The Heritage Foundation
LEADERSHIP FOR AMERICA

BACKGROUNDER

No. 2679 | APRIL 12, 2012

Comparative Effectiveness Research Under Obamacare: A Slippery Slope to Health Care Rationing

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Abstract

One element of the Patient Protection and Affordable Care Act (PPACA) is the advancement of "comparative effectiveness research" (CER). Intended to compare available treatment options, CER can benefit patients if used for informational purposes only, but it could also be harmful in practice. The expansion of the Medicare bureaucracy under the PPACA will allow the use of CER for more government micromanagement of personal medical decision making—hurting patients, doctors, and the practice of medicine.

This paper, in its entirety, can be found at **http://report.heritage.org/bg2679**

Produced by the Center for Health Policy Studies

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One of the most important goals of health care reform is to slow down the runaway growth in health care spending. The United States spent 17.6 percent of its gross domestic product (GDP) on health care in 2009, projected to rise to almost 20 percent of GDP by 2020. Federal spending on Medicare, the federal health care program for the elderly and disabled, is of particular concern. Medicare's cost accounted for 3.7 percent of GDP in 2011 and is growing faster than any other area of federal spending due to increasing health care costs and the rising number of elderly eligible for the program. Another reason for the program's ballooning cost is its fee-for-service structure, which rewards providers for quantity of services and offers little incentive for patients to avoid doctors and other providers who offer poor value.

Meanwhile, the idea of advancing comparative effectiveness research (CER)—defined by the Institute of Medicine as "the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat, and monitor a clinical condition or to improve the delivery of care"[1]—has gained traction. The Patient Protection and Affordable Care Act

Talking Points

- Due to ballooning health care costs, especially runaway spending on Medicare, paying for "what works" using comparative effectiveness research (CER)—comparing available treatment options—has gained traction.
- The Patient Protection and Affordable Care Act (PPACA) has created a quasi-governmental entity, the Patient-Centered Outcomes Research Institute (PCORI), to advance the use of CER by doctors, patients, and administrators.
- CER can be beneficial by informing patients and physicians about alternative options for treating a certain condition. But in order to improve quality of care, CER must not edge out other crucial factors guiding medical decisions, including the physician's training and experience and the patient's unique circumstance and preferences.
- The PPACA expands the Medicare bureaucracy and allows more government micromanagement of what should be personal medical decisions.
- Using research findings to strengthen bureaucracy is a losing combination that will erode quality of care for Americans.

(PPACA) has created a quasi-governmental entity, the Patient-Centered Outcomes Research Institute (PCORI), to advance CER and its use by doctors, patients, and others.

Comparing available treatment options could certainly be beneficial by informing patients and physicians of the trade-offs of alternative options for treating a certain condition. But to improve quality of care, CER findings must be considered just one part of decision making.

CER must not edge out other crucial factors guiding medical decisions, including a physician's training and experience and a patient's values, preferences, goals, and lifestyle. In countries with nationalized health care, such as the United Kingdom, comparative and cost-effectiveness information is used to inform mandatory coverage and payment decisions, and this limits choice. The PPACA expands the Medicare bureaucracy and allows more government micromanagement of what should be personal medical decisions.

CER in Practice

Being able to compare treatment options and pick the best, most cost-effective ones sounds ideal—in theory. Real-life applications of CER, however, can and often do take a different form.

The Patient-Centered Outcomes Research Institute. PCORI is established as a nonprofit organization funded by Medicare dollars and a new fee on private insurance. The institute is governed by key stakeholders in the health care system, appointed by the Government Accountability Office, and by the presidentially appointed directors of the National Institutes of Health and the Agency for Healthcare Research and Quality. PCORI is responsible for identifying national research priorities, establishing and executing a research agenda, and communicating research findings to interested parties.[2]

The first draft of PCORI's national priorities and research agenda did little to clarify how the information it produces will be used.[3] The draft includes few specifics beyond what was already established in the PPACA. PCORI's influence over how CER is actually used will be more or less limited to how it allocates its relatively small financial resources, but it will not be clear how it prioritizes funding for certain diseases and conditions until it actually begins to do so later in 2012. Obtaining cost information on different treatments will be one goal of the institute, the draft made clear.

While PCORI uses the term "patient-centered," its findings will not necessarily be used to promote patient-centered care. The institute was originally named the Comparative Effectiveness Research Institute, but the name was changed because of the controversy that this clear assertion of its intentions created.[4] The objectives of the institute remain largely the same, but according to PCORI's executive director, Joe V. Selby, the name change has inspired PCORI to become more patient-focused in its research.

According to the PCORI website, "Patients will play a major role in PCORI's work by telling PCORI what health care outcomes they value."[5] But it is imperative to differentiate between patient-centered research and patient-centered care—the former does not ensure the latter. Including input from patients and stakeholders in PCORI's research priorities and agenda could make findings more useful for doctors and patients, but the PPACA gives Medicare, in particular, the authority to use CER in ways that will limit patient choice and physician

1. Institute of Medicine, "Initial National Priorities for Comparative Effectiveness Research," *Report Brief*, June 2009, p. 1, at http://www.hrsonline.org/Policy/LegislationTakeAction/upload/CER-report-brief-6-22-09.pdf (accessed February 27, 2012).
2. Patient Protection and Affordable Care Act, Public Law 111-148, § 6301.
3. Kathryn Nix, "Inside the Patient-Centered Outcomes Research Institute: No Promise of Protection from Government Rationing," Heritage Foundation *WebMemo* No. 3474, January 26, 2012, at http://www.heritage.org/research/reports/2012/01/patient-centered-outcomes-research-institutes-health-care-priorities.
4. CER entered the national spotlight when the American Recovery and Reinvestment Act of 2009 (also known as the stimulus bill) granted $1.1 billion to the Agency for Healthcare Research and Quality, the National Institutes of Health, and the Department of Health and Human Services to fund CER. The law also created the Federal Coordinating Council for Comparative Effectiveness Research to coordinate research and funding, which was replaced by PCORI under the PPACA.
5. PCORI, "About Us," 2012, at http://www.pcori.org/about/ (accessed February 27, 2012).

autonomy, making the opposite of patient-centered care more likely than not.

