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The Politicization of Evidence-Based Medicine: The Limits of Pragmatic Problem Solving in an Era of Polarization

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#### Abstract

A key test of a political system is its capacity to solve important societal problems. Few policy areas in the U.S. are more problem-ridden than health care. Medical care is expensive and wasteful, and the quality often falls short of best practice. One idea to improve health care is to eliminate gaps in the medical evidence base through "comparative effectiveness research" (CER). By identifying what treatments, tests, and technologies work best, CER could help doctors, patients, and payers make better decisions and help reduce wasteful spending. CER was a technocratic, third-tier issue familiar mainly to policy experts based in universities, foundations, and think tanks, but hardly anyone else. This paper traces how this obscure policy initiative got caught up in the wider ideological struggle over national health reform.

**Keywords:** health care reform, The Affordable Health Care Act, comparative effectiveness research, evidence-based medicine

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THE CALIFORNIA Journal of Politics & Policy The Politicization of Evidence-Based Medicine: The Limits of Pragmatic Problem Solving in an Era of Polarization

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A key test of a political system is its capacity to solve important societal problems. Few policy areas in the United States are more problem-ridden than health care. American medical care is expensive and wasteful, and the quality of care (even for the well-insured) often falls short of best practice (Hacker 2008; McGlynn et al. 2003). One idea to improve health care is to eliminate gaps in the medical evidence base through "comparative effectiveness research" (CER). By identifying what treatments, tests, and technologies work best for patients with different diseases and conditions, CER could help doctors, patients, and payers make better decisions about medical options and help reduce wasteful health care spending.

Until fairly recently, CER was a technocratic, third-tier issue. It received attention from policy experts based in universities, foundations, and think tanks, but hardly anyone else. During the past few years, however, this obscure policy initiative got caught up in the wider ideological struggle over national health reform. The Obama Administration pushed for CER funding to be included in the massive economic stimulus bill to lay the groundwork for a more evidence-based medical system. In the context of the heated partisan debate over how to improve the American health care system, in turn, CER became the target of charges from conservatives that the Obama Administration was promoting "rationing" and government intrusion in the private lives of patients.

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The irony is that CER has been advocated by conservative health experts who share the belief of many liberal analysts that trying to learn what works in medicine is good public policy. As we explain below, the political communication and social learning process by which a fact-based understanding of a societal problem achieves a consensus among policy experts and then diffuses downward to politicians and the public (Zaller 1992) got short-circuited, accelerated, and warped. Evidence-based medicine became highly salient and politicized, and the CER solution arguably emerged on the agenda before the political requisites for sustainable policy reform were in place (Patashnik 2008).

The issue evolution of CER is fascinating and important in its own right, but also has a broader implication for scholars and public policy practitioners: namely, expert ideas for efficient solutions to societal problems should be isolated, to the extent feasible, from partisan contests over welfare state expansion and the politics of redistribution—lest these solutions become the "property" of one party and the electorally-charged object of political derision for the other. The story of how CER morphed into a symbol of crude rationing schemes and government interference with the doctor-patient relationship offers a cautionary lesson about the limits of pragmatic problem solving in an era of partisan polarization.

#### **Problem Solving and Policy Experts**

What do we mean by pragmatic problem solving? It is helpful to say what it is not. As David R. Mayhew observes, a democratic polity can make public policy in at least three ways (Mayhew 2006). The first two are familiar: *distributive politics*, in which my district gets a road, your district gets a road, everyone's district gets a road, and *partisan politics*, in which my party coalition gets what the government has to give and yours pays the taxes.

*"Problem solving"* is here conceived as a third approach, the goal of which is to promote the general welfare and not the well-being of narrow interests (Gerber and Patashnik 2006). Problem solving is thus instrumental, focused on the logical relation of means to ends. Moreover, problem solving is rooted in social learning: policy actors should use the best available evidence to identify important problems and craft effective solutions.

