

The need for health policy analysis has also become greater as the cost of medical care continues to accelerate, requiring an increasing percentage of the country's gross national product for health care. The increasing disparities in health experience based on geography, race, gender, and ethnicity all need both investigation and mitigation to create a more equitable health care system. The increased focus on the built environment and how it interacts with the health status of populations and individuals adds new dimensions to creating the conditions for a healthy population. Health policy analysis is in a position as never before to make a contribution to the health of individuals and the population.

What follows is a template as to how to construct a health policy analysis to assist policy makers. This template is a framework. As you work through the chapters, some elements of the framework will be more critical than others depending on the audience for which your policy analysis is intended. Working through this framework, the text will use the obesity epidemic in the United States as its main example, although other examples will be given as well.

SUMMARY

Health policy analysis is an area that requires knowledge and skills from a variety of disciplines and perspectives. In this chapter we started with some clarifications as to how this text uses terms such as *politics*, *policy*, and *health* as well as summarized models of the political policy process. These concepts will become important and will be expanded when we talk about developing a strategy for making policy analysis meaningful within the political system. In addition, we discussed the importance of evidence-based health policy and the promise and problems associated with implementing such a concept. We also discussed the importance of data and how various data systems become important in the gathering of evidence-based policy. We have noted particular health data sets that might be important in analyzing health policy and will revisit this information in Chapter 7, focusing on the systematic review of policy options. We also reviewed some major national organizations in the United States that are useful resources for those doing health policy analysis.

We further highlighted some important elements and issues from areas that are critical for conducting thoughtful health policy analysis. We will build on these concepts as we go through the policy analysis process, using obesity as an example of the types of things that need to be done.

SOME THINGS TO REMEMBER

- Politics is the authoritative allocation of values for society, and as such plays a central role in determining societies' relative values.
- Public programs and policies reflect those values.
- The policy process of policy formulation, policy adoption, policy implementation, policy evaluation, and policy modification all exist on a policy wheel. Policy can be developed anywhere on the wheel (Figure 1.1).
- Health is a complicated concept, and our current understanding of the inputs to health requires a multidisciplinary approach to solving society's health problems.
- Health policy analysis is an applied type of health research; you need to appreciate what works in the real world, with its many complications.
- You will find your policy initiative falling into one of the following categories of health research literature: effectiveness, efficiency, and/or equity. Understanding the methodological complications of those analytical areas is important.
- Evidence-based policy is the goal, no matter how difficult the path might be.
- There are multiple resources available to assist in policy analysis. Some are partisan and others are nonpartisan.
- Sources of health data in the United States are varied. There are multiple data sets using different definitions and computer systems that make combining data sets difficult. Understand the assumptions and methodologies of all data systems you access.
- There is a general hierarchy of analytical studies. However, you must be careful not to regard that hierarchy as sacrosanct. All methodologies have their strengths and weaknesses.
- Mixed-methods research has been gaining in popularity as a result of the complexity of health.

have a certain level of the particular disease being studied and/or a lack of other diseases to be accepted into the study. These clinical trial participants become "ideal patients" who might benefit from the intervention. In addition, providers need to be recruited as well. These tend to be specialists dealing with the disorder in question who possess a greater level of expertise than the typical physician who may be treating patients in the real world. In addition, these providers are frequently compensated for recruiting participants and for their own participation in the trial. Clinical trials can also involve a relatively small number of participants due to the difficulty and expense of getting participants.

As a result, clinical trials tend to involve ideal patients and practitioners rather than the routine patients and providers confronted in the real world. Although clinical trials provide comparisons between the populations receiving the intervention and the controls not receiving the intervention (internal validity), they generally do not compare those in the clinical trial to those patients who are likely to receive the treatment in the real world (external validity; Steinberg & Luce, 2005). Consequently, clinical trials have been accused of overstating the effectiveness of the intervention in the real world, even without intentional bias. John P. A. Ioannidis has published a number of provocative articles questioning the methodology of most clinical research (Ioannidis, 2005a, 2005b; Tatsioni, Bonitsis, & Ioannidis, 2007). Despite their imperfections, clinical trials remain the gold standard.

However, there is growing consensus that a "mixed-methods approach" is one of the most effective ways to evaluate the impacts of policy change, especially in public health. This means that both quantitative and qualitative information is collected in a strategic manner (Schifferdecker & Reed, 2009). For example, think about how one might study the impact of building a new bike path, as described in the previous RE-AIM discussion. One might use a combination of interviews and focus groups (qualitative methods) with city council members and neighborhood residents to better understand their motivations for wanting to build a bike path. One would also want to query them about any problems they foresee and potential opposition to the bike path. One can use methods such as "content analysis" and document review to study minutes of city council meetings or check whether the city has a published a Bicycle Plan to better understand the process of adopting and constructing the bike path. One can study records of city expenditures to determine how much money was allocated, and use direct observation,

engineering devices, or intercept surveys to study ridership before and after the bike path is built. One can collect survey data or obtain secondary data about health behaviors (such as bicycling to work or for leisure) from the target population. One may also collect or obtain secondary data about risk factors and health conditions, such as diabetes and heart disease in the surrounding area. One can conduct more interviews and focus groups after completion of the bike path to determine whether there are any barriers to usage or challenges in maintenance, and participatory action research techniques such as Photovoice can be used to empower residents to describe their neighborhood environment and their perceptions of the new bike path in their own pictures and words (Wang, 1999). All of these data sources can be considered together, or "triangulated," to gain a composite picture of the success or failure of the bike path. Most of these methods are lower on the hierarchy of studies, but they may be the most useful for your particular policy analysis.

It is important to understand the strengths and weaknesses of various types of analytical studies. Your analysis will depend on the integrity as well as the types of studies used to support your analysis.

Health Policy Analysis

The role of health policy analysis is more critical today than ever. Technology and the basic sciences have opened up more areas of knowledge regarding disease and health. Data sources have expanded, providing greater access to information. Computer systems allow for the analysis of huge quantities of data to provide more precise and sophisticated analytical processes. For example, the previously mentioned all-payer claims data systems being developed by some states provides a new opportunity to analyze health care utilization by the general population. The increasing use of electronic medical records will expand the opportunity to have more accurate and accessible information on individual medical care that can be aggregated for clinical research. The role of government has been expanded in terms of access to medical care, and the Medicare and Medicaid systems have taken on increased roles in developing new forms of medical care and payment systems, such as accountability care organizations (ACOs) and insurance exchanges.

ANALYTICAL STUDIES

In addition to difficulties with data, there are difficulties in what is done with data in terms of analysis. A number of frameworks have been created to weigh the level of evidence for health care. Steinberg and Luce discuss the weight of individual methodologies (Steinberg & Luce, 2005). Below is a modified version of their order of the strength of individual studies:

- Randomized clinical trials
- Quasirandomized (group randomized) trials
- Nonrandomized clinical trials
- Prospective or retrospective cohort studies
- Time-series studies
- Case control studies
- Cross-sectional studies
- Case series and registries
- Case reports

The gold standard for medical care studies has traditionally been the randomized clinical trial, especially a double-blinded clinical trial in which both patients and providers are blind in terms of those receiving treatment and those who are not.

However, individual studies, even clinical trials, should not be evaluated in isolation. Weighing the level of evidence is based on multiple factors. Biological connections are important. What are the hypothesized biological or social relationships that make the relationship between the intervention and outcome feasible? Is there a chain of reasoning that makes the relationship plausible? Although clinical trials may be the preferred analytical method, time, expense, or ethical considerations may require other types of studies.

How many studies of the policy issue have been done, and to what extent are they comparable? If there are few studies, the weight of evidence of even of a single clinical trial is less convincing. If studies use different definitions or different protocols for intervention, there may be very different outcomes. On the other hand, if different types of studies (cohort and clinical trials) come to the same conclusion, there may be increased evidence. Is there a consistency of findings in the individual

studies over time and using different populations? If studies basically confirm previous findings, there is a greater level of confidence in the results. Due to all these types of questions, systematic literature reviews and meta-analyses literature reviews become important in weighing the level of evidence in favor of or against a particular health policy proposal/program. Additionally, emerging analytic techniques from the fields of engineering and systems science are now being applied to policy analysis, particularly to enable us to visualize the simulated or projected outcomes of different policy alternatives (Madahian, Klesges, Kelesges, & Homayouni, 2012). All of this will be discussed in greater detail in Chapter 7, Systematic Review of Policy Options.

