

Access to Treatment Options for Women Living with HIV

Webinar:

15 November 2018



Salamander Trust
ON THE RIGHT(S) TRACK

Why is this
webinar
taking place?

Webinar Agenda

- Introduction
- What advocacy has taken place so far and what is new
- Updates from those leading on the work
- Discussion: Where do we go from here?
- Next steps and actions



What advocacy has taken place thus far?

1. May 8: [WHO Statement on DTG](#)
2. June 28: National Empowerment Network of people living with HIV in Kenya (NEPHAK) – Letter to MoH Demanding DTG
3. July 2018 Updated recommendations on first-line and second-line antiretroviral regimens and post-exposure prophylaxis and recommendations on early infant diagnosis of HIV: [interim guidance](#)
4. July 1: [Comparative safety of dolutegravir-based or efavirenz-based antiretroviral treatment](#) started during pregnancy in Botswana: an observational study: The Lancet
5. July 13 - 14: IAS2018: [Communique of the Kigali Dolutegravir Stakeholder Meeting](#) of African Women Living with HIV, hosted by African Community Advisory Board (AfroCAB)
6. July 16: [NOTHING FOR US WITHOUT US](#): Statement by the AfroCAB on Dolutegravir and neural tube defects in women living with HIV of child bearing age
7. July 18: [Time to realise our sexual and reproductive health and rights](#) – the Lancet
8. July 23 - [Give Women Living with HIV full information on the benefits and risks of DTG, Contraceptives for them to exercise choice](#)
9. Aug: [IPPF TECHNICAL BRIEF](#): Dolutegravir for women living with HIV of reproductive age
10. Aug 3 I-base: [No additional neural tube defects among a further 170 preconception dolutegravir exposures in Botswana: Tsepamo study \(July 2018\)](#)
11. August 20: [Dolutegravir drug is safe for women living with HIV](#): Martha Akello

What's new?

- 1-4 October 2018 European Medicines Agency (EMA) Pharmacovigilance Risk Assessment Committee (PRAC) [confirmed its precautionary advice](#) issued earlier this year on the use of DTG in pregnant women and for use of effective contraception while taking DTG in women who can become pregnant
- Sept - Nov 2018: [Forum on the risks of preconception dolutegravir exposure: an IAS - CDC.](#)
- 13 Nov: I-base: [Insufficient data on risk of neural tube defects](#) with exposure to elvitegravir or bictegravir exposure during preconception or first trimester
- 13 Nov: I-base [No additional neural tube defects with preconception dolutegravir](#): data from three birth outcome cohorts



Whats coming up?

Forum on the risks of preconception dolutegravir exposure (Supported by grants from the Bill & Melinda Gates Foundation and the PENTA Foundation)

- The Tsepamo study has expanded from 8 to 18 sites. The next in-depth assessment of the Tsepamo study will occur in April, 2019
- Birth surveillance has been expanded at sites outside the Tsepamo study by the Botswana MoH with support from US CDC.
- DTG has been implemented on a more limited basis in several other countries, including Kenya, Uganda, Brazil and Ukraine. Pregnancies occurring among women on DTG in these countries are being tracked.
- In the US, implementing DTG since 2013. They are currently matching state birth defect registries with HIV-exposed birth registries to identify birth defects by timing and category of ARV exposure. Data is expected in late 2018 or early 2019.
- Surveillance of all births for defects similar to the Tsepamo study has been implemented at several facilities in Uganda and Malawi, covering over 60,000 births/year.
- Two academic groups modelled outcomes of women and children taking DTG vs EFV. These models are being review and refined. Both models show that providing DTG for women, including those of childbearing potential, resulted in fewer deaths than those given EFV. And overall DTG – even with any risk – seems the better choice so far.



Updates from women in countries

Discussion:
Where do we
go from here?

Key Messages

Involve us
and
Respect our
rights to
informed
voluntary
choice

- All of this sits in a broader framework of upholding and respecting the SRHR and treatment options of women living with HIV.
- The recommendations offer an opportunity for countries to address the lack of integration around HIV and Sexual Reproductive Health Rights and Services for women living with HIV – these are important for our reproductive health decisions and choices.
- Women living with HIV being must be included in research
- We need to learn from the experiences around DTG and prepare for new evidence as ARVs evolve. What message do we send to WHO to ensure that our options, realities and treatment priorities are taken onboard and respected BEFORE warnings are issued that have serious implications for women living with HIV?
- As evidence does/doesn't emerge It is women who should have the right to full information and options to make their own voluntary choice and balance potential risks of DTG against its potential benefits.