Experts play a key role in the politics of problem solving, in part because the media and politicians often take their cues from policy specialists (Zaller 1992). Expert communities generate the empirical claims and general perspectives on policy issues that structure the political debate. When policy specialists of differing political orientations reach a fact-based consensus on the existence of a societal problem, this elite consensus may diffuse out to politicians and the public. Social

learning occurs, making it easier to build the broad majorities needed to overcome the veto points built into the American political system.

As Zaller stresses, however, this idealized process of expert-led social learning and governance neglects the important mediating role of partisanship and political competition (Zaller 1992: 328). When, as is the case today, the two parties are polarized and the majority party chooses or feels compelled to "go it alone" on major legislation, the minority party will possess a strong incentive to discredit the empirical claims and arguments offered by the other party—even if working from a common set of technical understandings of the policy problem would be in the nation's larger interest. An expert consensus on the seriousness of a given problem may then fail to unify political elites and the wider public around a course of action. This breakdown in expert-led social learning and problem solving is an underrecognized consequence of partisan polarization.

#### The Problem of a Medical Evidence Gap

Consider the struggles of the American political system to address the problem of a "medical evidence gap" (Deyo and Patrick 2005). Health experts associated with both parties agree that the lack of hard data about which medical treatments and diagnostic tests work best for patients with different diseases and conditions is a serious problem. The existence of this medical evidence gap harms the well-being of the young and the old, the rich and the poor, the ill and the currently healthy.

If the political system was performing well, the two parties would both acknowledge the problem, but compete over which was better equipped to solve it. Instead, what has happened, likely due to party polarization, is that the problem of a medical evidence gap has largely become "owned" by the Democrats (on issue ownership, see Petrocik 1996). Meanwhile, the Republicans have gained a stake in the discrediting of proposed solutions, since it would undermine the credibility of the Democratic Party in the eyes of voters.

Before turning to our political analysis, some background on the medical evidence gap is in order. Despite the rapid pace of technological innovation and the health spending highest per capita in the world, the scientific basis of U.S. medical care is surprisingly weak. Some health experts believe that less than half of all care is supported by adequate evidence about its comparative effectiveness (CBO 2007; see also Wennberg 2004). As a result, decisions about the tests and treatments to use are routinely made on the basis of anecdotes, local custom, and the personal experience of individual physicians. The Food and Drug Administration (FDA) conducts relevant research, but the core mission of the agency is to regulate market entry and labeling of products, not to determine best medical practice.

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Most clinical trials by the FDA investigate only the efficacy of drugs and medical devices relative to a placebo. The approval process at the FDA generally does *not* produce information about whether these products work better than treatment alternatives (Avorn 2005). Worse yet, surgical procedures can diffuse into widespread clinical use on the basis of no hard scientific evidence at all (Cohen et al. 2004). The persistence of this medical evidence gap should concern every American who seeks the best medical care for herself and her loved ones. As Shannon Brownlee of the New America Foundation writes:

[I]t seems completely crazy for a country that spends so much on health care to spend so little on systematically filling the gaps in medical knowledge.... What's the best way to get people to lose weight and exercise in order to prevent heart disease and diabetes? Nobody knows. Is a cesarean section necessary if a woman's previous child was delivered by cesarean? Can a million-dollar da Vinci surgical robot, touted by many hospitals that have purchased the device, really improve outcomes, or is it just a fancy way to spend money? If a man has prostate cancer, which remedy is best? (Brownlee 2007a)

There have been cases where thousands of patients have undergone risky procedures (e.g., high-dose chemotherapy with bone marrow transplants for breast cancer) that were later determined to be ineffective when properly evaluated (Mello and Brennan 2001). More often, patients receive treatments that are relatively safe but ineffective, increasing health costs without offsetting benefits for patients (Gerber and Patashnik 2006).

#### **Political Barriers to Problem Solving**

If the medical evidence gap wastes scarce resources, harms people across demographic and class lines, and is well recognized among experts, why has this problem not been solved? Economists would point to a market failure. The knowledge produced by CER is costly to produce—but once the knowledge exists, it can be disseminated at little or no charge to all users.