CER in the United Kingdom. CER use in the U.K. has been a far cry from what is implied by the rhetoric used to promote PCORI. Rather than focusing on the individual needs of patients, the United Kingdom's National Health Service (NHS) uses comparative and cost-effectiveness information to *limit* options as a budgetary tool.

The NHS offers health coverage to all British citizens and determines which treatments will be covered and paid for, and under which circumstances. Decisions are based on "recommendations" by the National Institute for Health and Clinical Excellence (NICE), whose stated purpose is to create clinical guidelines and standardize care using cost-effectiveness information, but the NHS is required to adhere to all of the recommendations made by NICE.

If a treatment is not covered, patients are able to go outside the NHS and receive it privately without regulatory or statutory obstacles—if they are able to afford this. (Because of Medicare's restrictions on private contracting, American seniors would not have this same option.)

Under the NHS, British patients have been refused effective treatments for several conditions because of cost.[6] After its initial assessment, NICE decided that fingolimod, a promising new medicine shown to reduce relapses and delay disease progression in multiple sclerosis (MS) patients, would not be covered. "Based on the available clinical evidence and economic analysis," NICE claimed, "our independent committee concluded that fingolimod would not be effective good use of NHS resources." But according to U.K. neurologist Eli Silber:

> The computer models used to determine cost effectiveness don't take into account the significant amount of money that would be spent on patients at the end of life with severe disability, when there isn't much we can do. ... MS often affects young people, with families and work, and this decision denies them the opportunity to have the risk of disability reduced at a much earlier stage.[7]

After receiving criticism for its decision, NICE changed its guidelines to allow access to the treatment for a subgroup of British MS patients.[8] However, other decisions made by the rationing body may not receive the same level of attention.

By focusing on short-term savings, decisions that deny coverage can worsen the health of the population and increase long-term costs. Helen Evans, a nurse and health fellow at the London-based Adam Smith Institute, highlighted NICE's decision to provide Protelos, a drug that treats osteoporosis, to only a small number of patients as a last resort. She writes that "clinicians and osteoporosis support groups have pointed out that more than 70,000 hip fractures result in 13,000 premature deaths in the U.K. each year and that these otherwise avoidable episodes needlessly cost the NHS billions of pounds."[9]

Bringing CER to the United States. Proponents of the PPACA dismiss concerns that a U.K.-style system will arise under the health law, but the evolution of PCORI implies that the idea may not be so farfetched. Senators Max Baucus (D–MT) and Kent Conrad (D–ND) first introduced the Comparative Effectiveness Research Act in 2008 in order to create a new entity called the Health Care Comparative Effectiveness Research Institute, with the goal of advancing CER.[10]

6. Helen Evans, "Comparative Effectiveness in Health Care Reform: Lessons from Abroad," Heritage Foundation *Backgrounder* No. 2239, February 4, 2009, at http://www.heritage.org/research/reports/2009/02/comparative-effectiveness-in-health-care-reform-lessons-from-abroad, and Gurjeet Guram and Robert E. Moffit, "The Concept of a Federal Health Board: Learning from Britain's Experience," Heritage Foundation *WebMemo* No. 2154, December 4, 2008, at http://www.heritage.org/Research/Reports/2008/12/The-Concept-of-a-Federal-Health-Board-Learning-from-Britains-Experience.
7. Jenny Hope, "Breakthrough MS Pill Rejected as Too Expensive by NHS Watchdog (but You Can Get It in U.S. and Germany)," MailOnline.com, August 5, 2011, at http://www.dailymail.co.uk/health/article-2022767/Miracle-MS-pill-rejected-expensive-NHS-watchdog-available-U-S-Germany.html (accessed February 27, 2012), and news release, "MS Drug Should Not Be Prescribed on NHS, Says Draft Guidance," National Health Services, August 4, 2011, at http://www.nice.org.uk/newsroom/pressreleases/MSDrugDraftGuidance.jsp?zbrandid=4337&zidType=CH&zid=7637383&zsubscriberId=1024035413&zbdom=http://npc.informz.net (accessed February 27, 2012).
8. National Institute for Health and Clinical Excellence, "Final Appraisal Determination: Fingolimod for the Treatment of Highly Active Relapsing-Remitting Multiple Sclerosis," March 2012, at http://www.nice.org.uk/nicemedia/live/12170/58500/58500.pdf (accessed April 4, 2012).
9. Evans, "Comparative Effectiveness in Health Care Reform: Lessons from Abroad."
10. Comparative Effectiveness Research Act of 2008 (S. 3408), at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_bills&docid=f:s3408is.txt.pdf (accessed February 27, 2012).

The proposal included almost no limitation on the use of CER within Medicare, and the Secretary of Health and Human Services, or the Secretary's designee, was included on the institute's board of governors, allowing the Department of Health and Human Services (HHS) ample opportunity to influence the direction of research.

In June 2009, Senators Baucus and Conrad offered a revised version of their earlier bill, changing the institute's name to today's Patient-Centered Outcomes Research Institute.[11] By the time the PPACA was signed into law, the original entity had been revised to include additional restrictions to make PCORI politically viable.

This idea of a CER board or institute was not unique. Before taking office, President Barack Obama chose former Democratic Senate Majority Leader Tom Daschle to serve as Secretary of HHS and director of the new White House Office of Health Reform and Jeanne Lambrew to serve as deputy director of the White House Office of Health Reform. In 2008, Daschle and Lambrew co-authored a proposal to overhaul the health care system, which included the creation of a Federal Health Board to use CER to make coverage decisions. The board would "define evidence-based health benefits and lower overall spending by determining which medicines, treatments, and procedures are most effective—and identifying those that do not justify their high price tags."[12]

Under their proposal, all federal health programs would have been required to adhere to the recommendations made by Daschle and Lambrew's Federal Health Board. Daschle and Lambrew even suggested linking the board's recommendations to the existing tax exclusion for health insurance, applying decisions to private coverage as well.[13] Ultimately, Daschle was not appointed as Secretary of HHS, but Jeanne Lambrew was chosen to serve as director of the HHS Office of Health Reform.

