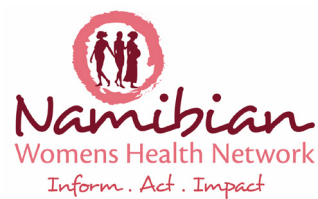


# Our Rights - Our Lives - Our Decisions!

A brief about ARV choices for women and girls living with HIV as a human right, with dolutegravir as a focus









We acknowledge and thank all those who supported the development of this document and, in turn, support our voice. In addition to all the named logos we also thank those who signed this in their own capacity: Consolata Achieng Opiyo (Kenya); Eunice Sinyemu (Zambia); Francine Ngehale (Cameroon); Florence Riako Anam (Kenya / S Africa); Fungai Murau (Zimbabwe / UK); Jacquelyne Alesi (Uganda); Mamoletsi Moletsi (Community of Women Living with HIV/AIDS Lesotho); Maura Elaripe Women Affected By HIV and AIDS (WABHA INC. PNG); Mwenya Chiti (Zambia); Nalwanga Resty Tendo (Uganda); and Patricia Asero Ochieng (Kenya).

[Citation: Our Rights – Our Lives – Our Decisions! A brief about ARV choices for women and girls living with HIV as a human right, with dolutegravir as a focus, 2019, Salamander Trust and partners. https://salamandertrust.net/project/the-dolutegravir-debate/](https://salamandertrust.net/project/the-dolutegravir-debate/)


A blue silhouette of a woman with curly hair, wearing a tank top and leggings, shouting into a megaphone. She is positioned on the left side of the page, facing right. The background is a light blue gradient with abstract, darker blue shapes at the top.

## Key Messages

Women and girls living with HIV in all our diversity have the right to access life-saving Antiretroviral therapy (ART). This is embedded in numerous human rights, including the rights to the highest attainable standard of health, to life, privacy, to scientific progress, to be free from discrimination and to gender equality.

Practices which directly or indirectly affect our choices, including barriers to treatment and goods, whether it is concerning access to ARV treatment options or contraceptive options or the combination of these, undermine human rights and have grave consequences, not only on our mental and physical health but in all spheres of our lives.

Now more than ever, we insist that all WHO departments, and all governments alike recognise our rights to be engaged in decisions that affect our own lives and those of our children, should we choose to have them. It is time that countries respect and implement the women-centred, rights-based approach, as set out in the [2017 WHO Guideline on the sexual and Reproductive Health and Rights \(SRHR\) of women living with HIV.<sup>1</sup>](#) Policies will not work without recognising our rights, and may undermine the effectiveness of investments. Engage us as active participants. Listen to us. Respect our autonomy. Give us the information we need, enable us to make informed choices – and support us in those choices, whatever they may be. This is the route to effective and ethical policy-making and programming.



Our choices should not be removed from us. Access to DTG CANNOT be solely defined by our potential, or an assumed, biological capacity to have children irrespective of our age, HIV status, profession, drug use status, and our sexual orientation or gender identity (SOGI). This approach excludes our access to DTG through the fact that in most places we face considerable barriers to access to contraceptive information and methods, and a chronic lack of integration of HIV and SRHR services, including for family planning.

We have, over many years, repeatedly asked:

- to be meaningfully engaged in policy that affects our own lives;
- that WHO upholds a stronger rights-based approach to DTG access; and a consistent women centred, adolescent-responsive/friendly and rights-based, gender-equitable approach to our health;
- to strengthen integration around HIV and sexual reproductive health programmes and services for women, including adolescent girls and young women, living with HIV. This includes the persistent and urgent need for a constant, reliable supply of a method mix of contraceptive options offered to women in all our diversity.

Too often, discussions ABOUT, and decisions made FOR women living with HIV in all our diversity, do not reflect our own priorities and treatment preferences. The WHO HIV Department's May 2018 response to DTG is the latest manifestation of the top-down, bio-medical approach to HIV which has repeatedly and consistently failed to engage with or respond to the rights and priorities of women including adolescent girls and young women, living with HIV. Almost 40 years into the epidemic, it is time for real change. We conclude that it is essential that WHO instead now leads by example, making use of its own 2017 WHO SRHR Guideline, as it encourages countries to adopt a framework which upholds and respects our fundamental SRHR. This includes our rights to informed, non-judgmental choice and support with regard to all our treatment, contraceptive and other SRH options as women, including adolescent girls and young women, living with HIV.

**The recommendations in here are important – Please act on them! (Pg. 12-16)**

# Introduction

Women and girls living with HIV, in all our diversity, have the right to access life-saving Antiretroviral therapy (ART). This is embedded in numerous human rights, including the rights to the highest attainable standard of health, to life, privacy, to scientific progress, to be free from discrimination and to gender equality. In fact, Antiretrovirals (ARVs) are listed in the World Health Organization's (WHO) model list of essential medicines that must be made available and affordable to all.<sup>2</sup>

A critical component of the right to health requires that states ensure access to a range of available treatments that are best suited to individual patients. Respect for women's bodily integrity requires that women and girls, in all our diversity be informed about the available treatment options; their benefits and side effects and that women and girls' autonomy be respected in making informed decisions regarding our treatment options. Furthermore, all women and girls, irrespective of our HIV status, age, profession, drug use status, and our sexual orientation and gender identity (SOGI) have the right to decide whether or not we want to have children. This includes the right to contraceptive access based on informed choice. Practices which directly or indirectly affect our informed choices, including barriers to treatment and goods, whether it is concerning access to ARV treatment options or contraceptive options or the combination of these, undermine human rights and have grave consequences, not only for our mental and physical health but in all spheres of our lives.

## What do we mean by 'in all our diversity'?

When we refer to women living with HIV in all our diversity we acknowledge that we include: heterosexual women, women who are lesbian, bisexual, transgender; women who use drugs; sex workers; adolescent girls and young women; women who are currently or have previously been incarcerated, detained or are homeless; women who are economic or political migrants; women who are indigenous; and women living with disabilities.

At the heart of the Sustainable Development Goals (SDGs) is the commitment to ensuring that no one is left behind.<sup>3</sup> This recognizes that often the most marginalized populations, which include women and girls living with HIV in our diversity, are those whose interests are often disregarded, negatively impacting their lives, including their health. Ensuring participation by those most affected and marginalized in all levels of policy development, including at the UN and at the national and local level, is central to the realization of human rights and to ensuring that SDG targets are met - including those regarding health, gender equality and participation, to name a few.

