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Risk Compensation and Clinical Decision Making — The Case of HIV Preexposure Prophylaxis

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Imagine a daily pill that prevents an unwanted consequence of sexual intercourse. Does it give users a "license for promiscuity"? Will its widespread availability lead to "sexual anarchy"? These questions were posed more than a half-century ago about oral contraceptive pills, which enabled condomless heterosexual sex with a far lower risk of pregnancy.[1]

Similar concerns have now arisen about preexposure prophylaxis (PrEP) for HIV, especially when it's prescribed to gay men and other men who have sex with men. PrEP, as currently approved by the Food and Drug Administration (FDA), is a once-daily antiretroviral pill that is more than 90% effective in preventing HIV infection when taken as prescribed. But as with oral contraception, some people view PrEP as a double-edged sword: PrEP may protect people against acquiring HIV, but absent that risk, users might have more partners or more condomless sex, thereby increasing their risk of non-HIV sexually transmitted infections (STIs). This anticipated pattern of behavior — greater risk taking in response to an increased sense of protection — is in keeping with a theory called risk compensation. Clinicians' concerns about risk compensation may be one reason for the slow uptake of PrEP in the United States.

PrEP is still in its infancy. The first trial demonstrating its efficacy, conducted among both men who have sex with men and transgender women, was published in 2010. FDA approval came in 2012. The Centers for Disease Control and Prevention (CDC) issued comprehensive clinical guidelines for PrEP in 2014 and updated its guidelines in 2017. Expanding access to PrEP is now a primary goal of the National HIV/AIDS Strategy.

PrEP was initially evaluated in clinical trials that promoted concurrent use of condoms, the mainstay of HIV prevention. Accordingly, CDC guidelines state that when discussing PrEP with patients, clinicians should encourage condom use. But some studies have suggested that, for some people, condom use decreases after PrEP initiation. This trend may reflect a broader decline in condom use among men who have sex with men, which predated PrEP; it may also reflect risk compensation.

Even when used by people who have condomless sex, however, PrEP has proven remarkably effective in real-world settings[2]; only a handful of HIV infections have been identified among people taking it as prescribed. At the same time, studies have demonstrated that people living with HIV cannot transmit the virus when they are successfully treated with antiretroviral therapy. As awareness of the effectiveness of these biomedical HIV-prevention

strategies grows, continued declines in condom use are likely.

The CDC estimates that 1.1 million people in the United States meet criteria for PrEP use, yet only about 100,000 used PrEP in 2017.[3] Uptake has been limited for multiple reasons, including low awareness of PrEP among providers and at-risk populations. Another important factor is clinicians' concerns about risk compensation. Although many PrEP users don't change their condom-use behavior, providers' anticipation of behavior change can make them reluctant to prescribe PrEP. Research supports this link: in one survey of primary care providers, the belief that PrEP use would lead to risk compensation was common — and more so among PrEP nonprescribers than prescribers.[4]

These concerns are not unfounded. PrEP doesn't protect against non-HIV STIs. Among people in the Kaiser Permanente Northern California health care system who started taking PrEP, 42% were diagnosed with gonorrhea, chlamydia, or syphilis during their first year of use.[2] High rates of STIs may be attributable, in part, to increased screening among PrEP users; they may also reflect higher rates of condomless sex. STIs are an important public health problem, given their clinical sequelae and the growing threat of multidrug-resistant gonorrhea, and new biomedical and behavioral approaches are needed for addressing this problem.

Nevertheless, we believe that concerns about risk compensation don't justify withholding PrEP from people at risk for HIV infection. Risk compensation hasn't led to higher rates of HIV acquisition among PrEP users, and routine follow-up enables prompt detection and treatment of other STIs.[2] Moreover, patient-centered care requires recognizing that disease prevention may not be the most important health outcome to patients. According to the World Health Organization, sexual health is not only the absence of disease, but also a holistic state of physical, emotional, mental, and social well-being in relation to sexuality. By enabling condomless sex with less fear of HIV transmission, PrEP has the potential to facilitate the intimacy and pleasure that can enhance sexual well-being for many people.