As indicated previously, clinical trials are generally considered to be the gold standard of evidence. Clinical trials involve the provision of treatment to one group and the lack of the same treatment to another. Both groups of patients are generally randomly assigned as to who receives treatment, and investigators are careful to note any differences in the populations that might explain different outcomes other than the existence or lack of treatment. Due to the random assignment of treatment, other confounding factors will, on average, be equally distributed between the two groups. If both the providers and the patients are unaware of who is receiving the intervention, it is a double-blind study and has increased credibility by removing potential provider bias.

Despite historic reliance on clinical trials, there are multiple problems with them, especially for the development of policy. Clinical trials are expensive and lengthy, and the sponsors of the clinical trials may have a substantial stake in the outcome. Therefore, there may be a potential built-in bias of the clinical trial in terms of seeking a favorable outcome. Another difficulty with clinical trials is the difference between efficacy (the demonstration of what works in a research setting) as opposed to effectiveness (the demonstration of what works in the real world; Steinberg & Luce, 2005). This is especially important in the policy world, where a number of different demographic and social factors in the real world become important factors.

Clinical trials rely on volunteers of both patients and providers to follow rigorous protocols. It may be difficult to get volunteers to participate in a clinical trial if there is a 50/50 chance they will not receive the intervention, especially if this intervention "promises" a chance at survival. Not all volunteers are accepted in clinical trials. Patients have to

are now increasing the sample size for their BRFSS survey to be able to compare subpopulations (Whites versus Blacks) or various counties within that state. However, this increases the cost of such surveys. Given tight state budgets, the additional costs may not be politically possible even though the health policy implications can be profound. You may want to examine whether your state's BRFSS reports provide you with the information you need for your policy analysis.

Some states and larger local communities have developed geographic information systems (GISs) and begun using data-visualization tools that allow health data to be displayed and analyzed spatially and longitudinally. Specific neighborhoods can be highlighted as having a high incidence of mortality, morbidity, or automobile accidents. Using these systems can be a very effective way to demonstrate where policy intervention might be most effective. However, such systems and capacities are very inconsistent across the United States. Foundations such as the Robert Wood Johnson Foundation (RWJF) have led efforts to make "place-based" health data more accessible. Some examples include:

- RWJF County Health Rankings, <http://www.countyhealthrankings.org/>
- Community Health Status Indicators (CHSIs), <http://wwwn.cdc.gov/CommunityHealth/homepage.aspx?j=1>
- Health Disparities Maps, http://www.rwjf.org/content/dam/images/Sandbox/2013%20Commission/Charts/2013DCMetroMap_full.pdf

Although it might appear that there is a great deal of data available, here are problems with almost any data source. The data that is available frequently does not match the problem being analyzed. Age categories may not match, or the definition of a disease using the International Classification of Diseases (ICD) codes may vary (<http://www.cdc.gov/nchs/cd.htm>). There will be a release of the ICD-10-CM on October 1, 2014, that might cause some disruption in comparisons of studies using ICD-9-CM. Use of data becomes even more complicated if you need to use more than one data set. Due to monetary constraints, many of these data systems are not collected every year. For example, one of the most important data sources, the U.S. Census, is used to calculate the denominator for disease rates as well as provide important socioeconomic data. The census is

conducted every 10 years. This 10-year gap is particularly important for communities that are growing or losing population rapidly or that have significant health problems in minority populations. The lack of timely census information inhibits large-scale studies on the impact of socioeconomic variables (e.g., education, employment, and income) on disease. Statistical estimates may be provided for interim periods for some of the census data elements collected, but interim estimates are not provided for all data elements within the census.

An additional problem is that for those data systems that are collected on a regular basis there is always the temptation to change questions or definitions of a particular measure in order to better reflect current understandings or needs. For example, one might want to change the definition of "obesity" or "overweight." However, such changes must be done very conservatively because any change in definitions can lead to the inability to compare results to previous years, thus losing important trend data over time. One has to carefully weigh the loss of longitudinal data against the use of a better definition or a change in a survey question.

Standard data systems may not use the exact measure or variable that you need for your analysis. For example, a survey may collect "individual income" when "family income" or "household income" is really what is needed. The definition of a "family" versus a "household" can be very important. This becomes even more critical when one needs to link two or more data systems, each using its own definition for "family" or "household."

When one is confronted with imperfect data, one must either use a variable that is not quite right, but perhaps close enough, or go to the expense of collecting a new set of data. The new set of data might be better suited for the study, but the time and expense of collecting this new data set would tend to be high. In addition, data collected for a particular study or policy may be challenged as being biased toward finding what was intended. There will be a natural suspicion as to the reliability and validity of the data that you collected for a specific purpose. Using a recognized national or state standard data set also allows others to verify your findings. However, there are times when you may indeed want or need to collect very specific data for your policy initiative, especially if this is a relatively new area of policy analysis.

- National Health and Nutrition Examination Surveys (NHANES) (<http://www.cdc.gov/nchs/nhanes.htm>)
- National Ambulatory Medical Care Survey (NAMCS) (<http://www.cdc.gov/nchs/ahcd.htm>)
- National Hospital Discharge Survey (NHDS) (<http://www.cdc.gov/nchs/nhds.htm>)
- National Survey of Ambulatory Surgery (NSAS) (<http://www.cdc.gov/nchs/nsas.htm>)
- National Home and Hospice Care Survey (NHHCS) (<http://www.cdc.gov/nchs/nhhcs.htm>)
- National Nursing Home Survey (NNHS) (<http://www.cdc.gov/nchs/nnhs.htm>)
- National Survey of Residential Care Facilities (NSRCF) (<http://www.cdc.gov/nchs/nsrcf.htm>)

The Department of Health and Human Services has other agencies involved in data collection. For example, the Agency for Health Research and Quality collects data under the Health Care Cost and Utilization Project (HCUP; <http://www.ahrq.gov/research/data/hcup/index.html>). The Surveillance Epidemiology and End Results (SEER; United States Institutes of Health, National Cancer Institute, 2013) for cancer has been an important source of information on the experience of cancer patients. There are also national and state disease registries that collect information on specific diseases.

Some of the information collected by governments includes the entire population (Census and Vital Records, <http://www.census.gov/>; Medicare, <http://www.medicare.gov/>; and Medicaid, <http://www.medicaid.gov/> data sets), but most national data-collection systems rely on samples of the population. As a result, analyses using sample populations use extrapolations to the general population. This raises questions of external validity, and the ability of the data to reflect the larger population.

For example, although Medicare data is fairly complete and collected nationally, whether the experience of this subpopulation can be applied to the entire population composed of people aged 18 to 64 is questionable. An example of this is the literature on the geographic variation in medical practice. The only national data system that can address how extensive medical variation exists is data from Medicare. However, whether

disparities in Medicare expenditures can be extrapolated to the entire population can be debated. For example, one of the variables that influences medical expenditures is the health status of the population. Whether a Medicare recipient had insurance prior to being enrolled in Medicare could have a major impact on the variation in Medicare expenditures. Those individuals coming from areas with low employer health insurance may experience higher Medicare expenditures once they become eligible for Medicare due to their previous lack of health insurance. Consequently, additional Medicare expenditures in particular areas may have less to do with the "practice of medicine" than with the elderly having been previously uninsured. Each data set has its own inherent problems regarding its ability to make generalizations to the population as a whole.

The primary way to become familiar with the strengths and weaknesses of any data set is to go to the original source of the data set and examine the methodology used in data collection and the definition of data elements. Another way to learn about the strengths and weaknesses of data sets is to examine studies using those data sets, because those studies will generally point out some of the limitations of the data set in their sections on methodology for that study.