This brief is developed by women, including young women living with HIV. It explores our rights to ARVs in general, and specifically reflects our voices and concerns over recent measure taken which restrict access to Dolutegravir (DTG), after the issuance of a WHO statement on the subject. Now is the time to reaffirm our commitment to the SDGs and uphold global norms: to support and encourage inclusion in decision making; to address intersecting inequalities facing women in all our diversity; and to commit to ensure our human rights are respected and upheld in our treatment choices.

# Background

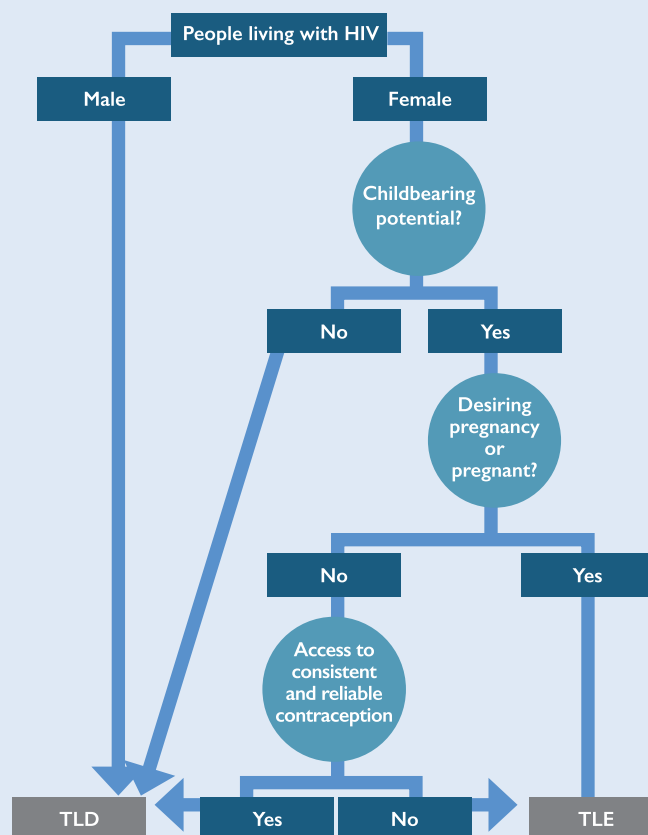
## WHO May 2018 Signal on Dolutegravir (DTG)

Barriers to treatment access and to 'options' for women living with HIV have become increasingly visible since May 8, 2018 when a WHO HIV Department warning<sup>4</sup> caused mixed reactions. The warning (known as a 'signal') cited a potential risk of neural tube defects (NTDs) for babies born to women taking DTG during conception and pregnancy in Botswana. The WHO statement, based on its 2016 ARV guideline, recommended that pregnant women already on DTG should 'not stop their ARV therapy'; but that "Antiretroviral (ARV) therapy for women of childbearing age, including pregnant women should be based on drugs for which adequate efficacy and safety data are available; an efavirenz-based regimen is a safe and effective firstline regimen". The statement added that: "If other first-line ARVs cannot be used in women of childbearing age, DTG may be considered in cases where consistent contraception can be assured". This signal and the response of some governments caused high levels of consternation and frustration amongst many women, adolescent girls and young women living with HIV, whose access has been impacted as a result.

Thirty-nine women living with HIV representing 18 countries, met in Kigali in July to discuss the safety signal regarding women taking DTG. Their resulting statement expressed clear recommendations to policymakers, including the meaningful engagement of women living with HIV, and a stronger rights-based approach to DTG access.<sup>5</sup>

Later in July 2018, after this and many other [strong reactions and statements](#) from civil society, WHO released [updated recommendations on first-line and second-line antiretroviral regimens and post-exposure prophylaxis and recommendations on early infant diagnosis of HIV](#). This update cited the 2017 [WHO Consolidated guideline on the Sexual and Reproductive Health and Rights \(SRHR\) of women living with HIV](#) (hereafter called the 2017 WHO SRHR Guideline) and highlighted the urgent need for a consistent women-centred, adolescent-responsive/ friendly and rights-based, gender-equitable approach.<sup>8</sup> Whilst this WHO guidance narrative is an improvement on the May signal, in that it focuses on women-centred decision making, there is a flow chart (see Figure 1) that remains problematic: for example it indicates that women who are not on birth control should automatically be placed on regimens other than DTG.

Fig.1 Diagram from WHO July 2018 document



<sup>a</sup> TLD (fixed-dose combination of TDF + 3TC + DTG) could be considered for pregnant women identified as receiving or starting ART later in the pregnancy (second and third trimester), although the switch to TLE (fixed-dose combination of TDF + 3TC (or FTC) + EFV) should be ensured after delivery in case the woman does not have access to reliable contraception. TLD can be safely used in adolescents weighing more than 30kg.

<sup>b</sup> Women should be advised on the possible effects of TLD on the pregnancy outcome and on the available contraceptive methods. Consistent and reliable contraception implies that contraceptive methods are widely available and easily accessible to the population, especially long-acting contraceptive methods and dual contraceptive methods with condoms.

<sup>c</sup> TLE is a safe and effective ART option for women desiring pregnancy or currently pregnant to use until the signal of potential risk of neural tube defects associated with using DTG in the periconception period is confirmed refuted.



This advocacy brief sets out to explain why advocates call for more effective and ethical strategies for decision making about HIV treatment options for women living with HIV in all our diversity, at all levels, moving forward.

## **The Tsepamo Study**

The finding which prompted WHO's May 2018 signal came from preliminary unscheduled analysis of an ongoing birth surveillance study of all women giving birth at eight sites in Botswana (the Tsepamo study), which reported that “four women out of 426 who conceived whilst taking DTG gave birth to infants who had NTD”<sup>6</sup> in pregnancy. (This is a rate of approximately 0.9%, compared with approximately 0.1% for infants of women taking other ARVs). The next formal analysis will be released in April 2019 and will include the tracking of women who were already taking DTG from conception before the recent change in guidance. The Tsepamo study has now been expanded from eight to 18 sites, increasing surveillance of all births from 45% to 72% in Botswana. The next analysis will include: neglected tropical diseases (NTDs); all major malformations; and other adverse birth outcomes (stillbirth, preterm birth, ‘small for gestational age’<sup>7</sup> and neonatal death).

