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

(c) Salamander Trust, IAC July 2018

DTG and East and Southern African Where are we now?

8 October 2019

Salamander Trust
ON THE RIGHT(S) TRACK

DTG & East and Southern Africa (ESA): Where are we now?

JACQUE WAMBUI- OCTOBER 8, 2019

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Making Noise at the right time

The Kigali meeting emphasized the need to involve the community in new product introduction rollout

- Major global bodies, donors, and partners, such as WHO, CHAI, and Unitaid recognized the **Kigali meeting as a global best practice**
- Going forward, organizations have been creating mechanisms to ensure that community is involvement is **routine**, not just a response to major events.

Kigali meeting, July 2018

The Johannesburg meeting brought WLHIV from 20 PEPFAR supported countries to discuss country experiences on DTG roll out post the cautionary note and WHO interim guidance released at IAS 2018

Making Noise at the right time

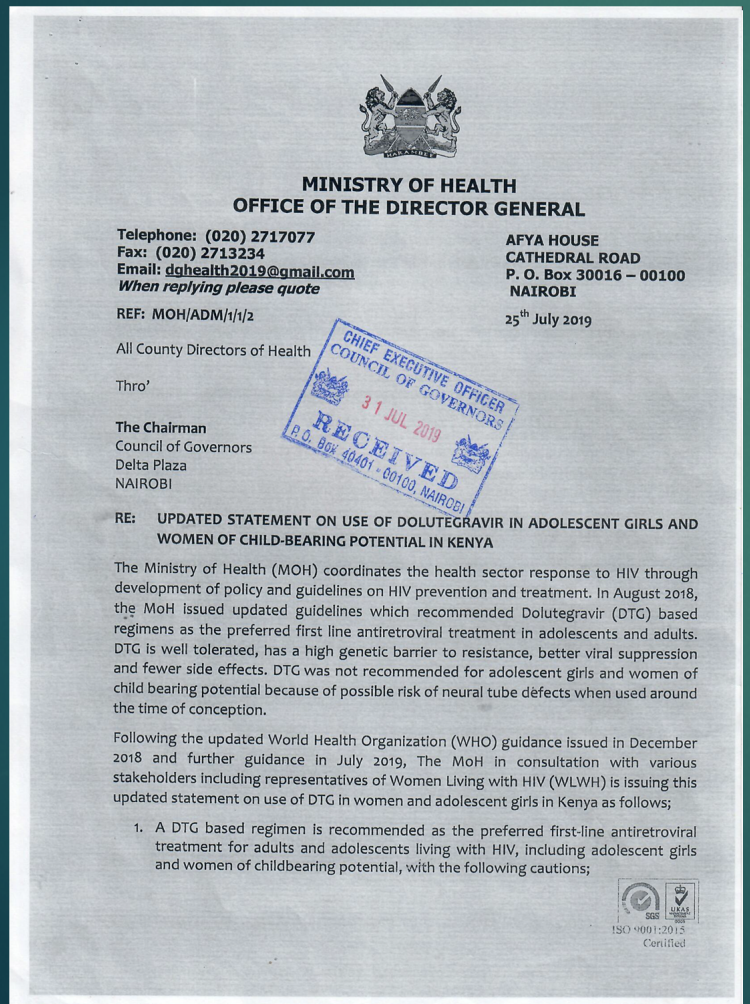
- A **communique** of the Community consultation was released.
- This communique fed into the IAS Forum white paper

Johannesburg meeting, November 2018

Access to DTG in Malawi

- Malawi, has access to Dolutegravir (DTG) through TLD. The transitioning process started in January this year, 2019.
- Earlier treatment guidelines provided for men, women beyond 45 years of age and those on permanent contraception to have access to the DTG-based regimen, TLD.
- The issue with this perspective was that of leaving behind women living with HIV (WLHIV) of child bearing age bracket. WLHIV falling within that age bracket felt they were being denied the right to a better treatment product, in the name of DTG. Advocated against the policy.
- Now anybody can access DTG, regardless of gender, age or reproductive status.

