Key Issues in Outcomes Research

Policy Research
Using Evidence to Improve Healthcare Delivery Systems

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If pressed to identify the person or persons who has most directly affected their health and healthcare, most people would name their family members and friends, along with doctors, nurses, and others they’ve encountered at clinics or hospitals. Few would identify a politician or other policy-maker because health policy is made far from the bedside. Yet the enactment of health policies can be transformative to the practice of medicine and the delivery of healthcare. For instance, in 1946, US President Harry S. Truman signed the Hospital Survey and Construction Act (also known as Hill-Burton), providing federal grants and guaranteed loans to improve hospital systems, vastly increasing the availability of hospital services throughout the nation. On July 30, 1965, US President Lyndon B. Johnson signed into law amendments to the Social Security Act authorizing the creation of Medicare and Medicaid insurance, providing accessible and affordable healthcare for untold numbers of poor, disabled, and older Americans.

Most health policy initiatives are not as far-reaching as the Hill-Burton Act or the Social Security Act. Rather, they are enacted with specific objectives in mind. For instance, the New York City Department of Health and Mental Hygiene initiated 2 policies explicitly designed to improve public health by focusing on people’s behaviors: banning indoor tobacco smoking in any public space and prohibiting the use of trans fats in food preparation by all restaurants and retailers.1,2 Many more health policy initiatives focus on the healthcare delivery system, including the care provided by doctors, nurses, clinics, hospitals, and short- and long-term care centers.

Health policy research generally attempts to determine the success or failure of policy initiatives, focusing on the complex, bidirectional interaction between policy and health. This inquiry is often conducted by interdisciplinary groups of investigators, taking advantage of the varying perspectives offered by physicians and nurses, economists and epidemiologists, psychologists and sociologists, political scientists and statisticians, and advocates and administrators. The field is quite heterogeneous; health policy research subjects include healthcare coverage, access and costs, markets and financing, public and private health insurance, management and organizations, disparities in care, knowledge implementation, and quality of care delivered by physicians, hospitals, and long-term care facilities among many others. Nevertheless, this research is distinguished by its attempt to characterize and examine health and healthcare delivery in the context of enacted health policies to inform future health policy.

The purpose of the present commentary is to provide a general orientation to health policy research for a cardiovascular readership, as we discuss how to use evidence from this field of inquiry to improve healthcare delivery systems, emphasizing examples from the cardiovascular literature. We will begin by describing the objectives of policy research, offering 3 distinct purposes for which health policy research is often used. Afterward, we will describe methodologies best suited for policy research, followed by several main challenges currently facing the field. Finally, we will conclude by discussing the importance of conducting health policy research.

Objectives of Policy Research
The central purpose of all health policy research is to examine the effect of enacted health policies to inform future health policy. There are 3 broad categories of health policy research: (1) descriptive: characterizing health and healthcare delivery; (2) analytical: examining the relationship between existing health policies and healthcare delivery; and (3) experimental: examining the real or potential impact of policy changes on healthcare delivery. Each will be described in more detail with relevant examples from the cardiovascular literature.

Descriptive Health Policy Research
The most frequently conducted type of health policy research seeks to describe or characterize health and healthcare delivery across an entire population or system of care or within subpopulations (the uninsured or Californians) or subsectors of care (safety-net hospitals or outpatient clinics). This type of policy research is critical in the evaluation of the healthcare delivery system, examining how the system is functioning for

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patients, clinicians, or hospitals and identifying problems or opportunities to improve healthcare delivery.

