

POLICY BRIEFING



DOLUTEGRAVIR IN SOUTHERN & EASTERN AFRICA AND THE RIGHT TO CHOOSE

NOVEMBER 2018

By Maureen Milanga and Lotti Rutter

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An important new antiretroviral medicine will soon become available to people living with HIV in various Sub-Saharan African countries. Unfortunately, many women might be denied access to this new drug due to an inability of regulators and health departments to see potential risks associated with the drug in the proper context.

In May 2018, preliminary findings from an observational study in Botswana raised a potential concern about the use of dolutegravir for women. Dolutegravir was in the process of being recommended in national HIV guidelines in almost 70 low- and middle-income countries, following the earlier move by richer countries.

However, once this potential concern emerged things changed. The World Health Organization (WHO) issued new treatment guidelines that countries put into effect with varying degrees of conservatism – some countries giving women the option to choose, and others not providing women with dolutegravir at all.

Yet again, policy makers are making unilateral decisions, and not always good decisions, over women's health. In most countries, women living with HIV have not even been asked what they think. Instead they are being excluded from accessing a game-changing HIV medicine that will be widely available to men.

What is dolutegravir?

Dolutegravir or “DTG” was first approved by the United States Food and Drug Administration in 2013. It is part of a class of antiretroviral medicine called integrase inhibitors. When HIV infects a cell, it combines its viral genetic code into the human cell's own code – this is called integration, using the integrase enzyme. DTG blocks this integration enzyme, so HIV can't make any more copies of itself, hence “integrase inhibitor”. Dolutegravir is the first integrase inhibitor that would be widely used by people living with HIV in the developing world.

What are the advantages of dolutegravir?

1. **DTG IS EFFECTIVE:** DTG is very effective at suppressing someone's viral load quickly¹ (the amount of copies of HIV in the blood). This is important for the long-term health of the person taking it. An undetectable viral load also means the person will no longer be able to transmit HIV to anyone else.
2. **DTG IS WELL TOLERATED:** In clinical trials there have been far fewer side effects reported from people using DTG as compared to people using the drug that DTG will replace, efavirenz (EFV)². This includes fewer central nervous system side effects such as depression and anxiety. The improved tolerability of DTG should make it easier for people to adhere to treatment in the long term. While not totally free from side effects, it is a big step forward.
3. **DTG IS EASY TO TAKE:** People only require a small dosage of DTG. The small dose makes it ideal to combine in a single tablet with other antiretrovirals. It also means the pills can be much smaller.
4. **DTG HAS FEW INTERACTIONS WITH OTHER MEDICINES:** DTG has fewer drug interactions compared to EFV. One interaction we know about is with the tuberculosis medicine rifampicin. This is important given high rates of TB and HIV co-infection. While more evidence is needed, right now people with HIV and TB are being given an increased dose of DTG to account for the drug interaction. Another interaction is with a diabetes drug called metformin (where we drop the dose of metformin a little if used with DTG). It also should not be taken at the same time as with antacids or food supplements, if possible (you can take these at a different time of the day).
5. **DTG HAS A HIGH BARRIER TO RESISTANCE:** DTG has a higher genetic barrier to developing drug resistance compared to EFV³. This will reduce the need for people to switch treatment lines since it is anticipated that extremely few people will develop resistance to dolutegravir. This is also important for people who are already resistant to another type of antiretroviral medicine – called a non-nucleoside reverse transcriptase inhibitor (NNRTI).
6. **DTG CAN BE MORE AFFORDABLE:** The smaller dose means less active pharmaceutical ingredient (API) is needed (the bit of the drug that actually works in the body). The low dosage means DTG could be produced by itself profitably by generic manufacturers for around ZAR 300 / US\$ 21 per person each year. A deal was announced in September 2017 capping the public sector price in 92 low- and middle-income countries at US\$ 75 per person a year for a combination tablet of tenofovir, lamivudine and dolutegravir (TLD). This price cap was for countries covered in the Medicines Patent Pool (MPP) license, thus excluded 39 countries including Thailand and Malaysia despite the fact that the drug is not protected by any patents there⁴. After one year of active advocacy with the MPP, the Clinton Health Access Initiative (CHAI), the originator pharmaceutical company and the generic supplier; treatment advocates succeeded to ensure that the pricing deal will be honoured in those 39 countries too given the MPP licence allows supply to countries where there are no patents. CHAI publicly announced this during the MENA Community Advisory Board meeting held in Morocco in October 2018. The full list of countries who are entitled to purchase DTG at this price from Mylan will be updated soon. As per today all African countries could benefit from this deal except Algeria. This country and others excluded should take other steps to ensure price reductions, such as issuing compulsory licenses.