Data on various diseases differs greatly. Although some diseases are reportable and, therefore, must be reported to a central data source (typically a state Department of Health, which then reports it to the CDC), most diseases are not reportable and so our knowledge of the number and distribution of those diseases rests on estimates from smaller population samples. In addition, many of these nonreportable diseases are self-reported and, therefore, lack a professional formal diagnosis for verification. As a result, we have relatively precise numbers of people diagnosed with syphilis in a given year (a reportable disease), but much less precise numbers of those people with arthritis. Arthritis is a very debilitating and expensive disease, but its prevalence in the United States or any particular state rests on estimates from population samples. Likewise, the "obesity epidemic" tends to be based on estimates, not actual numbers. Whether or not something is counted may have little to do with its importance for the health of the population. If the disease you are covering rests on estimates, you need to question the reliability of your data. Does the data reflect only those who have been hospitalized for a particular diagnosis, or does it include those living with the diagnosis in the community

or analysis done by the Kaiser Family Foundation. Policy institutes also reflect the full political spectrum. The Heritage Foundation (<http://www.heritage.org/>) and the CATO Institute (<http://www.cato.org/>) have long been identified as a source of conservative and free market health care proposals. The Brookings Institution (<http://www.brookings.edu/>) and the Center for American Progress (<http://www.americanprogress.org/>) tend to do more liberal-oriented policy research.

Human Impact Partners (HIP; <http://www.humanimpact.org/>) is one of the few organizations in the United States that conducts policy analyses with an explicit focus on uncovering and then addressing the policies and practices that make communities less healthy and that create health inequities. Emphasis is placed on policies outside the medical arena (e.g., housing, education, transportation, or urban planning). One important process for considering such policies is a health impact assessment (HIA; Dannenberg et al., 2008). An HIA is a practical tool that uses data, research, and stakeholder input to prospectively determine a policy's potential impact on the health of a population. HIAs also provide recommendations to address these impacts.

The above examples demonstrate the richness of nongovernmental research centers. There are many others that are relevant for particular areas of health policy analysis. For example, if you were focusing on a particular disease, there are organizations at the state and local levels that would be important resources.

DATA

Despite the ideal for use of evidence-based medicine and public health, evidence is frequently difficult to attain. Data is not always readily available, especially in the United States, where there is a focus on individual privacy and proprietary ownership of data. States generally have specific rules regarding the aggregation of data and the reporting of analyses so as to protect individuals from being identified. Specific health policies (e.g., Health Insurance Portability and Accountability Act of 1996 [HIPAA]) have tried to address these privacy rules for health care.

Much health data in the United States is collected by private corporations (e.g., insurance companies, hospitals, clinics, physicians, etc.).

Consequently, such data is considered to be proprietary data and generally unavailable to the public and to researchers without specific authorization by the owners of the data. In addition, because data tends to not be centralized in the United States, it is collected in different ways by different organizations, making comparisons between health data from different organizations very difficult. This is because organizations may use different definitions of variables, different means of measurement, and different computer software programs. Consequently, combining data from different organizations can become very difficult, even if these private organizations give approval for sharing data.

More recently, conversations among policy makers, practitioners, and private industry have centered on better data for decision making and improving medical care. There have been multiple calls for a transition to electronic medical records. Progress, however, has been slow, largely due to the issue of patient confidentiality and privacy. Creating linked data across multiple sites of patient care becomes problematic when the data systems capturing those data are privately developed and not interoperable, or in other words, cannot talk to one another. In addition, these data are also generally not linkable to population-based census data, so it is difficult to relate these data to important demographic and socioeconomic information.

The federal government, through the Department of Health and Human Services (<http://www.hhs.gov/>), collects much of the health data that is publically available. This is frequently done through cooperative agreements with state governments. For example, hospital discharge data is collected uniformly through the Uniform Hospital Discharge Data System (UHDDS), although control and analysis of the data may vary from state to state. Other standardized data sets include: Uniform Ambulatory Care Data Set (UACDS), Minimum Data Set for Long-Term Care and Resident Assessment Protocols (MDS 2.0), Outcome Assessment Information Set (OASIS), Data Elements for Emergency Department Systems (DEEDS), and Essential Medical Data Set (EMDS).

The National Center for Health Statistics conducts a number of different surveys. Some of the more popularly used health data sources are:

- National Health Interview Survey (NHIS) (<http://www.cdc.gov/nchs/nhis.htm>)

of these studies will potentially have major implications for the future allocation of scarce resources. Due to the stakes involved for medical care providers, the political pressures on such agencies are high. Whether this new U.S. agency will be able to escape the political pressures faced by previous efforts remains to be seen.

Centers for Disease Control and Prevention

The CDC's Policy Research, Analysis, and Development Office (CDC, 2013h) spearheads and coordinates policy work, including establishing policy priorities at multiple levels (federal, state, local, global, and with the private sector); conducting policy analysis; developing and implementing strategies (e.g., regulatory, legal, economic) to deliver on policy priorities; and coordinating agency work with the health care system and relevant organizations to advance the CDC's policy agenda. The CDC also assesses policy best practices and helps diffuse and replicate those practices.

The CDC recently funded the Center of Excellence for Training and Research Translation (Center TRT). The Center TRT recently developed an evaluation framework for obesity-related policy interventions that draws on RE-AIM and other processes mentioned previously (Leeman, Sommers, Leung, & Ammerman, 2011; Leeman et al., 2012). Policy analysts who are evaluating the formulation of a policy can use the framework to identify inputs such as data needed to assess political will, develop the policy, and identify stakeholders (formative evaluation). They then identify activities and outputs that are relevant to formulating policy, such as engaging stakeholders, raising awareness, and drafting policy solutions (process evaluation). Intended outcomes are also identified, but these may change as the process evolves. Through the use of "emergent logic models" (logic models that evolve over time), policy interventions can be examined in relation to the iterative policy process that we described in Figure 1.1.

In addition, the CDC (<http://www.cdc.gov/>) collects data, conducts and sponsors scientific research, administers national health efforts, promotes healthy and safe behaviors, and provides support to state tribal and local health initiatives. For example, the Nutrition and Obesity Policy Research and Evaluation Network (NOPREN), is funded by the CDC to conduct

transdisciplinary nutrition- and obesity-related policy research and evaluation in certain states. NOPREN helps to promote understanding of the effectiveness of policies related to preventing childhood obesity through improved access to affordable, healthy foods and beverages in a variety of settings, including communities, workplaces, health care facilities, child-care institutions, and schools (Ascher, Blanck, & Cradock, 2012). Several of the state-level policy research examples showcased in subsequent chapters of this book were funded in part through the CDC's NOPREN initiative.

The CDC is an essential resource for any health policy analysis. Some of the data-collection activities of the CDC are listed in the Data section, which follows.

Private Policy Research Institutes

There are literally hundreds of health policy research institutes around the country. There are too many to list them all and many specialties in health care have their own major research institutes. Some of these are imbedded in universities (public and private) and some are supported through federal and state grants or private funding. Some health institutes focus on rural health care (e.g., the six federally designated rural health research centers funded by the Health Resources and Services Administration's (HRSA) Office of Rural Health Policy, <http://www.hrsa.gov/ruralhealth/policy/rhrctdirectory/index.html>) and others focus on particular aspects of health, such as disabilities (e.g., the Association of University Centers on Disabilities, <http://www.aucd.org>). Some are focused on state health policy initiatives (e.g., National Academy for State Health Policies, <http://www.aucd.org>). The Rand Corporation (<http://www.rand.org>) has long been a center for major health care studies and reports. When talking about health insurance, one always has to mention the landmark "Rand Study" demonstrating the impact of cost sharing on patient outcomes (Newhouse, 1993). It remains the only clinical trial on health insurance. Rand continues to publish important health policy research, some of it published in peer-reviewed journals and others by Rand itself. The Henry J. Kaiser Family Foundation (<http://www.kff.org/>) has been a source of important policy studies on Medicare, Medicaid, the uninsured, and health care reform. Most studies involving Medicare or Medicaid generally cite some information

or scientific research groups that are published in limited noncommercial publications and tend to not be peer reviewed).