The Cooperative Cardiovascular Project (CCP) provides an excellent example of descriptive health policy research because it was undertaken to identify and characterize problems in healthcare delivery. In the early 1990s, the Health Care Financing Administration (known today as the Centers for Medicare and Medicaid Services) transitioned from being a large payer of healthcare for older Americans to an insurer also focused on quality of care. Accordingly, it began a series of quality initiatives to characterize the state of quality of care for all Medicare beneficiaries. The CCP focused on the treatment of patients with acute myocardial infarction (AMI), first convening a steering committee to draft quality indicators (measures of processes and outcomes of care) heavily based on clinical practice guidelines, then collecting information on all Medicare beneficiaries admitted to all US hospitals with a principal diagnosis of AMI over an 8-month period between 1994 and 1996. The CCP examined 10 quality indicators, including 3 outcome measures (inpatient, 30-day, and 1-year mortality) and 7 process measures with varying eligibility criteria (reperfusion within 12 hours of admission, aspirin on admission and discharge, β-blocker and angiotensin-converting enzyme inhibitors on discharge, avoidance of calcium channel blockers, and tobacco cessation counseling) and demonstrated substantial underutilization of high-quality care; only 67% of eligible patients underwent reperfusion during hospitalization, only 50% received β-blocker therapy at discharge, only 59% received angiotensin-converting enzyme inhibitors at discharge, and only 42% received tobacco cessation counseling. Moreover, there was wide geographic variation in healthcare quality, such that, as an example, in some regions, 100% of patients received an aspirin on admission, whereas only 68% did in others.

Descriptive health policy research frequently makes use of publicly available data to characterize health and healthcare delivery, often collected through US government–sponsored programs, such as the National Center for Health Statistics. For instance, the Behavioral Risk Factor Surveillance System (collected by the Centers for Disease Control and Prevention) was used to describe healthcare utilization among adults with and without health insurance, finding the uninsured and those with lower incomes to be less likely to receive recommended preventive and chronic disease care, including cholesterol and hypertension screening, cholesterol monitoring among patients with hypertension or cardiovascular disease, and weight loss and smoking cessation advice from a physician. In addition, the Medical Expenditure Panel Survey (collected by the Agency for Healthcare Research and Quality) was used to describe how the financial burden from healthcare has changed in the past decade, finding that people with chronic diseases, such as cardiovascular disease and hypertension, are at greater risk of incurring large healthcare costs.

It is important to distinguish descriptive policy research from clinical effectiveness studies. Clinical effectiveness research seeks to determine the relative risks and benefits of different treatment strategies in routine clinical practice. For instance, for the treatment of AMI, substantial amounts of research have been devoted to determining whether a medication, such as an aspirin, improves patient outcomes. In other words, an outcome, such as mortality, is compared between 2 groups: 1 receiving aspirin after AMI, another receiving placebo (a comparison that when studied found 36 fewer deaths, AMIs, and strokes per 1000 aspirin users over 2 years). However, this and most other effectiveness studies are clinical research investigations. In contrast, “descriptive” policy research examining the treatment of AMI would focus on whether aspirin is being appropriately and widely used, that is, aspirin use after AMI might be compared among men and women (a comparison that when studied has consistently found lower rates of aspirin use among women or among patients receiving care at nonprofit and for-profit hospitals (a comparison that when studied found nonprofit hospitals discharging post-AMI patients with aspirin at higher rates). Importantly, there are a number of policy-level solutions that could improve the frequency and appropriateness of use of aspirin for AMI or use of another medication for another disease, including changing reimbursement schemes or providing performance feedback.

Analytical Health Policy Research

Analytical health policy research focuses on the relationship between existing health policies and healthcare delivery. These studies, which also generally involve using large samples of healthcare utilization data, allow “big-picture” hypotheses to be examined and are often cautiously interpreted, providing a starting point for future study through experimental research (or impetus for policy change). In this way, analytical research offers important initial opportunities to explore healthcare delivery and outcomes in the context of existing health policy (or within existing health systems), functioning as a stepping stone of sorts between the first and third broad categories of policy research.