Others in the Obama Administration have been no less vocal about their support for the top-down use of CER. Peter Orszag, former director of the Office of Management and Budget, testified before the Senate Finance Committee: "To alter providers' behavior, it is probably necessary to combine comparative effectiveness research with aggressive promulgation of standards and changes in financial and other incentives."[14]

Finally, President Obama appointed Donald Berwick, M.D., to serve as administrator of the Centers for Medicare and Medicaid Services (CMS). Much of Berwick's commentary praises the United Kingdom's NHS, about which Berwick claims, "I am romantic about the NHS; I love it."[15] His vision for health care reform depends on strong centralized power: "I cannot believe that the individual health care consumer can enforce through choice the proper configurations of a system as massive and complex as health care. That is for leaders to do."[16]

Berwick's comments about the role of government and elected officials are exactly what must be avoided as CER makes its way to the United States. Under the PPACA, CER will clearly not be used solely as a passive informational tool to guide decision making.

Do PPACA Limits on CER Use Carry Any Weight? The PPACA does limit PCORI's role and its use of research findings. The institute is forbidden from issuing coverage guidelines or making treatment recommendations and "shall not develop or employ a dollars-per-quality adjusted life year ... as a threshold to establish what type of health care is cost effective or recommended."[17] But while the institute may not develop a dollars-per-quality measure of value, it is not explicitly restricted from supporting research on cost-effectiveness.

The PPACA also limits how PCORI findings can be used in administering Medicare, but it does not prevent CER findings from

11. Patient-Centered Outcomes Research Act of 2009 (S. 1213), at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_bills&docid=f:s1213is.txt.pdf (accessed February 28, 2012).
12. Tom Daschle, *Critical: What We Can Do About the Health-Care Crisis* (New York: Thomas Dunne Books, 2008), p. 136.
13. Ibid., p. 179.
14. Peter R. Orszag, "Opportunities to Increase Efficiency in Health Care," testimony before Health Reform Summit of the Committee on Finance, U.S. Senate, June 16, 2008, at http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/93xx/doc9384/06-16-healthsummit.pdf (accessed February 28, 2012).
15. Donald M. Berwick, "A Transatlantic Review of the NHS at 60," Physicians for a National Health Program, July 1, 2008, at http://www.pnhp.org/news/2010/may/a-transatlantic-review-of-the-nhs-at-60 (accessed February 28, 2012).
16. Ibid.
17. Patient Protection and Affordable Care Act.

influencing this or other arms of the government in their decisions on coverage and payment. Sean Tunis, president of the Center for Medical Technology Policy, states that "the PPACA's statutory language does not prevent Medicare from considering CER studies generated by PCORI or other researchers for making coverage decisions, although it does impose some restrictions."[18]

The Secretary of HHS is prohibited from using CER to treat the lives of the elderly as being of less value than others and from using quality adjusted life-years or other similar measures "as a threshold to determine coverage, reimbursement, or incentive programs."[19] But beyond this, the limits are decidedly vague, leaving the future role of CER in Medicare open-ended. Meanwhile, other parts of the health law open the door for Medicare to use CER to micromanage the practice of medicine.

The New Medicare: More Bureaucracy, Less Freedom

The PPACA threatens patient choice and physician autonomy for patients and providers who participate in Medicare. Reductions in provider payments and delivery system changes implicitly allow the program to ration care through so-called improvements in value and efficiency.

The PPACA allows government to micromanage the cost and utilization of medical goods and services in an attempt to eke out relatively small savings from a wildly insolvent program. This approach will not be sufficient to save Medicare, nor will it benefit patients since CER is a required tool in this failing exercise.

The Independent Payment Advisory Board. The new Independent Payment Advisory Board (IPAB), composed of 15 members appointed by the President and confirmed by the Senate, was created by the PPACA to enforce a per capita spending growth target in Medicare. If spending exceeds the set threshold, the board's recommendations will automatically go into effect unless Congress passes legislation that equally reduces growth in spending. Otherwise, IPAB's decisions will bypass congressional approval and require a two-thirds majority of Congress to override them.

IPAB is mostly limited to tinkering with provider payments to reduce cost growth and is restricted from explicitly rationing care (though no definition of "rationing" is supplied). But IPAB could still give other government authorities the ability to ration care using information like that produced by PCORI. American Enterprise Institute scholar and physician Scott Gottlieb warns, "Rather than making the tough clinical judgments themselves, the IPAB would grant CMS authority to rely on judgment of the agency's largely thin clinical staff about the relative benefits of competing treatments."[20]

According to Gottlieb, IPAB could give the Centers for Medicare and Medicaid Services the authority to consolidate drugs, medical devices, and other services under one payment code and then pay for the "least costly alternative" among comparable approaches.

Medicare Hospital Value-Based Purchasing. Another way that Medicare could end up rationing care is by adjusting provider reimbursement under the new value-based purchasing program (VBP). Value-based purchasing was included in the PPACA as acknowledgment that Medicare has long struggled to reward certain providers and punish others based on value of care.

