



RESULTS FROM J-PAL NORTH AMERICA SUPPORTED RANDOMIZED CONTROLLED TRIALS TO IMPROVE US HEALTH CARE DELIVERY

This publication describes some work to date supported by J-PAL North America's **US Health Care Delivery Initiative (HCDI)**. It summarizes the results of several randomized controlled trials supported by HCDI, as well as several publications related to studies supported by HCDI.

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OVERVIEW AND POLICY ISSUES

This publication highlights several examples of studies J-PAL North America's Health Care Delivery Initiative (HCDI) has supported that demonstrate the rigor and value of randomized evaluations for improving health care delivery and people's lives in the United States. We hope that it serves as an inspiration for governments, insurers, employers, health care providers, and more to identify opportunities to use randomized controlled trials (RCTs) in this field. It is not meant to be exhaustive, but we will update it periodically.

Health care delivery shapes the quality of every American's life, yet in many ways it is inefficient, ineffective, and inequitable. On average, the United States spends more than twice as much per person on health compared to other wealthy countries yet performs less well on many health outcomes.¹ Often, there are stark disparities in health outcomes and health care access related to factors like a person's income or race.² Health care leaders run innovative programs and implement new policies to address these challenges every day. But the effects of many

of these policies and programs are not known, making it challenging for decision-makers to determine which interventions are truly improving health outcomes.

RCTs can be used to evaluate the effectiveness of health care policies and programs, but they are too rarely used. An RCT is a type of impact evaluation that uses random assignment to allocate resources, run programs, or apply policies as part of the study design. Well-conducted random assignment ensures that there are, on average, no systematic differences between those who receive the program and those who do not. Random assignment can therefore produce accurate (unbiased) results about the effect of the program. RCTs are

¹ Papanicolas I, Woskie LR, Jha AK. Health Care Spending in the United States and Other High-Income Countries. *JAMA*. 2018;319(10):1024–1039. doi:10.1001/jama.2018.11150

² Schiller JS, Lucas JW, Peregoy JA. Summary health statistics for U.S. adults: National Health Interview Survey, 2011. National Center for Health Statistics. *Vital Health Stat* 10(256). 2012. https://www.cdc.gov/nchs/data/series/sr_10/sr10_256.pdf

routinely used to test new medical innovations, particularly new drugs. Yet between 2009 and 2013 across top journals in medicine, health services research, and economics, less than 20 percent of studies of interventions in US health care delivery are randomized.³ By contrast, in top medical journals, about 80 percent of studies of US medical interventions are randomized.⁴

When RCTs are conducted in health care delivery, they can have enormous influence, due to the simplicity, transparency, and credibility of their design. One example is the 2008 Oregon Health Insurance Experiment, which was the first RCT on the impact of Medicaid.⁵ The study found that, for low-income adults, Medicaid increased the use of health care services, decreased financial strain, improved self-reported health, reduced depression, and increased total health care spending by about 25 percent. However Medicaid had no detectable effect on physical health outcomes, employment, or earnings. Numerous front-page, high-profile articles and opinion pieces featured the results, which also served as the primary input into several government reports on the impact of expanding Medicaid under the Affordable Care Act.⁶

The influence of the Oregon Health Insurance Experiment, together with the dearth of RCTs in US health care delivery, helped catalyze the 2013 launch of J-PAL North America's Health Care Delivery Initiative. In turn, HCIDI is part of a larger, growing movement of health care providers and health policy makers creatively addressing commonly cited barriers to RCTs and using them more often in US health care delivery.

This publication features selected examples of randomized evaluations HCIDI has supported to date conducted by J-PAL's affiliated professors, as well as related studies conducted by researchers outside of J-PAL's network. These studies have produced clear, credible results on pressing issues in US health care policy. The examples run the gamut. One evaluated low-cost outreach letters on reducing drug over-prescription while another evaluated Medicare payment reform. Some randomized at the physician- or patient-level in a single health care center while another randomized at the metropolitan area-level in a nationwide RCT. All of the studies we hope will inspire others to identify opportunities to use RCTs to improve health care delivery in the United States.

Government letters to reduce overprescribing.

Overprescribing of pharmaceutical drugs exposes patients to potentially unnecessary health risks—such as cognitive decline or even death—and increases health care costs. The Center for Medicare and Medicaid Services (CMS), a US federal agency, is interested in identifying ways to reduce overprescribing of drugs. Evidence from various contexts suggest that letters can influence behavior, so one potential low-cost approach is to send letters to providers writing prescriptions at substantially higher rates than their peers.

