

Two PrEP medications are now available. Equally safe/effective. The biggest difference? The price tag.

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With a significantly costlier medication for HIV preexposure prophylaxis (PrEP) approved in 2019, a new study examined reasons patients switched to the new drug. Study results indicate that a minority of those who switched had a documented clinical reason to do so.

The study was led by researchers at Harvard Medical School, Harvard Pilgrim Health Care Institute, and The Fenway Institute, and appears online on August 5 as an Editor's Choice article in *Open Forum Infectious Diseases*.

PrEP is an antiretroviral pill that is 99% effective in preventing HIV acquisition when taken as prescribed. It is available in two forms: coformulated tenofovir disoproxil fumarate and emtricitabine (TDF/FTC, or Truvada) and the newer tenofovir alafenamide with emtricitabine (TAF/FTC, or Descovy). TAF/FTC was approved by the FDA in 2019 for preventing sexual transmission of HIV, except for people at risk through receptive vaginal sex.

Both PrEP medications are highly effective and extremely safe. TDF/FTC has been associated with small decreases in <u>renal function</u> and bone mineral density, and TAF/FTC has been associated with minor weight gain and dyslipidemia, but these incremental differences have not translated to differences in adverse clinical events.

The medications differ substantially, however, when it comes to price: generic TDF/FTC became available in the U.S. in October 2020, and now costs as low as \$30 per month, compared with about \$1800 per month for branded TAF/FTC.

"One of the most critical barriers to broad and equitable PrEP use in the U.S. has been cost, including both perceived and actual costs," said lead author Julia Marcus, Ph.D., Associate Professor in the Department of Population Medicine at Harvard Medical School and Harvard Pilgrim



Health Care Institute. "Generic TDF/FTC could revolutionize PrEP access, but that opportunity will be missed if resources are invested in a far more expensive <u>medication</u> without proportional improvements in clinical outcomes."

The researchers extracted electronic health record data from 2,892 adults who were assigned male sex at birth, were prescribed TDF/FTC for PrEP in the year before FDA approval of TAF/FTC, and had at least one PrEP prescription in the following year. All patients were seen at Fenway Health, a Boston community health center that specializes in care for sexual and gender minorities.

The team evaluated how many PrEP users switched to TAF/FTC and whether patients had a clinical indication for switching. They found that 11.9% of the study population switched to TAF/FTC in the first year it was available. Consistent with the known side effect profiles of the two medications, renal dysfunction was associated with switching to TAF/FTC, while switching was less likely among those with dyslipidemia. Based on documented renal, bone, and cardiovascular risk factors, however, only 7% of those who switched to TAF/FTC had clinical indications to do so. When indications for switching also included risk factors for developing renal dysfunction, such as hypertension and diabetes, up to 27% of switching was clinically indicated.

The findings indicate that a minority of switching to TAF/FTC was clinically indicated, although some patients appear to have been switched in anticipation of clinical indications developing, and others may have had indications for switching that were not documented in electronic health records.

"Efforts to end the HIV epidemic may be threatened if more expensive medicines are used when comparably effective, cheaper options are



available," said co-author Kenneth Mayer, MD, Professor at Harvard Medical School and Medical Research Director at Fenway Health. "Our study highlights the need to ensure that decisions about PrEP medications are both clinically sound and cost-effective."

More information: Julia L Marcus et al, Switching From Tenofovir Disoproxil Fumarate to Tenofovir Alafenamide for Human Immunodeficiency Virus Preexposure Prophylaxis at a Boston Community Health Center, *Open Forum Infectious Diseases* (2021). DOI: 10.1093/ofid/ofab372

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