In other areas of the economy, where the purchaser of a good or service and its user are generally one and the same, consumers achieve these goals. Supporters of the PPACA, however, ignore this fact by trying to replace the role of the consumer with more central planning. As Ethics and Public Policy Center fellow James Capretta states, "Efforts to control costs from the top-down have always devolved into price setting and across-the-board payment-rate reductions, which is detrimental to the quality of American medicine."[21]

Despite claims by PPACA supporters that improvements in quality and efficiency in the PPACA will reverse Medicare's growing financial predicament, the Congressional Budget Office finds that "demonstrations

18. Sean R. Tunis, Robert A. Berenson, Steve E. Phurrough, and Penny E. Mohr, "Improving the Quality and Efficiency of the Medicare Program Through Coverage Policy," Urban Institute and Robert Wood Johnson Foundation, August 2011, at http://www.rwjf.org/files/research/72761summarymedicarecoveragequickstrike20110816.pdf (accessed February 28, 2012).
19. Patient Protection and Affordable Care Act.
20. Scott Gottlieb, "IPAB: The Controversial Consequences for Medicare and Seniors," statement before the Subcommittee on Health, Committee on Energy and Commerce, U.S. House of Representatives, July 13, 2011, at http://republicans.energycommerce.house.gov/Media/file/Hearings/Health/071311/Gottlieb.pdf (accessed February 28, 2012).
21. James C. Capretta, "Why the Obama Health Plan is *Not* Entitlement Reform," Galen Institute, July 2010, p. 17, at http://www.thenewatlantis.com/docLib/20100804_CaprettaHealthPlan.pdf (accessed February 28, 2012).

that paid bonuses to providers on the basis of their quality scores, estimated savings, or both, produced little or no savings."[22] Nevertheless, the PPACA requires Medicare to measure providers' performance and alter their payments based on a scoring system in its new value-based purchasing program.

Beginning in 2013, hospitals will face financial incentives to comply with federal quality measures. The Secretary of HHS is responsible for determining the performance standards and methodology used to calculate hospital performance scores, which will reflect achievement and improvement, and, beginning in 2014, include efficiency measures, such as Medicare spending per beneficiary. The law also calls for extension of VBP into other areas of care.

Hospital payments will reflect performance on the scored measures, but the performance payment is not a true bonus, since its funding is made available by first cutting base payments across the board by 1 percent ($850 million) in the first year, gradually increasing to 2 percent by 2017. Hospitals will be scored on both their achievement relative to other hospitals and their improvement, and payment will reflect the higher score of the two. Penalizing some in order to reward others is like grading on a curve, which makes it impossible for every student in class to get an "A."

The 13 measures chosen to "grade" hospitals in the program's first year were selected from those used currently under the Medicare Hospital Quality Reporting Program for five prevalent conditions, and the Secretary of HHS has broad discretion to add or remove measures. Though the first year includes only a handful of quality measures, it is clear that more will be added in the future.[23]

In its first year, the VBP program may seem fairly benign, but it is unlikely to remain so. Even IPAB could use the program to exercise its role as arbiter of cost-containing changes in Medicare. One of the few mechanisms available to the IPAB is to reduce provider reimbursements. One way that IPAB could do this and simultaneously claim to advance its other goal to "protect and improve Medicare beneficiaries' access to necessary and evidence-based items and services" (a directive that gives the board just as much authority to limit care as it does to protect it) would be to drastically reduce base hospital payments and make an increasing portion of provider reimbursement contingent on performance scores and adherence to VBP program quality measures.

As CER and other evidence is used to inform the quality measures and increase their size and scope, IPAB could effectively make the measures mandatory for providers. Even if the VBP program as created in the statute is left unchanged, it could still harm patient care.

Consequences of Value-Based Purchasing for Patient Care

CER is already seen as a viable basis for health care quality measures, and the door is open for its use in the VBP program. According to HHS, "When hospitals follow these types of proven best practices, patients receive higher quality care and see better outcomes."[24] But the evidence indicates otherwise. Measuring and rewarding quality according to measures of processes or outcomes can have negative consequences for patients and physicians alike. VBP could encourage physician behavior that does not put the patient first, meanwhile treating providers in ways that are unfair, inequitable, and unlikely to truly reflect better-value, high-quality care.

A Strategy Doomed from the Start. Evidence from government demonstration programs shows that value-based purchasing is an ineffective strategy to improve outcomes. Even so, the authors of the PPACA allowed it to become law, affecting almost every hospital in the country.

Legislation in 2001 and 2003 gave CMS the authority to collaborate with Premier, a nationwide organization of not-for-profit hospitals, to perform the Premier Hospital Quality Incentive Demonstration (PHQID). The demonstration program offered 278 participating hospitals incentive payments to improve their performance based on 34 quality measures, 27 of which measured process and seven of which measured outcomes.

CMS reported early on that the program led hospitals to improve their performance scores by 17.2 percentage points within the first three years. Other studies reached similar

22. Congressional Budget Office, "Lessons from Medicare's Demonstration Projects on Disease Management, Care Coordination, and Value-Based Payment," January 18, 2012, at http://www.cbo.gov/doc.cfm?index=12663 (accessed February 28, 2012).
23. News release, "Administration Implements New Health Reform Provision to Improve Care Quality, Lower Costs," HealthCare.gov, April 29, 2011, at http://www.healthcare.gov/news/factsheets/2011/04/valuebasedpurchasing04292011a.html (accessed April 4, 2012).
24. Ibid.

conclusions.[25] But the focus of these studies was on process measures, not actual outcomes, which do not tell the whole story. Rodney Hayward, M.D., warns that "experience with performance measurement ... has generally shown that 'what you measure improves,' but unfortunately, we often settle for measuring that which is simple and easy to gauge and then sit back and celebrate the improvements in our 'measures.'"[26]

Other studies assessed whether the quality of outcomes improved under the demonstration and came to different conclusions. One study analyzed the demonstration's short-term effects on mortality and cost reduction, following a previous analysis that showed that the demonstration had no impact on mortality for patients suffering from acute myocardial infarction.[27] The results showed that the demonstration did not significantly reduce mortality or cost. While mortality did decrease for the measured conditions, similar reductions occurred at hospitals that did not participate, and reductions were also observed for conditions that were not measured. The study concluded that "by not reducing mortality or cost growth, the PHQID has made little impact on the value of inpatient care purchased by Medicare."[28]

CBO analysis later concluded that the Premier demonstration "had no effect on Medicare spending" and only "slightly improved quality of care based on the measures adopted for those demonstrations."[29] A study published in *The New England Journal of Medicine* assessing the long-term effects of the six-year program at its conclusion echoed these results. According to the authors, they "found no evidence that the largest hospital-based pay-for-performance program led to a decrease in 30-day mortality. Expectations of improved outcomes for programs modeled after Premier HQID should therefore remain modest."[30] The PPACA's value-based purchasing program, which begins in 2012, falls directly under this category.

