inclusion of a two-week campaign aimed at limiting television use and encouraging physical activity.

Planet Health targets a population on the basis of evidence that supports the efficacy of such programs in focusing on risky health behaviors. It also addresses the alarming increased prevalence, noting that it becomes more difficult for aging, overweight children to return to normal weight, who are then at risk for developing a host of obesity-related conditions. Thus, middle-aged adolescents are at a critical age for interventions such as Planet Health, strengthening the potential effectiveness of such a program. It is encouraging to learn that researchers are expanding Planet Health programs for fourth and fifth graders throughout Massachusetts. Per Question 3, schools, policymakers, and other stakeholders may perceive advantages to Planet Health implementation due to its low startup and subsequent costs, cost-effectiveness, and high administrative feasibility. That it is a school- and community-wide collaborative effort—requiring active participation from teachers and families—only ensures that the program is likely to be sustained. Finally, per Question 4, Planet Health was scientifically proven to deliver on several program goals and objectives: lowering obesity rates in schools, decreasing time of television viewing, and increasing quality of diet. Clearly, this program can deliver tangible results within just one program cycle (two years) when fully implemented.

Next Steps in Research

Perhaps the biggest strength of Planet Health—its randomized outcome evaluation—also reveals an inherent weakness. The evaluation is one of the first to assess a school-based program targeting obesity among this age bracket, and although its results are strong, it may have limited impact (particularly to policymakers). Sound evaluative research is a challenge to conduct, although Planet Health is relatively simple to implement. Schools may lack the human and financial resources necessary to conduct an evaluation. School staff may be busy with school-related responsibilities, with little time for or interest in evaluation. The absence of long-term cohort data is another area of major concern. These data would show that Planet Health is effective well beyond the middle-school years, but its collection would require a large commitment of resources. There is also little data showing the effectiveness of Planet Health on other age groups or populations (e.g., elementary school students, minority populations). However, this information may be forthcoming with the recent expansion of Planet Health throughout the state of Massachusetts and among other grades. As alluded to in Question 3, political feasibility is often swayed by evidence-based arguments proving the efficacy and financial soundness of policy and program alternatives. Furthermore, policymakers and school administrators alike look to best practices when considering the implementation of new and innovative programs. In this regard, "best practices" databases that compile data on various school-based health promotion programs would be useful. The widespread implementation of Planet Health and similar programs may be stymied due to such current limitations.

In broader terms, there is a clear need for research on the relationships between other midlevel distal obesity determinants outlined in Question 1, including demographics, family characteristics, and home environment. Planet Health is successful in reducing obesity and certain behavioral measures *only* among females. These results suggest that mediating forces exist in the direct relationship between gender and obesity—a hypothesis that is mostly unsupported in the scientific literature and merits further research. Further research would be prudent to elucidate the association between obesity and risk in ethnically or culturally diverse populations (Freedman et al. 2006). The federal government has identified this as a crucial area of obesity research, but evidence for adults or children still lacks substance (National Task Force on the Prevention and Treatment of Obesity 2000). Finally, SES remains a complex yet distal determinant tied to obesity. Little evidence exists that adds to better understanding of this relationship; thus, there exists a need for research in this area.

Next Steps in Interventions

To date, the Planet Health program has been implemented in a number of demographically and socioeconomically diverse schools. The relatively simple implementation strategy is a major draw for school administrators interested in adding health education to school curriculums. However, a potential limitation of the current program is that it is only available in one form, which could hamper widespread implementation. The factor of race, ethnicity, or culture plays a potentially large role in obesity development, and expansion of Planet Health's curriculum could account for a variety of community needs. Multiple versions of the didactic materials specific to various cultures, ethnicities, languages, and even religions could be produced. The development of culturally competent materials need not be overly burdensome. Planet Health seems to thrive on school and community involvement; thus, disparate stakeholders throughout a community could collaborate to tailor the program to the specific needs of students served by community schools in keeping with the broad programmatic goals.

Planet Health is effective in helping students overcome risks associated with obesity by giving them the competencies to make healthy decisions in schools and beyond. However, the framework in Question 1 showed that distal factors, such as neighborhood safety, availability of food choices, and built environments, can have an effect on obesity. The program is somewhat limited by forces that exist beyond the school walls. The CDC supports and funds interventions designed to fall within one or more parts of the Coordinated School Health Program—a systematic model aimed at promoting student health through a multifaceted approach (Fisher et al. 2007). Thus, many possible interventions can be implemented throughout the school and community to address these distal determinants, such as initiatives to add or enhance the presence of community recreational facilities or to deliver comprehensive after-school programs for students and families. To this end, Planet Health is ahead of the curve through the addition of coordinated after-school programs throughout Massachusetts.

