cost problems in health care and the amount of money invested in mitigating these problems, the public, providers, and policymakers need to have confidence that money used to improve care is being well spent. It's true that improvement science requires mixed methods and is difficult, but all good science is difficult. Failing to attend closely to issues of design, methods, and metrics leaves us with little confidence in an intervention. For the PPP, which required thousands of hours of clinicians' time and large sums of money, that lack of confidence is particularly unfortunate. More important, the failure to generate valid, reliable information hampers our ability to improve future interventions, because we are no closer to understanding how to improve care than we were before the PPP. And that is the biggest cost of all.

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The Impact and Evolution of Medicare Part D

Julie M. Donohue, Ph.D.

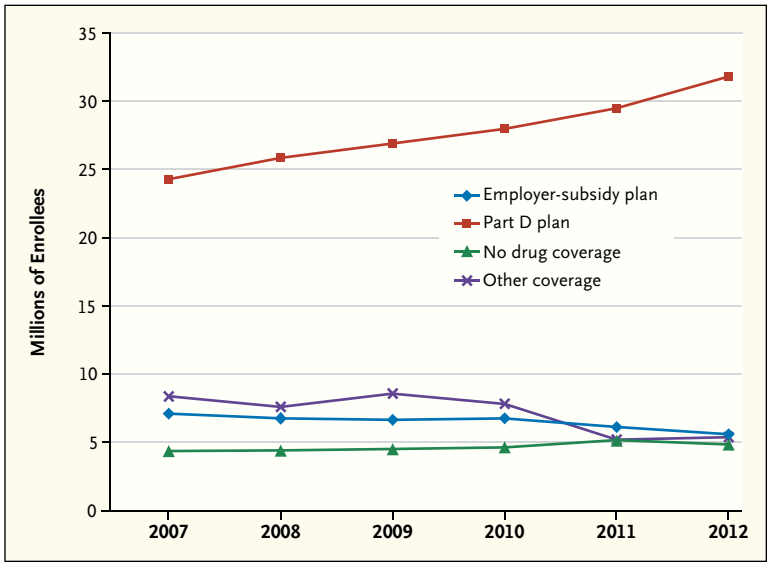
It has been 10 years since the Medicare Prescription Drug, Improvement, and Modernization Act was signed by President George W. Bush, and 8 years since its centerpiece — a new Medicare drug benefit (Part D) — was implemented. Criticisms during Part D's implementation — citing poor communication with beneficiaries, computer glitches, complicated plan choices, and cost concerns — bear a striking resemblance to those currently voiced about the Affordable Care Act (ACA). Yet Medicare Part D successfully expanded drug benefits to millions of beneficiaries and improved access to medications, at lower-than-expected cost.

Part D has its challenges, however, and policymakers continue to modify various aspects of the program. The concerns raised about Part D relate to the key choices policymakers face when establishing any new insurance program — regarding enrollment, competition, coverage, and pricing.

The first question was whether Medicare beneficiaries would enroll. Unlike the ACA, Part D was established as a voluntary benefit. That decision raised concerns that too few people would participate and that enrollees would be sicker than average, which would lead to higher premiums and even lower enrollment in subsequent years. The legislation therefore included a late-enrollment penalty, although surveys suggest that few beneficiaries were aware of it.

In fact, Part D participation has been high. Kaiser Family Foundation data indicate that by June 2006 (8 months after enrollment began), Part D covered 22.5 million beneficiaries (53% of Medicare beneficiaries). Enrollment grew to 35.7 million beneficiaries (69%) in 2013. Another 20% of beneficiaries have coverage through other sources (e.g., retiree health plans). Thus, 10% still lack drug coverage — somewhat more than originally forecast (see graph). ACA participation may be higher because of the mandate that individuals obtain coverage.

The second question was whether beneficiaries would have enough plan choice and would make good choices. Part D established a new insurance product, inviting plans to compete for enrollees in 34 regions. Competition was intended to lower premiums and allow beneficiaries to find plans that would best meet their needs. Concerns centered on whether enough plans would



Medicare Beneficiary Enrollment in Drug Coverage by Source.

Data are from Medicare enrollment reports, the 2013 annual report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplemental Medical Insurance Trust Funds (Centers for Medicare and Medicaid Services), and the MedPAC Data Books (Medicare Payment Advisory Commission).

participate and whether plans would have a financial incentive to stint on the coverage of drugs used by vulnerable, high-cost beneficiaries to discourage them from enrolling. The legislation addressed these concerns through risk adjustment of premiums and risk sharing with plans.

Plan participation has been high, with 1429 plans participating in 2006, according to the Kaiser Family Foundation. Although the number of plan offerings has decreased somewhat, 1169 plans (28 to 39 per state) were available in 2014. Yet a multitude of choices does not guarantee that beneficiaries will choose wisely. Unfortunately, a recent study indicated that only 5% of beneficiaries choose the plan that gives them the lowest out-of-pocket costs.[1] It will be important to monitor whether consumers choose plans on the ACA's health insurance exchanges that minimize their out-of-pocket burden.