What are the concerns?

In May 2018, an ongoing observational study in Botswana (the Tsepamo study) found a potential concern about the use of dolutegravir at the time a woman conceives⁵. Preliminary analysis from the study showed that four women out of 426 who conceived while taking DTG gave birth to infants who had neural tube defects. This worked out to a rate of 0.9%, higher than the average of 0.1% of women in the rest of the population. Updated data since shows an additional 170 births, with no additional neural tube defects reported (thus bringing the rate down to 0.67%)⁶. At the time of writing, the number of conceptions in the study are over 800, and no more babies have been born with neural tube defects.

Neural tube defects can be caused by a number of factors, such as a woman having insufficient folic acid at conception, or diabetes. The cause of these four cases is not conclusive and we do not know if DTG causes birth defects when taken during conception. In fact, while an increase in neural tube defects was observed in Botswana, it has not been observed in any other countries conducting similar studies. A forum on the risks of preconception dolutegravir exposure has developed frequently asked questions (FAQs) designed to help provide context and to support decision making around DTG⁷. In summary, it all may be by chance, or it may be a real danger. We need more time to be sure. The final outcomes of Tsepamo are expected in April 2019.

One pertinent issue the Botswana caution raises, is the fact that pregnant women are consistently left out of clinical trials. When new medicines are developed, those conducting clinical trials often exclude groups like pregnant women, children and people taking other medicines (for instance someone living with HIV who also has TB and is taking anti-TB medicines). This means we only learn later, after these medicines start being rolled out more widely, the impact they have on these people. Activists and researchers have raised this concern time and again, but are simply ignored by funders, donors and governments.

What does the World Health Organization (WHO) say?

The WHO issued guidelines recommending dolutegravir as an alternative option for first line treatment of HIV in 2016. After the preliminary Tsepamo findings were released, the WHO issued updated guidelines in July 2018⁸ outlining how countries should proceed in rolling out DTG. The guidelines stated:

“Adolescent girls and women of childbearing potential who do not currently want to become pregnant can receive DTG together with consistent and reliable contraception.”

And that;

“Woman-centred health services involve an approach to health care that consciously adopts the perspectives of women and their families and communities. This means that health services see women as active participants in and beneficiaries of trusted health systems that respond to women’s needs, rights and preferences in humane and holistic ways. Care is provided in ways that respect women’s autonomy in decision-making about their health, and services must provide information and options to enable women to make informed choices. The needs and perspectives of women, their families and communities are central to providing care and to designing and implementing programmes and services. A woman-centred approach is underpinned by two guiding principles: promoting human rights and promoting gender equality”.

How did some countries in Eastern and Southern Africa respond?

Following the WHO caution many countries have taken a conservative approach on women's access to DTG, and in some cases slowed or stalled progress altogether. Below we outline the guidelines (or proposed language for guidelines) of eight countries in the region (accurate at time of publishing), and most importantly how this impacts women's ability to access DTG.