Next Steps in Policy

Per Question 3, the Planet Health program has a high degree of political feasibility, mostly due to its low cost and simple administration and the high salience of the problem among lawmakers and the American public. The program has important implications for targeted policy initiatives. The first is regarding research support. Question 3 outlined mechanisms from federal sources that exist to fund programs such as Planet Health. Clearly, federal financial support is critical to most schools that are interested in implementing Planet Health; the precarious nature of federal grants for health promotion programs reinforces the need for policies that ensure sustained support to states and communities. Similarly, the challenges to conducting valid, reliable, and long-term evaluations of Planet Health are questionable. Many grant mechanisms for health promotion programs fail to support long-term goals, indicating the need for policies that ensure sustained funding. Finally, one weakness of Planet Health concerned its implementation and sustainability within schools that may have limited budgets or serve poor socioeconomic populations. Priority funding could be allocated to such schools to implement Planet Health and similar programs (Veugelers and Fitzgerald 2005).

A unique strength of Planet Health is its effect on television viewing. Question 1 hypothesized the effect of commercial messaging on obesity. Policy options to this end include a ban on food product advertising targeted toward children, mandatory marketing about nutrition and fitness that is equal in time to "junk food" ads, or a prohibition on the use of children's characters to promote unhealthy food (KFF 2004; Mello, Rimm, and Studdert 2003). Advocacy groups are persistent in pushing this issue, and Congress has directed incremental regulations aimed at the food manufacturing industry or media corporations. In 1990, Congress passed the Children's Television Act, mandating advertising limits during children's programming. This action is a step in the right direction but likely not enough to strengthen the effects of a program such as Planet Health.

Finally, schools across the United States are decreasing or eliminating physical or health education from curriculums, partly due to financial constraints. Public schools also face pressures in meeting academic standards to obtain funding. Few states require the recommended level of physical education for students, and of these states, many either lack the resources for implementation or freely grant participation waivers to excuse students. School nutrition standards suffer from similar circumstances—nutritious foods are often expensive for schools and difficult to prepare. Moreover, many schools depend on subsidies from food or vending machine manufacturers that provide unhealthy food options to students. The Planet Health program could fall victim to this circumstance, thereby confusing students in schools that provide lessons on healthy eating yet offer unhealthy food options. Federal or state policies that mandate physical education or set standards for school food options would address these problems. Advocates continue to push this issue at both levels, although states have been more receptive to such policies than Congress has.

Most Important Next Step

The most crucial step in addressing childhood obesity relates to research—to develop and evaluate initiatives focused on gender and certain sociodemographic groups. The link between obesity and gender, SES, and race or ethnicity is poorly understood, yet these are powerful confounders affecting the pathways between many other determinants and obesity. Females, youth of low SES, and racial or ethnic minorities still disparately suffer from obesity and its concomitant conditions. Strong research findings could feed the political "problem stream" (Kingdon 2011) and drive broad-based policy changes, such as increased funding toward initiatives for certain marginalized populations. This point is particularly important when considering that issues related to the aforementioned groups typically have moderate social or political acceptability (although issues related to children are much more salient). A further important step is federal, state, or local financial support of health promotion programs and accompanying evaluations among these groups. As stated, evidence proving the efficacy of such programs—particularly among youth—is sparse. Policymakers need to know which types of interventions are successful and a prudent use of public funds. Childhood obesity is a major health problem that is complex in its origin and the potential avenues for solutions, which warrants continued research to understand its determinants. Such research drives development of evidence-based health promotion interventions aimed at primary prevention in youth. Research and the development of interventions aimed at certain marginalized groups, set in either schools or communities, appear to be the most important steps when considering how best to address the problem. While entities face many challenges in how they choose to address childhood obesity, the growing magnitude and salience of the problem will continue to drive science and practice solutions.

KEY POINTS

- The public health problem identified was obesity, especially among youth, in the United States.
- The health determinants of obesity in the United States are complex and can be classified as proximate, midlevel distal, or macrolevel distal, of which the most important one is behavioral and lifestyle choices of youth, a proximate determinant.
- The intervention chosen to address obesity in the United States was Planet Health, an interdisciplinary school-based intervention that integrated health education in the curriculum.
- The economic feasibility of this intervention was demonstrated with a cost-benefit analysis that showed cost savings of reducing obesity through Planet Health, and administrative and political feasibility were also proven with studies showing acceptability among the program stakeholders.
- The most important next step to address obesity among youth in the United States is for research to be conducted on the effect of determinants of gender, race or ethnicity, and socioeconomic status. Other steps include studying populations other than youth, creating a database of best practices, developing culturally sensitive materials, investigating distal determinants, and creating policies for funding.

