

Biomedical STI prevention evidence may be inadequate for cisgender women

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Scanning electron micrograph of Neisseria gonorrhoeae bacteria, which causes gonorrhea. Captured by the Research Technologies Branch at the NIAID Rocky Mountain Laboratories in Hamilton, Montana. Credit: NIAID



Pivotal studies of some biomedical HIV and sexually transmitted infection (STI) prevention interventions have excluded cisgender women or demonstrated low efficacy among them, limiting their prevention options relative to other populations who experience high HIV and STI incidence.

Findings from a study <u>published</u> in *The New England Journal of Medicine* show doxycycline postexposure prophylaxis (better known as DoxyPEP) did not prevent STI acquisition in cisgender women, despite showing <u>promising</u> results in gay, bisexual, and other men who have sex with men and transgender women in a previous study.

Jeanne Marrazzo, M.D., M.P.H., director of the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, discusses these disparities—and the opportunity to correct them—in an accompanying editorial.

The study, conducted among Kenyan cisgender women, found no significant reduction in STI incidence among those taking DoxyPEP compared to a control group. This is in contrast to the findings from a U.S. study published earlier this year in which oral doxycycline given within 72 hours of condomless sex reduced the incidence of common bacterial STIs by two-thirds among gay, bisexual, and other men who have sex with men and <u>transgender women</u>.

Investigators suggested these results may be due to low DoxyPEP use, high existing resistance to doxycycline among Neisseria gonorrhoeae bacteria, that cause gonorrhea, in the study location, and a local syphilis incidence too low to enable significant efficacy estimates.

In the accompanying editorial, Dr. Marrazzo describes the need to better



understand the biological and behavioral factors that influence STI acquisition in cisgender women, and to consider those factors when designing future biomedical prevention studies, rather than employing a "one-size-fits all" approach for all populations.

Specifically, Dr. Marrazzo highlights insufficient evidence on how HIV and STI prophylaxis drugs perform in cervicovaginal versus rectal tissues. She also stresses the need for studies to reflect cisgender women's sexual activity preferences, as well as common power dynamics with sex partners.

Dr. Marrazzo explains that these knowledge gaps have implications for improving the efficacy and acceptability of biomedical prevention interventions among cisgender women. Finally, the editorial highlights the need to address these gaps given alarmingly high rates of congenital syphilis in the United States as well as steady HIV incidence and low HIV pre-exposure prophylaxis uptake among U.S. cisgender <u>women</u>.

NIH strives to increase the meaningful inclusion of diverse and representative populations in the planning, conduct, and translation of clinical research so that everyone can enjoy the benefits of scientific progress and its applications.

More information: Jenell Stewart et al, Doxycycline Prophylaxis to Prevent Sexually Transmitted Infections in Women, *New England Journal of Medicine* (2023). DOI: 10.1056/NEJMoa2304007

Jeanne Marrazzo, Doxycycline Postexposure Prophylaxis for STIs in Women—Uncertain Benefit, Urgent Need, *New England Journal of Medicine* (2023). DOI: 10.1056/NEJMe2311948



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