KENYA

National Guidelines (or proposed language for guidelines) & interim circulars	What does this mean for women's ability to access DTG?	DTG rollout	What do activists want?
<p>DTG is not currently recommended for women and adolescent girls of childbearing potential because of possible risk of birth defects when DTG is used around the time of conception.</p> <p>Women who are on effective contraception may opt to use DTG and should be supported in their decision.</p>	<p>VERY LIMITED ACCESS</p> <p>The reality is that healthcare workers in Kenya are not <i>offering</i> DTG to women at facilities.</p> <p>Immediately following the WHO caution, Kenya's Department of Health issued a circular telling healthcare providers to deny women aged 15 – 49 access to DTG. It has been reported that since then some women who had been started on DTG prior, were then switched back to an EFV based regimen. There has been no real option to access DTG as the guidelines suggest. Instead a blanket approach is being taken that all women be put on EFV based regimens.</p> <p>Only a few women part of civil society organisations have been able to access DTG due to individual activist interventions at facilities.</p>	<p>DTG is currently being rolled out in Kenya for men and women who are not of reproductive age (above 50 years).</p>	<p>Kenya must revise national guidelines to reflect the DTG based regimen (TLD*) as a preferred first line regimen.</p> <p>Information on women's right to choose DTG should be clearly outlined on the initial pages of the guidelines, ensuring that healthcare workers are able to access this information and put it into practice effectively.</p> <p>A circular should be issued to clarify the updated guidelines and to clarify any misconceptions held by health workers.</p>

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<p>There is currently no confirmation that DTG is safe in early pregnancy. DTG-based regimens are therefore not to be used as standard 1st line regimens for girls and women within the fertility age range.</p> <p>DTG will be given to women above 45 years old or those on permanent contraceptive.</p> <p>DTG may be offered to women "on request." The decision to give a DTG based regimen (TLD) will remain with the healthcare worker and will be based on "sufficient information" provided by the woman.</p> <p>Documentation of informed consent is also being explored by government as a mechanism to ward off lawsuits.</p>	<p>NO ACCESS</p> <p>First women of child bearing age are being denied access to a more efficacious drug.</p> <p>Secondly placing the final decision with the healthcare worker has removed the power from women to make independent choices.</p> <p>Therefore, on what basis is the healthcare worker making the decision?</p> <p>In practice, women of child bearing age will face challenges in accessing DTG in Malawi.</p>	<p>DTG will be rolled out in Malawi in January 2019 to men, boys and women on permanent contraceptives.</p>	<p>The country needs to state what sufficient information from women is needed to access DTG and develop a checklist that healthcare workers can use in making an assessment.</p> <p>The country needs to make it clear that the DTG based regimen (TLD) is also a preferred regimen.</p> <p>The guidelines should ensure that women are informed about their options and able to choose a DTG based regimen.</p>

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<p>1ST PHASE:</p> <ol style="list-style-type: none"> 1. Sensitive TB co-infected male patients; 2. Resistant TB co-infected patients (men and woman). <p>2ND PHASE:</p> <ol style="list-style-type: none"> 1. New and stable Patients in ART (Men only and Woman that have reached menopause); 2. Therapeutic regimes containing NVP and other complex regimes (Men only and Woman that have reached menopause); 3. Patients with adverse reactions to EFV, TLE Level III & IV (Men and Woman); <p>All other women will be given an EFV based regimen.</p>	<p>LIMITED ACCESS – WHEN ROLLED OUT</p> <p>The reality in Mozambique is that women under 50, other than those with drug-resistant TB, will have virtually no option to access DTG.</p>	<p>DTG roll out is scheduled to begin in Mozambique in November 2018.</p>	<p>The guidelines should be changed to ensure that all women who have been informed are able to choose between DTG and EFV based regimens.</p>

