

# Communique of the Kigali Community Meeting on Dolutegravir and Weight Gain

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We, the 39 representatives of people living with HIV (PLHIV) from 21 countries in Africa, met in Kigali on February 26 and 27, 2020 to discuss the emerging data related to dolutegravir (DTG)-associated weight gain and hyperglycemia, and to develop a joint position on behalf of PLHIV.

## Key Outcomes

### Discussion

We deliberated on the emerging data on DTG-associated weight gain and hyperglycemia, and **based on the data currently available and the balance of these risks and DTG's benefits – reduced side effects, improved efficacy, and a high barrier to resistance – we determined unanimously that DTG should remain the preferred first-line regimen and be accessible to all.**

*“Every drug has side effects. The fact that it has a side effect does not mean that it should be taken away. We need to work on managing the side effects of drugs. DTG is a good drug and the best we have in Africa” – meeting participant*

Although this decision was reached unanimously, we recognize that DTG, like all antiretrovirals (ARVs), has associated risks of side effects, including a potential for increased weight gain. Importantly, in the ADVANCE trial, weight gain was associated with all ARVs included in the trial, specifically tenofovir disoproxil fumarate/emtricitabine/efavirenz (TDF/FTC/EFV), TDF/FTC/DTG, and tenofovir alafenamide (TAF)/FTC/DTG<sup>1</sup>. However significantly more weight gain was observed with TAF/FTC/DTG, and weight gain with TDF/FTC/DTG arm, while lower than the TAF/FTC/DTG arm, was higher than in the TDF/FTC/DTG arm. Furthermore, weight gain did not plateau with TAF/FTC/DTG. However, after three years of DTG introduction and over two-thirds of patients on DTG-based regimens in Botswana, **severe weight gain** was only observed in very rare instances, underscoring the need for more research in low- and middle-income countries (LMICs) to understand varying risk profiles across different geographies and populations and to inform patient choice.

The risks associated with EFV use in settings with high rates of background EFV resistance must be recognized and factored into the evaluation of risks and benefits, just as the potential risk of weight gain for some patients on DTG must be weighed against the benefits of DTG. Further, the short- and long-term side effects of EFV cannot be ignored simply because it has been in use longer than DTG. We, and others in our community, encounter severe everyday challenges using EFV, including constant tiredness, nightmares, dizziness, lethargy, changes in body shape, and headaches. As one of our colleagues expressed:

*“I cannot go back to EFV. I will not go back to EFV” – meeting participant*

**We conclude that DTG should be made available, with monitoring for side effects such as weight gain and hyperglycemia, and appropriate clinical guidance and management.** We call for urgent action in finding a better tolerated alternative to EFV for those who cannot tolerate DTG but do not wish to go back to EFV. The following are key takeaways and recommendations for policymakers:

### Takeaways:

1. We reviewed the risks and benefits associated with DTG, and affirm that DTG must remain as the first-line preferred regimen – **policy makers and stakeholders must maintain access to DTG.**
2. We believe that people should be **fully informed about the benefits and possible side effects of DTG.** As the beneficiaries, we believe in our ability to make informed decisions and we demand a choice in our treatment options.

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<sup>1</sup> The ADVANCE trial showed weight gain and metabolic syndromes at 96-week across all three studied regimens, with the greatest weight gains among the TAF/FTC+DTG group (7.7 kg), followed by the TDF/FTC+DTG group (4.2 kg) and the TDF/FTC+EFV group (2.1kg).

3. We strongly believe in our diversity – we will **not be forced or coerced to switch regimens based on restrictive guidelines** that do not take account of our personal circumstances.
4. We believe that PLHIV that **experience DTG-based weight gain and/or hyperglycemia should be given the option to switch**, if they choose to. However, **we must have better alternatives than EFV**.
5. We call for the **expanded use of TAF and urge clear pathways**, including research into pregnancy and TB, are established for accelerated access to TAF.
6. We believe that there is an **important place for TAF with certain population groups**, including people over 50 with bone and/or renal issues and adolescents. More data is needed to see where TAF may be beneficial over and above these specific populations.
7. In light of DTG associated weight gain and the concerns highlighted by the 2018 WHO safety signal related to NTDs, we strongly believe that this is an opportunity for **integrating care for non-communicable diseases (NCDs) and sexual and reproductive health (SRH)** within HIV treatment programs in order to achieve universal reproductive health care for all.
8. We, the recipients of care, must be involved in **local, national, regional and global decision-making** in regards to our treatment access.
9. We call for commitment from donors, Ministries of Health and partners to **strengthen health systems, include routine monitoring for weight gain and metabolic disorders**.

### **Action Required**

**We are calling for all PLHIV to be able to make an informed choice about their own treatment.** We call on key stakeholders to join us and help us make access to DTG, and improved health services, a reality for everyone.

1. We call for **expanded research and evidence generation in LMICs**, with data sharing across countries, to fully understand the context and specific nuances of weight gain and metabolic disorders associated with use of DTG and TAF across different geographies and settings.
2. We call on national programs to ensure that **people initiating treatment are receiving baseline screening and routine monitoring for weight gain and hyperglycemia, and to integrate screening for other diseases within HIV care**, including NCDs, as a holistic package of care.
3. We call on **all programs to include nutrition and wellness counseling in HIV clinical practice**. Healthcare workers should be capacitated to counsel PLHIV on side effects and risks associated with HIV treatment, as well as to help clients make lifestyle changes, should they choose to, instead of being forced to switch treatment.
4. We note that the current data on DTG associated weight gain appears to be elevated in combination with TAF. We call for **more research on TAF**, through further studies in LMICs, to discover if this associated weight gain occurs in combination with another non-integrase strand transfer inhibitor (INSTI).
5. We call on all stakeholders to **empower communities through treatment literacy**, particularly on DTG-based regimens and possible side effects to clarify prevailing misconceptions and fears.
6. We call on the World Health Organization (WHO) and researchers to **urgently explore alternatives to EFV, including reviewing data on new generation non-nucleoside reverse transcriptase inhibitors (NNRTIs) with better resistance profiles**, and identifying what research is required to pave the way for using such drugs in LMICs.
7. We recognize the benefits that **smaller pill size may have with adherence and appreciate how cost savings for drug can be applied to strengthen health systems and increase treatment access**. We urge policy makers to factor these considerations, in combination with the clinical evidence, into decision-making.



## A VOICE FOR MORE EFFECTIVE AND BETTER TOLERATED MEDICINES FOR PLHIV IN AFRICA

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