In addition to the growing evidence that VBP will be ineffective, several other studies highlight the harmful consequences that can arise from these kinds of pay-for-performance programs. Researchers in the United Kingdom examined the impact of pay-for-performance in the U.K. and in California on primary-care physicians and concluded that adverse effects included "encouraging physicians to avoid sicker patients, exacerbating disparities, and neglecting types of care for which quality is not measured."[31]

Misaligned Incentives Threaten Quality of Care. Quality measures do not always translate into what is best for an individual patient, in which case practicing medicine "to the test" can harm patients. Harvard School of Medicine's Jerome Groopman, M.D., writes, "Over the past decade, federal 'choice architects'—i.e., doctors and other experts acting for the government and making use of research on comparative effectiveness—have repeatedly identified 'best practices,' only to have them shown to be ineffective or even deleterious."[32]

In 2007, the *Journal of the American Medical Association* published the findings of a study which showed that none of the measures

25. "Premier Hospital Quality Incentive Demonstration: Rewarding Superior Quality Care," Centers for Medicare and Medicaid Services *Fact Sheet*, July 2009, at http://www.qualitycoalition.net/Data/Sites/2/media/position-statement/hqid-fact-sheet.pdf (accessed February 28, 2012), and Peter K. Lindenauer et al., "Public Reporting and Pay for Performance in Hospital Quality Improvement," *The New England Journal of Medicine*, February 2007, at http://www.nejm.org/doi/full/10.1056/NEJMsa064964#t=articleMethods (accessed February 28, 2012).
26. Rodney A. Hayward, "Performance Measurement in Search of a Path," *The New England Journal of Medicine*, March 2007, p. 951, at http://www.nejm.org/doi/full/10.1056/NEJMe068285 (accessed February 12, 2012).
27. Andrew M. Ryan, James F. Burgess, Christopher P. Tompkins, and Stanley S. Wallack, "The Relationship Between Medicare's Process of Care Quality Measures and Mortality," *Inquiry*, Vol. 46, No. 3 (September 2009), pp. 274–290, at http://www.inquiryjournalonline.org/doi/abs/10.5034/inquiryjrnl_46.03.274 (accessed February 28, 2012).
28. Ibid.
29. Congressional Budget Office, "Lessons from Medicare's Demonstration Projects on Disease Management, Care Coordination, and Value-Based Payment."
30. Ashish K. Jha, Karen E. Joynt, E. John Orav, and Arnold M. Epstein, "The Long-Term Effect of Premier Pay for Performance on Patient Outcomes," *The New England Journal of Medicine*, March 28, 2012, at http://www.nejm.org/doi/full/10.1056/NEJMsa1112351#t=article (accessed April 4, 2012).
31. Ruth McDonald and Martin Roland, "Pay for Performance in Primary Care in England and California: Comparison of Unintended Consequences," *Annals of Family Medicine*, Vol. 7, No. 2 (March 2009), pp. 121–127, at http://www.annfammed.org/cgi/reprint/7/2/121 (accessed February 28, 2012).
32. Jerome Groopman, "Health Care: Who Knows 'Best'?" *The New York Review of Books*, February 11, 2010, at http://www.nybooks.com/articles/archives/2010/feb/11/health-care-who-knows-best/ (accessed February 28, 2012).

commonly used to quantify performance for treating heart failure was strongly associated with better mortality rates.[33] A 2010 University of Michigan study came to a similar conclusion when comparing surgery outcomes at 2,189 hospitals for their adherence to process measures reported by Hospital Compare, a website used to publicly report hospital compliance with measures under the Medicare Hospital Quality Reporting Program.[34] The authors "found little evidence of a consistent relationship between hospital compliance with processes of care and operative mortality rate." Furthermore, they claim, "Currently available information on the Hospital Compare website will not help patients identify hospitals with better outcomes for high-risk surgery."[35]Again, a rigid model with the wrong focus may be at fault.

Since such performance measures have fallen short time and again, Medicare's value-based purchasing program is most likely, at best, to lead to arbitrary reimbursement levels for hospitals at inequitable rates with no resulting benefit. Worse is the possibility of encouraging medical professionals to act in ways that are unnecessary or even harmful to a patient in order to comply with the measures. Groopman cites several examples:

> Medicare specified that it was a "best practice" to tightly control blood sugar levels in critically ill patients in intensive care. That measure of quality was not only shown to be wrong but resulted in a higher likelihood of death when compared to measures allowing a more flexible treatment and higher blood sugar. Similarly, government officials directed that normal blood sugar levels should be maintained in ambulatory diabetics with cardiovascular disease. Studies in Canada and the United States showed that this "best practice" was misconceived. There were more deaths when doctors obeyed this rule than when patients received what the government had designated as subpar treatment (in which sugar levels were allowed to vary).[36]

In addition to potentially encouraging physicians to do the wrong thing, quality measures with financial strings attached can punish doctors for doing the right thing. Related to the VBP, the PPACA will also financially penalize hospitals with high readmission rates for certain medical conditions beginning in 2012.[37] Again, however, this model could fail to achieve its intended goal of improving quality.