FOR DISCUSSION

1. What public health problem was identified and investigated in this policy analysis?
2. Explain the major categories of health determinants that influence this public health problem. Give examples of specific determinants. Which is considered the most important one, and why?
3. What intervention was selected to address the public health problem? List example programs.
4. Which intervention program was chosen for this policy analysis? Describe its components.
5. How was the feasibility of implementing this program determined? Explain the results.
6. What evaluation of this intervention was chosen? Describe its design and variables.
7. List the suggested next steps to address the health issue. Which is the most important next step?

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GLOSSARY

activities of daily living (ADLs) Measure of an individual's functioning that includes six basic activities: eating, bathing, getting dressed, maintaining bowel and bladder continence, using a toilet, and transferring (e.g., getting out of bed or moving into a chair).

administrative simplification Provision in the Health Insurance Portability and Accountability Act and the Affordable Care Act that aims to reduce administrative costs through the adoption of electronic transactions and standardization of operating rules.

agency relationship In healthcare, delegation by the patient of some authority to make decisions and perform actions on the patient's behalf to an expert such as a physician or other healthcare provider.

agenda Issues targeted for policy consideration.

agenda setting The ability to influence the priorities of issues for policy consideration.

amendment Change or addition to a piece of legislation under consideration in the US House of Representatives or Senate. Amendments can also be introduced in Congress to change a current federal law.

attrition Loss of participants during a study that measures outcomes over time.

avian influenza A type-A influenza viral infection in wild or domestic birds. The avian influenza virus can become a public health danger if a change (mutation) allows it to more easily infect humans, and it can potentially start a worldwide epidemic.

capitation A fixed fee for each patient.

clinical practice guidelines Systematically developed protocols (statements) used to assist healthcare providers in making appropriate healthcare and clinical decisions regarding specific conditions or circumstances.

communicable diseases Illnesses caused by organisms such as bacteria, viruses, fungi, and parasites. Communicable diseases, also called *infectious diseases*, may be transmitted by one infected person to another, from an animal to a human, or from an inanimate object to an individual, depending on the disease.

conceptual framework A preliminary model of the problem under study that depicts relationships among critical variables of interest and between variables and concepts of interest.

Conditions of Participation Health and safety standards defined by the Centers for Medicare & Medicaid Services (CMS) as the minimum requirements that hospitals and medical centers must meet to serve publicly insured patients.

corporate America An informal term referring to the corporations based and operating in the United States; they are not under direct governmental control.

cost sharing The obligation of patients to pay for a portion of the healthcare services they receive. Cost sharing is typically used as an incentive to avoid excessive or unnecessary utilization. However, it may also deter appropriate utilization.

cross-sectional survey A descriptive research method used to examine characteristics of a population within a short time frame.

culturally appropriate services Efforts by healthcare organizations and providers to increase understanding and produce effective interventions for patients by taking into account patients' cultural and linguistic characteristics.

deductible The amount an insured patient must pay out of pocket for medical care every year before the insurance plan covers costs.

defensive medicine The practice of medicine in which the main goal is to avoid malpractice claims, not to ensure good health for the patient or maximum medical efficiency.

democratic Processes carried out in the representative tradition of government by the people, as through free elections.

dependent variable The variable that is examined to determine whether its observed value changes when the independent variable is present or when exposed to the independent variable.

determinants of health Factors that influence health status. Typically, they include socioeconomic status, environment, behaviors, heredity, and access to medical care.

disability A physical or mental condition that limits an individual's ability to perform functions generally considered normal.

disability-adjusted life years (DALYs) A measure of the loss of healthy life. The DALY measurement is intended to capture the economic, social, and functional realities that a person with a disability faces and the corresponding loss in health status and quality of life.

discounted fee-for-service A fee agreed on between an insurance plan and physicians to provide medical services at a lower cost than is common for the area, in exchange for access to the insurance plan's pool of patients.

distributive policies Regulations that provide benefits or services to targeted populations or subpopulations, typically as entitlements.

efficiency analysis Thorough examination of the overall direct and indirect costs and benefits of an intervention; can be used to compare interventions or programs that have similar goals.

enabling services Services that enhance access to medical care, such as transportation, interpretation, education, and community outreach.

evidence-based medicine Using the best available evidence acquired through the scientific method to guide clinical decision making.

fast food Ready-to-eat, often portable and inexpensive foods available through many outlets in the United States. This type of food tends to be less healthy than homemade food and has been criticized for contributing to the obesity epidemic in the United States.

federal poverty level (FPL) A calculation that reflects federal government guidelines for assessing need from income, based on cost of living (the amount of income needed by families to be self-supportive). Many federal assistance programs use a percentage of FPL as part of their eligibility criteria.