Since private actors generally can obtain the benefits of the research without paying for it, they have a weaker incentive to produce it than they would if they could internalize all the benefits (CBO 2007). In sum, effectiveness information is a "public good," and the market will not supply the socially efficient amount. This insight helps explain why private-sector investment in CER is modest (MedPaC 2008).

Yet this explanation for the medical evidence gap is incomplete. When markets fail to deliver the efficient amount of a public good, the government can provide missing incentives or supply the public good itself. Given the increasing pressure that health spending is placing on the federal budget, taxpayers would appear to have a huge collective stake in learning about the relative effectiveness of different medical services. Yet federal investments in CER have likewise been meager less than one-tenth of one percent of GDP—relative to the need for information, and past reform initiatives have been politically unsustainable. Several factors help explain the poor track record of the government, too, in this area.

First, precisely because benefits from comparative effectiveness information are widely dispersed across society, there are no organized private constituencies to pressure government to provide them. Meanwhile, the perceived costs of more rigorous scrutiny of treatments, tests, and technologies are concentrated on wellorganized groups such as device manufacturers and medical specialty societies. This is a classic "diffuse benefits/concentrated costs" situation (Wilson 1973). It is nonetheless possible to overcome the lack of organized constituency support and build majoritarian pressure for general-interest legislation in American democracy (see Arnold 1990). However, the two primary mechanisms for doing so have proved inadequate in the medical evidence case.

The first mechanism is "public interest" lobbying. The millions of patients who suffer from cancer, heart disease, and other chronic conditions are dispersed across the nation. Sadly, the patients who are in most desperate need of unbiased information about treatment options are often least able to mobilize politically. The interests of such patients are ostensibly represented by "patient advocacy" groups. The number of patient advocacy organizations has exploded in recent years.

While patient advocacy organizations have the capacity to accelerate FDA drug reviews (Carpenter and Fendrick 2004), their activities may not counterbalance the informational biases of marketing research. Many patient advocacy groups are underwritten by drug companies and focus on raising public awareness of particular diseases and conditions and the need for more government support for basic biomedical research. Few patient groups have made CER a lobbying priority.

The second mechanism is political entrepreneurship. Political entrepreneurs who can include legislators and agency heads as well as people outside government, including social activists and journalists—are actors who perform a variety of functions in a democracy. They frame new issues, create new public demands and new coalitions, and expand the set of issues considered legitimate and expected for government to address (Oliver 2004; Sheingate 2003; see also Posner 2003). They also can educate the public about the need for public policy to address a problem. The remarkable situation of licensed physicians performing procedures and ordering tests in the absence of hard evidence about what works would seem to be precisely the kind of societal problem where a healthy dose of political entrepreneurship is warranted.

Yet while a few actors, including then-Senator Hillary Clinton, have offered constructive proposals, no political entrepreneur has made a long-term effort in educating the public and making the case for fundamental reform in the use of medical evidence by the nation's health system, in the way, for example, that Ralph Nader made the case for auto safety reform in the 1960s. Political entrepreneurship around the problem of medical evidence may simply be riskier than those examples; it requires the political entrepreneur not only to attack the prerogatives of esteemed medical societies, but to challenge deeply held public beliefs, for example that one's own doctor knows best.

A notable previous attempt to address the medical evidence gap in the United States occurred two decades ago under President George H. W. Bush. With the support of White House health adviser William Roper and little opposition on Capitol Hill, the Agency for Health Care Policy and Research (AHCPR) was established in 1989 to provide independent, evidence-based, clinical practice guidelines that would help physicians determine what treatments are most effective (Gray, Gusmano, and Collins 2003). But when the agency in 1995 announced that there was little objective evidence to support surgery as a treatment for low back pain, back surgeons and patients complained vehemently to Congress. In the same kind of political reaction that led to the demise of the Office of Technology Assessment in 1995 (Bimber 1996), the AHCPR's budget was slashed and its authority to make policy recommendations was severely curtailed (Brownlee 2007b).