Evidence from two RCTs with CMS suggest that sending letters can reduce overprescribing if the intervention is designed well. In one study published in 2016, CMS sent a letter to a randomly selected half of 1,525 Medicare providers who prescribed Schedule II controlled substances (including opioid pain relievers like morphine) at exceedingly high rates. The letter used text and graphics to show that the prescriber had supplied far more Schedule II controlled substances than their peers. There was no detectable difference in prescribing, thirty and ninety days after the mailing. Based on these results, the researchers then launched a study to test a new letter intervention. In this RCT published in 2018, CMS sent letters to a randomly selected half of 5,055 Medicare prescribers of the antipsychotic drug Seroquel who were prescribing at high rates.⁷ In the new intervention, CMS sent the letter multiple times (instead of just once); the researchers also changed the framing of the letter to emphasize that the physician's prescribing was extremely high relative to their within-state peers, and that the physician was under review by CMS. The more strongly-worded peer comparison letters from CMS substantially reduced Seroquel prescribing for at least two years, with no evidence of negative effects on patients. Although the reductions were larger for potentially inappropriate prescribing to patients without FDA-approved indication, the letters also reduced appropriate prescribing to patients with FDA-approved indications.

These research projects highlight that research teams can build on any RCT finding—positive, negative, or null. Once they found no effect of the letters on Schedule II prescribing, the team innovated and built on additional research to design the letters sent to Seroquel prescribers, which effectively reduced prescribing. Similar collaborations between researchers and program and policy implementers can help test, iterate, and improve health care delivery.

³ Finkelstein A and Taubman S. Randomize evaluations to improve health care delivery. *Science*. 2015;347:6223:720-722. <https://doi.org/10.1126/science.aaa2362>

⁴ Ibid.

⁵ Insuring the Uninsured. Cambridge, MA: Abdul Latif Jameel Poverty Action Lab (J-PAL), January 2014. https://www.povertyactionlab.org/sites/default/files/publications/Insuring_the_Uninsured.pdf

⁶ Finkelstein A and Taubman S. "Using Randomized Evaluations to Improve the Efficiency of US Healthcare Delivery." Cambridge, MA: Abdul Latif Jameel Poverty Action Lab (J-PAL), 2015. <https://www.povertyactionlab.org/sites/default/files/publications/Using%20Randomized%20Evaluations%20to%20Improve%20the%20Efficiency%20of%20US%20Healthcare%20Delivery.pdf>

⁷ Specifically, 2,527 prescribers were assigned to the treatment group and 2,528 were assigned to the control group.

Medicare payment reform.

In an attempt to improve quality and reduce spending, Medicare—the public health insurance for the elderly and disabled in the United States—is shifting away from the traditional fee-for-service (FFS) payment model, which pays providers for each medical service delivered to patients. One primary alternative payment model for US medical care is bundled payments, where one payment is made for all services related to a specific episode of care. The goal is that by paying providers a fixed amount per patient no matter what services they deliver, providers will have an incentive to reduce unnecessary over-provision of care, thereby reducing costs to Medicare. The concern, however, is that bundled payments could result in under-provision of care because providers will not be paid for providing more care, even when it is medically appropriate.

Results from four different studies of a nationwide bundled payment RCT for hip and knee replacement consistently indicated bundled payments caused a modest reduction in health care utilization, without harming health care quality or changing patient volume or patient composition. In April 2016, CMS launched a five-year national, Metropolitan Statistical Area (MSA)-level RCT of the mandatory Comprehensive Care

for Joint Replacement (CJR) bundled payment model for knee and hip replacements. CMS implemented its policy at the MSA-level, which is a core geographic area with a large population that is tied together economically and socially. Results from the first two years of a bundled payment RCT indicate that it modestly reduced health care utilization—primarily driven by reduced discharges to post-acute care (PAC) facilities—with no evidence of an impact on quality of care, patient volume, or patient composition. The results indicate that bundled payments reduced Medicare spending, but the savings may have been offset by the bonus payments CMS made to hospitals that beat the spending target set by CMS. Regardless, the estimated spending reductions were substantially smaller than those found by several prior, observational studies of voluntary bundled payment models for hip and knee replacement.

This example illustrates how RCTs can be used to learn about the impacts of nationwide reforms at scale. Policies implemented at the community level like CMS' bundled payments policy can be randomized to learn about their impacts. CMS is now poised to launch similar nationwide RCTs for payment reform in Medicare's End Stage Renal Disease program and in Radiation Oncology.



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Hotspotting to address needs of “super-utilizers.”

