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Being PrEPared — Preexposure Prophylaxis and HIV Disparities

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If current trends persist, one in six U.S. men who have sex with men will be infected with human immunodeficiency virus (HIV) in their lifetime, according to the Centers for Disease Control and Prevention (CDC).[1] This prediction highlights the long road ahead if we are to end the spread of HIV in the United States, but it does not tell the full story, which is complicated and nuanced. Of the 39,782 new HIV infections that occurred in the United States in 2016, nearly half were in black or Latino men who have sex with men, and 52% occurred in the South (a region defined by the CDC as Alabama, Arkansas, Delaware, the District of Columbia, Florida, Georgia, Kentucky, Louisiana, Maryland, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, Virginia, and West Virginia).[1] Preexposure prophylaxis (PrEP) with tenofovir disoproxil fumarate and emtricitabine (TDF–FTC), which the CDC has recommended since 2014 as a safe and very effective method of preventing HIV infection in high-risk populations, is an underused tool for reducing this alarming imbalance.

Approved by the Food and Drug Administration (FDA) in 2012, TDF–FTC as PrEP is a once-daily pill that reduces the risk of HIV transmission by more than 90%.[2] As longer-term data are becoming available, the recognized benefits of PrEP deployment continue to accumulate — not just decreased HIV transmission rates but also improved surveillance for sexually transmitted infections and enhanced links to primary care. Real-world demonstration projects confirm the feasibility and efficacy of large-scale rollouts of PrEP. But though the CDC estimates that more than 1.1 million people in the United States would benefit from PrEP, it has been prescribed to less than 150,000 people since it went on the market.[3] Of these prescriptions, nearly 75% went to white gay or bisexual men, predominantly those living in the Northeast or on the West Coast. Stigma, lack of provider knowledge, and limited awareness among men who have sex with men represent substantial barriers to improving uptake in the communities at highest risk. These factors are especially problematic in the South, where the incidence of HIV is the highest in the country and both mistrust of the medical system and perceived stigma

against gay and bisexual men are prevalent.[4]

Additional barriers related to cost and insurance coverage further complicate expansion of PrEP use. In recent months, insurance companies have denied coverage for PrEP and life insurance companies have rejected applications from men taking TDF–FTC for prevention — penalizing those who pursue PrEP for risk reduction and health promotion. For example, Publix, a large, employee-owned supermarket chain that operates largely in the Southeast, recently denied prescription coverage for PrEP to a Georgia-based employee. Despite the fact that Georgia has the country's highest per capita incidence of HIV infection, Publix cited strict criteria for coverage of the medication regimen: active HIV infection, postexposure prophylaxis because of occupational exposure, or nonoccupational postexposure prophylaxis within 3 days after exposure. When HIV activists challenged Publix, however, the company reversed course, adding preexposure prophylaxis to the eligibility criteria and expanding PrEP access to a population in need.

Still, more generally, lack of insurance and underinsurance limit the reach of this intervention. Without adequate health insurance coverage, the costs of PrEP are likely to be prohibitive for many at-risk people. A typical year on PrEP includes three or four office visits, including provider counseling on safer sex and adherence; laboratory testing; and prescription refills — for an average total cost of more than $10,000 per year.[2] Despite this high price tag, the intervention has been found to be highly cost-effective for high-risk populations.[2]

Black and Latino gay and bisexual men and transgender women, who are at the highest risk for HIV acquisition and are likely to benefit the most from PrEP, are also more likely than white and cisgender (i.e., non-transgender) populations to be uninsured or underinsured.[5] The Affordable Care Act (ACA) has narrowed these differences, but in the South, where many legislators have repeatedly voted against adopting the ACA Medicaid expansion, disparities in insurance coverage have widened. Additional barriers, such as limits to the indications for TDF–FTC prescription, will most likely intensify these inequalities.

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Beyond the cost of the medication, stigma and distrust of the medical system prevent at-risk people of color from obtaining and benefiting from PrEP. In the South, both the number of PrEP prescriptions and the rate of retention in PrEP care are lower than the national average.[3] In Jackson, Mississippi, black gay and bisexual men who engage in unprotected anal intercourse were recruited to participate in qualitative interviews on HIV risk; they described a strong aversion to medical care, related to mistrust of health care institutions and concern about bias in their care.[4] Few were aware of PrEP, and those who were expressed skepticism about its efficacy for HIV risk reduction and were reluctant to accept a prescription.

In some geographic areas, state and city public health agencies have partnered with the CDC to educate the public and clinicians about the benefits of PrEP in combination with safer sex — and have had some notable successes. Public and private PrEP drug-assistance programs are available to provide the medication at reduced cost to people at risk. New York City, previously an epicenter of the HIV epidemic, has used these interventions and broad marketing campaigns to increase PrEP awareness and uptake. The city has seen a substantial decrease in the number of new HIV infections, with the once-unimaginable goal of zero new infections by 2020 now in sight.

Communities with high HIV risk can look to areas that have had success in PrEP expansion. Fulton County has the highest HIV prevalence in Georgia. The Fulton County Task Force on HIV/AIDS was established in 2014 to address the burden of HIV in the jurisdiction and to reduce its incidence. PrEP was a cornerstone of the task force's recommendations, and the county increased access to PrEP providers by involving the community, reducing stigma, and expanding education. Although access for uninsured and underinsured PrEP candidates and limited community aware-

ness remain obstacles to a significant decrease in new infections, the task force demonstrated the power of advocacy and an evidence-based approach to HIV prevention.

Responding to the disproportionate burden of HIV among black men who have sex with men, the San Francisco Department of Public Health has launched askaboutPrEP, a website, hotline, and media campaign developed in collaboration with black communities. Nikole Trainor, a PrEP health educator involved with the campaign, notes that askaboutPrEP is built on the premise that "addressing people's whole lives — work, friends, family, and aspirations — is more meaningful than narrower messages about sex or race, which can feel reductive and disrespectful." The program works to build trust with communities throughout San Francisco and to understand how individuals think about themselves and the ways they can prevent HIV transmission. By affirming individual choices and expressions, askaboutPrEP empowers people at risk.

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

The gap between the number of people who are eligible for PrEP according to CDC guidelines and the number actually receiving it is wide, and even wider for some particularly vulnerable populations. Decisions by employers and insurers to limit coverage of PrEP reduce the availability of an evidence-based HIV prevention strategy and constrain providers. Confronting these barriers and boosting community comfort with and knowledge about PrEP are critical aspects of a public health effort to address stigma against the gay, bisexual, and transgender communities and to end the HIV epidemic.

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Dialysis-Facility Joint-Venture Ownership — Hidden Conflicts of Interest

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Since 1972, when the U.S. government began covering the costs of dialysis for nearly all Americans with end-stage renal disease (ESRD), dialysis has become big business. In 2015, the Centers for Medicare and Medicaid Services (CMS) spent roughly $34 billion on its beneficiaries with ESRD. In recent years, the two largest U.S. dialysis companies, DaVita and Fresenius Medical Care (FMC), which between them control roughly 70% of the U.S. dialysis market, have each reported an annual net income in the range of $1 billion.

One of the most notable but perhaps least discussed and least understood features of the U.S. dialysis landscape is the prominence of joint ventures between nephrologists and dialysis companies. Joint ventures allow the participating partners to share in the management, profits, and losses of an outpatient maintenance dialysis facility. In such arrangements, the dialysis company typically owns a majority share and nephrologists who see patients at the facility or serve as its medical directors obtain minority shares by investing in the facility's development. Such ventures have been promoted as a