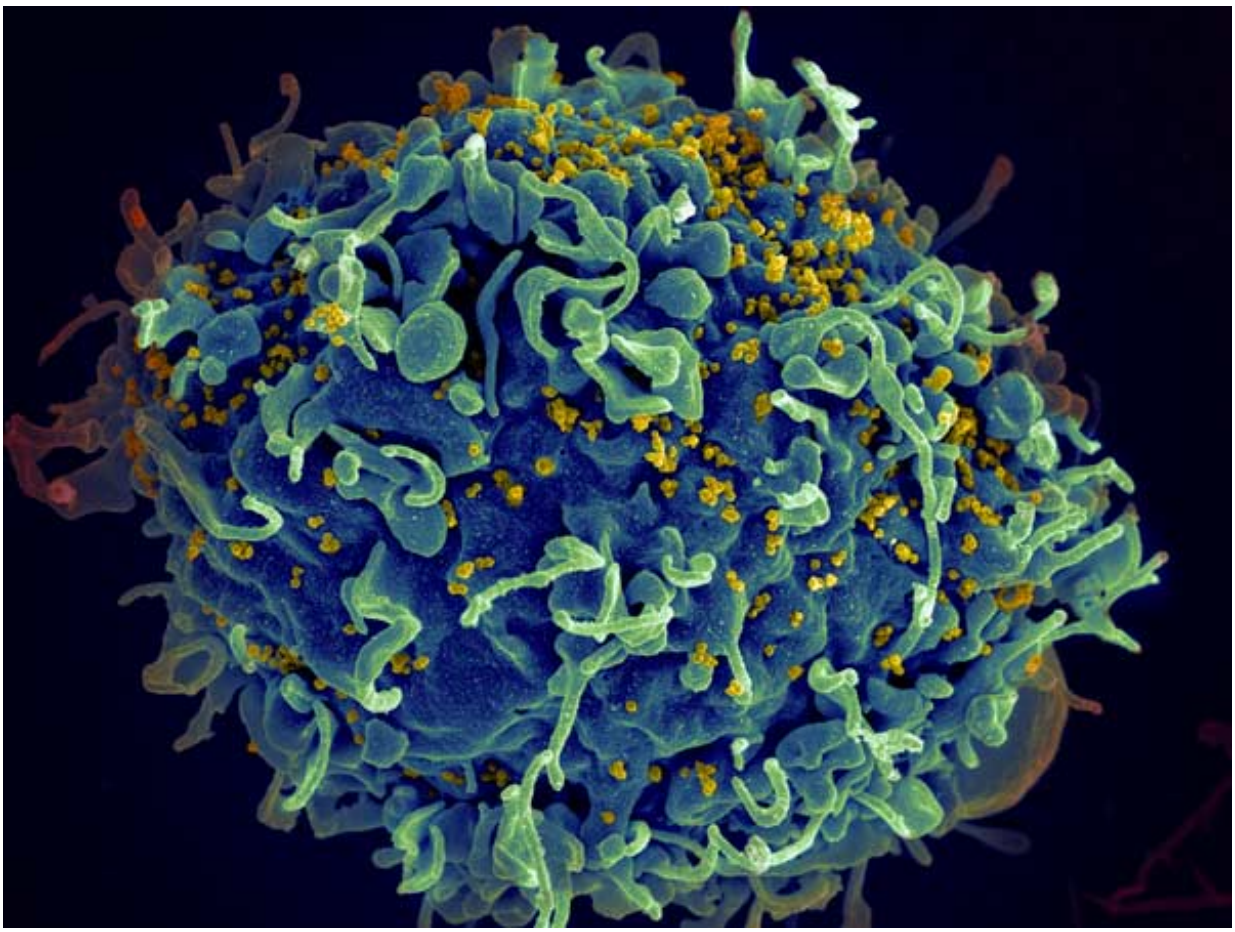
Risks to babies of mothers with HIV from three antiretroviral regimens appear to be low

April 25 2018



HIV infecting a human cell. Credit: NIH

The risk for preterm birth and early infant death is similar for three antiretroviral drug regimens taken by pregnant women with HIV according to a new study from Harvard T.H. Chan School of Public Health.

The study will be published in the April 26, 2018 issue of the *New England Journal of Medicine*.

Global use of three-drug antiretroviral therapy (ART) by pregnant women with HIV has reduced the risk of mother-to-child transmission of the virus to less than 1%, but an earlier trial, the PROMISE trial, had raised concerns about the safety of one regimen.

In that trial, it was found that women in sub-Saharan Africa and India who took TDF-FTC-LPV/r (tenofovir disoproxil fumarate, emtricitabine, and ritonavir-boosted lopinavir) had infants at greater risk for very premature birth (less than 34 weeks of gestation) and death within 14 days after delivery than those taking ZDV-3TC-LPV/r (zidovudine, lamivudine, and ritonavir-boosted lopinavir).

Because the World Health Organization recommends a once-daily TDF-FTC-based regimen as first-line therapy for all HIV-infected adults, including pregnant women, the Harvard Chan researchers wanted to compare the risks posed by the two regimens studied in the PROMISE trial and an additional regimen using TDF-FTC and a different protease inhibitor (drug that prevents viral replication) called ATV/r (ritonavir-boosted atazanavir).

The study analyzed data from 1,621 mothers in two U.S.-based cohort studies—the Surveillance Monitoring for ART Toxicities (SMARTT) study of the Pediatric HIV/AIDS Cohort Study (PHACS) and the P1025 study of the International Maternal Pediatric Adolescent AIDS Clinical Trials (IMPAACT) Network—who had started taking one of the three

drug combinations before or during pregnancy.

The researchers found that all three regimens pose similar risks for adverse birth outcomes. In addition, women using TDF-FTC-ATV/r had lower risks of preterm birth and low birth weight than those using TDF—FTC-LPV/r, and a similar or lower risk than those using ZDV-3TC-LPV/r. However, the authors noted that TDF-FTC-LPV/r is rarely used in the United States, which may have limited the statistical accuracy of the study to identify risks associated with this combination.

"It was reassuring to see that the use of TDF-FTC-ATV/r during pregnancy was not associated with an increased risk of poor birth outcomes in our study," said first author Kathryn Rough, who conducted the study as a doctoral student at the School. "But based on the earlier results from the PROMISE trial, it may be wise to continue limiting the use of TDF-FTC-LPV/r in pregnant women with HIV."

More information: "Birth Outcomes for Pregnant Women with HIV Using Tenofovir-Emtricitabine," Kathryn Rough, George R. Seage, III, Paige L. Williams, Sonia Hernandez-Diaz, Yanling Huo, Ellen G. Chadwick, Judith S. Currier, Risa M. Hoffman, Emily Barr, David E. Shapiro, and Kunjal Patel, *NEJM*, online April 26, 2018, doi: DOI: 10.1056/NEJMoa1701666

Provided by Harvard T.H. Chan School of Public Health