Despite the AHCPR debacle, health experts continued to push for evidencebased medicine, and some progress began to be made under both Democratic and Republican presidents. The Clinton Administration promoted evidencebased practice centers (Cohen et al.). Under President George W. Bush, Medicare program administrator Mark McClellan attempted to improve the use of medical evidence in coverage determinations. In addition, the Medicare Modernization Act of 2003 contained an obscure provision promoting more federal research on the clinical effectiveness of treatments (Neumann et al. 2005). But CER remained a low priority issue and lacked salience.

#### The Obama Administration's Surprising Initiative

All this changed when the Obama Administration decided to push for CER funding through the American Recovery and Reinvestment Act of 2009. By all accounts, key officials in the administration, including Office of Management and Budget director Peter Orszag, were convinced that CER was a health reform "game changer" that could "bend the cost curve," potentially freeing up resources to help pay for coverage expansions over time. As passed by Congress, the \$787 billion economic stimulus bill included \$1.1 billion for CER (Pear 2009).

In the context of the \$2 trillion we spend each year on health care, \$1.1 billion for research on what medical tests and treatments work best is a small investment. Unlike covering the uninsured, CER is not the kind of redistributive

issue that naturally divides the two parties. One might have expected the Obama Administration's CER initiative to have earned respect from conservatives, especially because health economist Gail R. Wilensky, a former Medicare program administrator under George H. W. Bush and an adviser to John McCain in the 2008 presidential campaign, has been CER's most prominent expert advocate (Wilensky 2006; on the McCain campaign's interest in CER, see Alonso-Zaldivar 2008).

Things did not turn out that way. As Harvard Medical School professor Jerry Avorn writes, "In calmer times, fiscal conservatives might have been expected to support a plan to generate information about treatment benefits, risks, and costs so that physicians, consumers, and payers could use this knowledge in making purchasing decisions. But these are not normal times" (Avorn 2009: 1928). Our interviews with Hill staffers confirm that the CER funding provision, despite its modest size, generated more controversy than any other item in the stimulus bill.

Rather than fact-based arguments from experts structuring the political debate, conservatives and others opposed to President Obama's domestic agenda made explosive accusations that frightened a wary public. The Republican Study Committee sent out an alert stating that that purpose of the CER measure was "to enable the government to ration care" (quoted in Avorn 2009: 1928). Former New York Lieutenant Governor Betsy McCaughey warned on Bloomberg.com that the elderly would be hardest hit, and that the government would use electronic medical records to monitor the behavior of physicians, punishing those that did not comply with the government's treatment guidelines (McCaughey 2009).

Rush Limbaugh then disseminated the rationing charge on his radio talk show (Pear 2009). While conservative critics acknowledged that doctors and patients needed good information about the effectiveness of treatment alternatives, they argued that the government would use research findings to reduce the quantity and quality of medical services.

Politicians in both parties faced strong pressure from industry groups who mounted a lobbying campaign against a robust CER program. Billy Tauzin, President of the Pharmaceutical Research and Manufacturers of America, said that his industry's mobilization was intended to send a signal to politicians. "I hope it is a clear warning," Tauzin said. "There are a lot of beehives out there. You don't just go around punching them" (quoted in Levey 2009). While Democrats responded to the industry pressure by softening CER language in a Senate committee report (Medical Devices Today 2009; National Alliance for Hispanic Health 2009), Republicans focused on discrediting the overall role of government in promoting evidence-based medicine.

It is easy to stoke public skepticism toward expert recommendations on issues where citizens feel they are personally well-informed (see Wilson 1990), and Republicans strategically exploited voter fears about changes to the existing health delivery system. To a nervous and confused public, CER was of a piece with two other controversial health reform proposals under consideration: voluntary end-of-life counseling for Medicare patients and the creation of an independent commission with the power to recommend politically unpopular Medicare cuts. These three elements (with prompting from conservative politicians like Sarah Palin) combined in the public mind to give birth to the charge that Obama was seeking to create "death panels" for seniors.<sup>1</sup>

The arguments against CER resonated with the public. We conducted several national public opinion surveys in 2009–10. Our studies found that the public supports the use of comparative effectiveness studies but is anxious about proposals to use CER findings to allocate government resources, mandate treatment decisions or mediate the doctor-patient relationship. Opposition to CER is strongest among Republican voters and senior citizens (Gerber et al. 2010).