Studies examining the effectiveness of Medicare insurance provide a good example of analytical health policy research because these studies attempted to characterize healthcare utilization among all Medicare beneficiaries receiving care governed by the same health policies. For instance, several studies demonstrated that important preventive and chronic care services that were poorly reimbursed, including cholesterol and breast and colorectal cancer screening and management of hypertension and cardiovascular disease, were underused among Medicare beneficiaries, potentially resulting in poorer health outcomes. These findings stimulated policy changes, including the Medicare Cholesterol Screening Coverage Act of 2003 to guarantee Medicare coverage of preventive cardiovascular screenings as well as a provision in the Balanced Budget Act of 1997 to ensure Medicare reimbursement for colon cancer screening procedures (the colon cancer screening provision was subsequently found to be associated with an increased use of colonoscopy among Medicare beneficiaries and an increased probability of early-stage diagnosis).

Research examining geographic variation in healthcare utilization and medical spending offers another example of analytical health policy research. Medicare has long provided fixed fee-for-service payments for treatment of its beneficiaries for both hospital and physician services, with modest
regional fee variation based on regional price level. Despite this policy, 2 decades of research have documented persistent and substantial geographic variations in use of services, generally focused on rates of admission to the hospital and of procedures, such as hysterectomy or coronary artery bypass surgery, that are not accounted for by variations in price or patient illness.\textsuperscript{20–24} Health policies have been proposed in an attempt to reduce variation in healthcare delivery, particularly because higher spending does not result in more effective care or better health outcomes,\textsuperscript{20,25} although none have been enacted.

**Experimental Health Policy Research**

Experimental health policy research focuses on examining how policy changes might affect healthcare delivery. There are 2 broad approaches to such research, experimental and quasi-experimental, the latter of which make use of observational methods. However, this type of policy research is challenging because it is costly to conduct experimental studies and quite difficult to use observational methods to isolate the specific effect of changing a policy on healthcare delivery.

**Experimental Design**

The effect of a policy on health or healthcare delivery can be examined as an intervention within a randomized controlled trial. This approach has the advantage of accounting for differences between the 2 groups via randomization, although its cost is a disadvantage. For instance, a randomized controlled trial was used to examine the effect of modest financial incentives to enroll in a tobacco cessation program on cessation rates (enrollment and 75-day quit rates were higher, but there was no difference in 6-month quit rates\textsuperscript{26}). The RAND Health Insurance Experiment is a far better known example of experimental health policy research. In the 1970s, 7700 people aged <65 years were enrolled in a randomized controlled trial of health insurance plan cost sharing, whereby subjects living in 6 urban and rural areas were randomly allocated to receive healthcare for 3 to 5 years through 1 of 5 different health insurance plans: a plan offering fully subsidized care (free), a plan offering care at a percentage of cost (25%, 50%, or 95% cost sharing) coupled with a maximum annual healthcare expenditure per enrollee (catastrophic insurance), or a nonprofit health maintenance organization. There were 3 key findings. First, greater degrees of cost sharing were associated with lower healthcare expenditures that resulted from using fewer services rather than from receiving less costly physician or hospital care.\textsuperscript{27} Second, greater degrees of cost sharing were not associated with changes in overall health (as measured with 11 outcomes), except among the sickest and poorest 6% of subjects.\textsuperscript{28} Finally, although greater degrees of cost sharing were associated with decreased healthcare utilization, subjects were not preferentially decreasing care that was considered inappropriate; both appropriate and inappropriate healthcare utilization decreased.\textsuperscript{29,30}

**Quasi-Experimental Design**

Observational methods can also be used to examine the effect of a policy on health or healthcare delivery, with the use of quasi-experimental approaches, and are generally of 2 types: pre-post or comparative. An observational approach has the advantage of being able to make use of previously or concurrently collected data, making it less costly, but it is at a disadvantage in being able to account for differences between the 2 compared groups. For instance, pre-post studies need to account for secular trends, which may be associated with changes in care unrelated to policy enactment, whereas comparative studies need to account for unobserved differences between the 2 groups.