## **What Causes Neural Tube Defects**

The exact causes of NTDs are unknown. Many different factors, including our genetics, what we eat, and environmental factors, are known to play a role. Research shows that “getting enough folic acid [from our healthcare provider] (also known as folate or vitamin B9) before conception and early in pregnancy can greatly reduce the risk of spina bifida and other NTDs”<sup>8, 9</sup> for all women planning a pregnancy. So it is important to ensure that folic acid supplements, starting before conception, form one part of a protective strategic approach to good perinatal care for all women, especially in resource-poor settings.<sup>1</sup>

## **About Dolutegravir**

As noted in a recent civil society policy briefing, [Dolutegravir in Southern & Eastern Africa and the Right to Choose](#),<sup>10</sup> DTG is effective; well tolerated; easy to take; has few interactions with other medications; has a high barrier to resistance; and can be cost-effective. DTG is not yet available in all countries. Some have already launched it, others are in the process of doing so.

## **Country Responses**

Countries where DTG was already available for general use by all adults with HIV before the WHO May 2018 signal have responded with concern to the WHO statement. Other countries, where DTG roll-out had been planned for 2018 and 2019, have responded by either totally or partially delaying the introduction of DTG altogether.

Some countries have entirely banned our access to DTG if we are of reproductive age (ie between 15 and 49 years), or have limited it if healthcare providers consider that we are not able to access and use consistent and reliable contraception.

---

<sup>1</sup> NB Folic acid alone may not be enough to protect against NTDs however.



These issues are further compounded for women from marginalised communities such as women who use drugs. Women who use drugs are often grossly misinformed by health workers about the impact of their drug use on pregnancy before even beginning to have options presented such as DTG. In addition, instead of being offered contraceptive options, women who use drugs are particularly subject to coerced sterilisation.

This blanket approach means that our choices as individual women are effectively removed from us.<sup>2</sup> Our access to DTG is now solely defined by our potential, or an assumed, biological capacity to have children – a huge issue for women of reproductive age in all our diversity. This approach also effectively excludes our access to DTG through the fact that in most places we face considerable barriers to access to contraceptive information and methods, and a chronic lack of integration of HIV and SRHR services, including for family planning.<sup>11, 12</sup>

In addition to these challenges, many of us also face violence and discrimination in our homes as well as in healthcare settings. These different forms of violence both act as additional barriers<sup>13, 14</sup> to treatment access, as well as barriers to safe condom negotiation, with resulting unwanted/unplanned pregnancies and/or STIs. Some governments' responses to the WHO's May signal have thus only added to the many complexities that we already face in accessing our SRHR.

“ It is critical to not just view a pregnant mother, or any woman of childbearing potential, as a vessel for a baby, but as an individual in her own right, who deserves access to the very best, evidence-based treatment available and the right to be adequately informed to make a choice that she feels is best for her. As a result, women must not be forced to accept any one ARV regimen. All women should be able to make an informed choice for their own treatment and we call on key stakeholders to join us and help us make access to TLD, and improved health services, a reality for everyone. ”

AfroCAB Statement, 23 July 2018, Kigali, Rwanda.

## What have we learnt since May?

A comparative observational study (June 2018) was conducted in Botswana on the safety of DTG-based or efavirenz-based antiretroviral treatment started by women when they were already pregnant. Findings showed “no significant differences by regimen in the individual outcomes of stillbirth, neonatal death, preterm birth, very preterm birth, small for gestational age (SGA), or very SGA”. The findings stated that “adverse birth outcomes were similar among pregnant women who initiated DTG-based and efavirenz-based ART. DTG-based ART can be safely initiated in pregnancy”. This study also noted that “although further studies are needed to determine the safety of dolutegravir exposure from conception and to confirm its efficacy for prevention of mother-to-child HIV transmission, these results should pave the way for wider use of dolutegravir in pregnancy throughout the world”.<sup>15</sup>

Also, research presented at the International AIDS Conference in July 2018 showed that from 1 May to 15 July 2018 there were no more reported NTDs among infants born to women taking DTG at conception in the Tsepamo study. (which includes all births to all women at 18 sites). “Since May, there have been two more neural tube defects among this cohort: one in an infant exposed to DTG started during pregnancy at eight weeks’ gestation and one birth to an HIV negative woman”.<sup>16</sup>

On Tuesday 13th of February (just before this booklet was published) a webinar, organised by HIV Online Provider Education (HOPE) took place on ART safety in Pregnancy - updates from Botswana. Dr Rebecca M. Zash highlighted ‘no major updates’. To listen to this webinar click [here](#) to register and access the recording.



### More than mothers

The recent questions raised about the safety of DTG during conception are important to us as women living with HIV in all our diversity. No one cares more about our babies than we do.<sup>17,18</sup> At the same time we also highlight that we are more than just mothers – we are human beings. Many of us desire children at different stages of our reproductive years and some of us choose not to have children at all.<sup>19</sup> The relationship between treatment, women's choice, and giving birth to healthy babies should not become a zero-sum game where our rights are violated and we are left with no choices. These issues are more challenging for women who use drugs living with HIV, who are often pressured into terminating their pregnancy.<sup>20</sup> Due to drug prohibition and punitive criminalisation, women who use drugs face limited access to maternal healthcare and other human rights violations, including misleading information about the effects of drugs during pregnancy; forced and/or coerced abortion and sterilization; and the removal of children from women's custody,

#### Making Sure We and Our Babies Are Safe:

A paper published in 2017 - [Values and preferences of women living with HIV who are pregnant, postpartum or considering pregnancy on choice of antiretroviral therapy during pregnancy](#), identified six factors as being important to pregnant women living with HIV when considering ART:

- a desire to reduce vertical transmission
- a desire for the child to be healthy
- concern about side effects to the foetus
- a desire for oneself to be healthy
- concern about side effects
- concern about pill burden.

regardless of their parenting ability. This structural violence leaves women who use drugs reluctant to seek medical services.<sup>21</sup> The right to the highest attainable standard of health includes ensuring acceptable ARV treatment as well as the right to safe motherhood and is interrelated to the right to decide whether or not to have children. These rights are guaranteed to all women, including women living with HIV in all our diversity.

