

Range of Potential Spending on Solanezumab during 4-Year Period from 2013 through 2016, with Varying Annual Drug Costs and Population Uptake.

year.⁵ For another monoclonal antibody, adalimumab (Humira), widely used to treat rheumatoid arthritis, inflammatory bowel disease, and psoriasis, the annual spending per Medicare patient, according to the 2015 Medicare Drug Spending Dashboard from the Centers for Medicare and Medicaid Services, was \$29,278. With almost 57,000 Medicare patients receiving the medication, the total cost that year was \$1.7 billion.

Even conservative estimates suggest that the total costs of solanezumab would have been staggering. Of the more than 5 million people in the United

States with Alzheimer's disease, about half can be categorized as having mild disease, the subgroup initially thought to benefit from solanezumab. If the price had been set at \$10,000 per patient per year and just one tenth of those patients had been treated, the cost would have been almost \$10 billion over the past 4 years. Had the price been set higher, or had promotion yielded faster uptake and more prescriptions, the cost might well have been many times that amount. The graph shows the range of potential spending on solanezumab, based on varying price and uptake.

As the FDA's role and drug-approval standards undergo new scrutiny, it's instructive to assess instances in which current regulatory standards prevented ineffective medications from reaching patients and averted unnecessary spending (as well as unanticipated side effects). The public and private funds not spent on a useless drug remained available for other interventions that have been proven to work. Bringing novel treatments to people who need them is a critical mission, and the FDA has created various expedited approval pathways for drugs that treat diseases in which there is substantial unmet need. But ad-

vancing the development of the next generation of therapeutics should not be confused with approving drugs without first acquiring appropriate evidence that they work at all.

Disclosure forms provided by the authors are available at NEJM.org.

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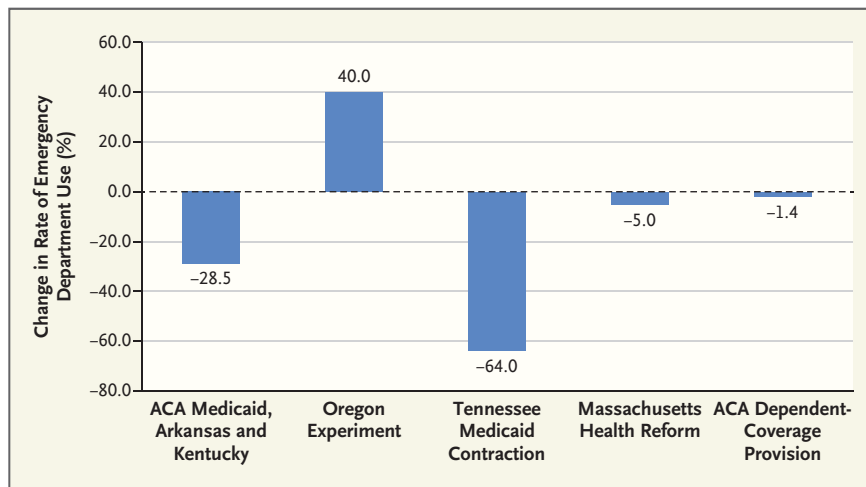
Health Insurance and Emergency Department Use — A Complex Relationship

Benjamin D. Sommers, M.D., Ph.D., and Kosali Simon, Ph.D.

Throughout the nearly decade-long debate over the Affordable Care Act (ACA), policymakers

have questioned how having health insurance affects health care utilization and, in particular,

what expanded insurance coverage means for use of the emergency department (ED). ED use



Estimates of the Effect of Health Insurance Coverage on Emergency Department Visits.

The three estimates on the left are from studies of individual-level data, whereas the two on the right are based on counts of aggregated emergency department visits.

is of particular interest because of evidence of rising visit rates per capita, the perceived expense of emergency care, and the status of ED use as a potential proxy for inaccessible or low-quality outpatient care. Economic theory suggests that expanding access to health insurance could either increase or reduce ED use. Coverage reduces the out-of-pocket cost of going to the ED, which could lead to more frequent visits. But if the ED has been used as a substitute for outpatient care by the uninsured, insurance coverage might shift care to office settings and reduce ED visits. Politicians have used related arguments to oppose or defend the ACA in a debate that has only become more pressing with the future of the law in doubt after the 2016 elections. So what does the evidence show?

Some of the most widely cited findings regarding the effect of expanding insurance on ED use come from the Oregon Health Insurance Experiment, a randomized trial of Medicaid coverage in

Oregon from 2008 to 2010. In a recent update to that study, investigators found that Medicaid coverage was linked to an increase of approximately 40% in ED use, which persisted over 2 years of follow-up.¹ ED visit rates increased even as newly insured adults increased their use of outpatient services, suggesting that ED visits complement rather than substitute for office visits. Previous evidence from the same study showed that both urgent and nonurgent ED visits increased among people who acquired Medicaid coverage. The authors concluded that coverage expansions are likely to increase ED use significantly, in both the short and long term.