Access to DTG in Kenya



MINISTRY OF HEALTH
OFFICE OF THE DIRECTOR GENERAL

Telephone: (020) 2717077
Fax: (020) 2713234
Email: dghealth2019@gmail.com
When replying please quote

AFYA HOUSE
CATHEDRAL ROAD
P. O. Box 30016 – 00100
NAIROBI

REF: MOH/ADM/1/1/2

25th July 2019

All County Directors of Health

Thro'

CHIEF EXECUTIVE OFFICER
COUNCIL OF GOVERNORS
31 JUL 2019
RECEIVED
P.O. Box 40401 - 00100, NAIROBI

The Chairman
Council of Governors
Delta Plaza
NAIROBI

RE: UPDATED STATEMENT ON USE OF DOLUTEGRAVIR IN ADOLESCENT GIRLS AND WOMEN OF CHILD-BEARING POTENTIAL IN KENYA

The Ministry of Health (MOH) coordinates the health sector response to HIV through development of policy and guidelines on HIV prevention and treatment. In August 2018, the MoH issued updated guidelines which recommended Dolutegravir (DTG) based regimens as the preferred first line antiretroviral treatment in adolescents and adults. DTG is well tolerated, has a high genetic barrier to resistance, better viral suppression and fewer side effects. DTG was not recommended for adolescent girls and women of child bearing potential because of possible risk of neural tube defects when used around the time of conception.

Following the updated World Health Organization (WHO) guidance issued in December 2018 and further guidance in July 2019, The MoH in consultation with various stakeholders including representatives of Women Living with HIV (WLWH) is issuing this updated statement on use of DTG in women and adolescent girls in Kenya as follows;

1. A DTG based regimen is recommended as the preferred first-line antiretroviral treatment for adults and adolescents living with HIV, including adolescent girls and women of childbearing potential, with the following cautions;

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- DTG appears to be safe when started after the first trimester of pregnancy.
- Exposure to DTG at the time of conception and during first trimester of pregnancy may be associated with neural tube defects in infants.

2. Adolescent girls and women of child-bearing potential should be provided with all the information regarding DTG based regimen. This information should include the benefits and potential risk of neural tube defects with DTG use during the period of conception until the end of first trimester as well as benefits and risks of Efavirenz (EFV) based regimens and they should be supported to make informed treatment choices.
3. DTG should be used with caution during the period of conception until the end of first trimester.
4. An Efavirenz based regimen is safe and effective and can be used for adolescent girls and women of child-bearing potential during the period of conception until the end of first trimester.
5. Adolescent girls and women of child-bearing potential who do not intend to become pregnant are eligible to receive DTG and should be encouraged to use consistent and reliable contraception.
6. The MoH recommends a woman centered approach that adopts the perspectives and expectations of adolescent girls, women and their families with health care that respects their autonomy in decision making.

In light of the above directions, kindly note that DTG is available at KEMSA Stores and is ready for distribution as per the HIV Commodity Management Guidelines for patients in your care.

Thank you for your continued support.

Dr. J. Wekesa Masasabi
Ag. DIRECTOR GENERAL FOR HEALTH
Encl.

Copy to: County Executive Committee Member for Health (CEC)
County Chief Officers of Health (COH)
County Commissioners
County AIDS & STI Coordinators (CASCOs)

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Access to DTG in Zambia

- Zambia is rolling out TLD and have nearly 400.000 Plhiv on the new drug.
- There are also about 10,000 additional plhiv about to be enrolled on TAFED ie TAF DTG and FTC.
- All Women are included but can opt out

Access to DTG in South Africa

- The rollout of TLD has not started in South Africa after being put back several times since the Ministry of Health announcement regarding the transition. The latest date that was provided was 01 December 2019 where TLD will be launched. The rollout will start in a smaller scale before then.