The global response to HIV must uphold and affirm these rights as well as the rights to scientific progress, to information and to informed choice.<sup>1</sup> The 2017 WHO SRHR Guideline spells this out clearly: yet its clear statements were overlooked in the May 2018 signal. Informed access to treatment options is our right and should not just be a privilege for the few who can afford private health care.

**A Woman-Centred Approach:** 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.

Source: 2017 WHO SRHR Guideline<sup>8</sup>

## **DTG for children too**

Almost all of us live in countries struggling to provide access to medication that already exists. In addition, issues surrounding DTG extend beyond the barriers we as women face. To add to the concerns above, we also urgently require action around access to DTG for the children in our care, given that DTG is still not available in paediatric formulae for babies and children below 15kg. Progress in creating this dosage is and has been too slow.

## **Facing multiple complexities – needing rights-based supportive policies and programmes**

Conversations amongst women living with HIV around the world over the past months since May have demonstrated once more how very complex our lives are as women living with HIV. The ‘intersectionalities’ in our lives – for example, our age, race, disability, ethnicity, where we live, our key population status as women who use drugs or engage in sex work, our SOGI, livelihood, economic status, the way society and law regulate and criminalise our behaviour, and many other variables - often define our ability to access services and how we are received and treated by service providers. This factor cannot be overlooked or ignored when formulating effective and ethical healthcare.

In Figure 2 on page 13, the dimensions of each woman’s life, depicted by each outlying circle, at least need to be considered when discussing ARV choices with each individual woman who is expected to place herself in the care of healthcare providers. These are in addition to the intersectionalities described above. If women in all our diversity, including women whose labour and behaviour is criminalised or stigmatised, were able to access the care, information and support listed in the central circle, as a basic package of services, then the work of policy makers and healthcare providers would be much easier and we would feel much better informed and supported as we make these complex decisions about our lives. For many women, the connection between the impact of gender inequality, structural violence in healthcare and punitive legal frameworks must be understood as reinforcing each other. Structural gender inequality impedes the development of effective policies that adequately understand and address the rights of all women.<sup>21, 22</sup>

As the 2017 WHO SRHR Guideline emphasises, ensuring a woman-centred, rights-based, gender-equitable approach to our linked SRH and HIV-related health care, is fundamental to ensure that we can be supported as we navigate the multiple and ever-changing contexts and complexities of our life-stages when living with HIV.

We recognise these multiple complexities because we each live and experience many of them every day, and as they change throughout our lives.

Now more than ever, we insist that all WHO departments, and all governments alike recognise our rights to be engaged in decisions that affect our own lives and those of our children, should we choose to have them. It is time that countries respect and implement the women-centred, rights-based approach, as set out in the 2017 WHO SRHR Guideline. Policies will not work without recognising our rights, and may undermine the effectiveness of investments. Engage us as active participants. Listen to us. Respect our autonomy. Resolve punitive legal frameworks that do not enable us to access care, treatment and support. Give us the information we need, enable us to make informed choices – and support us in those choices, whatever they may be. This is the route to effective and ethical policy-making and programming.



