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BRIEF REPORT

Increased HIV Transmissions With Reduced Insurance Coverage for HIV Preexposure Prophylaxis: Potential Consequences of *Braidwood Management v. Becerra*

A. David Paltiel,[1] Ali R. Ahmed,[2] Elena Y. Jin,[2] Meredithe McNamara,[3] Kenneth A. Freedberg,[2] Anne M. Neilan,[2,a] and Gregg S. Gonsalves[1,a]

[1]Public Health Modeling Unit, Yale School of Public Health, New Haven, Connecticut, USA, [2]Medical Practice Evaluation Center, Massachusetts General Hospital and Harvard Medical School, Boston, Massachusetts, USA, and [3]Department of Pediatrics, Yale School of Medicine, New Haven, Connecticut, USA

A US federal court recently ruled against requiring health insurers to cover human immunodeficiency virus (HIV) preexposure prophylaxis (PrEP) under the Affordable Care Act. For every 10% decrease in PrEP coverage resulting from this ruling among US men who have sex with men, we estimate an additional 1140 HIV infections in the following year in that population.

Keywords. Affordable Care Act; health policy; HIV; HIV prevention; preexposure prophylaxis.

Prevention of human immunodeficiency virus (HIV) with preexposure prophylaxis (PrEP) is a proven [1], cost-effective [2], and guideline-recommended [3] cornerstone of the United States (US) federal plan to end the HIV epidemic [4]. Since 2019, the US Preventive Services Task Force (USPSTF) has assigned a Grade A rating to HIV PrEP for persons at high risk of infection [5]. Under the 2010 Patient Protection and Affordable Care Act (ACA), this rating requires employers and insurers to provide full HIV PrEP coverage without cost sharing to all persons for whom it is indicated by the USPSTF and applies to almost all private plans—fully insured and self-insured plans in the individual, small group, and large group markets [6]. But in September 2022, a US federal court ruled in *Braidwood Management v. Becerra* [7] that requiring private insurers to cover HIV PrEP violates their rights under the Religious Freedom Restoration Act. In particular, the judge ruled that requiring the plaintiffs to purchase insurance that covers PrEP substantially burdened their religious exercise because they believe this requirement facilitated sex between unmarried and same-sex partners and that the Bible condemns such behavior [8]. As contributors to a report challenging the court's ruling [9], we sought to estimate the expected additional HIV transmissions if access to private health insurance coverage for PrEP in the US were curtailed.

METHODS

Analytic Overview

Using inputs obtained from the US Centers for Disease Control and Prevention (CDC) [10, 11]—and informed by both the HIV Prevention Trials Network (HPTN) 083 clinical trial [12] and our own previous work [13]—we compared new HIV transmissions under alternative PrEP coverage assumptions. Specifically, we estimated HIV incidence over a single year in a population of PrEP-indicated men who have sex with men (MSM), some fraction of whom receive PrEP for HIV prevention. Recognizing that individuals might secure alternative means of paying for PrEP, we varied coverage levels from an initial base case value with ACA-mandated private insurance to some lower—but non-zero—level, if ACA requirements were removed.

Because our aim was to obtain a conservative estimate of the adverse effects of decreasing access to HIV prevention services, we deliberately "tipped the scales" to understate the potential consequences of the *Braidwood* ruling. We only considered primary HIV transmission effects in the year after the ruling took effect, ignoring both infections occurring beyond 1 year and all secondary transmissions. We focused exclusively on MSM, disregarding HIV transmissions in other populations likely to be affected by the federal ruling. We chose a baseline PrEP efficacy estimate on the low end of the published range. Finally, we did not address the racial, ethnic, and socioeconomic disparities that magnify the adverse consequences of restricted access to prevention services for subpopulations at elevated risk for HIV infection.

Estimation Procedure

To estimate HIV transmission in a population of MSM with indications for PrEP (sexual activity and either a serodiscordant sex partner, inconsistent condom use, or recent sexually transmitted infection) [5], we let:

N = number of PrEP-indicated MSM;

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[a]A. M. N. and G. S. G. contributed equally to this work as co–senior authors.

Correspondence: A. David Paltiel, PhD, Yale School of Public Health, 60 College St, New Haven, CT 06510 (david.paltiel@yale.edu).

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i = untreated HIV incidence among PrEP-indicated MSM (an annual, per-person probability);

e = PrEP effectiveness (% reduction in incidence); and

c = coverage (ie, % of PrEP-indicated MSM receiving PrEP).