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SOUTH AFRICA

National Guidelines (or proposed language for guidelines) & interim circulars	What does this mean for women's ability to access DTG?	DTG rollout	What do activists want?
<p>The DTG based regimen (TLD) will be available for all men, all women on reliable hormonal contraceptives, and all women not of childbearing potential.</p> <p>The EFV based regimen (TEE**) will be available to all women of childbearing potential and those not on reliable hormonal contraceptives.</p>	<p>LIMITED ACCESS</p> <p>The proposed language in the South African guidelines would not permit access to TLD for women unless they are on hormonal contraception. Given the frequency of contraceptive stockouts and shortages seen in South Africa recently, as well as the state of the broken healthcare system including overstretched and overburdened healthcare workers, the reality is likely that DTG may not be available to many women.</p> <p>Civil society have not been meaningfully consulted in the development of the guidelines.</p>	<p>DTG is being used in third line patients routinely, as well as in the private sector; tenders are issued, and will be announced in Dec 2018, with DTG rolled out in first and second line as early as April 2019 across the country. Guideline development is currently underway.</p> <p>The fact that women who are able to afford it can buy generic TLD in the private sector currently for around R700 (USD 50) per month raises a further class element to this access issue.</p>	<p>The guidelines must be revised to ensure women are able to make an informed choice to take DTG.</p> <p>Women must get access to information about the benefits and possible risks of DTG-containing regimens, regardless of their age or contraceptive status.</p> <p>In addition, women must be able to choose which form of contraceptive suits their needs and government must ensure that these are actually made available in facilities.</p> <p>Funding for PLHIV groups must be made available for community education efforts that ensure better levels of treatment literacy in communities.</p>

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National Guidelines (or proposed language for guidelines) & interim circulars	What does this mean for women's ability to access DTG?	DTG rollout	What do activists want?
<p>The following group of HIV positive clients are eligible for DTG containing regimens:</p> <ol style="list-style-type: none"> 1. adult men; 2. adolescent boys; 3. women and adolescent girls with effective contraception and/ or not of childbearing potential; 4. women and adolescent girls of childbearing potential provided they have been given necessary information on DTG containing regimens to make an informed decision. <p>Women who expect to be pregnant and choose not to take DTG will be given option to use TLE.</p> <p>All women expecting to be pregnant should routinely receive high dose Folic acid (5mg) pre-conception and during pregnancy.</p>	<p>ACCESS IN THEORY – WHEN ROLLED OUT</p> <p>The Tanzania guidelines are some of the most progressive in the region in allowing women to make informed choices around DTG. Contraceptives will also be offered to women taking up DTG at facilities. It is anticipated that 10% of women will opt out of using DTG based regimens.</p> <p>The provision of 10% supply of TLE will cover proportion of people with conditions which contraindicates DTG. This will also cover people with DTG containing regimen drug intolerance, pre- and early pregnancy < 8 weeks, women who fail to use consistent or long-acting contraception, people not consenting to use DTG and people who opt to maintain their current regimen with clinical and virology stability.</p>	<p>Tanzania has already initiated procurement of TLD fixed-dose combination and DTG planning for a phased transition. The first phase of DTG roll out will begin in January 2019. DTG roll-out is will take 3 to 6 months due to the country's supply chain.</p>	<p>Given the roll out has not yet started, it remains to be seen how it will be implemented. Activists will be closely monitoring the roll out for any challenges that arise.</p>

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<p>The country will roll out the DTG based regimen (TLD) as a preferred regimen and will allow women access if they are using 'effective' contraception. Women not on contraception will also be permitted to choose TLD.</p>	<p>ACCESS IN THEORY – WHEN ROLLED OUT</p> <p>The Ugandan guidelines are progressive and ensure women have the right to choose. PEPFAR and the national government are planning for increased demand for contraceptives. PEPFAR is working with the national supply chain systems to ensure increased stocks and to monitor stock status.</p>	<p>DTG based regimen roll out will be phased. 250,000 men and women will have access to TLD by the end of 2018.</p>	<p>Activists will be closely monitoring the roll out of DTG, and the accessibility of contraceptives, to ensure the implementation of this policy reflects the guidelines.</p>

