Coupling Policymaking with Evaluation — The Case of the Opioid Crisis

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The gravity of the opioid epidemic in the United States barely needs introduction. The numbers speak for themselves: in 2015, more than 33,000 Americans died from an opioid overdose, according to the Centers for Disease Control and Prevention — similar to the 35,000 and 36,000 deaths attributable to motor vehicle accidents and firearms, respectively, in the same year. The dramatic rise in opioid prescribing in the United States since the 1990s is frequently blamed as a driver of this epidemic, and policymakers have focused substantial energy on curbing prescribing rates.

Two theories are central to policymaking regarding opioid prescribing: that reducing prescribing will also reduce the quantity of drugs available for abuse and that it will reduce the chance that opioid use disorder will develop in people using opioids for the first time. The evidence behind these theories is incomplete, however. The challenge for policymakers is how to design effective opioid-prescription policies to stem the flood of overdoses without having to wait several years to accumulate additional evidence. One possible solution is to couple policymaking with an evaluation plan that uses existing databases with nearly real-time health data, such as cloud-based health records and prescription drug monitoring databases.

To explore how policy and evaluation could be closely linked, we examined the effect of a recent policy aimed at reducing opioid prescribing in Massachusetts, which had the seventh highest rate of opioid-overdose deaths in the United States in 2015. On March 1, 2017, the state's Department of Public Health e-mailed confidential reports to all controlled-substance prescribers that included information on the number of opioid prescriptions they wrote and the total volume of opioids they had prescribed in the previous year, as well as the mean and median rates for other clinicians in the same specialty. Such peer comparisons have shown promise for influencing physician behavior in other settings. How they affect opioid prescribing, however, particularly when comparisons are done on a statewide level, is unknown. Such programs can easily backfire, if they inadvertently provide an incentive to increase opioid prescribing among physicians with below-average prescribing rates, or they may simply be ineffective.

Swift action in a rapidly evolving crisis requires rapid evaluation, ideally with a control group.

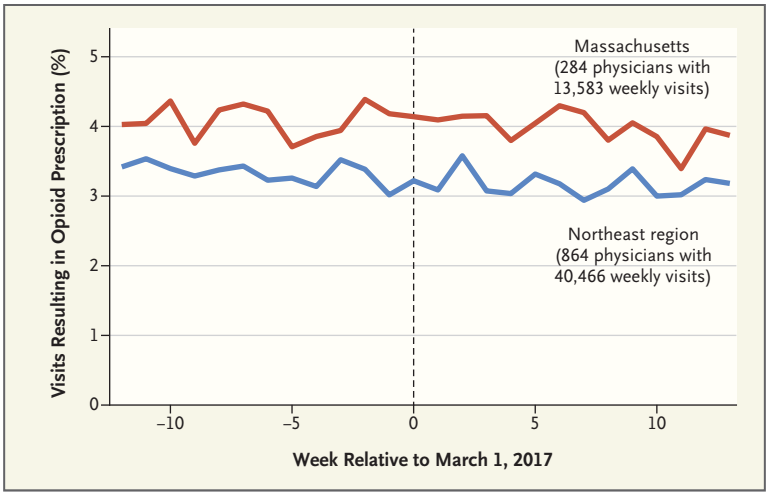
We evaluated the reports' possible effects on short-term prescribing patterns of primary care physicians in Massachusetts. Using electronic health record (EHR) data from athenahealth, an information technology company, we measured average weekly rates of opioid prescribing at office visits for all primary care physicians who used athenahealth in Massachusetts (284 physicians with 13,583 average weekly visits) and in the rest of the Northeast (864 physicians with 40,466 average weekly visits) for 12 weeks before and after March 1, 2017. We found no evidence that opioid-prescribing rates in Massachusetts fell as compared with rates in other states after the reports were released (see graph). We also observed no reductions in opioid prescribing among the highest-volume opioid prescribers, who would presumably have been alerted that their prescribing rates differed substantially from the norm.

There are several reasons why these reports may have been ineffective. First, the Department of Public Health had less than a year to plan, analyze, prepare, and disseminate the reports for every doctor. The staff thus had little time to reflect on the most appropriate approach for presenting data for peer comparison. The lack of effectiveness may also reflect the challenge of adapting techniques and ideas from behavioral economics to new contexts. For example, mean and median prescribing rates may not have

been the most appropriate comparators to send to clinicians. Effective peer-comparison interventions have used outliers, such as physicians in the 10th or 90th percentile, as benchmarks. Also, the state government may not be a particularly influential source of communication to physicians. Peer comparisons may be more meaningful when they come from medical boards or health systems, for instance.