Congressional Budget Office

One source of policy analysis that is frequently overlooked is the Congressional Budget Office (CBO; <http://www.cbo.gov/>). Established to serve Congress, the CBO is a nonpartisan research group established to conduct studies for members of Congress. It is also the official scorekeeper for estimating the cost of legislative proposals. Consequently, its results tend to have a major political impact on legislative discussion and votes. For example, during past and recent debates on health care reform, the CBO's cost estimates of various proposals sunk some proposals and elevated others. CBO studies are done on the cost impacts of various legislative proposals, the number of uninsured, lessons from Medicare's demonstration projects on value-based payment or disease management, lessons from various Veterans Administrations programs, and other programs.

Government Accountability Office

The Government Accountability Office (GAO; <http://www.gao.gov/>) is an independent and nonpartisan organization that works for Congress. It is designed to assist Congress in improving the performance and ensuring the accountability of the federal government for the benefit of the American people. It is designed to provide members of Congress with timely information that is objective, fact-based, nonpartisan, nonideological, fair, and balanced. Its studies are generally in response to a hot political topic and are, therefore, done relatively quickly given the limitation in terms of time and data. There are several reports issued daily on various topics. The GAO also provides testimony to Congressional committees. Individual members of Congress can request studies to be done on topics of interest to them for potential legislation. Health topics might cover such things as Medicaid's response to states during economic downturn, the impact of changes in Medicare Part D, and premium changes in Medicare Advantage Programs, among others.

The Institute of Medicine

The Institute of Medicine (IOM; <http://www.iom.edu/>) was founded in 1970 and is one of the five national academies of science. It is a private, independent entity that attempts to provide best-evidence reports and information to the public and to decision makers. Much of its work is the result of Congressional mandates. Two of its most seminal works were *To Err Is Human* (Institute of Medicine, 2000) and *Crossing the Quality Chasm* (Institute of Medicine, 2001), which have been the foundation for much of the quality improvement work in the health sector in the past decade. The IOM has been an important source of information for shaping health policy discussions. Because we are using obesity as our primary example, it is important to point to the IOM's publication: *Bridging the Evidence Gap in Obesity Prevention: A Framework to Inform Decision Making* (Kumanyika, Parker, & Sim, 2010).

Patient-Centered Outcomes Research Institute

As mentioned previously, one of the contributions of the Patient Protection and Affordable Care Act of 2010 (ACA) was the establishment of the Patient-Centered Outcomes Research Institute (PCORI; <http://www.pcori.org/>). Its mission is to provide people with evidence-based information on the comparative effectiveness of various treatments. It is housed in an independent, quasipublic body. As reflected in its initial draft of priorities, it aims to take a patient perspective versus a purely clinical perspective in looking at the outcomes of alternative medical practices.

Some have viewed outcomes research as the beginning of personalized medical information, the indication that one procedure may be more effective for given subpopulations. PCORI tends to be different from effectiveness organizations set up in other countries, such as the National Institute for Clinical Excellence (NICE; <http://www.nice.org.uk/>) in Great Britain, in that it is not a governmental agency, it is limited in its ability to use cost-effective analysis or use its findings to recommend policy, and it is chartered to take a patient perspective. PCORI is designed to address one of the major questions in health care: Although both procedures X and Y are effective, is procedure X more effective than procedure Y? The results

as the Behavioral Risk Factor Surveillance System (BRFSS), or referring to published literature for estimates.

"Adoption" in the RE-AIM framework considers which political entity has the authority to decide to build the bike lane and the process it uses (e.g., the city council and the Department of Transportation would be responsible for making decisions about the bike lane, and which funds could be used).

"Implementation" in the RE-AIM framework considers how the policy is actually carried out. For example, are enough funds to build the bike lane actually allocated? Is the project completed? Who enforces use of the bike lane (e.g., are police officers or crossing guards deployed to manage dangerous intersections)?

"Maintenance" has two considerations, one at the setting level and one at the individual user level. For example, who will make sure that the bike lane remains free from trash and debris? Will additional city funds be allocated to maintain it? At the user level, one can measure ridership at different points in time to determine whether people keep using the bike lane or whether use drops off after a period of time.

NATIONAL EFFORTS OF HEALTH POLICY ANALYSIS

Health policy questions have been with us for a very long time. Perhaps one of the earliest efforts in the United States to methodically address these issues based on evidence was the study done by the Committee on the Costs of Medical Care that produced a multivolume study of the United States health care system and made recommendations for its improvement (Committee on the Costs of Medical Care, 1932). It is not surprising given the current debates on health policy that the recommendations from the 1920s were not unanimous and that there was a spirited minority report.

However, many of the recommendations of that committee would be familiar to current debates on health care policy. One of the consistent recommendations has been the collection of data so as to identify the precise nature of the problem. Within health policy, this is generally called "type 1 evidence." It provides information to document the existence of

a problem. An example of "type 1 evidence" would be the incidence rate of a specific disease that demonstrates either its increase or decrease over time. The collection of obesity data has done much to stimulate health policy action in the United States. It demonstrates the existence of a problem. Type 1 evidence does not attempt to explain the cause or the potential solution to the problem. The collection of demographic, epidemiologic, and medical use data has been an ongoing activity of federal, state, and local health departments. In 1956 the National Health Security Act led to the establishment of the National Center for Health Statistics (NCHS). Health data collection remains an important aspect of knowing where we are in terms of improving the health of the population.

Agency for Healthcare Research & Quality

Through the 1980s and 1990s there was a concerted effort to improve the analysis of the health care system through the establishment of the Agency for Health Care Policy and Research (AHCPR), which later became the Agency for Healthcare Research & Quality (AHRQ; <http://www.ahrq.gov/>). Here the focus was not just on the collection of data, but the analysis of data to demonstrate that one approach may be more effective, efficient, or equitable than another. This is generally referred to as "type 2 evidence." It requires a higher level of data analysis by taking into account confounding factors and potential spurious relationships. A large number of sponsored research projects are conducted and supported by the AHRQ as well as the National Institutes of Health (NIH) and the CDC to demonstrate the efficiency, effectiveness, or equity of medical and public health practices. These studies are generally carried out by research universities or consulting companies as well as by private foundations (e.g., the Kaiser Family Foundation or the Robert Wood Johnson Foundation). In addition, most levels of public and private funding require formal evaluations of their sponsored projects. The lessons learned from these projects help to inform policy makers of the successes and failures of funded efforts to solve particular health problems. The products of these studies frequently end up in the peer-reviewed literature (journals with blind peer review of submissions) as well as grey literature (studies conducted by government

2013; Kumanyika, Brownson, & Cheadle, 2012; Work Group for Community Health and Development, 2013). These include PRECEDE-PROCEED, RE-AIM (Reach, Effectiveness, Adoption, Implementation, Maintenance), and L.E.A.D. (Locate evidence, Evaluate evidence, Assemble evidence, Inform Decisions). L.E.A.D. is discussed in more detail in later chapters.

PRECEDE-PROCEED is an evaluation framework that was developed in 1974 by Dr. Lawrence Green. It describes a process that starts with desired outcomes and then works backward to identify the best combination of strategies for achieving those outcomes. The framework assumes that the program participants (or "consumers") will play an active role in defining their own problems, establishing their goals, and developing their solutions. Health behavior is conceptualized as being influenced by both individual and environmental factors, and the framework is broken into two distinct parts. The first, *PRECEDE* (Predisposing, Reinforcing, and Enabling Constructs in Educational Diagnosis and Evaluation), provides an educational diagnosis. For example, predisposing factors include knowledge, attitudes, beliefs, personal preferences, existing skills, and self-efficacy toward the desired behavior change. Reinforcing factors include conditions that reward or reinforce the behavior change, such as social support, economic rewards, and social norms. Enabling factors include skills, availability and accessibility of resources, and other services that facilitate behavior change.

The second part of this framework, *PROCEED* (Policy, Regulatory, and Organizational Constructs in Educational and Environmental Development), provides an ecological diagnosis. This framework has been widely used in public health and behavioral medicine (Freire & Runyan, 2006).