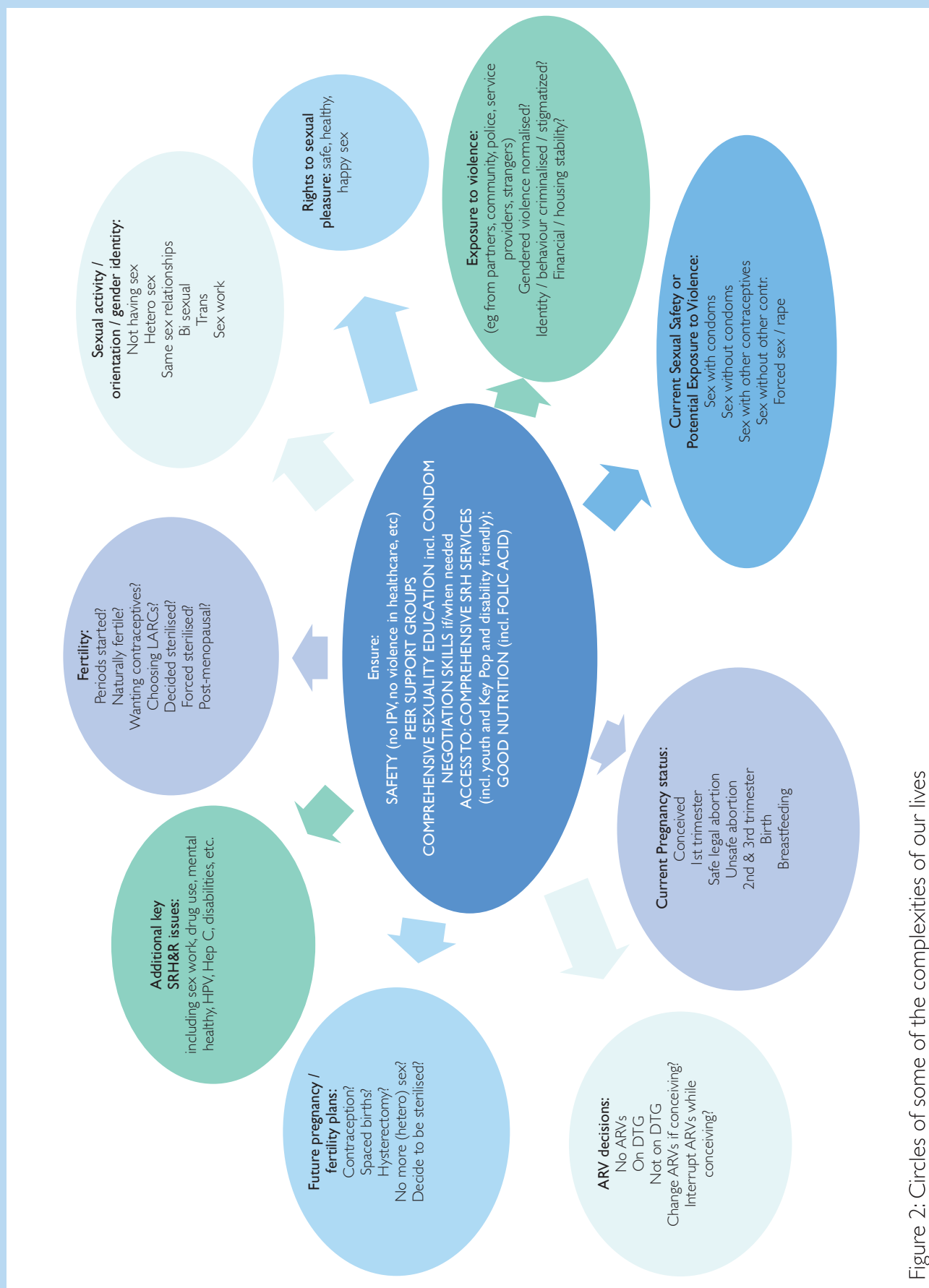


Figure 2: Circles of some of the complexities of our lives

## Conclusion and Recommendations

This advocacy brief is about much more than DTG. It is about the rights of women living with HIV in all our diversity and across our life stages to access informed, supportive choices regarding our HIV treatment; contraception; and other SRHR-related information, education and services. What has happened in 2018 is a wake-up call to us all that the publication of the 2017 WHO SRHR Guideline is not enough without it being upheld by all those who should be its standard bearers.

The WHO HIV Department's May 2018 warning, and the response of governments in many countries resulted in severe limitations to DTG for women aged 15-49. DTG is accessible only to men and to women not of child bearing potential. In some countries it can be prescribed to women only if we are taking 'reliable' contraceptives.

These events are further examples of the structural denial of our sexual and reproductive rights, and the violence against women which has characterised the global response to HIV for decades.<sup>22</sup> We know that both intimate partner violence (IPV), including rape and marital rape, and structural violence are key treatment access barriers for women living with HIV.<sup>9, 10</sup>

“ Some of us have heard stories of some women living with HIV, who cannot now access DTG, preferring to abandon taking medication altogether in order to have a child, rather than go back to Efavirenz. We ask why a woman should be expected to go back to using a drug that doesn't suit her, when she should be getting all the support required to achieve her own SRHR, whatever form that might take. ”

In the case of IPV, it is often hard enough for a woman to uphold her right to choice over if, when; how; and with whom to have sex; or to take ARVs, without the risk of violence, unplanned pregnancy and/or STIs. Early child marriage is one extreme institutionalised form of IPV in many settings, which is of special concern, where young brides have virtually no agency over their SRHR.<sup>23</sup>

Structural violence is an ongoing issue for many women in healthcare settings. It is a serious barrier especially for women who are criminalised for their migration status, drug use, sex work, SOGI, who are exposed to sexual violence at the hands of state and non-state actors. Too often research, policies and programs still prioritise a narrow top-down bio-medical approach, focusing on 'elimination of mother to child transmission' of HIV and, in this case, on NTDs. If we as women do not 'conform' for any reason to the narrow clinical criteria recommended in programs with such narrow bio-medical results, then we are the ones who are criticised, rather than the approach.<sup>13</sup>

Instead, the WHO SRHR Guideline recognises and recommends the critical importance of a holistic woman-centred approach to these issues, which ensures that all the structural barriers we face are recognised, and minimised and that our own SRHR, including our own psychosocial well-being, are placed front and centre of the response. The 2017 WHO SRHR Guideline was shaped and informed by a [global values and preferences](#) survey which Salamander Trust undertook in 2014. This highlighted that global health policy should be doing its utmost to support our rights to informed choice over if, which and when we should choose to take ARVs, and over linked comprehensive sexual and reproductive health services, as key components of the holistic umbrella goal of upholding our SRHR – for women in all our diversity. As our global values and preferences survey clearly stated, when our own SRHR are

achieved, the health and well-being outcomes for others around us, including our babies, are far more likely to be positive also.

No matter what the outcome in early 2019 regarding the effects of DTG during pregnancy and conception, one aftermath of this DTG experience is that women's trust in global and national leadership needs to be rekindled. In the spirit of rebuilding this trust we make the following strong recommendations to UN partners (WHO and UNAIDS), governments, researchers and donors alike.

## WHO

- **UPHOLD A WOMAN-CENTRED, RIGHTS-BASED APPROACH:** The WHO HIV Department must uphold its own policies and commit to meaningfully engage women living with HIV in all our diversity at all stages of design and review; and should encourage national ministries to work with and engage women living with HIV in their own review, planning, implementation and monitoring and evaluation processes. This will also require more cohesive and concerted coordination across WHO departments that work to address HIV and the SRHR of women, including sex workers, women who use drugs, and adolescent girls and young women living with HIV. Too often, discussions ABOUT, and decisions made FOR women in all our diversity, do not reflect our priorities and treatment preferences. The WHO HIV Department's May 2018 response to DTG is the latest manifestation of the top-down, bio-medical approach to HIV which has repeatedly and consistently failed to engage with or respond to the rights and priorities of women living with HIV in all our diversity. Almost 40 years into the epidemic, it is time for real change. We conclude that it is essential that WHO instead now leads by example, making use of its own 2017 WHO SRHR Guideline, as it encourages countries to adopt a framework which upholds and respects our fundamental SRHR. This includes our rights to informed, non-judgmental choice and support with regard to all our treatment, contraceptives, and other sexual and reproductive health options as women living with HIV in all our diversity.
- **ENABLE US:** Support women living with HIV to engage with a [generic Checklist](#) created by women living with HIV and community activists to guarantee effective implementation of the 2017 WHO SRHR Guideline. The uptake of any guideline should include the meaningful engagement of women living with HIV in all our diversity. This of course includes funding for us to engage in our own self-care; and for our networks, to undertake global and national advocacy work.<sup>26, 27</sup>
- **LEARN FROM THIS EXPERIENCE:** Many women in countries where DTG has been rolled out are now being denied access to DTG as their first choice. WHO must learn from this experience, follow your own organisation's Guideline and avoid future crises for many women in all our diversity, as we learn more about DTG – and about other ARVs as they evolve. The WHO HIV Department must ensure that firm procedures are in place moving forward, so that it meaningfully researches WITH us our options, realities and treatment priorities, and takes these onboard, BEFORE warnings are issued that have serious implications for women living with HIV in all our diversity. We are ready to work with you on this – connect us, engage with us, use our Real-World Evidence<sup>28</sup> to inform your work, to achieve value-based, effective and ethical healthcare.<sup>29</sup>

- **PROMOTE ENABLING ENVIRONMENTS THAT UPHOLD OUR RIGHTS:** Respecting informed choice also means supporting women in all our diversity, especially sex workers, women who use drugs, adolescent girls and young women, to negotiate safe condom and other contraceptive use with our partners if we want this; and enabling women to take ARVs regularly without fear of violence from partners and punitive laws, if we want to do so.
- Efforts must address the structural barriers, including gendered violence, legal barriers to accessing contraception for married and young women, criminalisation of abortion, same sex sexual behaviour and identities, sex work and drug use, and structural violence in healthcare settings.
- Respecting informed choice also means enabling women to make supported decisions around interrupting our ARVs during contraception and the first three months of their pregnancy - if our viral load is low and our CD4 count is high - should we not wish to switch back to Efavirenz.