But the relationship between insurance and ED use appears to be more complex than any single study, even a high-quality one, can fully describe. Evidence from other settings — including the ACA's expansion of dependent coverage, health care reform in Massachusetts, and state Medicaid expansions — indicates that under some circumstances, health

insurance can reduce ED utilization (see graph).

The ACA expanded coverage for young adults by enabling them to remain on their parents' insurance plan until 26 years of age. Numerous studies have assessed the impact of this provision by comparing young adults 19 to 25 years of age with their slightly older peers, and several studies have documented significant reductions in ED use after the provision took effect in 2010. For example, using a national ED database, we found a 1.4% greater reduction in the aggregate number of ED visits by young adults in this age group (not all of whom obtained coverage through the policy) than among slightly older adults. This change was driven primarily by reductions in weekday visits and in visits for nonurgent conditions — a result that makes sense, because office visits are less likely to be a viable alternative for patients with urgent conditions or those needing care on weekends.²

Why might findings among young adults differ from those in the Oregon study? For one thing, the dependent-coverage provision affected a young and relatively healthy population and expanded private insurance, which means that provider payments were high and ED-related cost sharing for patients was often substantial. In contrast, Medicaid typically imposes little or no cost sharing, though several states have recently experimented with charging higher copayments for nonurgent ED visits (and found mixed evidence on their effectiveness).

Studies of Massachusetts's 2006 health care reform suggest that insurance expansion may reduce ED use even when the population

isn't young and doesn't obtain only private coverage. The Massachusetts experience is important, since the ACA was modeled largely on the state's design. Using county-level variation in the baseline uninsured rate, one study identified a 5 to 8% reduction in ED use in Massachusetts in the 2 years after expansion. Again, the reduction was concentrated among patients seen for non-urgent conditions, a finding consistent with coverage shifting care to other settings.³ Unlike the ACA's dependent-coverage provision, the Massachusetts policy included substantial increases in publicly subsidized insurance (through Medicaid and the state's Commonwealth Care program) and large gains in coverage for older adults.

Published research also offers a nuanced picture when it comes to reforms specifically targeting Medicaid. Some quasi-experimental studies have shown an increase in ED use similar to that seen in Oregon after coverage expansion. But two recent studies indicate that Medicaid coverage may indeed reduce ED visits. The first examined a coverage contraction, when Tennessee removed nearly 170,000 adults from Medicaid in 2005 and found that ED visit rates increased.⁴ More recently, a study of Medicaid expansion under the ACA found that reliance on the ED as a usual source of care decreased, and the overall likelihood of any ED visits decreased by roughly 6 percentage points more (reflecting a relative reduction of nearly 29%) among low-income adults in Kentucky and Arkansas than among their counterparts in Texas, which didn't expand Medicaid. Mean-

while, the number of outpatient visits and use of primary care services increased. The findings were similar in Kentucky, which expanded traditional Medicaid, and Arkansas, which used Medicaid funds to enroll low-income adults in marketplace coverage.⁵

So why might different forms of coverage expansion produce different effects on ED use? One potential explanation is methodologic. Only the Oregon data come from a randomized trial, and the remaining quasi-experimental studies may be affected by unmeasured bias. However, given the range of data sources, policy interventions, and findings from those studies, we think it unlikely that all the results are attributable to confounding.

Instead, our interpretation of these studies is that the precise effects of coverage on ED use depend on numerous factors, such as characteristics of the population affected by expansion (including age, income, and health status), characteristics of the insurance plans covering those patients (including degree of cost sharing, generosity of provider payments, and network adequacy), the types of outpatient providers seen by patients and their ED-referral patterns, and characteristics of the geographic area where expansion occurs (including the availability of charity care and transportation options). As the saying goes, "If you know one state's Medicaid program, you know one state's Medicaid program." Similarly, Oregon's wait-list lottery — although invaluable for research purposes — differs from the numerous other coverage expansions that have occurred during the past decade.

Thus, the relationship between health insurance and emergency care isn't straightforward. In some cases, greater access to outpatient care as a result of expanded coverage may result in reduced ED use. In other cases, cost reductions enabled by health insurance may swamp that effect and simply induce more ED visits. One caveat is clear: even in the studies showing a reduction in ED use, no evidence suggests that overall costs of care decline when coverage is expanded. At best, we may see a more efficient allocation of spending with less ED use and more outpatient care — but coverage expansion is still a costly enterprise. After all, ED costs account for only 2 to 10% of national health care spending, according to varying estimates drawn from federal survey and health expenditure data. If more effective approaches could be identified that reduce ED as well as inpatient spending without harming patient outcomes, that would be the holy grail — improved access and quality at lower cost. But to date, there is little evidence that coverage expansion will achieve that goal. Rather, the benefits of coverage expansion — better access, financial protection, and health — must ultimately be weighed against its increased cost.

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