Pre-post studies examine the effect of a policy intervention by comparing groups expected to be affected both before and after the policy was implemented. For example, a critical component of the CCP initiative discussed earlier was feedback of each hospital’s performance in a positive manner that emphasized approaches for improvement. With the use of a pre-post study design, performance on all outcome and process measures of quality was found to improve significantly after feedback, including 2% to 3% lower mortality rates and 2% to 18% higher rates of performance of process measures.\textsuperscript{4} Similarly, pre-post designs have been used to examine the effect of public reporting of hospital outcomes, which is particularly relevant today because in July 2007, the Centers for Medicare and Medicaid Services began to publicize hospital-specific risk-standardized all-cause mortality rates for AMI and heart failure.\textsuperscript{31,32} Most of the public reporting research has focused on the New York State Cardiac Surgery Reporting System and has repeatedly found decreases in coronary artery bypass graft surgery mortality after the initiation of public reporting.\textsuperscript{33–38} However, some have attributed this effect to referring high-risk patients to out-of-state surgeons\textsuperscript{39} or to nationwide technical improvements and medical advances.\textsuperscript{40} Nevertheless, public reporting of surgical outcomes seems to be associated with improved care, whereas the evidence for public reporting of medical outcomes remains inconclusive.\textsuperscript{41,42} Comparative studies examine the effect of a policy intervention by comparing groups that are otherwise expected to be similar, except that 1 group is exposed to the examined policy, whereas another is not. For example, supplementary insurance plans may affect medication use. With the use of a comparative study design, use of statins and β-blockers among Medicare beneficiaries with cardiovascular disease was found to be far lower among those without supplementary insurance compared with those with supplementary Medicaid insurance or employer-sponsored coverage.\textsuperscript{43} Similarly, comparative studies were used to examine the effect of certificate of need (CON) regulation by comparing states with and without the specific policy. The 1974 National Health Planning and Resources Development Act mandated CON regulation to restrain healthcare costs and improve healthcare quality, in part by limiting the number of facilities providing complex, high-cost medical care such as cardiac, surgical, and imaging services. However, these regulations are now voluntary, and approximately two thirds of US states make use of these regulations, whereas the other third does not. Comparative research has demonstrated that CON regulation is not associated with substantially restrained healthcare costs,\textsuperscript{44,45} its effect on utilization seems to vary by service/procedure,\textsuperscript{46} and its effect on healthcare quality is inconsistent. Research focused primarily on cardiac procedures has demonstrated that states with CON regulation were more
likely to have patients treated at higher-volume centers.\textsuperscript{47–50} CON regulation of either coronary artery bypass graft surgery or cardiac catheterization was associated with lower mortality in only 1 study\textsuperscript{60} and not in 4 others\textsuperscript{47–49,51} but was associated with lower rates of equivocally and weakly indicated cardiac catheterization after admission for AMI.\textsuperscript{52}

**Conducting Rigorous Policy Research**

Methods for conducting rigorous policy research have been described in detail in textbooks.\textsuperscript{53,54} A useful paradigm for evaluating the quality of policy research is to consider the following 4 aspects of a study: (1) study population (external validity); (2) study design (internal validity); (3) choice of outcomes measured; and (4) statistical methods, aspects that are critical to all types of healthcare research.

**Study Population**

When policy research is evaluated, it is important to consider context, such as the size and diversity of the study population, as well as the health system in which the patients are receiving care. Findings from 1 healthcare system (ie, insurance plan or hospital) or location (ie, country, state, city, or smaller) may not be generalizable to another healthcare system or location. In other words, narrowly focused study populations are unlikely to have strong external validity with regard to extrapolating findings to a broader population. Ideally, data used for policy research should reflect as large and diverse a segment of the population as possible. Hence, population-based data are ideal.