A major reason why conservative elites attempted to turn the public against CER was partisan polarization. Conservatives believed, with some cause, that the Obama Administration had designed the stimulus bill not only to revive the economy, but to lay the groundwork for its domestic reform agenda. The most ambitious and controversial element of that agenda was of course an overhaul of the nation's health system. The administration's push for a publicly regulated (if not financed) universal insurance system, in the context of both the deepest crisis of capitalism since the Great Depression and the most rapid growth in federal spending in decades, constituted a direct challenge to the market-oriented ideology of the Republican party.

In this context, the incentive to oppose almost *anything* the Obama Administration proposed, and to stoke public mistrust in government in the process, was overwhelming (on the connection between public mistrust in government and lower support for redistributive programs, see Hetherington 2007). Republicans and their surrogates challenged the entire array of health reform proposals—even ideas, like CER, that had bipartisan origins in expert analysis. As Morris Fiorina writes, in an era in which party elites are highly polarized, "Policies are proposed and opposed relatively more on the basis of ideology and the demands of the base, and relatively less on the basis of their likelihood of solving problems" (Fiorina 2006; see also Quirk 2009).

#### Prospects

While Republican and industry opposition failed to kill the CER funding in the stimulus bill, the sharp partisan debate over CER caused it to lose much of its pragmatic character. CER became a Democratic Party issue, associated with rationing and death panels for seniors rather than with research that would empower *all* doctors and patients to make better-informed decisions. The window of opportunity created by the economic meltdown allowed CER to advance on the policy agenda far more rapidly than expected.

President Obama's sweeping health care reform overhaul builds on the stimulus legislation. The new law establishes a private, nonprofit "Patient-Centered Outcomes Research Institute" to set priorities for comparative outcomes research. The Institute's funding will come from the Medicare trust fund and a new tax on insurers. These design features are intended to insulate CER from political battles over funding.

In response to industry lobbying, however, the legislation guarantees representatives of drug, device, and diagnostic-testing companies seats on the Institute's board of governors and permits "stakeholders" to serve on its methodology committee (Selker and Wood 2009). The law also states that study findings may "not be construed as mandates for practice guidelines, coverage recommendations, payment, or policy recommendations" (P.L. 111–48). Given strong GOP opposition and public skepticism, the effort to promote evidence-based medicine in the United States remains vulnerable to reversal and erosion (Wilensky 2009; Patashnik 2008).

The most worrisome aspect of the partisan debate over CER over the past year has been the denigration of policy expertise and of pragmatic problem-solving. While the medical evidence gap may impose costs on millions of Americans in their roles as patients and taxpayers, ordinary citizens would never have grasped the extent of the problem had policy experts not called attention to it. The American political system greatly needs experts who can spot subtle breakdowns in the performance of institutions and processes and develop innovative solutions. Unfortunately, while pragmatic problem solving is crucial to effective governance, it may be on the wane in American politics today (Mayhew 2006).

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#### Notes

<sup>1</sup>Leaving aside the scientific merits of the recommendation, the public skepticism towards evidence-based medicine helps explain why in November of 2009 the Obama Administration felt compelled to distance itself from new guidelines for breast cancer screening, contained in a poorly timed report of the U.S. Preventative Services Task Force. A Pew survey found that 68 percent of people who followed the news about the change in these guidelines very or fairly closely disagreed with the task force's recommendation that most women should not start routine screening until age 50 (Pew 2009). The Obama Administration responded to the public outcry against the change by promising that government insurance programs would continue to cover mammograms for women starting at age 40 (Stein and Eggen 2009).