A study by Cleveland Clinic researchers showed that high provider readmission rates might not necessarily indicate lower quality care: While the Cleveland Clinic had a higher-than-average readmission rate for heart failure, its average 30-day mortality rate for the same condition was lower than average.[38] The researchers concluded that "if a hospital has a lower mortality rate, then a greater proportion of its discharged patients are eligible for readmission. As such, to some extent, a higher readmission rate may be a consequence of successful care."[39] One of the researchers, Dr. Eiran Z. Gorodeski, further warns that "the message to patients and the general public is that they should be wary of seemingly simple measures of quality of care."[40]

Several health care systems already use electronic health records and evidence-based quality measures to standardize care, but the crucial difference is that physicians

33. Gregg C. Fonarow et al., "Association Between Performance Measures and Clinical Outcomes for Patients Hospitalized with Heart Failure," *Journal of the American Medical Association*, Vol. 297, No. 1 (January 2007), at http://jama.ama-assn.org/cgi/reprint/297/1/61 (accessed February 28, 2012).
34. Lauren H. Nicholas, Nicholas H. Osborne, John D. Birkmeyer, and Justin B. Dimick, "Hospital Process Compliance and Surgical Outcomes in Medicare Beneficiaries," *Archives of Surgery*, Vol. 145, No. 10 (2010), pp. 999–1004, at http://archsurg.ama-assn.org/cgi/content/short/145/10/999 (accessed February 28, 2012).
35. Thomas M. Burton, "Medicare Faulted on Surgery Evaluation," *The Wall Street Journal*, October 18, 2010, at http://online.wsj.com/article/SB10001424052702303496104575560522424599924.html (accessed February 28, 2012).
36. Groopman, "Health Care: Who Knows 'Best'?"
37. Patient Protection and Affordable Care Act, § 3025.
38. Karen Pallarito, "High Readmission Rates May Not Mean Worse Hospital Care," Bloomberg *Businessweek*, July 14, 2010, at http://www.businessweek.com/lifestyle/content/healthday/641139.html (accessed February 28, 2012).
39. Eiran Z. Gorodeski, Randall C. Starling, and Eugene H. Blackstone, "Are All Readmissions Bad Readmissions?" *The New England Journal of Medicine*, Vol. 363, No. 3 (July 15, 2010), at http://www.nejm.org/doi/full/10.1056/NEJMc1001882 (accessed February 28, 2012).
40. Pallarito, "High Readmission Rates May Not Mean Worse Hospital Care."

are usually able to document and defend their reasoning for deviating from best practices. One study assessed the frequency with which quality measures were ignored for appropriate exceptions and found that, of 650 exceptions reported during a seven-month period, 93.6 percent were medically appropriate.[41]

Under Medicare's VBP program, physicians will not have the opportunity to justify deviations from established standards. Instead, they will have to choose between compliance for payment and what they consider to be most appropriate for the patient.

Cherry-Picking Endangers the Doctor–Patient Relationship. Another significant issue in a system that pays providers based on quality measures is that providers are not single-handedly responsible for health outcomes. Individuals, their behavior, and several other factors can significantly affect health outcomes. Rewarding or punishing providers based on factors beyond their control is unfair and threatens patient-centered care by altering the way physicians interact with patients and encouraging them to "cherry-pick" patients and treatments that will enhance their performance score.

The University of Manchester study showed that this occurred in the pay-for-performance programs in California and the United Kingdom.[42] The researchers reported that physicians "expressed resentment about patients who refused to comply with their advice" and that "interviews contained reports of seriously dysfunctional or coercive behavior" by doctors when patients were noncompliant. In extreme cases, doctors threatened to un-enroll patients, accused them of hurting their ratings, or lied about the consequences for failing to comply with their orders. Physicians even reported disregarding informed-consent procedures to meet screening targets for certain diseases.

Another study reinforces the fact that patients, not just the care they receive, can drastically change performance ratings.[43] Primary-care physicians who ranked highest according to widely used measures generally attended to older patients with more complex illnesses. Compared to the lowest-ranked physicians, those physicians also treated fewer minority patients, non-English speakers, and patients covered by Medicaid or what the authors categorize as underinsured. When the researchers adjusted the ranking system to account for these factors, 36 percent of primary-care physicians were reclassified.

Pay-for-performance programs could encourage providers to cherry-pick procedures as well, focusing on the measured services to the neglect of others:

> [R]ather than creating a culture of quality, [pay for performance] could lead to distortions in reporting or misplaced quality improvement efforts driven primarily by bonus payments. Such developments could lead to the unintended consequence of hospitals narrowly focusing their interventions at the expense of broadly improving care.[44]

Even the PPACA's strategy to punish hospitals for high readmission rates is misguided, since it focuses incentives on hospitals even though they are not responsible for a patient's care following a discharge. Reducing readmissions rates is widely considered to be a goal for health care reform, and success requires improving care coordination following a hospital stay. Evidence shows that private plans in Medicare Advantage are already doing a better job on several measures of quality, including reducing readmissions by increasing other types of care after an inpatient episode.[45]

The Inevitable Bias of Quality Measures. Only patients can truly and effectively define value in the health care system, and any attempt to do so by the federal

41. Stephen D. Persell, Nancy C. Dolan, Elisha M. Friesema, Jason A. Thompson, Darren Kaiser, and David W. Baker, "Frequency of Inappropriate Medical Exceptions to Quality Measures," *Annals of Internal Medicine*, Vol. 152, No. 4 (February 2010), pp. 225–231, at http://www.annals.org/content/152/4/225.abstract (accessed February 28, 2012).
42. McDonald and Roland, "Pay for Performance in Primary Care in England and California."
43. Clemens S. Hong, Steven J. Atlas, Yuchiao Chang, S. V. Subramanian, Jeffrey M. Ashburner, Michael J. Barry, and Richard W. Grant, "Relationship Between Patient Panel Characteristics and Primary Care Physician Clinical Performance Rankings," *Journal of the American Medical Association*, Vol. 304, No. 10 (2010), pp. 1107–1113, at http://jama.ama-assn.org/content/304/10/1107.abstract (accessed February 28, 2012).
44. Charles N. Kahn III, Thomas Ault, Howard Isenstein, Lisa Potetz, and Susan Van Gelder, "Snapshot of Hospital Quality Reporting and Pay-For-Performance Under Medicare," *Health Affairs*, Vol. 25, No. 1 (2006), pp. 148–162, at http://content.healthaffairs.org/cgi/reprint/25/1/148 (accessed February 28, 2012).
45. Kathryn Nix, "How Competition Improves Quality: The Case of Medicare Advantage," Heritage Foundation *Center for Policy Innovation Research Summary* No. 2, January 11, 2012, at http://www.heritage.org/research/reports/2012/01/how-competition-improves-quality-the-case-of-medicare-advantage.