Federal Register A publicly accessible source that publishes presidential and federal agency documents; a daily publication of the US federal government.

focus group A small group (8–12 people) whose reactions to a given topic are studied to provide an in-depth understanding of the topic.

gatekeeper A qualified health professional, usually a primary care physician, who must approve specialist visits before they are covered by an insurance program.

general interview guide approach or semistructured interview A method of conducting an in-depth interview that provides an outline of issues that the interviewer must explore but allows the interviewer flexibility with regard to the type and order of questions asked.

global health A field of study, research, and practice that focuses on improving health and wellness and attaining health equity for all people worldwide.

globalization Worldwide changes in many aspects of people's lives driven by the exchange of information across borders and characterized by increased production of goods and services by developing countries and the expanded interdependence of developed and emerging economies.

gross domestic product The value of all goods and services produced within a country for a given period; a key indicator of the country's economic activity and financial well-being.

healthcare policy The part of health policy specifically related to the financing, delivery, and governance of health services for the general population or subpopulations within a jurisdiction.

health maintenance organization (HMO) A managed care organization that integrates medical care with payment and typically requires the use of a specified panel of providers.

health policy Legislation over individuals, organizations, or society whose goal is to improve health for the general population or subpopulations.

heterogeneous Consisting of different types; a term used to describe a sample or a population composed of subjects that have dissimilar characteristics.

homogeneous Consisting of the same type; a term used to describe a sample or a population composed of subjects that have similar characteristics.

H1N1 (swine) flu A respiratory disease caused by influenza type-A viruses, first detected in 2009. The new strain of influenza A (H1N1) virus is a mix of swine, human, and avian influenza viruses that is contagious and can cause seasonal flu.

independent variable The variable representing the treatment, characteristic, exposure, or other intervention that is being examined to determine its effect on the dependent variable.

informal conversational interview A face-to-face in-depth interview, conducted in person during observational studies, that does not adhere to a prescribed set of questions.

informal labor market A workforce made up of people who engage in productive activities that are not taxed or registered by the government.

institutional review board (IRB) A committee that examines the ethical implications of research to protect study subjects from physical or psychological harm.

instrumental activities of daily living (IADLs) Measure of an individual's ability to perform activities necessary to live independently in noninstitutional settings, such as driving a car, shopping, preparing meals, and performing light housework.

interest group A collective of individuals or entities that hold a common set of preferences on a particular health issue and often seek to influence policymaking or public opinion.

jurisdiction The authority to interpret and apply the law.

legislation Law made by the government to achieve a particular objective.

legislator An individual responsible for making or enacting laws.

life expectancy Anticipated number of years of life remaining at a given age.

lobbying Activities seeking to influence an individual or organization with decision-making authority.

longitudinal survey A survey administered to the same sample or similar samples at repeated intervals over a predetermined length of time.

managed care A care model characterized by a designated provider network, standardized review and quality improvement measures, an emphasis on preventive rather than acute care, and financial incentives for doctors and patients to reduce use of unnecessary medical care.

managed care organizations (MCOs) Organizations that seek to apply the components of managed care to a population to provide high-quality care at a lower cost than that incurred by fee-for-service care.

marginalization A process in which a person or an idea is pushed aside in favor of another. A marginalized subject typically receives few resources and little attention.

matching The process of ensuring equal representation among experimental and control groups by matching participants or proportions of participants on the basis of selected characteristics.

measurement reliability The extent to which results are similar if the measurement tool is reapplied in a consistent way.

measurement validity The extent to which the measurement tool accurately measures the intended concepts.

Medicaid Jointly administered federal and state insurance plan for the indigent.

medical outcomes research Research that examines the comparative effectiveness of available treatments for a patient with specified characteristics.