Clinicians may discount the importance of the psychological aspects of sexual health, however. Among medical students who were surveyed about acceptable reasons for PrEP users to discontinue condom use, 69% deemed desire for conception to be an acceptable reason, whereas less than a quarter deemed intimacy, pleasure, and sexual functioning to be acceptable reasons.[5] If such responses reflect physician attitudes in general, they suggest that clinicians value sex for reproduction more than sex for other purposes. This bias could result in inequitable prescribing, such as prescribing of PrEP to HIV-serodiscordant heterosexual couples who wish to conceive but not to men who have sex with men, which could exacerbate disparities in the HIV epidemic.

Over the past 50 years, condomless heterosexual sex among people using hormonal or other contraceptives — a possible form of risk compensation — has arguably become medically acceptable. Guidelines from the American College of Obstetricians and Gynecologists, for example, don't state that access to hormonal contraceptives should depend on intended condom use. Similarly, if PrEP use becomes more widespread and leads to declines in HIV incidence, clinicians' concerns about risk compensation may play a more minor role in clinical decision making regarding PrEP. With nearly 40,000 new HIV infections diagnosed annually in the United States, however, we cannot afford to wait.

Three initiatives could help expedite patient-centered and equitable dissemination of PrEP. First, clinical guidelines and training curricula could explicitly endorse offering PrEP to patients regardless of intended condom use. Current CDC guidelines don't address whether clinicians should prescribe PrEP to patients who plan to reduce or discontinue condom use, even though such patients are among those most in need of PrEP. Second, clinicians could engage patients in ways that help patients make informed decisions about options for HIV prevention — including PrEP and condoms — that are in keeping with their values and desires. Finally, clinical training curricula could include strategies for minimizing the influence of personal attitudes regarding sexuality on clinical decision making, just as clinicians may be trained to recognize and mitigate other biases, including racial bias.

Providers routinely navigate the trade-off involved in prescribing hormonal contraceptives: pregnancy prevention versus risk of acquiring HIV and other STIs. Disease prevention doesn't always trump other priorities for patients, for whom consistent condom use may not

be realistic or desired. The same reasoning applies to PrEP. Even if risk compensation occurs among PrEP users, we believe that clinicians should offer PrEP to patients at risk for HIV infection. Making PrEP more widely available, regardless of patients' intended condom use, won't lead to sexual anarchy. Rather, it will promote patients' sexual health; clinicians' ability to offer patient-centered, evidence-based care; and public health efforts to combat the ongoing HIV epidemic.

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

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Addressing a Core Gap in Cancer Care — The NCI Moonshot Program to Help Oncology Patients Stop Smoking

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Despite making great progress in caring for people with cancer, the oncology community has often neglected to capitalize on a highly feasible, readily available, and cost-effective strategy for increasing the success of cancer treatment and rates of recovery — smoking cessation. Effective smoking-cessation treatments can double or triple a smoker's chances of quitting successfully, and new treatment innovations that further boost quit rates continue to emerge. But such treatments are infrequently provided to patients as part of their cancer care.

Our failure to effectively address smoking in patients with cancer exacts steep costs. Evidence shows that continued smoking after a cancer diagnosis increases post-treatment mortality as well as the risk of a new primary cancer, the risk of cancer recurrence, and rates of adverse side effects from cancer treatment.[1,2] Conversely, quitting smoking after a cancer diagnosis is associated with longer survival and a reduced risk of new cancers.[1] The evidence is clear: for the approximately half of cancer patients who smoke at the time of their diagnosis, a cancer diagnosis signals an important and highly feasible opportunity to improve the effectiveness of cancer treatment and avert future cancers.

Despite recommendations (e.g., from the National Comprehensive Cancer Network) that all patients with cancer be offered effective treatment to help them quit smoking, such treatment is an often-neglected element of cancer care. For example, a 2009 survey of 58 National Cancer Institute (NCI)–designated clinical and comprehensive cancer centers in the United States revealed that 21% offered no tobacco-use treatment services, only 62% routinely provided tobacco-education materials to patients, half reported having systems in place to identify which of their patients use tobacco, and less than half reported having a staff person dedicated to providing tobacco-treatment services or a commitment from center leadership to provide such services.[3] Such inattention has had a predictable effect on the delivery of smoking-cessation interventions. Data show that just under half of cancer care providers consistently discuss cessation-medication options with their patients who smoke, and a similar proportion consistently treat their patients with cessation medications or refer them for treatment.[4] Among peo-