“Assure voluntary and informed consent: Programmes must promote individual's rights to decide on their own treatment and must accept their right to refuse services. All services should be voluntary, without any sense of coercion or conditional requirements for obtaining services or commodities. Information on services and treatment should be clear, explicit and in the appropriate language, and also provided in a way that is accessible for women with limited or no literacy.”

WHO 2017 SRHR Guideline

## Governments

Irrespective of whether your Ministry of Health has already introduced DTG or not, we call on you to:

- **RESPECT OUR RIGHTS TO INFORMED CHOICE AND GRANT ACCESS TO DTG:** As women, in all our diversity, we have the right to full information and options to make our own choices and balance potential risks against potential benefits regarding ARV choices and pregnancy options. Should we decide not to proceed with the pregnancy we also have the right to access safe, legal abortion services and post-abortion care.
- **DISAGGREGATE DATA ABOUT ALL WOMEN, INCLUDING WOMEN OF ‘CHILD-BEARING POTENTIAL’:** We request that countries take a more disaggregated view of women, especially adolescent girls and young women in all our diversity. The ages of 15-49 years cover a vast diversity of different circumstances, needs, and priorities for adolescent girls, younger and older women. Many women in this huge age-group have no intention of getting pregnant. Some are still in school and are not yet sexually active, others may be single and have no wish for children. Others may be lesbians, living in countries that do not acknowledge their sexuality, who may have no risk of unplanned pregnancy. Others may be regular condom or pill users, on long-acting contraceptives, sterilised, infertile or transgender and some women living with HIV, experience early menopause. (Yet others may have started their periods much earlier than at 15 years<sup>30</sup> – and this may be of particular concern in the context of girls exposed to child marriage)<sup>21</sup>. All of these contexts further challenge the rationale and validity of a blanket DTG ban for 15-49 year olds.



- **FOCUS ON INTEGRATION OF HIV AND SRHR SERVICES AND STRENGTHEN THE CONTRACEPTIVE METHOD MIX:** DTG is the ARV of choice for many women over Efavirenz. Since access to DTG is dependent on 'effective' contraception, countries must seize this opportunity to ensure and strengthen integration around HIV and sexual reproductive health programmes and services for women in all our diversity. This is key for all women but we emphasise access for adolescent girls and young women; sex workers and women who use drugs, migrants, women with disabilities, living with HIV who have greater barriers to accessing services. This includes the persistent and urgent need for constant, reliable and up-to-date information about, and supply of, a method mix of contraceptive options offered to women in all our diversity, and support to women to ensure safe condom negotiation (to avoid (other) STIs as well).

“In Botswana, we don't have a problem with healthcare providers giving women an informed choice around options: our problem is that if all of us decided to take contraceptives, we would very fast face a national stock-out.”

- **PROVIDE EFFECTIVE CONTRACEPTION:** We define 'effective contraception' as part of a package that upholds our choice and provides:
  - Information and support that enables women in all our diversity to select a contraceptive option of our own informed choice instead of being prescribed something that is considered 'best for them'.
  - Ensure services are safe and accessible, especially for those of us who are young, unmarried women, sex workers, women who use drugs, 'child brides' and women with disabilities, who continue to face additional stigma, discrimination, violence and violations of our SRHR. These violations include lack of, or limited information to make informed choices on the type of contraception to use, shortage of contraception commodities to prevent unintended pregnancies and, in some cases, forced and coerced sex, contraception and sterilization.<sup>31</sup>

As an example of good practice: Women in Kampala have described how at the Infectious Diseases Institute (IDI) women who choose to take DTG can choose the contraceptive method they want, including condoms, and/or the pill, and are supported throughout the process.

- Ensure funding and support for self-help peer support programmes led by and for women living with HIV, especially during pregnancy. These can often provide us much needed specialist support which is defined and enriched by shared lived experiences.<sup>32,33</sup>
- Invest in gender transformative community-based programmes (such as SASA! and *Stepping Stones*) and related approaches that enable women to negotiate safer sex and that also work to reduce IPV.<sup>34</sup>

“ In Bolivia, pregnant women are very afraid any medication will hurt the babies, so they just disappear, although tested in antenatal control. That is for women who discover they are living with HIV AFTER getting pregnant. If the woman knows her HIV positive status, she will prefer not to get pregnant or even have early abortion; though some get pregnant anyway due to the demands of men. The ones connected to self-support groups are more informed. Others I don't think they even consider quitting Dolutegravir since this will be available in 2019. ”

- Train and support healthcare providers to improve the quality of their clinical care, ensuring that health care providers have the necessary knowledge, skills and understanding to deal with the complex priorities and rights of women in all our diversity. This is especially important for sex workers, women who use drugs and adolescent girls and young women.<sup>35,36</sup>
- **WOMEN WHO WISH TO CONCEIVE WHILE ON DTG, NEED TO KNOW THE ABSOLUTE RISKS**, so that we may consider these and the effects of DTG on our pregnancy plans and have access to effective and accessible contraceptive services which work for us. Policies and programmes should respect and respond to the specific intentions, desires and priorities of each and all of the women and girls concerned. Our own individual intrinsic rights to informed supportive choices in healthcare should be paramount at all times; not just our ability to have babies. We also require – and have the rights to - ongoing support, regardless of the informed choices that we make and of any adverse outcomes.

**'CONVERSATIONS INVITING CHANGE' \*:**

This is the name of a program for healthcare providers. It describes seven strategies they can use, to develop advanced communication skills, to promote good healthcare and more effective medical outcomes:

- Conversations
- Curiosity
- Contexts
- Complexity
- Challenge
- Caution
- Care

\* Launer J., Narrative-based practice in health and social care: Conversations inviting Change. 2018. Routledge.