Another framework that evolved from PRECEDE-PROCEED and has gained popularity is RE-AIM (Reach, Effectiveness, Adoption, Implementation, Maintenance; Glasgow, Vogt, & Boles, 1999; King, Glasgow, & Leeman-Castillo, 2010). RE-AIM provides a set of criteria for planning and evaluating interventions that are intended to be broadly implemented, including policy interventions. To facilitate translation of research to practice and policy, RE-AIM emphasizes balancing internal and external validity. It also describes specific ways of measuring the potential public health impact of a program or policy.

The RE-AIM framework can be useful in comparing different public health policies, determining whether certain subpopulations benefit

more than others (equity), and identifying areas for integration of policies with other health-promotion strategies (Jilcott, Ammerman, Sommers, Glasgow, 2007). Application of the RE-AIM framework requires data (knowledge about the target population and the potential settings and organizations (e.g., clinics, worksites, schools) that can implement a policy change. Jilcott et al. (2007) describe how to apply RE-AIM to health policies, including policies that impact health in other sectors (such as urban planning policies that shape the built environment). Glasgow et al. (1999) offer examples based on actual community strategies employed in Colorado over the past 3 years (see <http://www.livewellcolorado.org>).

Questions to consider for RE-AIM include:

1. Whose health behaviors and health are to be improved?
2. Which stakeholders need to be included in the planning process and which agencies are responsible for approving or adopting the policy change?
3. Which agencies are responsible for implementing the change?
4. Which agencies are responsible for maintaining the change?
5. What funding needs to be secured to implement and maintain the change?

"Reach" includes the absolute number, percentage, and representativeness of those affected by a policy or environmental change. For example, to apply RE-AIM to our obesity issue, imagine that a city council decides to build a new bike lane to increase active transportation. Which populations are likely to be affected the most? Does the bike lane connect a low-income neighborhood to a park or school, or does it connect a wealthier neighborhood to a commuter rail station?

"Effectiveness" in the RE-AIM framework involves using research methods to study who actually uses the bike lane. This may involve collecting data before and after the bike lane is built. Alternatively, one can sometimes make an educated guess by referring to published studies from similar communities that have constructed bike lanes. As mentioned previously, effectiveness may also involve measuring changes in risk factors (e.g., obesity) and/or disease rates in the target population, although this would involve a longer period of study. This can be achieved by collecting primary data, using secondary data from a surveillance system such

Another type of efficiency study is a cost-utility study. This type of study does similar things as the other two; however, the results are weighted by society's preferences. For example, although a cost-effectiveness study might look at the results in terms of the number of lives saved, the cost-utility analysis would take society's (or the patient's) estimate of the value of the extra years of life saved. Cost-utility analysis takes into account the quality of that year of life saved. How much of a difference do patients value an additional year of life that is pain-free versus an additional year of life in severe pain? This is where economists and epidemiologists have used the concept of a quality-adjusted life year (QALY). Such measures can be controversial from theoretical as well as technical perspectives. Some argue that QALYs diminish the value of life of a "disabled" person. Others might take exception to the methodology by which the QALY is actually calculated. Despite these difficulties, most view these types of studies as useful inputs into programmatic and health program/policy considerations.

Economic analysis is a whole different area of policy analysis. If efficiency is a major focus of your policy proposal, you need to become familiar with the details of the various types of efficiency studies in greater detail than we can possibly do here.

EQUITY

The third major area of concern for health policy analysis is that of equity; generally, this means promoting fairness within the health system. This includes eliminating disparities in access to health-promoting resources for subpopulations (e.g., gender, sexual orientation, race, ethnicity, income, education, geography). This area of policy addresses how health policies can promote the elimination of unfair differences in health status. Why are certain minority populations differentially impacted by diabetes (Betancourt, Duong, & Bondaryk, 2012)? Blacks have a very different life expectancy than do Whites (Smedley, Smith, & Nelson, 2003). Former U.S. Surgeon General Dr. David Satcher and colleagues calculated that 83,570 of the African Americans who died in 2002 would not have died if Black and White mortality rates were equal. This means that there were 229 "excess deaths" per day, or the equivalent of an airplane loaded with

only Black passengers crashing every single day of the year (California Newsreel, 2008). What policies or programs can be enacted that will reduce such disparities? The major national health-planning document Healthy People 2020 (2013b) identifies the reduction in disparities as a health status between subpopulations within the United States as one of its major goals. The Centers for Disease Control and Prevention (CDC) recently developed a guide to assist practitioners with integrating the concept of health equity into local practices and policies, such as building organizational capacity, engaging the community, developing partnerships, identifying health inequities, and conducting evaluations (Center for Disease Control and Prevention, Division of Community Health, 2013). The guide offers lessons learned from practitioners within local, state and tribal organizations that are working to promote health and prevent chronic disease health disparities. It provides a collection of health equity considerations for several policy, systems, and environmental improvement strategies focused on tobacco-free living, healthy food and beverages, and active living.

Equity is divided into two aspects. One aspect is *procedural equity*, which assures that processes that are in place are fair and do not discriminate. For example, procedures are in place to guarantee that those who receive organ transplants are not those with the most money or who have connections to the medical community, but those who are in greatest need and have a higher chance of survival. The second aspect of equity is *substantive equity*, to reduce the disparities between survival rates that cannot be explained by biological conditions, such as infant mortality rates for Black children. What policies or programs can be implemented to help reduce the disparity in outcomes among various populations? If equity becomes a major aspect of your policy proposal, you should access major texts in epidemiology and public health and medical ethics.

INTEGRATIVE FRAMEWORKS

There are several integrative frameworks that enable health program planners, policy analysts, and evaluators to balance criteria when they analyze health programs and policies (Gielen, McDonald, Gary, & Bone, 2006; Green, 1974; Green & Kreuter, 2005; Human Nutrition, Foods and Exercise

imaging services, thus spreading the fixed costs of the service over more units of service (patients). Specialization, division of labor, and substitution of capital for labor are general strategies that are frequently used for increasing the production efficiency of particular units.

In contrast, allocative efficiency deals with maximizing outputs in society given limited resources; it focuses on the efficiency of one sector versus another. If one wants to produce the most health for a society, improving the production efficiency of a hospital might not necessarily increase the allocative efficiency of the health care system in producing a healthier society. Making hospitals more productively efficient does not solve the inefficiency of treating people after they become sick. The United States has dramatically increased its spending per capita and percentage of gross national product for health care (Kaiser Family Foundation, 2011). Shifting resources from medical care to public health could increase the allocative efficiency of the health care system by producing a healthy population, thus eliminating the need for some of the increased medical costs. Shifting resources from medical care to providing livable incomes for the poor, increased education, or improving the built environment in an inner city might improve the health status of the population at a much lower cost than increasing hospital expenditures, even in efficient hospitals. One can have very efficient hospitals within a health care system that does not maximize the health for the population given the limited resources available and the inputs that are the most important for producing a healthy population. Spending money on prevention or providing more general education to the population may produce much greater health at a lower cost to society as a whole. Whether the United States spends too much of its limited resources on medical care is an open allocative efficiency question.

Types of Efficiency Studies

The literature on efficiency is divided into three major types of studies: cost-effectiveness studies, cost-benefit analyses, and cost-utility studies. Cost-effectiveness studies catalog all of the input costs (wages, equipment, buildings, time, etc.) in comparison to the results of that effort (lives saved, procedures done, etc.). It is a systematic analysis of

the cost of alternative methods to reach the same objective. As a result, comparisons can be done contrasting different procedures to see which is more cost-effective. One of the difficulties of such studies is making accurate calculations in terms of the total costs. Studies may take a very institutional focus by thoroughly cataloging institutional costs, but might forget about the patient's costs. An institution can shift some of its costs to patients, thus making the results look more cost-effective than they actually are, if one includes patient costs as well. For example, the early discharge of patients from hospitals reduces hospital costs and increases its efficiency, but shifts patient costs onto supporting family members who must care for the patient at home. Despite potential technical problems, cost-effectiveness is an important tool in public health policy analysis (Grosse, Teutsch, & Haddix, 2007). You should become familiar with what makes a solid cost-effectiveness study.

