

Despite risk of birth defects, HIV drug should be considered for women in South Africa

1 April 2019



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Although a woman's use of the HIV drug dolutegravir at conception may increase the risk of often-fatal neural tube defects in her child, a new study suggests that the risk may be offset by the drug's ability to decrease deaths among women and prevent HIV transmission to their children and sexual partners. The report, led by researchers at Massachusetts General Hospital (MGH), is being published online in the *Annals of Internal Medicine*.

"Dolutegravir is one of the most effective drugs that we have to treat HIV and could be a 'game-changer' in sub-Saharan Africa," says Caitlin Dugdale, MD, of the MGH Division of Infectious Diseases and the Medical Practice Evaluation Center, who led the study. "However, as countries consider replacing current first-line treatment with now less expensive dolutegravir-based treatment, it is important to evaluate the risks and benefits of using it globally for millions of [women](#) who could

become pregnant."

Dolutegravir has been available in the US since 2013 and is part of recommended first-line HIV treatment in resource-rich countries. It has fewer side effects and lower rates of treatment failure than efavirenz, the current first-line treatment in most low- and middle-income countries. While dolutegravir was previously unaffordable in these countries, recent negotiations led to development of a generic version that costs only \$75 per person per year. Many developing countries most affected by the HIV epidemic had planned to roll out dolutegravir in 2018 but delayed these plans after a birth surveillance study in Botswana released preliminary data suggesting that dolutegravir may pose harm to unborn [children](#) by increasing the risk of neural tube defects.

Dugdale says, "We are waiting on more data to know if the preliminary results of the Botswana study were a statistical fluke or a finding of real concern; but while we wait, policymakers still have to make decisions about what treatment to recommend for women with HIV who could become pregnant."

To look at the potential effects of different HIV treatment options for women from a public health perspective, the researchers used a well-established mathematical model of HIV along with epidemiologic data from South Africa and treatment efficacy data from clinical trials. With this model, they projected clinical outcomes over five years for approximately 3.1 million women of child-bearing age with HIV in South Africa and their children. They compared a policy of using dolutegravir-based treatment for all women to the current policy of first-line efavirenz-based treatment for all women with HIV. The model projected the number of anticipated deaths from any cause among women

and children, HIV transmissions to men and children, and dolutegravir-related neural tube defects over five years in South Africa.

The researchers found that use of efavirenz-based first-line treatment would lead to 4,400 fewer deaths among children compared with dolutegravir-based treatment, largely due to the reduced risk of birth defects. However, dolutegravir-based treatment was projected to lead to more than 13,000 fewer deaths among women, nearly 60,000 fewer HIV transmissions to male partners, and over 7,000 fewer HIV infections in children. Overall, the study found that there were fewer deaths with dolutegravir-based treatment than with efavirenz-based treatment.

Study co-author Linda-Gail Bekker, MD, Ph.D., of the University of Cape Town and the past president of the International AIDS Society says, "The results of this modeling study show us that the issue is not so simple as saying we should take dolutegravir off the table because a woman might become pregnant. Instead these results highlight the importance of making sure that women are given all of the information about the benefits as well as the risks of dolutegravir so that they can make an informed decision about the best choice of treatment."

Rochelle Walensky, MD, MPH, of the MGH Division of Infectious Diseases and the Medical Practice Evaluation Center, senior author of the study adds, "The findings of our analysis suggest that, when looking at the 'bigger picture' effects of dolutegravir-based treatment beyond the risk of birth defects, [dolutegravir](#) offers many benefits for women, their partners and their children over currently recommended first-[treatment](#)."

More information: *Annals of Internal Medicine* (2019). [DOI: 10.7326/M18-3358](https://doi.org/10.7326/M18-3358)

Provided by Massachusetts General Hospital

APA citation: Despite risk of birth defects, HIV drug should be considered for women in South Africa (2019, April 1) retrieved 26 August 2022 from <https://medicalxpress.com/news/2019-04-birth-defects-hiv-drug-women.html>

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