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<p>We have seen a circular stating that health workers should not prescribe DTG containing regimens in all women of childbearing potential. Instead, these women should use the efavirenz based combination in first line. Additionally, adolescent girls between the age group 10-15 should also be initiated or maintained on TLE***.</p> <p>However, the government says this is only an interim recommendation outside the guidance. They say that if a woman of child bearing potential wants DTG, "despite being counselled", they are able to access DTG based formulations.</p>	<p>LIMITED ACCESS</p> <p>In Zambia a circular was issued stating that women will not get a choice to take DTG at all, even if on contraceptives. Subsequent information from the government denies this.</p> <p>If Zambia is following the interim guidance and not providing women, even those on contraceptives, with DTG, the approach would be one of the most restrictive in the region.</p>	<p>DTG has been rolled out in all facilities for men and women not of child bearing potential.</p>	<p>A new circular should be urgently issued outlining that all women are able to make an informed choice on whether or not to take DTG.</p>

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National Guidelines (or proposed language for guidelines) & interim circulars	What does this mean for women's ability to access DTG?	DTG rollout	What do activists want?
<p>The Zimbabwean guidelines will be published on 1st December 2018.</p> <p>The Department of Health convened an adoption committee consisting of two parts. Firstly, the National Medicines and Therapeutics Policy Advisory Committee (NMTPAC) defined the content of the guidelines. Secondly, the committee has conducted consultations to develop the operational service delivery manual. 14 dialogues were held across the country including women living with HIV between 15 to 50 years. The consultations have discussed DTG, the safety concerns, and the accessibility of contraceptives.</p>	<p>NO ACCESS</p> <p>While women do not yet have access to DTG, the consultative approach being taken by the Zimbabwean health department and their involvement of civil society is progressive.</p> <p>While consultations took place to operationalise the guidelines, women living with HIV were not consulted on the content of the guidelines.</p>	<p>Zimbabwe will be rolling out TLD next year in June in order to first finish stock of TLE.</p>	<p>Activists are watching to see if the final guidelines will allow women of reproductive age to have a choice with regard to DTG use.</p> <p>DTG should urgently be rolled out for the health benefits of people living with HIV in Zimbabwe.</p>

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Why are we concerned?

While we are cautious, it is worth remembering that initially efavirenz also seemed to increase neural tube defects upon wider roll out. Women were initially denied access and instead given nevirapine – a drug with known severe side effects at the time – putting their health on the line for an unconfirmed link to neural tube defects, later shown not to be a true risk.

The conservative stance being taken in restricting women's ability to choose DTG, echoes other age-old struggles for women to be able to make choices about their own health. In this instance, policy makers are rushing to change treatment guidelines to recommend that DTG be reserved only for men and for women above 50 years of age. In doing so they are taking away women's right to make an informed choice over their own bodies and health needs.

Women of childbearing age have the right to make an informed decision on whether they want to use DTG or not. The Tsepamo data is as yet not conclusive, and is one study from a single country. We do not know if DTG causes birth defects when taken during conception. On the other hand, DTG's side effect profile of decreased risk of development of drug resistance, decreased costs, and superior ability to suppress high viral loads late in pregnancy, make it an important option for use in the region.

All women should be provided with information and treatment literacy in order to weigh up the safety concerns on both sides and make their own choice over their bodies.

What do we demand?

1. Women living with HIV need better access to treatment information

To ensure better levels of information around antiretroviral choices it will be critical for there to also be community education and treatment literacy. However, the reality is that certain governments are not willing to fully and quickly invest in treatment literacy efforts. In order to urgently begin this engagement at a ground level, it will be necessary to ensure financing specifically assigned to people living with HIV led community groups able to carry out this work effectively.