We believe that the Massachusetts state legislature and public health department deserve praise for passing and quickly implementing a statewide policy based on modern behavioral economics principles. However, this example highlights a major challenge in addressing such a rapidly evolving crisis: swift action requires rapid evaluation, ideally with a control group. There is little time to waste on ineffective — or, worse, counterproductive — policies that use the finite resources of local governments and tax the limited ability of physicians to respond to new regulations.

Many other prescription-opioid–control policies have had mixed effects, made particularly apparent when control groups are included in analyses or a broad set of outcomes is evaluated (see table). For example, prescription drug monitoring programs (PDMPs) are statewide databases that clinicians can use to detect high-risk behavior such as "doctor shopping." PDMPs exist in 49 states and Washington, D.C. (the exception is Missouri, which recently signed an executive order to create one), but evidence on their effects has lagged many years behind implementation. Rigorous studies are showing that PDMPs are most effective when they have robust design features, such as weekly updates, or when legislation mandates their use.[1,2] When such features aren't included and use is optional, clinician adoption is disappointingly low and valuable data are neglected.



Rates of Opioid Prescribing at Primary Care Office Visits in Massachusetts and the Rest of the Northeast before and after Distribution of Provider Benchmark Letters.

Other Northeast states include Connecticut, Maine, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, and Vermont. Linear regression was used to estimate differential trends in prescribing rates after March 1 versus before March 1 (a difference-in-differences analysis) and revealed no differential change between the two groups, either in the average prescribing rate or in the slope of change ($P>0.31$ for both). Data are from athenahealth. This analysis was deemed not to be human-subjects research by the institutional review board at the Harvard T.H. Chan School of Public Health.

Another example of a policy that has had mixed results is the reformulation of extended-release oxycodone (OxyContin) to make crushing the pills much more difficult. This reformulation did reduce demand for OxyContin, but a substantial proportion of users apparently switched to heroin, with a concomitant increase in heroin-overdose deaths. Other well-intentioned policies that make intuitive sense — such as setting limits on the quantity of opioids that patients can receive at one time, making doctor shopping illegal, and sending letters to physicians who have the highest opioid-prescribing rates — have had no meaningful effect.

National trends show that we do not yet understand how to stem the tide of opioid overdoses by changing physicians' prescribing practices. Although the volume of opioid prescriptions has fallen by 12% since its peak in 2012, the rate of overdose deaths continues to increase faster than ever, driven by an influx of potent synthetic opioids such as fentanyl. How and when decreased prescribing will translate into fewer deaths is unclear. In the meantime, there is a real danger that aggressive opioid-prescribing policies could drive more people to use more dangerous injection opioids or force patients to live with inadequately treated pain. We simply do not know which policies will strike the right balance between promoting safe opi-

Evidence for Effects of Selected Opioid-Control Interventions.

Policy or Intervention	Description	Evidence for Effect
Prescription drug monitoring programs (PDMPs)	Statewide databases of all prescriptions filled for controlled substances; allow clinicians to check for high-risk behaviors such as doctor shopping	Low rates of use by clinicians; reduced rates of overdoses, high-dose opioid use, and doctor shopping, but mostly in states with robust PDMP design and provider use mandates[1,2]
Prescription limits	Policies or dispensing regulations that limit the time during which an opioid prescription can be filled or the quantity of opioids supplied	No significant effect on high-dose opioid use or doctor shopping among disabled Medicare beneficiaries[3]
Restrictions on doctor shopping	Policies that make it illegal for patients to withhold information from providers about prior opioid prescriptions	No significant effect on high-dose opioid use or doctor shopping among disabled Medicare beneficiaries[3]
Abuse-deterrent formulations	Reformulation of extended-release oxycodone to make it more difficult to crush pills into an injectable or inhalable form	Reduced prescribing of reformulated oxycodone, but with a concomitant increase in heroin use[4]
Notification letters for high-volume prescribers	"Informative letters" sent to physicians with the highest levels of opioid prescribing	In Medicare Part D, no significant effect on controlled-substance–prescribing in a randomized, controlled trial[5]

oid use and avoiding unintended consequences.