A second type of efficiency study is a cost-benefit analysis. It uses the same approach as a cost-effectiveness study in calculating the cost of the procedure. However, it is different from a cost-effectiveness study in that the benefits are measured not in terms of procedures done or lives saved, but in terms of dollars. Thus, the comparison of cost and benefit is dollars to dollars. The complication here is that the number of lives saved needs to be converted to a dollar amount, thus requiring a dollar value to be placed on a life. There are multiple ways that have been used to measure the value of a life. Although some may raise ethical objections to such an approach, in fact, placing a dollar value on life is done fairly frequently, such as when an individual is compensated by insurance for the loss of a limb, survivors are compensated for the loss of a loved one, or when proven life-saving technology is intentionally not used due to its expense. Cost-benefit analyses make such decisions as to the value of adding 3 additional years of life for an 85-year-old person or the potential of an additional 62 years for a 25-year-old. Frequently, foregone earnings are used as an approximation of the earning potential of someone at a given age. Doing this again raises ethical problems. How does one value the life of someone who has not been working but has been doing child care? Is the value of the life of a retired person zero? Despite these difficulties, economists use conventions to address these and other issues. It is important for you to understand the implications of these conventions for policy and to learn to appreciate the utility of cost-benefit studies.

Efficiency

A second major aspect of health policy analysis revolves around the issue of efficiency, the ratio of outputs to inputs. As indicated by Victor Fuchs in his groundbreaking book from 1974, "No country is as healthy as it could be; no country does as much for the sick as it is technically capable of doing. . . . The grim fact is that no nation is wealthy enough to avoid all avoidable deaths" (Fuchs, 1974, p. 17). This recognizes the fact that societies have a limited amount of resources and that spending in one area may reduce the ability for spending in another. Within a health care system one would want to maximize the health of the population in order to conserve resources for other sectors of society, such as education or national defense. This is typically measured by the percentage of the gross national product spent on health care. By this measure, the United States spends by far the highest percentage of any industrialized country in the world on health care (Kaiser Family Foundation, 2011). When a society realizes its resources are limited, one would hope that those medical services that do the least good are the ones to be reduced or eliminated in order to be able to expend additional resources on those services that are more cost-effective. The Institutes of Medicine recently convened the Committee on the Learning Health Care System and identified three main themes, efficiency of an underperforming system relative to its potential being one of them (Institute of Medicine, 2012).

In 2009, Thomson Reuters estimated that between \$250 and \$325 billion in unwarranted medical services are wasted each year in the United States (Kelley, 2009). The Good Stewardship Working Group developed a list of the top five activities primary care physicians could stop doing in order to improve care and reduce costs (The Good Stewardship Working Group, 2011). They then calculated that the annual savings of not doing these things (e.g., not using brand-name drugs when initiating lipid-lowering drug therapy) could result in a cost savings of \$6.76 billion per year (Kale et al., 2011).

The International Federation of Health Plans developed an interesting international comparison of prices for specific medical procedures and pharmaceuticals; for example, a hip replacement in 2010 cost \$9,637 in Britain, \$10,753 in Canada, \$12,629 in France, \$15,329 in Germany, and 4,454 in the United States (Klepper, 2004). The magnitude and cause of

the inefficiency of the U.S. medical system might be in dispute, but there is a consensus that there is a great deal of waste within the existing system. The amount of waste and inappropriate care was indeed popularized and became a factor in the political discussions for health care reform with Atul Gawande's comparison of the differences in health care costs in two Texas communities (Gawande, 2009).

Of course, one of the major areas of efficiency is the area of disease prevention and health promotion versus medical treatment. Public health advocates generally site that the efficiency of the health system can be enhanced by preventing disease and disability in the first place. Studies using cost-benefit and cost-effective analyses have demonstrated that prevention activities can save money by foregoing medical expenditures (Graham, Corso, Morris, Segui-Gomez, & Weinstein, 1998; Grosse, Teutsch, & Haddix, 2007; Mays & Smith, 2011). This aligns with the well-known proverb that an ounce of prevention is worth a pound of cure. Vaccines are a typical example of this policy focus on prevention. However, here, again, one must be careful not to apply this universally. For example, if a disease is fairly rare and the consequences of getting that disease are not too harmful, providing a vaccine to the entire population, or even a large proportion of that population, may be far more costly for society than providing medical care treatment for the few individuals who actually acquire the disease. Generally, however, disease prevention and promotion are less costly than treatment, especially taking into account the adverse experiences of people having to experience the disease process, treatment, and sequelae.

Allocative and Production Efficiency

Of "allocative efficiency" and "production efficiency," production efficiency is the more generally understood term. It involves maximizing the ratio of outputs to inputs for producing a given item. For example, one can improve the production efficiency of a medical practice by using physician assistants or nurse practitioners. The latter are typically paid less than physicians and can perform a number of frequently performed tasks at a lower cost. The use of scheduling protocols can improve the flow of patients and, thereby, increase the number of people screened per day for

University, 2013). What tends to explain this variation? What are the consequences of this variation? Given that variation in medical care exists, what is the right level of medical care? Geographic variation has multiple potential explanations. How much variation is warranted and how much is unwarranted is a part of the difficulty of current efforts to restructure payment systems in order to create the right incentives for increased efficiency and effectiveness of medical care (National Institute for Health Care Reform, 2011).

It is important to note several important aspects of effectiveness of medical treatments. Generally, effectiveness of medical care is tied to the biological aspects of disease and proposed therapies. Do statins reduce cholesterol and thereby reduce the risk of cardiovascular diseases? Is the use of statins related to memory loss? To test these questions, the gold standard has been a clinical trial, by which a comparison is done between those receiving treatment and those not receiving treatment. We will discuss the strengths and weaknesses of clinical trials later in this chapter.

In some areas, such as pharmaceuticals, the federal government's Food and Drug Administration (FDA) is authorized to approve or disapprove such medical interventions. Formal approval by the FDA does not end the process of evaluation of effectiveness, because payers (Medicare, Medicaid, and private insurance companies) make their own decisions regarding whether they will categorize the treatment as "experimental" and, therefore, not list it among their covered services.

However, the FDA is restricted in terms of its authority; although it has authority to approve appliances (e.g., implants) and pharmaceuticals, it is not authorized to approve or disapprove medical procedures. There has been medical controversy over the effectiveness of vertebroplasty, a surgical procedure used for people with severe back problems (Wulff, Miller, & Pearson, 2011). As a medical procedure, the FDA was not involved in its approval. There are thousands of these procedures performed each year in the United States, at a cost of \$5,000 to \$6,000 per patient. This procedure also became accepted in medical practice prior to any clinical trials demonstrating its effectiveness. However, in 2009 the results of two clinical trials were published and both demonstrated that the procedure was no more effective than a sham procedure (a procedure recognized as not providing any medical benefit; Buchbinder

et al., 2009; Kallmes et al., 2009). Despite these findings, the procedure continues to be performed and paid for by major insurance providers in the United States.

The analysis of comparative effectiveness has the possibility of initiating a more precise recommendation for the most effective treatment for different subpopulations and the beginning of "personalized medicine." Frequently, the criteria for effectiveness do not take into account the experience and perspective of the patient. This is particularly important in terms of taking into account the sequelae of a particular procedure. For example, prostate surgery may remove cancerous tissue, but due to the slow-growing nature of prostate cancer in general, the patient might die of another disease before he would have died from prostate cancer. However, by undergoing the surgical procedure for prostate cancer the patient may have a diminished quality of life due to incontinence and impotence following the procedure. The effectiveness of such treatment from the patient's perspective is far from clear. As noted by the example, the effectiveness of treatment is more complicated than the removal of cancerous tissue. The Patient-Centered Outcomes Research Institute (PCORI) has been established, not only to do comparative effectiveness research, but to also take into account the patient's perspective, culture, and values (Garber, 2011; Patient-Centered Outcomes Research Institute, 2012). PCORI offers great possibility for dramatically changing medical care in the future and it has the potential to provide the patient with information that will allow greater control over the application of more complex medical technologies (Institute of Medicine, 2012).