Nevertheless, studies focused on specific population subgroups, such as members of a large health plan or even participants in a particular clinical trial, might still yield valuable insights. Investigators are increasingly making use of existing clinical trial data to address topics that are distinct from the primary study outcome, such as patterns of care and costs. For instance, data from the Global Utilization of Streptokinase and t-PA for Occluded Coronary Arteries (GUSTO) trial have generated numerous studies relevant to the care and outcomes of patients with AMI. Reports based on GUSTO data suggested important sex-based disparities in angiography use and regional variation in \(\beta\)-blocker use.\textsuperscript{55,56} A key question is whether these reports were idiosyncratic findings particular to the GUSTO trial participants or an accurate representation of the larger national healthcare system. To address this concern, investigators compared findings from these GUSTO reports to study results based on data collected through the CCP (discussed above). Because the CCP involved a comprehensive and systematic record review of Medicare patients with AMI at the national level, CCP data are thought to be generalizable to all older adults. When comparing study results derived from each of these 2 databases, the authors found that the degree of variability in \(\beta\)-blocker use (across geographic regions) and angiography use (between sexes) was remarkably similar when studied with the use of either CCP or GUSTO data.\textsuperscript{55–58} As expected, the overall rates of death and treatment-related complication were higher in the GUSTO patients. These findings suggest that large data repositories, such as data collected within clinical trials, may provide valuable and accurate assessments of health and healthcare delivery for policy research. Nevertheless, care must be taken to assess the generalizability of the data source,\textsuperscript{59} considering issues such as patient selection and the degree to which trial participants differ from other community-based patients with regard to age, sex, health status, comorbidities, or healthcare access.\textsuperscript{60–65}

**Study Design**

Policy research study designs should attempt to maximize internal validity by minimizing bias and confounding. Randomized controlled trial evidence is rare in policy research, due to the challenge of funding such studies, as well as the complexity involved in randomizing people to blindly receive care within differing healthcare delivery systems or under differing policies.

Commonly, observational studies using routinely or previously collected data are used for policy research and therefore to guide policy. However, the observational nature of most health policy research should instill caution when interpreting findings, recognizing that cross-sectional studies do not (and cannot) imply causation. Nevertheless, well-designed observational research can provide evidence as informative and accurate as that provided by randomized controlled trials.\textsuperscript{66}

In addition, some policies are difficult to evaluate by either experimental or observational methods because they are implemented at an organizational level or within a geographic area, necessitating the use of other methodologies. For instance, door-to-balloon time, in reference to providing percutaneous coronary intervention within 120 minutes to patients with ST-elevation AMI, is a quality indicator reported by the Health Quality Alliance, and hospital performance on this measure has historically lagged behind performance on other measures. Qualitative research methods identified common organizational approaches among higher-performing hospitals,\textsuperscript{67,68} which were subsequently tested in a cross-sectional, national study.\textsuperscript{69}

**Outcomes**

Good policy research examines outcomes that are important to patients, providers, and payers. Preferred outcomes include patient quality of life, satisfaction, mortality, rehospitalization, and disability, in other words, outcomes that patients and policy makers can identify and make reasonable determinations of value and importance. Outcomes that provide scientific value but are less important to patients (and clinicians and policy makers) include laboratory measurements, diagnostic test findings, or other surrogate markers of disease. This is particularly important because surrogate outcomes do not always reflect central outcomes of interest. For instance, the recent ILLUMINATE trial of the pharmacological agent torcetrapib found that it increased levels of high-density lipoprotein cholesterol, a surrogate marker for better health outcomes, but increased deaths.\textsuperscript{70} This same counterintuitive relationship has been observed in quality of care research as well because publicly reported AMI process measures were found to capture only a small proportion of the variation in hospitals’ risk-standardized short-term mortality rates.\textsuperscript{71}

Policy research that examines costs must be evaluated by which costs were considered, how they were calculated, and from whose perspective. All outcomes should be considered
in the context of their value, utility, and tradeoffs. For instance, studies of pay-for-performance programs tend to focus on whether incentivized processes of care are performed at higher rates. However, these studies would provide more information if they also evaluated the costs required to increase performance rates, in fiscal terms and in clinical terms, such as whether high-quality processes of care that are not being measured are "crowded out" by measured care.72

Statistical Methods
Statistical approaches used within policy research will vary in order to deal with missing variables, account for nonindependence of outcomes, and minimize bias. Missing data are a common problem, especially when large, administrative data sources are used. Ignoring missing data may lead to inefficiency or, worse, bias, although a variety of methods exist for addressing this problem.73