Health care spending in the United States is heavily concentrated. Five percent of the population accounts for 50 percent of annual spending; one percent accounts for almost one quarter of annual spending. This has generated interest in how to reduce costs and improve the quality of care delivery through interventions targeting patients with very high use of health care services. Also referred to as “super-utilizers,” this small group of individuals with medically and socially complex needs and frequent hospitalizations accounts for a disproportionately large share of health care costs. There are a number of promising observational studies of interventions targeting super-utilizers. However, regression to the mean—the tendency for patients selected as exceptionally high-cost patients at a moment in time to move closer to average cost over time—may lead observational studies of super-utilizer programs to produce misleading estimates of program effects.

In a 2020 study, researchers evaluated the impact of a well-known care transition program that provides intensive, time-limited clinical and social assistance to “super-utilizers” of the health care system with complex needs. Specifically, researchers studied the impact of the Camden Coalition of Healthcare Providers’ Core Model, which has received national attention as a promising super-utilizer intervention, and federal funding has expanded versions of the model to other cities. Researchers found no impact on the rate of six-month hospital readmission. There was also no impact on readmissions over shorter (one month) or longer (one year) time frames, or on mortality. The results suggest challenges in reducing hospital readmission rates for a medically and socially complex patient population with very high health care utilization rates.

The results also underscore the importance of using RCTs to measure the impact of interventions targeting patients with high health care utilization rates. While the results from this RCT indicate no impact of the intervention on the rate of hospital readmission, a study comparing readmission rates within the intervention group alone before and after participating in the program would have suggested substantial reductions in readmissions. This is because super-utilizers are typically targeted for intervention during periods of high health care utilization, often when their illnesses are flaring, and many such patients will naturally return to lower rates of utilization. This phenomenon, known as regression to the mean, can lead observational studies to produce misleading estimates of program effects.

Physician-patient race concordance.

On average, black males in the United States live 4.5 fewer years relative to white males. More than half of the difference in life expectancy for black men is attributable to preventable chronic conditions such as hypertension, diabetes, HIV, and some forms of cancer, suggesting that some of the disparity is due to inferior care or underutilization of preventive health care services. One common proposal to combat these disparities and advance health equity is to increase minority representation in health professions. Presently, just 3.8 percent of physicians are black, compared to 12.6 percent of the United States population.

In a 2019 study at a clinic in Oakland, California, researchers found that when black men saw a black male doctor, they used substantially more preventive health services and especially more invasive procedures. In the first phase of the study, black men received a tablet with a randomly assigned photo of a black or non-black (white or Asian) health care provider and were shown a list of preventive services to select to receive with their provider. When just seeing a photo of their doctor, black men selected to receive preventive services at the same rate regardless of the race of their doctor. However, when patients met with the doctor and could revise their decisions, black men who were randomly assigned to see a black doctor were much more likely to select every preventive service, particularly invasive services (like a flu shot). The results suggest that better communication by the black physicians, rather than their race alone, seems to be what drove the results. The researchers are using another RCT to learn which aspects of communication are important for influencing health behaviors.

Their RCT findings on a driver of disparities in health have significant health and policy implications. The researchers estimate that having more black doctors could reduce the black-white gap in cardiovascular mortality by 19 percent.

Workplace wellness programs.

In 2018, more than 80 percent of large firms and half of small employers in the United States offered a wellness program to their employees. The US workplace wellness industry’s revenue has tripled in size since 2010 to \$8 billion. This growth has been partly bolstered by policies such as the Patient Protection and Affordable Care Act that encouraged firms to adopt wellness programs. Although the specific components vary widely, workplace wellness programs often include a biometric screening, health risk assessment, and promotion of wellness activities such as smoking cessation, and physical activity. These programs aim to foster healthy behaviors, reduce medical spending, increase productivity at work, and improve well-being.

RCTs published in 2019 of two recent workplace wellness programs found limited impact on employees' health habits—such as self-reported regular exercise and weight management—and no impact on health, health care spending and utilization, or employment outcomes like absenteeism or productivity. One RCT took place at an university that randomized at the individual employee level, whereas the other occurred at a large private-sector employer that randomized at the worksite level. Both programs share common features with most wellness programs in the United States today. These results run counter to prior observational studies, which found substantial positive associations between wellness program participation and employee health, by simply comparing employees who participated in such programs to those who did not participate. Based on the RCT findings, workplace wellness programs may have had limited impacts in part because the employees who stood to benefit the most from workplace wellness programs, such as those with poor health habits, were less likely to participate.