government is certain to reflect an Administration's political priorities and influence from special interests. As some health policy experts point out, "Although the quality measures are evidence-based and supported by clinical science, collapsing the measures into composite scores and specifying bonus and penalty formulas require policy choices for which there is no scientific foundation."[46]

The practice of medicine inherently requires some level of subjectivity and judgment. Because it is an imprecise science, it would be impossible, even for the most expert of central planners, to remove all gray areas from medicine. Thus, patients and their physicians are best positioned to make the most reasonable decisions.

In 2009, the United States Preventive Services Task Force (USPSTF) changed its rating of mammography for women between the ages of 40 and 49 to "not recommended," intending to signal that women in this age bracket should determine with their doctors whether they should receive routine screening.[47] If such a recommendation were made a requirement, this intent would be ignored. Physicians Kerianne Quanstrum and Rodney Hayward explain that:

> [S]cientific evidence can only help us describe the continuum of benefit versus harm. The assessment of whether the benefit is great enough to warrant the risk of harm ... is necessarily a value judgment. When either side in the mammography wars claims that the evidence suggests that women should or should not undergo routine mammography starting at the age of 40 years, they are deceiving themselves and the public about what the evidence can tell us. They are really just making different value judgments about where to set the threshold.[48]

It would be impossible to remove all judgment calls from the practice of medicine. The next best option is to allow the providers closest to each case and the patients affected to make the decisions in order to keep others' priorities—political, budgetary, or otherwise—from shaping their outcome.

Lawmakers should continue to support Medicare reform that rewards value and does not reduce quality of care, but while several private health systems have begun to use financial incentives to encourage adherence to quality measures, the federal government is simply incapable of replicating the private sector's success. When innovations prove unsuccessful in the private sector, they are simply discontinued, while governments need to issue new regulations or pass new laws. Also, in the private sector, physicians who go against best practices, as defined by CER or other evidence, for the unique case of a specific patient can often explain their reasoning in order to avoid penalties. And physicians and patients alike have the option of going elsewhere if dissatisfied.

Impact on Medical Innovation

CER can either serve as a complement to the creation and introduction of new treatments or as a strong deterrent. Which becomes the reality will, again, depend on how the research findings are applied to the practice of medicine. Using CER to guide provider payment or make coverage decisions would have repercussions extending far beyond the bedside. Since focusing on existing treatments for which data is available stacks the deck against new ones, this reactionary approach would discourage further medical innovation.

The United States "is both a major producer and consumer of health care which means that both demand for and supply of medical technology is very high. Investment in new medical technologies is very high as [are] their levels of availability and rate of diffusion."[49] The U.S. is the largest producer of medical technology in the world due to this unique demand for health care advancements and a welcoming environment where the

46. Kahn et al., "Snapshot of Hospital Quality Reporting and Pay-For-Performance Under Medicare," p. 160.
47. The Senate later agreed to prohibit the use of this specific recommendation from the USPSTF in its determination of required "free" preventive services under the Affordable Care Act. See David M. Herszenhorn, "Senate Blocks Use of New Mammogram Guidelines," *The New York Times*, December 3, 2009, at http://prescriptions.blogs.nytimes.com/2009/12/03/gop-amendments-aim-at-new-cancer-guidelines (accessed April 4, 2012).
48. Kerianne H. Quanstrum and Rodney A. Hayward, "Lessons from the Mammography Wars," *The New England Journal of Medicine*, Vol. 363 (September 9, 2010), p. 1077, at http://healthpolicyandreform.nejm.org/?p=12525 (accessed February 28, 2012).
49. Meir P. Pugatch and Helen Davison, "A Healthy Market: Health Technology Assessment in Context," Stockholm Network *Paper on Health Technology Assessment* No. 2, July 2007, p. 13, at http://www.stockholm-network.org/downloads/publications/Health_Technology_Assessment_in_Context.pdf (accessed February 28, 2012).

public sector invests in research and private-sector talent leads to the development of new technology.[50]

However, experts warn that the nation's gradual move toward policies of top-down cost containment in health care spending could jeopardize the country's ability to produce new treatments and make them available to patients.[51] Cleveland Clinic chief executive Toby Cosgrove states that "if we only pay for one of those, we begin to limit what people are willing to do in terms of developing new products."[52] Research shows that CER could reduce investment in research and development of medical technology by $10 billion—approximately 10 percent to 12 percent—each year.[53]

The impact of CER on "personalized medicine," which includes the identification and use of a disease's genetic origins to indicate the correct treatment or medication dosage, is especially worrisome. Advances in this area already affect patients with lung, colon, or breast cancer and hold great potential for other areas of medicine. According to a Lewin Group study:

> [T]he absence of [personalized medicine] considerations in CER could be suboptimal for patient interests, particularly to the extent that CER findings are used to support gatekeeping or other authoritative functions, such as product labeling, clinical practice guidelines, coverage policies, and quality measures and criteria.[54]

Personalized medicine could replace the widely used "trial-and-error" treatment paradigm, improve health outcomes, and reduce health care spending. Currently, most physicians choose a treatment that is most likely to be effective and then try another if the first is not successful. This is costly and clearly not ideal for the patient. However, the problem might not be that the first treatment was ineffective, but that it was not effective *for all patients*. CER might discourage the option that is effective less often when what is really needed is information revealing for which patients it is effective and how to identify them.