In addition, large data sources often have a hierarchical structure, in which there may be multiple levels of nested observations that are therefore not independent. For example, some hospitals or physicians may be more likely to care for patients with specific characteristics. This structure can be accounted for with the use of hierarchical regression modeling to account for patients nested within physicians nested within hospitals nested within cities. If studies do not account for the nonindependence of these observations, results may be biased.74

Standard statistical methods are likely to produce unbiased findings when the distribution of unmeasured factors is similar between the groups being compared, such as after randomization. Observational studies are more prone to bias if groups differ in unmeasurable ways from one another and should utilize multivariable adjustment for measured variables that are different between the groups being compared. Both instrumental variable analysis and propensity score analysis are methods for inferring the effect of policy on a range of potential outcomes in situations in which randomization is unethical or impractical and strong selection bias exists. Propensity score analysis involves matching individuals from each group to address overt bias, whereas an instrumental variable is an observable variable that can be used in lieu of a coin flip in assigning patients to the policy of research interest. This type of analysis minimizes the confounding that complicates observational studies without random assignment because unobserved characteristics of patients and clinicians may influence outcomes and whether or not patients receive care under an examined policy.75 As an example, recent systematic reviews of randomized controlled trials of routine invasive versus conservative management of AMI have found that between 8% and 21% improved relative survival in the more invasively treated groups,76,77 but a population-based observational study found little benefit to invasive therapy in US regions in which medical management was of higher quality.78 Attempting to reconcile these contrasting findings, subsequent research determined that the estimated effect was sensitive to the analytical method used, in that the estimated benefit from invasive therapy depended on the statistical method used to adjust for overt (measured) and hidden (unmeasured) bias. In this study, invasive therapy predicted a 50% relative decrease in mortality with the use of standard risk adjustment methods, including a rigorous propensity-based matching analysis, but only a 16% relative decrease in mortality with the use of instrumental variable methods.79 Hence, estimates of relative treatment effectiveness varied by a factor of 3, depending on which analytical technique is used, underscoring the importance of the statistical method.

Challenges for Policy Research
Health policy research is faced with challenges that are similar to those faced by other research fields: developing evidence that is both high quality and timely, ensuring that it informs policy decisions when the decisions are being made, and focusing research efforts on policy initiatives that promise to have the greatest impact on health and healthcare and are of the greatest interest to patients. However, other challenges may be more specific to policy research.

Data Access
Privacy Concerns
Minimizing risk to patients is a key principle guiding the acquisition and use of data for health policy research. Potential harms to patients must be minimized by safeguarding patient privacy. A key element of the Health Insurance Portability and Accountability Act (HIPAA) instructed the Department of Health and Human Services to draft regulations concerning the privacy of health information. Enacted in 2003, the HIPAA Privacy Rule required written authorization from patients before their personal health information could be used or disclosed for research purposes, although several exceptions are in place. In some cases, data with limited information can be accessible with appropriate data use agreements and structures in place to protect privacy. Additionally, data with patient identifying information can be accessed if the health information is to be used to prepare for future research or if patients are deceased. Although the regulatory framework established by HIPAA has increased the degree of oversight of research using patient health information,80,81 likely with accompanying increases in time and cost, the degree to which these changes have deterred health policy research or protected patient privacy remains controversial.81

Social Justice Concerns
A 2003 initiative in the state of California, Proposition 54, would have banned the collection or use of race or ethnicity data by public agencies, limiting the conduct of health policy research that addresses the needs of vulnerable populations.82 Proponents argued that systematic classification of citizens into racial groups perpetuates racism. Opponents argued that exclusion of race and ethnicity data would harm the very people that Proposition 54 was supposed to be protecting, by prohibiting documentation of the presence or consequences of health disparities and limiting any evaluation of programs designed to address disparities. Although Proposition 54 was defeated, its presence on the ballot is a reminder of the social and political tenuousness of maintaining access to data for health policy research.