Observers also asked whether the benefit would provide adequate coverage. The generosity of drug benefits is determined by the level of beneficiary cost sharing and the number of drugs covered on formularies. The legislation set forth a standard benefit featuring a small deductible, 25% cost sharing beyond the deductible, and a coverage gap (doughnut hole) in which beneficiaries face 100% of their drug costs. Plans were given flexibility, however, regarding which drugs to cover and how to structure cost sharing.

During implementation, the Centers for Medicare and Medicaid Services (CMS) faced a classic issue in insurance-market regulation: the trade-off between efficiency and selection. Allowing plans to impose limits on some drugs would give them bargaining power to negotiate lower prices with manufacturers. However, the same tools could be used to discourage enrollment by the sickest beneficiaries (selection). CMS addressed this tension, in part, by requiring plans to cover all drugs in six protected categories (antineoplastics, anticonvulsants, antiretrovirals, antipsychotics, antidepressants, and immunosuppressants) used by vulnerable beneficiaries.

Data on Part D's effects on medication use and out-of-pocket spending suggest that the drug benefit has helped — but may require modification. It has significantly reduced Medicare beneficiaries' risk of medication nonadherence due to costs.[2] Though few studies have directly measured Part D's effects on health outcomes, there is evidence that expanding drug benefits reduced hospitalizations and non–drug-related medical spending among beneficiaries who had had poor coverage before 2006.[3] Concerns remain, however, about the adequacy of coverage, given that cost sharing tends to be higher in Part D than in employer-based health plans and that exposure to the doughnut hole is associated with reduced adherence.

Concern about the program's costs arose in part because the legislation prohibited Medicare from negotiating drug prices with manufacturers. Medicare would rely instead on the negotiating power of private plans.

According to the Medicare Payment Advisory Commission (MedPAC), Part D cost $62.5 billion, or 10% of Medicare spending, in 2012. The costs have been approximately 30% lower than projected by the Congressional Budget Office, a difference that analysts attribute more to the lower-than-expected enrollment and a general slowdown in U.S. drug spending than to the program's specific features. But evidence also suggests that costs could be even lower: an analysis showed that drug rebates negotiated by Part D plans are much

smaller than those achieved in Medicaid,[4] though they may be similar to those negotiated by commercial plans. Even if Medicare doesn't change the way it pays for drugs, spending could probably be reduced through greater use of generic medications.[5]

Experience with Part D highlights important political and practical considerations for CMS. First, in our complex health system, downstream modification to legislation and regulation is essential but also politically challenging. An ACA provision to substantially increase the generosity of Part D benefits — phasing out the doughnut hole by 2020 — encountered little opposition. The reaction to CMS proposals issued in January 2014 for improving Part D's efficiency tells a different story. CMS signaled a willingness to become a more active purchaser by setting limits on plan and medication choice and encouraging greater transparency. One proposal included restricting Part D sponsors to offering at most two plans per region, in an effort to create "more meaningful plan choices." Another was to eliminate the protected status for three of the six protected drug categories to give plans more leverage in price negotiations. After receiving many criticisms of these and other proposals from interest groups representing pharmaceutical firms, health care providers, and patients, CMS decided not to implement the changes. This experience illustrates the way in which new government programs create constituencies that may effectively resist policy modifications, especially when they involve financial losses to consumers or government contractors. Because the ACA's impact on the health sector is even more far-reaching than Part D's, one can expect even greater resistance to changes to essential benefits or the generosity of coverage.

An audio interview with Dr. Donohue is available at NEJM.org

Second, CMS should consider Part D's evolution in the context of broader Medicare reforms. Many ACA provisions position Medicare for major payment and delivery-system changes that are designed to improve quality and reduce spending growth. These reforms include altering provider reimbursement to encourage efficiency and improving care coordination among providers. In some ways, the Part D program, which is run by stand-alone plans that don't carry risk for total medical spending and have no financial relationships with providers, is out of sync with such changes. Notably, many of the performance measures for Medicare accountable care organizations (ACOs) are related to medication use. The performance of ACOs on these measures may be substantially affected by actions of Part D plans with which ACOs have no fiduciary relationship. Thus, the long-term success of payment and delivery-system reforms will depend in part on integrating Part D policy with broader reforms — either by requiring data sharing for monitoring quality or by aligning financial incentives between provider organizations and Part D plans.

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HISTORY OF MEDICINE

The Challenges of Challenge Experiments

Susan E. Lederer, Ph.D.

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Challenge experiments that involve infecting healthy human subjects as a means to test the efficacy of a new vaccine can be invaluable. Great strides in understanding how to treat and prevent such infectious diseases as smallpox, yellow fever, malaria, and influenza have resulted from research involving human beings — both volunteers and those who were "volunteered" to