2. Women living with HIV must be involved in the decision-making process

Women living with HIV must be involved in all aspects of policy and process surrounding DTG usage. This need was vocally expressed by a forum of women living with HIV organised by AfroCAB in July 2018⁹ – and in protest during the International AIDS Conference¹⁰. However, in some countries where women are empowered and seeking audience with governments and policy makers, they are either not invited to participate or are invited as a “token” and their sentiments ignored. We demand women living with HIV are meaningfully engaged in the policy process.

3. Women must be able to access contraceptives and abortions

DTG usage must go together with improved access to a range of contraceptive options and termination of pregnancy (TOP) services to allow women to plan for pregnancies when or if they want them, regardless of HIV status or ARV treatment choice. However, the reality is that often contraceptives are unavailable, inaccessible or unaffordable. For instance, in South Africa in recent months there have been ongoing reports of various stockouts and shortages at primary health facilities. In Botswana, all women are being given DTG based regimens, this while contraception is not readily available, and termination of pregnancy is illegal unless medically indicated.

Governments across the region must strengthen access to sexual and reproductive health (SRHR) services, better integrating SRHR services with HIV services, and ensure that all evidence-based contraceptives are available to the women who want them.

We also take issue with language around only allowing DTG to women using ‘safe’ or ‘reliable’ forms of contraceptives. In some cases, we know that these terms are referring to healthcare worker controlled long term methods of contraception including the IUD and implant, methods that rely on a healthcare worker to discontinue. User controlled methods such as the pill, condoms and even the injection would not be deemed ‘safe’ or ‘reliable’ given that women are in control of using, or returning to use them. Inherently, in this rhetoric women are seen as not able or not trusted to effectively adhere to a contraceptive they have chosen.

4. We need a feminist approach to DTG rollout, with women living with HIV at the front

Right now, the reality is that men will get to take DTG and in most cases women who want to take it will not. Many women who do not want to have children will not be provided with DTG. Many women using condoms will not be provided with DTG. Many women on all other forms of contraceptives will not be provided with DTG. In this policy environment women are being viewed simply as vessels to procreate. Women should not be forced to take, or not take, any medicine against their will!

5. We need action from governments, WHO, and donors that put women first

The WHO has a role to play in ensuring equitable and informed access to DTG for women. This must include

1. WHO organising regional meetings to facilitate open, frank discussions with more conservative countries, alongside countries that are recommending DTG for women of childbearing age;
2. WHO providing a new circular/document, with community review, clarifying the guidance in order to encourage countries to allow women to make informed decisions; and
3. WHO urgently counselling countries on access to DTG for pregnant women (> 8 weeks gestational age) as some countries are switching women during pregnancy, creating potentially increased risk of vertical transmission; national guidelines are inconsistent.

Donors such as PEPFAR and the Global Fund to Fight AIDS, Tuberculosis and Malaria must assist governments in the transition to DTG based regimens. Not only through the procurement of medicines, but by strengthening health systems and ensuring enough trained healthcare workers in order to provide adequate information to women to make an informed choice. Funders should finance people living with HIV led efforts to educate and mobilise communities on treatment literacy about ARV treatment options.

Overall there needs to be many more studies like Tsepamo that look at these types of issues. It is unacceptable that there are still so many unknowns – and that some studies with important results remain unpublished.

Access to quality and dignified healthcare services is everyone's human right, including women. Too often women are left behind in the health system, despite being the largest seekers of health services at facilities. Taking away the right of women living with HIV of reproductive age to choose the best treatment option for them is a violation of their rights. The right of women to access the highest attainable standard of health should not be curtailed and programmes in countries should not be allowed to discriminate, offering one regimen for men and women past reproductive age, and another for women of reproductive age.

Lotti Rutter and Maureen Milanga are Associate Directors of International Policy & Advocacy at Health GAP based in South Africa and Kenya respectively.

www.healthgap.org
www.spotlightnsp.co.za

lotti@healthgap.org
maureen@healthgap.org

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