One of the modern classics of effectiveness studies is that done by McGlynn et al. (2003) on the quality of care in the United States. It concluded that patients in the United States received a little more than half of what was recognized as quality care. The study sent a shock wave through the medical community and it remains a seminal piece of evidence in the effectiveness of our medical care system.

As seen above, determining what is effective is not as clear-cut as one might initially think. This becomes compounded, given rapidly changing technology. What may appear to be effective today might be outmoded in 1 or 5 year(s). If effectiveness is a major part of your policy proposal, you should access texts in epidemiology and effectiveness research.

and minority populations are at heightened risk of diabetes, how should Medicare and Medicaid policies be developed to minimize the impact of diabetes on individuals, specific groups, and society as a whole (Fradkin, 2012)? Obesity has become a modern-day American epidemic, but logical and scientifically based programs to fight obesity tend to flounder for lack of political action.

There has been a recent focus on the importance of evidence-based medicine and evidence-based public health (Anderson et al., 2005; Brownson, Chiqui, & Stamatakis, 2009; Green, 2006; Kumanyika, Parker, & Sim, 2010; Swinburn, Gill, & Kumanyika, 2005), underscoring the need for systematic evaluation of what works in medicine and public health. Although this is encouraging, evidence-based health care is something that is easier said than done. Evidence-based health systems and policy remain the goal, no matter how difficult the path may be.

EVIDENCE-BASED HEALTH POLICY

There is a great deal of literature focusing on medicine and the medical care system. Aday, Begley, Lairson, and Balkrishnan (2004) have created a useful paradigm of health policy analysis by dividing the literature into three areas of concern: effectiveness, efficiency, and equity. You will need to think about this as you develop your own policy. Is your program/policy proposal designed to increase effectiveness, efficiency, or equity? We shall briefly explore these concepts so that you have a better idea as to how to structure your policy analysis. We will discuss this in greater detail in Chapter 7, which deals with the systematic review of policy options.

Effectiveness

The effectiveness literature focuses on demonstrating what works to improve the health of the individual or the population. Certainly, public policies should encourage those treatments that work and discourage those that waste resources or do not improve the health of the population and/or potentially cause harm. The regulation of the medical care industry from the licensure of health professionals, accreditation of health

care organizations, and approval of pharmaceuticals are predicated on protecting the public from harmful practices and encouraging those that are effective. Since the days of codeine-laced cure-alls, effectiveness and prevention from harm have been key components of health policies.

Effectiveness needs to be discussed from two different perspectives, population effectiveness and medical effectiveness. Medical effectiveness tends to deal with individual patients and the impact of a specific intervention. These are typically evaluated by conducting clinical trials that take a similar group of people and then randomly assign them to either the prescribed treatment or to a placebo to test the effectiveness of the treatment.

Population effectiveness rests on Geoffrey Rose's population strategy that has become the theoretical basis for public intervention to prevent disease (Rose, 1992). Rose maintained that prevention should not just focus on high-risk individuals, but on the population as a whole. Thus, reducing salt consumption benefits not only those with hypertension, but also those who are prehypertensive. By reducing the average intake of salt for the entire the population, the population as a whole benefits. Although this reduction of the average intake in salt may not make a perceptible difference to some individuals, it is effective for the population as a whole.

In addition to the biological aspects of effectiveness, there are also the health systems and social system aspects of effectiveness. For example, although certain pharmaceuticals have been demonstrated to be effective for diseases on the individual level, the lack of clinical facilities, refrigeration, social support systems, or cultural norms may prevent those same pharmaceuticals from being effective for the population in a developing country.

The focus on evidence-based medicine is not new. However, it gained a great deal of momentum with the pioneer work done by Wennberg and Gittelsohn (1973). Their research focused on the variation in the practice of medicine from one geographic area to another and what could potentially explain such variations. The Dartmouth Atlas documents the geographic variation in the practice of medicine within the United States (<http://www.dartmouthatlas.org/>). In addition, there is also great variation in health status across the United States. Studies conducted by the Joint Center for Political and Economic Studies have shown that life expectancy in some parts of the United States can vary by as much as 30 years when comparing one zip code to another (Virginia Commonwealth

shaped by the actions of both individuals and society through the policy process; the health of a society is not predestined, and public policies play a major role in determining health.

Our understanding of these different inputs to health has changed over time. For example, efforts to increase physical activity and improve nutrition among the general population were historically aimed at changing individual-level health behaviors. Individuals were told to exercise more and eat healthier meals. The focus was on how to get the individuals motivated to change their behavior and to adopt healthy eating patterns. Thaler and Sunstein (2008) refer to this as "the nudge" or "libertarian paternalism." However, such approaches have been found to be minimally effective, costly, and difficult to sustain (Lyn et al., 2013).

As a result, public health professionals have begun to address this problem using a more comprehensive approach referred to as "policy, systems, and environmental change." This approach includes: (a) policy interventions that seek to change laws, ordinances, regulations, or legislation (e.g., a city council zoning ordinance prohibiting fast-food chains within a certain distance of a school); (b) system-level interventions, which promote changes that impact organizations, institutions, or communities (e.g., a school deciding to buy a certain percentage of its cafeteria food from local sources, and training the food-service staff to cook and serve vegetarian meals on certain days); and (c) environmental interventions, which involve changes to the physical environment (e.g., a school constructing bike lanes and bike storage facilities to encourage active transportation to school), often resulting from policy decisions such as zoning and transportation expenditures (Lyn et al., 2013; Michigan Cancer Consortium, 2012). As a result, our increased understanding of the interaction of various factors of health has complicated the policy process because one simple intervention is probably not going to be sufficient. These initiatives are also built on the notion that individual decisions for healthy behavior can be facilitated or frustrated by political decision making.

HEALTH POLICY ANALYSIS

As a result of this more comprehensive and systematic understanding of the inputs to health, the breadth of "health policy" has increased dramatically.

Policy regarding transportation has an impact on health. Environmental policy has an impact on health. Educational policy has an impact on health. Economic policy has implications for health. The 2010 Adelaide Statement describes this approach as "Health in All Policies" (KreValentine, Reinders, & Albrecht, 2010; World Health Organization, 2010). The Adelaide Statement emphasizes the need to examine policies for the health inputs across different policy areas. It calls on the health sector to be involved in the development of policies in other sectors to maximize health status as well as to ensure health equity. This is a significant broadening of the scope of the health sector within public policy making. Adelaide Statement describes innovative models emerging from around the world. Of critical importance to the success of this approach will be the aggregation of evidence, including studies of policy adoption and implementation in different geographic and political environments.

Health policy analysis is a type of applied research. Although one might think that our health care system is evidence based and dependent on research, research demonstrates to be valuable, that is not always the case. In fact, it is not usually the case. Many health programs and proposals that have been demonstrated to have scientific validity never get broadly implemented and, even more commonly, many existing programs and practices in medicine have never been formally proven to be effective. The Institute of Medicine has estimated that about 4% of health services have evidence to back them and that more than half have no evidence or evidence to support them (Field & Lohr, 1992). Researchers have identified several aspects of policy analysis that are in need of particular attention (Brownson et al., 2006; Brownson, Chiqui, & Stamatakis, 2009; SchPratt, & Witmer, 2006). These include: (a) documenting *how* an impact is achieved in a particular context; (b) understanding barriers to successful implementation; (c) delineating multiple outcomes that could be implemented (including unintended consequences and differential impacts on different vulnerable populations); and (d) developing tools to help prioritize policy choices, including specific criteria to evaluate policy impacts.