If employed correctly, CER does not have to pose a threat to innovation. It could, in fact, complement personalized medicine by illuminating areas in which differing responses are due to genetic differences.

Researchers Robert Epstein and J. Russell Teagarden highlight an example in which CER compared two statin treatments used to lower cholesterol in high-risk cardiovascular patients. The findings supported the conclusion that the stronger dose of statins lowered the risk of adverse outcomes. But that was not the entire story. Later genetic analysis revealed that the stronger treatment held no added benefit unless a patient carried a particular gene variant.[55] While CER on its own might have concluded that the higher dose was better, more in-depth research revealed that this was not the case.

What Congress Should Do

Regrettably, the PPACA puts CER use on the wrong path. Allowing unelected officials to determine how and to whom resources are allocated rather than empowering doctors and patients to make decisions is the wrong approach. Though the PPACA may not immediately result in overt rationing of care, its changes in Medicare open the door to top-down use of CER and interference with the care seniors receive.

As Medicare spending rises, PCORI and the research it produces will increasingly be considered a viable resource to micromanage the practice of medicine, and the PPACA creates the machinery to make this happen. For these reasons, the step forward should be to repeal the law and start over.

The alternative is not to discourage the development of CER, since research findings can positively influence treatment decisions. Instead, after fully repealing the PPACA, Congress should

50. Battelle Technology Partnership Practice, "Gone Tomorrow? A Call to Promote Medical Innovation, Create Jobs, and Find Cures in America," June 10, 2010, at http://www.americanmedicalinnovation.org/sites/default/files/Gone_Tomorrow.pdf (accessed February 28, 2012).
51. Pugatch and Davison, "A Healthy Market," p. 14.
52. Diana Suchetka, "Cleveland Clinic CEO Toby Cosgrove Talks About Health-Care Reform and More at City Club," Cleveland.com, August 19, 2010, at http://www.cleveland.com/healthfit/index.ssf/2010/08/cleveland_clinic_ceo_toby_cosg.html (accessed February 28, 2012).
53. Benjamin Zycher, "Comparative Effectiveness Reviews: Quantitative Analysis of Research and Development Investment Effects," Pacific Research Institute, July 15, 2011, at http://www.pacificresearch.org/docLib/20110715_Zycher_CER_F.pdf (accesses February 28, 2012).
54. Clifford Goodman, "Comparative Effectiveness Research and Personalized Medicine: From Contradiction to Synergy," The Lewin Group, October 2009, p. 22, at http://www.lewin.com/publications/publication/386/ (accessed February 28, 2012).
55. Robert Epstein and J. Russell Teagarden, "Comparative Effectiveness and Personalized Medicine: Evolving Together or Apart?" *Health Affairs*, Vol. 29, No. 10 (October 2010), at http://content.healthaffairs.org/cgi/content/abstract/29/10/1783 (accessed February 28, 2012).

focus on transforming the failing Medicare program to avoid bureaucratic intrusion into patient care, for which CER is a tool, not the source. Transitioning seniors' health benefits to a premium support system like that included in The Heritage Foundation's *Saving the American Dream* budget reform proposal would not only make the program solvent, but also prevent further central planning and its unwanted consequences.[56]

Reform should build on the proven success of the Federal Employees Health Benefits Program, which provides health coverage to the nation's 8 million federal workers, retirees, and their families, and Medicare Part D, which provides seniors with a voluntary prescription drug benefit.[57] In both programs, enrollees receive a contribution to apply to the private plan of their choice and can shop around for a better option if costs increase or they become otherwise dissatisfied. Moreover, evidence suggests that Medicare Advantage, which offers traditional Medicare benefits to seniors through a menu of private plans, is providing its beneficiaries with a higher quality of care than traditional Medicare.

Conclusion

As patients and consumers, Americans support the idea of using more information to reveal the comparative benefits of their treatment alternatives. They do not, however, favor allowing the government to use such information to limit their options.[58]

Increased attention to comparative studies of medical interventions can have a positive impact on the practice of medicine, but it must be limited to assisting doctors and patients to determine the right course of action. If treated as a budgetary constraint, CER will cease to be purely informational and will have widespread negative effects. The PPACA creates the infrastructure to propel the U.S. health care system, and Medicare in particular, in this flawed direction.

There is no debate over the fact that health care resources are limited and that Congress must act to reduce runaway health care spending, but Congress must do so without using CER to allow the government to micromanage the practice of medicine. Using research findings to strengthen bureaucracy is a losing combination that will erode quality of care for Americans.

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56. Stuart M. Butler, Alison Acosta Fraser, and William W. Beach, eds., *Saving the American Dream: The Heritage Plan to Fix the Debt, Cut Spending, and Restore Prosperity*, The Heritage Foundation, 2011, at http://savingthedream.org.
57. Walton Francis, "The FEHBP as a Model for Medicare Reform: Separating Fact from Fiction," Heritage Foundation *Backgrounder* No. 1674, August 7, 2003, at http://www.heritage.org/research/reports/2003/08/the-fehbp-as-a-model-for-medicare-reform-separating-fact-from-fiction, and Kathryn Nix, "A Recipe for Reform: Success of Consumer-Driven Principles in Medicare Programs," Heritage Foundation *WebMemo* No. 3340, August 10, 2011, at http://www.heritage.org/Research/Reports/2011/08/Consumer-Driven-Medicare-Reform-Models-for-Success.
58. Alan S. Gerber, Eric M. Patashnik, David Doherty, and Conor Dowling, "The Public Wants Information, Not Board Mandates, from Comparative Effectiveness Research," *Health Affairs*, Vol. 29, No. 10 (October 2010), pp. 1874–1875, at http://content.healthaffairs.org/cgi/content/abstract/29/10/1872 (accessed February 28, 2012).