State and federal governments could take several practical steps to enable rapid evaluation of new programs with adequate rigor. First, policymakers could collaborate with local public health experts to understand how such evaluations could fit into the policymaking process. Evaluations do not have to be multiyear, multimillion-dollar projects to provide actionable results if the right relationships can be facilitated between researchers and data providers. Second, governments could cultivate resources to enable rapid data gathering using existing systems. PDMPs contain detailed information on opioid prescriptions. Several EHR vendors have cloud-based systems with up-to-the-minute data on physician practices. Partnerships among data providers such as PDMPs, state health departments, and EHR vendors could permit nearly real-time public health surveillance.

There is also a need to link existing data resources related to opioid prescribing with data on public health outcomes such as overdose deaths, opioid-related hospitalizations, and use of naloxone by emergency services. Massachusetts and Maryland have been leaders in this type of data linkage; for example, both states combined information from correctional services and public health to learn that recently incarcerated people are at increased risk for opioid overdose after release. Linking data on other outcomes with prescribing and health care data is critical for examining the potential unintended consequences of opioid-control policies.

The opioid crisis requires the swift creation of decisive policies that promote safe use of opioids and prevent overdoses. In addition to regulating opioid prescribing, there are many other policy challenges, such as controlling the illicit market for powerful synthetic opioids like fentanyl and improving access to addiction treatment. In all these cases, delaying the evaluation of new programs could cost thousands of lives if ineffective policies are aggressively pursued. Productive collaborations among state governments, data providers, researchers, and public health officials to couple policy with evaluation could help to identify lifesaving policies worth spreading.

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Using Medicare Prices — Toward Equity and Affordability in the ACA Marketplace

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As the U.S. Congress debates the future of the Affordable Care Act (ACA), the public has increasingly called for bipartisan solutions on health care reform. An immediate challenge is stabilizing the ACA marketplace, where 10.3 million people enroll in coverage. Given that certain areas of the country have few insurers participating in the marketplace — because of high enrollee costs, uncertainty over cost-sharing–reduction payments from the federal government, and the expiration of protections for insurers such as reinsurance and risk corridors (which limit how much they can gain or lose through risk sharing) — policies that encourage insurers to enter and stay in the marketplace are needed.

Largely missing from the current debate are proposals to improve the affordability of care provided to people with marketplace plans by directly reducing costs for participating insurers and, in turn, for the federal government and enrollees. One such idea is to close or narrow the disparity in prices paid (largely by the government) for the same medical services billed to different federal programs.

Medical care for traditional Medicare beneficiaries is currently reimbursed at fee-for-service Medicare prices set by the Centers for Medicare and Medicaid Services (CMS). Yet for the same services provided to low- or moderate-income marketplace enrollees who receive federal subsidies — 84% of enrollees, or 8.7 million people — government contributions are based on commercial prices negotiated between insurers and providers.

Disparities between prices for services provided to traditional Medicare beneficiaries and services provided to marketplace enrollees with subsidized coverage can be substantial. Studies have shown that commercial prices for hospital care range from roughly 130% to more than 200% of traditional Medicare prices,[1,2] and commercial prices for common physician services range from about 107% to more than 200% of traditional Medicare prices.[3]

More recent data from a large national sample of traditional Medicare claims and commercial claims spanning multiple insurers show that the commercial "markup" over Medicare prices is not uniform throughout the country (see table). For both hospital care and physician services, more populated metropolitan areas tend to have lower markups than less populated areas. For example, commercial prices in 2015 for a hospitalization for total hip replacement averaged 116% of the Medicare price in Phoenix, Arizona, and 237% of the Medicare price in Owensboro, Kentucky. Similarly, commercial prices for a midlevel office visit averaged 105% of the Medicare price in Kansas City, Missouri, and 135% of the Medicare price in Morgantown, West Virginia.

Higher prices can increase premiums charged by insurers, increase patient cost sharing, or hasten the exit of insurers from the marketplace by raising costs for insurers. Price disparities also mean that the government pays disproportionately more for the care of marketplace enrollees with subsidized coverage than for the same care of traditional Medicare beneficiaries.

Legislation requiring that providers be paid traditional Medicare prices for out-of-network services delivered to marketplace enrollees would close the gap between marketplace and Medicare prices. Such a policy would have both direct and indirect effects. It would directly reduce the costs of out-of-network care paid by insurers and, in turn, by CMS. As a result, it would save taxpayers money and relieve pressure on insurers to exit the market or raise premiums. The precise