The importance of conducting sound policy analysis is highlighted by the fact that one considers the problem of chronic diseases such as obesity. Although there is much we know about the cause and consequences of obesity, how the political and health systems should respond to that knowledge becomes the focus of health policy analysis. For example, because e-

HEALTH AND HEALTH POLICY

Health policy is part of the larger field of health services research, an area devoted to the discovery of new information for the improvement of individual and population health. Due to the nature of health, both health services research and health policy analysis are interdisciplinary by nature, using the knowledge of both the biological sciences and the social sciences. The evolving fields of implementation science, decision science, and sustainability science also address health policy analysis (Clark, 2007; Clark & Dickson, 2003).

Health is a complicated concept. The most famous definition of health comes from the World Health Organization (WHO): "health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity" (World Health Organization Constitution Preamble 1948, p. 100). This definition points to the comprehensive nature of health: there is both a physical and mental aspect of health as well as a sense of well-being. The definition tends to be more aspirational, with a focus on what it takes to achieve human potential rather than a description of reality. Individuals and societies transition from one state of health to another over time. Given the WHO definition, "health" may be a very temporary state.

Health is not a given. Societies create conditions that promote both disease and health. As demonstrated by Evans and Stoddart and other similar social-ecological and systems science models, societies produce health or disease through the interaction of multiple variables (e.g., policy, the natural and created environments [the built environment building medical care systems, as well as individual behavior; Evans Stoddart, 2003; Huang, Drewnowski, Kumanyika, & Glass, 2003; McLeroy, Bibeau, Steckler, & Glanz, 1988; Stokols, 1992; Stokols, Allen, Bellingham, 1996). Manipulating any one of these variables (e.g., education or the transportation systems) creates greater disease or health for individuals and for society as a whole. Therefore, by implication, societies have the ability to influence their own health through their public policies. The creation and distribution of wealth; the educational system; natural and built environments, including but not limited to the creation of safe living and work environments; and access to the medical care system all play critical roles in determining the health status of a given population or a particular individual. All of these inputs to health are

diagram, these component parts of the process are quite iterative in practice. That is to say, they do not always flow linearly from one to the other, nor do they have definitive boundaries. In some cases, the activities overlap. However, for descriptive purposes, we describe them generally here. The first step in the policy process is typically policy formulation (policy development). This includes identifying a problem or issue, considering value orientations, framing the issue, proposing one or multiple approaches to addressing the problem/issue, defining the policy objectives, estimating impacts, and then drafting the policy content and strategically moving the policy toward adoption. This phase is the primary focus of this text.

However, this phase bridges with the other phases in the political process. It involves all the strategic and negotiation points one must consider and engage in to get support for a formal piece of legislation. We will focus on some of this in Chapter 8, Recommendation and Strategies. Once a policy has been legislatively passed into law and adopted, the policy implementation phase begins. This involves "who does what and when" to make the program operational. At times, this is distinct from the adoption phase; for example, creating a detailed blueprint for action. At other times, this phase overlaps with the adoption phase and the legislation prescribes specific implementation guidelines. For example, the adoption process could stipulate when various components of the law are to begin and allow time to build the capacity for implementation. In both cases, there should be clear goals and measures of success to evaluate outcomes. These are expanded on in Chapter 6: Criteria for Success.

After some period of implementing programs/policy, progress toward the stated goals and outcomes must be measured. This is the policy evaluation phase. Here it is important that the previous phases be clear and explicit so that success (or lack thereof) can be empirically demonstrated. The final phase, policy modification, is the closing of the policy feedback loop where adjustments to a given policy are made if necessary. Here one might examine costs relative to benefits. Programs and policies are frequently modified due to changing needs and expectations as well as changes in the partisan control of the political system. There may also be calls to repeal the policy if outcomes are deemed negative or to expand the policy to other groups. Adjustments are made continuously.

and interests collide. We will discuss this in greater detail in Chapter 5, which examines normative and stakeholder analysis. For now, what is important to remember is that the political system makes decisions (no matter what its actual political components and procedures might be) as to what is of relative value and makes those decisions binding on its citizens through laws, rules/regulations, executive orders, court decisions, and other official actions taken by the political system. The political system uses its monopoly of the police powers of the state to enforce those decisions.

Public laws, programs, policies, and public expenditures adopted by the political system are all designed to impact individuals, organizations, and other levels of the political system in order to reach the desired outcomes for that society. Of course, one of the important decisions made by the political system determines when individuals are free to act according to their own desires and when they are required to act in the interest of society as a whole. An example of this is the debate as to whether the federal government of the United States should require individuals to purchase health insurance for the good of the whole. The United States Supreme Court settled the legal issues relative to this in *National Federation of Independent Business et al. v. Sebelius, Secretary of Health and Human Services, et al.* (2012), about which it was decided that the federal government can impose such an individual mandate for health insurance; the political and policy issues as to whether it *should* have an individual mandate remain outstanding issues for the political system.

There are multiple definitions of policy. Some definitions are more general than others and each has its own advantage. We do, however, wish to provide an understanding as to how the term is going to be used throughout this book. We use the term *policy* to refer to a product or outcome of the political system, the system that is designated to make decisions regarding the collective good. Some scholars categorize policy as "big P" and "little p" policy. "Big P" policy refers to legislation or formal laws, rules, and regulations enacted by elected officials, such as a state legislature or the United States Congress (Brownson, Chriqui, & Stamatakis, 2009; The Community Foundation for Greater Atlanta, 2008). These policies include laws that regulate the resources and behaviors of individuals, organizations, and businesses. Judicial decisions may determine policy through rulings on cases involving various public programs and procedures. In contrast, "little p" policy refers to institutional

policies (e.g., organizational guidelines, internal agency decisions, or memoranda) that guide organizational behaviors and functions. Although all types of policy have important implications for health, we will focus primarily on "big P" policy for the purposes of this book.

THE POLICY-MAKING PROCESS

Policy operates in an iterative manner, much as a turning wheel (see Figure 1.1). In this text we are mostly focused on the policy-formulation phase. However, as we will see in Chapter 8, Recommendations and Strategies, we cannot overlook the policy adoption and implementation phases of this policy wheel. Policy can be created anywhere on this wheel.

Policy making is a process that has often been described theoretically and modeled within the political science literature. Theories and conceptual models from the literature can help to better understand the policy process (Bacchi, 1999; Coveney, 2010; Jones, 1984; Kingdon, 2003; Lasswell, 1971; Sabatier & Jenkins-Smith, 1993). For example, one commonly used model is one proposed by Longest, which has four general elements: (1) policy formulation, (2) policy implementation, (3) policy evaluation, and (4) policy modification (Longest, 1998). Figure 1.1 is a modified version of Longest's model of policy making.

Figure 1.1 provides a composite view of several different theories about the policy process. As designated by the circular nature of the

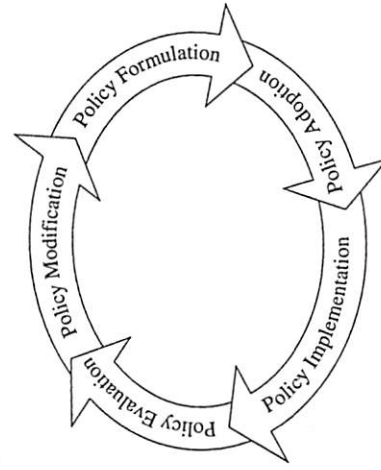


FIGURE 1.1 Policy wheel.
Source: Evenson and Aytur (2010).

One

Health Policy Analysis

The purpose of this introductory chapter is to provide an overview of important concepts that you will need to remember in doing your health policy analysis. It provides an overview of some of the interdisciplinary knowledge that is required for doing health policy analysis. You may wish to refer back to this chapter as you work through the remainder of the textbook. You may also wish to supplement the material here by accessing other texts within various disciplines.

POLITICS AND POLICY

David Easton has defined politics as "the authoritative allocation of values for a society" (Easton, 1953, p. 127). Harold Lasswell defined politics as described by the subtitle of his book as "who gets what, when, and how" (Lasswell, 1936). Politics encompasses the need for every society to make binding decisions for all members of a community governed by that political system regarding which values and interests are to be legitimized by the civil government. In this process, there invariably will be winners and losers. It is the political system that has the responsibility of making these decisions. This leads to tension among members of the political community when critical values