Their studies demonstrate the value of RCTs in identifying the returns of investment on large-scale policies and challenging conventional policy wisdom. Prior observational studies, which compared employees who participated in such programs to those who did not participate, found substantial positive associations between wellness program participation and employee health. However, these RCTs demonstrated that simply comparing participating employees to non-participants would have overstated the effect of workplace wellness programs on key outcomes. Their findings call into question whether the programs achieved what policymakers intended and identify opportunities to learn more about how to improve them, such as by better targeting employees to participate.

Clinical decision support to reduce inappropriate high-cost imaging.

In 2014, Medicare spent over \$4 billion on high-cost diagnostic imaging, such as magnetic resonance imaging (MRI) and computed tomography (CT) scans, even though research has suggested that up to 30 percent of these tests may be unnecessary. Medical professionals and payers are concerned with the health risks and health care costs from the inappropriate use of such high-cost scans. Policymakers are interested in reducing spending on health care that provides minimal value to patients. Reflecting concerns about inappropriate scanning, Medicare may no longer reimburse providers for high-cost scans unless they are ordered using a qualifying clinical decision support (CDS) system—an automated tool that provides guidance on the appropriateness of a scan.

In a 2019 RCT of CDS for high-cost imaging across physicians in a large, private, not-for-profit health care provider, researchers found that CDS moderately reduced the number of “inappropriate” high-cost scans targeted by the software but did not change the total number of low- or high-cost scans. These results suggested that requiring health care systems to adopt clinical decision support could modestly improve the appropriateness of high-cost imaging orders. Yet, contrary to findings in prior observational studies that found large reductions in targeted images, the results of this large-scale RCT suggest the vast majority of high-cost scans were not eliminated.

When implementing a CDS system, it is important to evaluate which clinical decision support features, such as the information provided at the time of ordering and complementary actions including supervisor reviews, can increase its effectiveness.

State health insurance Marketplaces.

State-level Medicaid expansion under the Patient Protection and Affordable Care Act (ACA) led to significant gains in insurance coverage and dramatically expanded the use of regulated Marketplaces to provide individuals with health insurance coverage. Yet millions of Americans who are eligible for free or heavily subsidized insurance, including Medicaid, remain uninsured. Prior research suggests there are a variety of barriers to take-up of Medicaid, including complexity of choosing and applying for benefits, lack of awareness of options, and stigma associated with participation.



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Results from three different RCTs—conducted in California, Colorado, and Oregon, respectively—suggest that adopting low-cost, behaviorally-informed mass outreach approaches could increase insurance coverage of vulnerable populations. One 2017 study in Oregon demonstrated that improved communication and low-cost “nudges,” such as behaviorally-informed postcards and automated telephone outreach, meaningfully increased Medicaid enrollment among likely eligible groups. This increase may be particularly durable among hard-to-reach, vulnerable populations, and these interventions may be just as effective as more resource-intensive, individualized outreach strategies. A 2019 study in California sent reminder letters from Covered California, the state’s health insurance Marketplace, which reduced informational and behavioral barriers to enrollment in health plans, such as forgetfulness or lack of awareness about plan attributes. Researchers found that the reminder letters modestly increased households’ insurance take-up and lowered the average market risk, suggesting that pairing subsidies with reminder letters may increase take-up substantially more than subsidies alone. Finally, a 2017 Colorado study evaluated the impact of mailing and e-mailing information about the potential to save if they switched insurance plans in the state Marketplace to households. While consumers who received the information were considerably more likely to shop for plans on the Marketplace website, they were not more likely to switch plans.

Increasing insurance enrollment, especially among populations historically left-behind, remains a challenge, but these studies show that low-cost nudges can be a part of broader efforts to increase access and equity of health care coverage.

CONCLUSIONS

RCTs have been too rare in US health care delivery, but they do not have to be. When feasible and ethical, RCTs have the power to provide credible insights into ways to improve health care delivery. Yet the RCTs in this publication studied only the tip of the iceberg of new potential models for health care delivery and policy. Many energetic people and organizations are at the forefront of creating innovative new health care delivery models to meet the needs of patients more effectively and efficiently. We owe it to these patients to rigorously evaluate these efforts. Governments, insurers, employers, health care providers, and more can identify opportunities to use RCTs and use them to improve US health care delivery and peoples’ lives.

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ABOUT J-PAL

The Abdul Latif Jameel Poverty Action Lab (J-PAL) is a global research center working to reduce poverty by ensuring that policy is informed by scientific evidence. Anchored by a network of more than 190 affiliated professors at universities around the world, J-PAL conducts randomized impact evaluations to answer critical questions in the fight against poverty.

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