Data Quality
At the core, the quality of health policy research is determined by the quality of the data. Many databases are not
collected specifically for the purpose of health policy research, particularly nationally representative data used to derive population estimates. Policy research typically examines complex organizational structures with the use of the best available data. Often, key information is not collected, limiting the potential insight from the work. In addition, increasing amounts of data will be available that are generated from health information technology. Managing these data to ensure that meaningful, well-designed studies are conducted, rather than studies that create ever more “noise” in which to lose informational signals, is paramount.

Funding

Perhaps the greatest challenge facing health policy research is its low prioritization within state and federal budgets. The total federal funding for health services research in fiscal year 2006 was $1.5 billion, principally funded by the National Institutes of Health ($938 million), the Agency for Healthcare Research and Quality ($319 million), and the Centers for Disease Control ($140 million). Yet this is <5% of a total federal research budget that exceeds $35 billion, the vast majority of which was used to support the conduct of biomedical (75%) and clinical research (20%). The Agency for Healthcare Research and Quality, a division within the Department of Health and Human Services (not within the National Institutes of Health), is the natural funding home for health policy research. But the budget of the Agency for Healthcare Research and Quality, which has not been increased in 4 years, allows for little discretionary funding because it is nearly completely appropriated to specific research projects related to health information technology, patient safety, and comparative effectiveness.

Moreover, because the purpose of health policy research is to inform future health policy and improve (ideally) future health and healthcare delivery, payers should also be expected to invest in and prioritize research. However, the Centers for Medicare and Medicaid Services, the largest insurance plan in the United States, spent only $58 million for research in fiscal year 2006, a substantial decrease from previous years and a fraction of the total Centers for Medicare and Medicaid Services budget that exceeds $545 billion. The Department of Veterans Affairs, which provides medical care for veterans, invested more heavily in research, $412 million in fiscal year 2006, but this remains a small proportion of a total Veterans Affairs budget that currently exceeds $30 billion. Amounts invested in policy research by private payers are unknown. Unless health policy research is sufficiently prioritized and sufficiently funded, its greater impact on health and healthcare will remain below its potential.

Conflicts of Interest

All types of research can be threatened by conflicts of interest, and health policy research is no exception. A conflict of interest occurs when a secondary interest of any type can affect judgment about a primary interest, such as a research study. Financial conflicts of interest have been associated with lapses in research integrity within clinical and cost-effectiveness research. Financial conflicts of interest have not been as thoroughly explored within health policy research. Although the broad ethical issues raised by conflicts of interest apply to all settings, health policy research is distinct in some respects. In clinical research, investigators may hold patents, stock, or other investments that may increase substantially in value if a trial yields favorable results. Because of the nature of health services research, this type of financial arrangement is much less likely. Rather, financial ties may be more aligned either with the researcher’s ability to solicit future funding from the sponsor or with the sponsoring organization’s financial security. It is also important to consider nonfinancial conflicts because the close relationship between health policy researchers and policy makers may lead to policy agendas affecting researchers’ objectivity. Above all, health policy research should be planned and conducted within a framework that supports investigator independence and ensures objectivity and transparency in the planning and conduct of research.

Importance of Policy Research: Looking Ahead

Politicians and policy makers are actively changing health and healthcare delivery, oftentimes for the better but sometimes not. Each year, a number of healthcare-related bills are proposed in both the US Senate and House of Representatives, a small number of which are passed by both branches of Congress and signed into law by the President. But these federal initiatives are only the tip of the proverbial iceberg. There is no accounting for the untold number of state, county, city, or town health initiatives that are initiated or the countless changes in practice and regulation that took place at facilities such as regulatory agencies, health plans, and hospitals. Characterizing and examining health and healthcare delivery in the context of enacted health policies, with the use of rigorous, carefully crafted methods, are of immeasurable value and deserve higher priority within both government and private healthcare insurer budgets. Health policy research informs past health policy efforts by investigating its intended and unintended consequences and provides evidence to improve healthcare delivery systems and inform future health policy. Significant challenges need to be addressed to ensure that there is continued production of health policy research to advance and improve health and healthcare delivery in the United States.

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Disclosures

None.