"In Canada, the national CHIWOS and women-centred HIV care program teams ensure that all research includes women living with HIV as Co-Principal Investigators. This has been seen to greatly enhance the quality of research findings and uptake."  
Dr Mona Loutfy,  
Women's College  
Hospital, University of  
Toronto, Canada.

## Researchers

**INCLUDE WOMEN, INCLUDING ADOLESCENT GIRLS AND YOUNG WOMEN LIVING WITH HIV IN RESEARCH:** More than 50% of adults living with HIV globally are women, yet we remain largely underrepresented in HIV clinical studies. This is because the majority of clinical trials and curerelated research take place in high income countries, where the HIV epidemic is predominantly driven by men who have sex with men.<sup>37, 38</sup> Where studies of women do exist, these are most often confined to the issue of pregnancy, a vital area of interest in relation to women, but not representing the totality of female experience.<sup>39</sup> In addition, the questions being asked are not providing the answers we need to fundamental concerns, such as 'will I be treated with care, respect and dignity?, will my anxieties be heard? will my questions be respected?' We have long called for our meaningful involvement in design, implementation and evaluation of all programmes that concern our lives.<sup>40</sup> As stated above, this is not just because of our intrinsic rights to meaningful involvement. It is also to make services become effective and ethical, with good health outcomes. This, ultimately, is a win-win for us all.

The 2017 WHO SRHR Guideline: "Research about women living with HIV should be conducted with, by and for women living with HIV, as equal research partners. Research that is pursued and funded in this area should include justification for why it is important to women living with HIV". The guideline goes on to say..... "One underlying reason for the limited evidence base on women living with HIV is that these women are often excluded from participation in research. Discouraging the use of HIV-positive status as a criterion for exclusion from study participation is important in order to build the evidence base. Funders should ensure that they support studies that include women who are living with HIV and who voluntarily agree to participate. They should ensure that these women are supported in understanding the research and that research results are reported back to these participants. In addition, the financial precarity which many women living with HIV face needs to be acknowledged and addressed when meaningfully engaging communities of women living with HIV, as their time and involvement is often not compensated".

To access a full repository of key resources on DTG, including statements and advocacy conducted by women living with HIV and other members of civil society click [here](#).

Full disclosure: this brief was commissioned by UNAIDS and is the product of discussions amongst women living with HIV from Latin America, Africa, West and East Europe, Asia, North America, the Caribbean and the Pacific. The two Salamander Trust-associated contributors to this brief take DTG themselves and have received project-related funding for work from ViiV Healthcare in the past year. That funding has no connection whatever with the production of this brief.

NOTE: whilst beyond the specific focus of this particular advocacy brief, we are also concerned to see that the WHO recommendation to move from a DTG-based regimen to an EFZ-based regimen still includes tenofovir. This despite a recent BMJ article raising concerns about the use of tenofovir in pregnancy, since it may increase the risk of neonatal death and pre-term delivery. We note from a letter from the co-authors under this article that a BMJ peer reviewer from WHO stated: "I really like their analysis and approach - its beautifully done" and "cannot find flaw with the methodology". We look forward to WHO urgently responding to this question also about the safety of this ARV for the fetus for women during pregnancy. Whatever the overall answer, we call once more for women's rights to fully informed choice to be upheld. Until women can trust that we are really receiving full available judgment-free information and choice about ARVs, their potential benefits and risks, many women will continue to vote with their feet and avoid healthcare settings altogether.

1. Consolidated Guideline on the SRHR of women living with HIV. WHO 2017, <https://apps.who.int/iris/bitstream/handle/10665/254885/9789241549998-eng.pdf;jsessionid=49908E88759EBCCC53A47FF63E0BAA2A?sequence=1>
2. 20th WHO Model List of Essential Medicines (March 2017) <http://apps.who.int/iris/bitstream/handle/10665/273826/EML-20-eng.pdf?ua=>
3. Ensuring that no one is left behind: Envisioning an inclusive world in 2030 .. Sustainable Development Knowledge Platform <https://sustainabledevelopment.un.org/index.php?page=view&type=20000&nr=291&menu=2993>
4. Statement on DTG – Geneva 18 May 2018 Potential safety issue affecting women living with HIV using dolutegravir at the time of conception [http://www.who.int/medicines/publications/drugalerts/Statement\\_on\\_DTG\\_18May\\_2018final.pdf](http://www.who.int/medicines/publications/drugalerts/Statement_on_DTG_18May_2018final.pdf)
5. IAS2018: Communique of the Kigali Dolutegravir Stakeholder Meeting of African Women Living with HIV, hosted by AfroCAB - Project Inform <https://www.projectinform.org/hiv-news/ias2018-communique-of-the-kigali-dolutegravir-stakeholder-meeting-of-african-women-living-with-hiv-hosted-by-afrocab/>
6. Dolutegravir in Southern & Eastern Africa and the Right to Choose Maureen Milanga and Lotti Rutter November 2018
7. To read more about all these terms click <https://www.urmc.rochester.edu/encyclopedia/content.aspx?ContentTypeID=90&ContentID=P02411>
8. What causes neural tube defects (NTDs)
9. <https://patient.info/health/anaemia-leaflet/folic-acid-deficiency-anaemia>
10. Dolutegravir in Southern & Eastern Africa and the Right to Choose Maureen Milanga and Lotti Rutter November 2018
11. Biddlecom AE et al., Protecting The Next Generation: Learning from Adolescents to Prevent HIV and Unintended Pregnancy, New York: Guttmacher Institute, 2007.
12. Facts on the Sexual and Reproductive Health Of Adolescent Women in the Developing World, Guttmacher Institute And International Planned Parenthood Federation (IPPF) April 2010
13. Key barriers to women's access to HIV treatment: A global review, UN WOMEN, <http://www.unwomen.org/en/digitalibrary/publications/2017/12/key-barriers-to-womens-access-to-hiv-treatment>
14. In Women's Eyes: Key Barriers to Women's Access to HIV Treatment and a Rights-Based Approach to their Sustained Well-Being Luisa Orza, Emily Bass, Emma Bell, e. Tyler Crone, Nazneen Damji, Sophie Dilmitis, Liz Tremlett, Nasra Aidarus, Jacqui Stevenson, Souhaila Bensaid, Calorine Kenkem, Gracia Violeta Ross, Elena Kudravtseva, and Alice Welbourn <https://cdn2.sph.harvard.edu/wpcontent/uploads/sites/125/2017/12/Orza.pdf>
15. Comparative safety of dolutegravir-based or efavirenz-based antiretroviral treatment started during pregnancy in Botswana: an observational study
16. No additional neural tube defects among a further 170 preconception dolutegravir exposures in Botswana: Tsepamo study (July 2018) – I-base
17. Values and preferences of women living with HIV who are pregnant, postpartum or considering pregnancy on choice of antiretroviral therapy during pregnancy. Lyubov Lytvyn Reed A Siemieniuk Sophie Dilmitis Allyson Ion Yaping Chang Malgorzata M Bala Veena Manja Reza Mirza Rene Rodriguez-Gutierrez Hassan Mir Laura Banfield Per Olav Vandvik Susan Bewley BMJ Open 2017; 7 - Published Online First: 11 Sep 2017. <https://bmjopen.bmj.com/content/bmjopen/7/9/e019023.full.pdf>