In the untreated fraction of the population ($1 - c$), the annual HIV transmissions are given by ($N \cdot i$). In the treated fraction (c), annual transmissions are $N \cdot i \cdot (1 - e)$. The weighted sum of these 2 terms simplifies to $N \cdot i \cdot (1 - ec)$, denoting total expected HIV transmissions in this population. Letting c_0 denote the current PrEP coverage level among indicated MSM and c_f be the coverage level should the restrictions on access via *Braidwood* take effect, we arrive at our primary outcome measure, the additional HIV transmissions in MSM arising from the *Braidwood* ruling: $N \cdot i \cdot e \cdot (c_0 - c_f)$. An important feature of this straightforward measure is the before-versus-after difference term, $(c_0 - c_f)$, which suggests that it is the "delta"—and not the absolute values of either c_0 or c_f—that matters most: Every 1% decrease in coverage translates into $N \cdot i \cdot e \cdot (0.01)$ new HIV infections in the following year.

Input Data Values

Table 1 reports inputs necessary for the calculations described above. In 2020, CDC reported [10] both the number of PrEP-indicated men (989 200) and the number prescribed PrEP (276 810), suggesting baseline coverage level (c_0) of 28%. We used these values as our base case estimates, recognizing the uncertainty surrounding MSM-specific measures [14–16]. Population sizes, the untreated annual incidence of HIV infection in PrEP-indicated MSM (i, 1.54%), and the reduction in that incidence for persons receiving PrEP (e, 75%) were informed by HPTN Study 083 [12] and our previous work [13]. We linked these inputs to 2020 CDC reports [11] of HIV incidence to allocate the 21 867 annual HIV infections in MSM to those occurring in MSM receiving PrEP (1066 [5%]), those occurring in PrEP-indicated MSM not receiving PrEP (10 971 [50%])—suggesting 12 037 infections among MSM with indications for PrEP—and those in MSM without indications for PrEP (9830 [45%]).

Table 1. Input Parameters for Estimating Preexposure Prophylaxis Coverage and Impact Among Men Who Have Sex With Men in the United States

Input Parameter	Base Case Value	Source
Number of MSM with indication for PrEP	989 200	[10]
Number of MSM with indication for PrEP prescribed PrEP	276 810	[10]
Total annual HIV infections among all MSM	21 867	[11]
Untreated incidence in MSM with indication for PrEP	0.0154	[12, 13]
PrEP efficacy as a % reduction in the untreated transmission	75%	[12, 13]

Abbreviations: HIV, human immunodeficiency virus; MSM, men who have sex with men; PrEP, preexposure prophylaxis.

Scenarios and Sensitivity Analysis

We used deterministic sensitivity analysis to understand the robustness of our findings to uncertainty in final coverage level c_f (base value 10%), PrEP effectiveness, and target population size. We also considered 2 extreme (but informative) benchmarking scenarios: first, using coverage level $c = 0\%$ (ie, PrEP is unavailable to anyone [NoPrEP]); and second, using $c = 100\%$ (all MSM with PrEP indications receive PrEP for HIV prevention [AllPrEP]).

RESULTS

Under current ACA provisions and 28% PrEP coverage of indicated MSM, we obtain the CDC estimate that 21 867 new HIV infections will occur among MSM in the US annually (Table 2). If suspension of ACA provisions lowers PrEP coverage to 10%, we predict 2057 additional HIV infections in MSM. These values lie inside the range defined by our benchmarking estimates that 25 064 MSM (15 234 of them PrEP-indicated) would be infected with HIV in the absence of any PrEP-related prevention (NoPrEP) whereas at the other extreme, 100% PrEP coverage for all indicated MSM (AllPrEP) would reduce new HIV infections among MSM to 13 639 (3808 among PrEP-indicated MSM).

For every 1% decrease in the number of indicated MSM receiving PrEP treatment, we predict 114 new HIV infections in the following year. If PrEP is more effective among MSM than we have assumed (90% rather than 75%), every 1% decrease in

Table 2. Impact on HIV Cases in the United States Over 1 Year With Reduced Preexposure Prophylaxis Coverage in the United States

Scenario	New HIV Infections	
	Among PrEP-Indicated MSM	Among All MSM
1. Benchmark 1: No PrEP for any MSM (NoPrEP)	15 234	25 064
2. Benchmark 2: PrEP for all indicated MSM (AllPrEP)	3808	13 639
3. PrEP under current ACA provisions	12 037	21 867
4. PrEP if *Braidwood*[a] is upheld	14 091	23 922
Incremental infections attributable to the *Braidwood* ruling[a] (4–3)	2057	2057

Values are subject to rounding error.