Medicare Federal government insurance plan for persons aged 65 years or older, individuals with disabilities who are entitled to Social Security benefits, and people who have end-stage renal (kidney) disease.

morbidity Incidence or prevalence of diseases in a given population within a specified period.

mortality Number of deaths in a given population within a specified period.

noncommunicable diseases Noninfectious medical conditions or illnesses, typically of long duration and slow progression.

Office of Management and Budget (OMB) The largest component of the Executive Office; implements and enforces the commitments and priorities of the president and assists executive departments and agencies across the federal government.

oversight Activities to review, monitor, or supervise the process of formulating, implementing, and modifying public policy.

panel study A study in which data are collected repeatedly over time from the same sample selected within the overall population to examine how individuals change over time.

pay for performance Payment-related incentives often used by insurance companies or government payers to reward healthcare providers, such as physicians and hospitals, for meeting preestablished performance measures for quality and efficiency.

policy analysis A systematic approach by which to assess problems and guide decision-making, based on existing information, often with limited information and time constraints.

policy entrepreneurs Public innovators who, from outside the formal positions of government, introduce, translate, and implement new ideas into public practice.

policy position The stand taken regarding a particular issue. A president's policy position often influences the focus and orientation of legislation.

policy research A rigorous, systematic process of scientific investigation that is used to formulate and evaluate policies.

preferred provider organization (PPO) A managed care organization that offers unrestricted provider options to enrollees and discounted fee arrangements to providers.

premium The amount an enrollee must pay to join a managed care plan. It serves as a membership fee and is typically adjusted annually.

privatization The movement of an industry in a country from public to private control or ownership.

purposive sampling or quota sampling A nonprobability sampling technique whereby the investigator selects the study sample from among accessible sites or participants to establish proportions of characteristics in the sample that are similar to the proportions found in the population.

quality-adjusted life years A combined mortality–morbidity index that reflects years of life free of disability and symptoms of illness.

quota sampling See *purposive sampling or quota sampling*.

random selection Methods by which subjects from a sampling frame are chosen to create a representative sample, such that each subject has a known probability of being selected and the selection process is not biased against any particular individual in the sample.

redistributive policies Deliberate efforts to alter the distribution of benefits by taking money or property from one group and giving it to another.

regular source of care (RSC) A usual place where, or a usual provider from whom, an individual receives healthcare services.

regulatory policies Regulations or rules that impose restrictions and are intended to control the behavior of a target group by monitoring the group and imposing sanctions if it fails to comply.

republican A type of democratic government in which the head of state is not a monarch; governmental activities and affairs are open to all interested citizens.

safety net providers As defined by the Institute of Medicine, "providers that by mandate or mission organize and deliver a significant level of healthcare and other health-related services to the uninsured, Medicaid, and other vulnerable patients."

sampling frame The population from which a sample is selected.

semistructured interview See *general interview guide approach or semistructured interview.*

Senate majority leader Senate leader elected by the party that holds majority in the US Senate. The majority leader serves as the chief Senate spokesperson for the party and is responsible for scheduling the legislative and executive business of the Senate.

social contacts The frequency of social activities a person undertakes within a specified period.

social resources Interpersonal relationships with social contacts and the extent to which the individual can rely on the people involved in these contacts for support.

Speaker of the House The presiding officer of the US House of Representatives, typically chosen from the majority party of the House.

standardized open-ended interview or structured interview An in-depth interview that is conducted by a researcher asking each respondent the same set of predetermined open-ended questions, recited verbatim in a specified order.

state executives Officials in the executive branch of state government. Examples include the governor, who is the chief executive of a state or territory, and the attorney general, who serves as the main legal adviser to the state government and has executive responsibility for law enforcement.

state legislature The legislative body of a US state, also called the general assembly or legislative assembly.

statutory authority The capacity to enforce legislation on behalf of the government as granted by the US Constitution.

strata Levels into which a population or a sample is divided on the basis of selected characteristics.

stratified random sampling A random selection of individual subjects from sampling frame subgroups, where each subgroup is made up of individuals who share a characteristic of interest.

structured interview See *standardized open-ended interview or structured interview.*

tabling legislation An action undertaken by Congress to postpone consideration of a bill.

trend study A series of cross-sectional studies examining how a characteristic or set of characteristics changes over time through repeated sampling from the overall population.

vector-borne communicable diseases Diseases spread to humans by another species, often an arthropod (e.g., insect).

veto As a verb, to unilaterally stop an official action; as a noun, the authority to do so.

World Health Assembly The decision-making and policymaking body of the World Health Organization (WHO), composed of delegations from all WHO member states.

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