Access to DTG in Mozambique

- From August 2019, DTG was officially approved to be administered to everyone (PLWHIV)who wishes to take it, including women at potential child bearing age
- BUT, for women who want to have children, and wish to continue taking DTG, they should sign an informed consent form

Access to DTG in Zimbabwe

- Zimbabwe is rolling out TLD in a phased approach. Roll out is slow because we have huge stocks of TLE 400 and 600. All Women are included and the barrier for effective contraception has been removed.
- Treatment literacy needs to be enhanced for communities especially now that the guidelines have been updated. Still a reluctance for both Nurses and patients to switch due to NTD safety caution.

Access to DTG in Uganda

- Uganda has revised the guidelines to include the WHO recommendations
- Now the challenge is to finish the big stocks of TLE which will slow TLD roll out.
- The use of consent forms has since been abandoned

Access to DTG in Tanzania

- DTG is being accessed but not in all health facilities as not all HCW have not been trained on the roll out
- Guidelines have been updated and recently translated to Swahili
- The Consent forms are in use for the WLHIV to access the drug. This is not sitting well with the community at all as literacy levels are quite low in Tanzania.

Country guidance on use of DTG among women of childbearing potential (WCBP) varies, but there is work that still needs to be done across all countries to ensure women have access to TLD.

1

Countries where WCBP can be given TLD regardless of contraception, following proper counseling and acknowledgment that risks/benefits have been fully explained

- **Consent forms create an unnecessary barrier** for women and should be removed.
- The community should be leveraged by the MOHs and partners to help **reverse the perceptions from the safety signa**l and be viewed as a central partner in this work to correct messaging.
- **Update communities on new WHO guidance** through community networks, forums, and mass distribution outlets, such as newspaper and radio.
- **Develop updated treatment literacy materials** for patients and healthcare workers, with input from communities, that clearly explain why the guidance has changed.

2

Countries where WCBP can be given TLD on "consistent and reliable contraception"

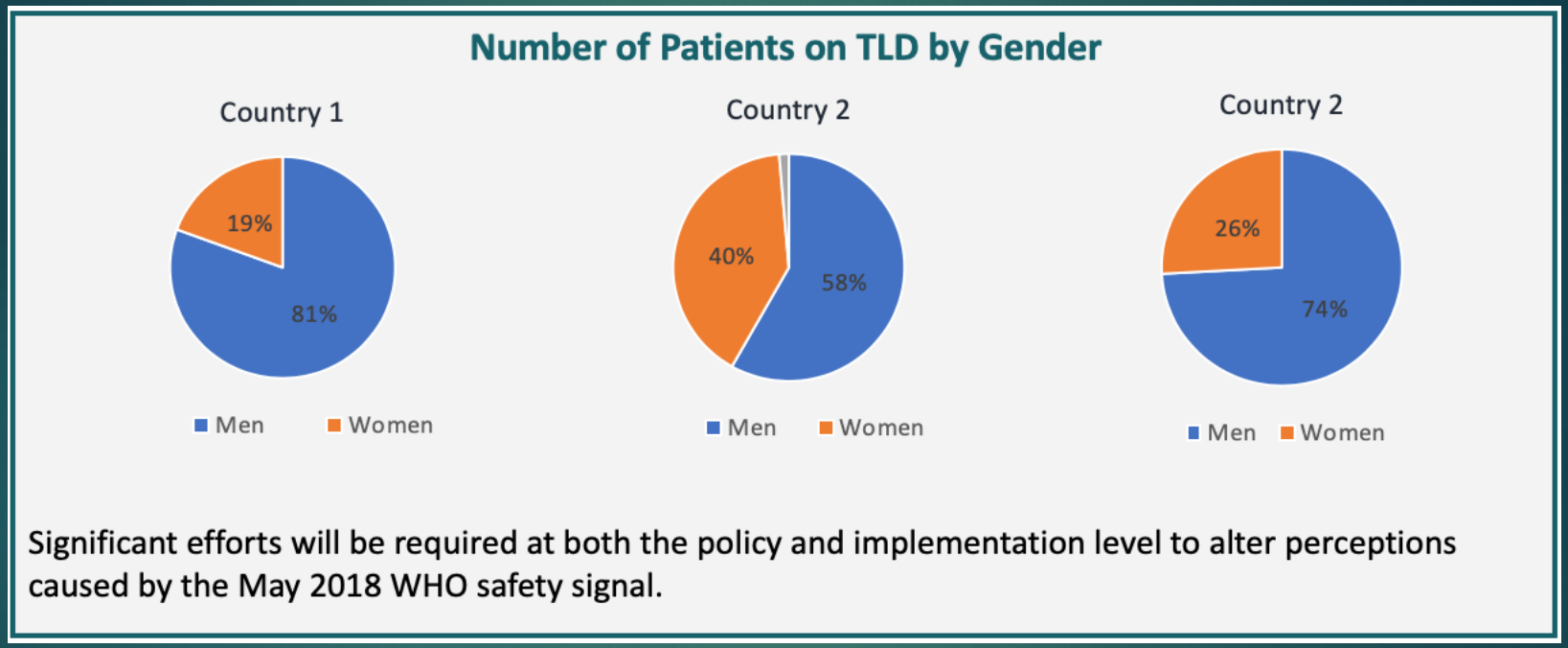
- More community advocacy is needed to lift restrictions for women of childbearing potential to access TLD.
- Engagement with communities, through community consultations and participation in national decision-making forums, can help inform updated guidance in alignment with the latest WHO recommendations (e.g. Zimbabwe community consultations).
- Ongoing collaborations with the community will be critical following any updates to the guidance to support the rollout of messaging around the guidance.