Abbreviations: ACA, Patient Protection and Affordable Care Act; HIV, human immunodeficiency virus; MSM, men who have sex with men; PrEP, preexposure prophylaxis.

[a] *Braidwood Management, Inc. v. Becerra* [7].

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the number of indicated MSM receiving PrEP treatment would result in even more—137 versus 114—predicted new HIV infections in the following year. Notably, any change in the assumption of 989 200 PrEP-indicated MSM will produce a proportional change in our estimate of new HIV transmissions attributable to the *Braidwood* ruling.

DISCUSSION

This analysis suggests that striking down provisions requiring insurers to cover PrEP under the ACA will have substantial and important adverse consequences: For every 1% decline in PrEP coverage among US MSM, we expect an additional 114 HIV infections the following year. We estimate that, at a minimum, the *Braidwood* ruling will result in more than 2000 entirely preventable primary HIV infections among MSM—and many more infections in other populations at high risk of HIV transmission—in 1 year alone. We also find that current PrEP interventions avert approximately 3200 (15 234 – 12 037 in Table 2) HIV transmissions each year among MSM in the US. More than 11 400 (15 234 – 3808) infections might be prevented in this population with improved PrEP uptake.

We remind readers that we arrive at this conclusion using assumptions that were deliberately chosen to portray the *Braidwood* ruling in a relatively benign light. For example, we restricted attention to the short term, 1 year, taking account of neither the additional primary HIV transmissions that will continue to accumulate beyond the first year nor the secondary transmissions that will result from these primary cases. Moreover, because of the nature of the case, and the plaintiff's focus on PrEP as promoting facilitated sex between unmarried and same-sex partners, we restricted attention to MSM, ignoring the many other populations at high risk for HIV infection (eg, people who inject drugs, transgender women) for whom current guidelines recommend PrEP. We also likely underestimate the number of individuals using private health insurance in the base case [17, 18]. Thus, our findings represent a lower bound on the potential impact of this decision. Similarly, we employed a conservative estimate of PrEP efficacy, one that applies more to tenofovir-based, oral regimens than to newer, long-acting cabotegravir for PrEP, which has been shown to be even more effective than oral PrEP in MSM [12] and which may soon be included in the USPSTF PrEP recommendations. Finally, we ignored the well-documented disparities in PrEP access and uptake in the US [19]. The adverse consequences of the *Braidwood* ruling would be borne disproportionately by racial and ethnic sociodemographic groups at particularly high risk for HIV infection. Even in our "best-case" scenario, the predominant burden of new restrictions on access to PrEP will likely fall on Black and Latino gay and bisexual men, as well as transgender women, who already face significant barriers to HIV prevention and care. We also note that while there are federal programs that support access to antiretroviral therapy for people with HIV (eg, AIDS Drug Assistance Programs), as of now, federal subsidies for PrEP for HIV-negative individuals are restricted to those without health insurance coverage for prescription drugs and may require copays for clinic visits and laboratory tests [20].

Our findings are robust in the face of what might appear to be some critical uncertainties. A case in point is parameter c_f, the fraction of PrEP-indicated MSM who maintain coverage of PrEP if the federal ruling is upheld. This value is unknowable. There is reason to believe that it will be less than the current value of 28%; there is equally good reason to speculate that it will be greater than 0%. While we believe that our baseline value (10%) represents a plausible assumption, we urge readers not to latch onto that value but to see it merely as a plausible point of departure. The driver in this analysis is the before-versus-after difference, $(c_0 - c_f)$: Every 1% decrease in coverage translates into 114 new HIV infections in the following year, independent of the assumed value of c_f. Similarly, the incremental infections attributable to *Braidwood* (final row of Table 2) is the same, whether one treats the population of interest as "all PrEP-indicated MSM" or "all MSM." In short, it's the "delta" that matters.

A final decision by the judge in the *Braidwood* case is imminent [21]. Remedies could narrowly apply to the plaintiffs in the case, or in more sweeping terms apply to all US health plans. In the most worrisome potential outcome, the judge could strike down the USPSTF's authority to issue binding recommendations on a range of preventive health services far beyond PrEP. This analysis suggests that by removing the requirement of insurers to cover PrEP—a clinical intervention with the highest level of scientific evidence behind it—the court's ruling will have dramatic and injurious consequences for both individuals and public health, undermining years of effort and investment to end the HIV epidemic in the US.

Notes

Patient consent. The authors affirm that this study does not include factors necessitating patient consent.

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