18. Siemieniuk RAC, Lytvyn L, Ming JM, Mullen RM, Anam F, Otieno T, Guyatt GH, Taylor GP, Beltrán-Arroyave C, Okwen PB, Nduati R, Kinuthia J, Luma HN, Kirpalani H, Merglen A, Lesi OA, Vandvik PO, Agoritsas T, Bewley S. Antiretroviral therapy in pregnant women living with HIV: a clinical practice guideline BMJ 2017;358:j3961 doi.org/10.1136/bmj.j3961. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5590100/>
19. Give Women Living with HIV full information on the benefits and risks of DTG, Contraceptives for them to exercise choice ICWEA, 2018
20. Center For Reproductive Rights: Punishing Women for Their Behavior During Pregnancy An Approach That Undermines Women's Health and Children's Interests
21. Women4GlobalFund Statement Support – Don't Punish Women who use drugs, June 26, 2018, <http://women4gf.org/2018/06/w4gfstatement-support-dont-punish-women-who-use-drugs/>
22. Orza L, Bewley S, Chung C, Crone E, Nagadya H, Vazquez M et al. "Violence. Enough already": findings from a global participatory survey among women living with HIV. Journal of the International AIDS Society <https://onlinelibrary.wiley.com/doi/full/10.7448/IAS.18.6.20285>
23. UNICEF et al: Understanding the Relationships between HIV and Child Marriage: Conclusions from an Expert Consultation. Article Under Review.
24. Salamander Trust (2014). Building a safe house on firm ground: key findings from a global values and preferences survey regarding the sexual and reproductive health and human rights of women living with HIV. WHO, Geneva <http://salamandertrust.net/wpcontent/uploads/2016/09/BuildingASafeHouseOnFirmGroundFINALreport190115.pdf>
25. Translating Community Research Into Global Policy Reform For National Action: A Checklist For Community Engagement To Implement The WHO Consolidated Guideline On The Sexual And Reproductive Health And Rights Of Women Living With HIV [http://www.unaids.org/sites/default/files/media\\_asset/who\\_sshr\\_guideline\\_checklist\\_en.pdf](http://www.unaids.org/sites/default/files/media_asset/who_sshr_guideline_checklist_en.pdf)
26. National Standards for Peer Support in HIV <http://hivpeersupport.com>
27. International Community of Women living with HIV Eastern Africa (ICWEA), October 2014
- Are Women Organisations Accessing Funding For HIV & AIDS?: A Rapid Situation Analysis Of Access To Funding By Organisations Of Women Living With HIV, Gender And Women Human Rights Organisations In Uganda <http://www.icwea.org/wpcontent/uploads/downloads/2015/04/ICWEA-Report-Are-women-accessing-funds-for-HIV.pdf>
28. Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices, <https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM513027.pdf>
29. What is value-based healthcare, and why is it so important? <https://www.weforum.org/agenda/2018/01/what-is-value-based-care>
30. Lacroix AE, Bhimji SS. Physiology, Menarche. [Updated 2019 Jan 11]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2018 Jan. <https://www.ncbi.nlm.nih.gov/books/NBK470216/>
31. Give Women Living with HIV full information on the benefits and risks of DTG, Contraceptives for them to exercise choice ICWEA, 2018
32. Beres et al <https://www.tandfonline.com/doi/full/10.1080/09540121.2017.1317324>
33. <https://salamandertrust.net/wp-content/uploads/2018/04/BHIVA20184MPoster.jpeg> and more refs to come here...
34. Miles to go—closing gaps, breaking barriers, righting injustices, UNAIDS Section on violence (page 132)
35. Conversations Inviting Change <https://vimeo.com/user4672630/review/169849023/7067282731>
36. Conversations inviting change Postgraduate Medical Journal 2008;84:4-5. <https://pmj.bmj.com/content/84/987/4> (Also need more recent ref for this)
37. Curno, J, Mirjam et al. A Systematic Review of the Inclusion (or Exclusion) of Women in HIV Research: From Clinical Studies of Antiretrovirals and Vaccines to Cure Strategies. JAIDS Journal of Acquired Immune Deficiency Syndromes: 1 February 2016. Vol 71, Issue 2. Last accessed June 2016.
38. Understanding HIV in women: Spotlight on the gender gap in HIV research, ViiV Healthcare's Global Director of Clinical Virology Development, Romina Quercia, [https://www.viivhealthcare.com/our-stories/partnerships-key-populations/understanding-hiv-in-womenspotlight-on-the-gender-gap-in-hiv-research.aspx#\\_edn3](https://www.viivhealthcare.com/our-stories/partnerships-key-populations/understanding-hiv-in-womenspotlight-on-the-gender-gap-in-hiv-research.aspx#_edn3)
39. Loutfy, M. R., Sherr, L., Sonnenberg-Schwan, U., Walmsley, S. L., Johnson, M., d'Arminio Monforte, A., Women for Positive Action (2013). Caring for women living with HIV: gaps in the evidence. Journal of the International AIDS Society, 16(1), 18509. doi:10.7448/IAS.16.1.18509
40. Chitembo A, Dilmitis S, Edwards O, Foote C, Griffiths L, Moroz S et al. Towards an HIV-free generation: getting to zero or getting to rights?. Reproductive Health Matters. 2012;20(39):5-13.