3

Countries where no WCBP can be given TLD

- Critical action is needed from all stakeholder to recommend removal of restrictions for women of child-bearing potential.
- Strong community advocacy should push MOHs to move quickly to review and update national guidance.

Data from countries shows that DTG safety signal has led to major gaps in women's access, which is lagging uptake amongst men. Barriers for women are likely to remain and community engagement will be essential to help bridge the gap.



Significant efforts will be required at both the policy and implementation level to alter perceptions caused by the May 2018 WHO safety signal.

The key gaps in SRH services brought to light by the safety signal offer an opportunity for a renewed focus on meeting the SRH needs of WLHIV to ensure that patients are able to obtain a comprehensive, rights-based, and integrated SRH/HIV package of care.

We cannot miss the opportunity to address this major gap that communities have been advocating around for years!

Countries have taken steps toward SRH/HIV integration – but more progress is needed to prevent widening gap in TLD access between men and women

To achieve the gold-standard 'one-stop shop' service delivery, actions are needed across domains including national policy, training, and supply chain

National working groups related to HIV and/or reproductive health should include representatives from across government departments	→	*For example, Zambia has added reproductive health dep't staff to TLD Introduction Steering Committee*
Clear responsibility for SRH service provision should be assigned to ART site staff through national guidelines or other official guidance	→	*For example, Cambodia and India have (or are adding) SRH guidance in their HIV treatment guidelines*
Training on comprehensive SRH service provision for ART staff should be integrated into TLD introduction training and other in-service ART training	→	*For example, Lesotho, Uganda, and a number of other countries are including SRH services in TLD training curricula*
Gaps / bottlenecks in the contraception supply chain should be addressed to ensure regular, rational delivery of commodities to ART site pharmacies	→	*For example, Eswatini is working to address equipment availability to enable all SRH services to be provided in ART room*

Key Takeaway

- Let's not lose momentum on:
  - SRH/HIV integration
  - Access to Viral load as VL in no longer a prerequisite for access to TLD
  - Scale up of TLD transition as we still have large stocks of TLE 400 and 600
  - Urgent need to update communities on new WHO ART guidance since most of the dissemination was done pre WHO Guidelines announcement in July 2019. The caution on TLD was so strong both patients and health care providers are reluctant to switch.

- There is a need to:
  - Strengthen treatment literacy and provider education

THANK YOU

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