



National roll-out of a dolutegravir-based first-line antiretroviral regimen among women of childbearing potential: a qualitative study with health system stakeholders in Uganda and South Africa

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Background & rationale

- Push for rapid roll-out of DTG in national HIV programmes. WHO 2018 guidelines recommended a cautious approach to DTG transition among women of childbearing potential.
- Rapid roll-out of a 'nuanced' transition among women of childbearing potential poses potential health system challenges.
- Historic evidence of health system challenges during transition of first line ART regimen in resource-constrained settings.



World Health
Organization

INTERIM GUIDELINES



UPDATED RECOMMENDATIONS ON
FIRST-LINE AND SECOND-LINE
ANTIRETROVIRAL REGIMENS AND
POST-EXPOSURE PROPHYLAXIS
AND RECOMMENDATIONS ON EARLY
INFANT DIAGNOSIS OF HIV

IN ACCORDANCE WITH THE 2016 CONSOLIDATED GUIDELINES
ON ANTIRETROVIRAL DRUGS FOR TREATING
AND PREVENTING HIV INFECTION

DECEMBER 2018

HIV TREATMENT

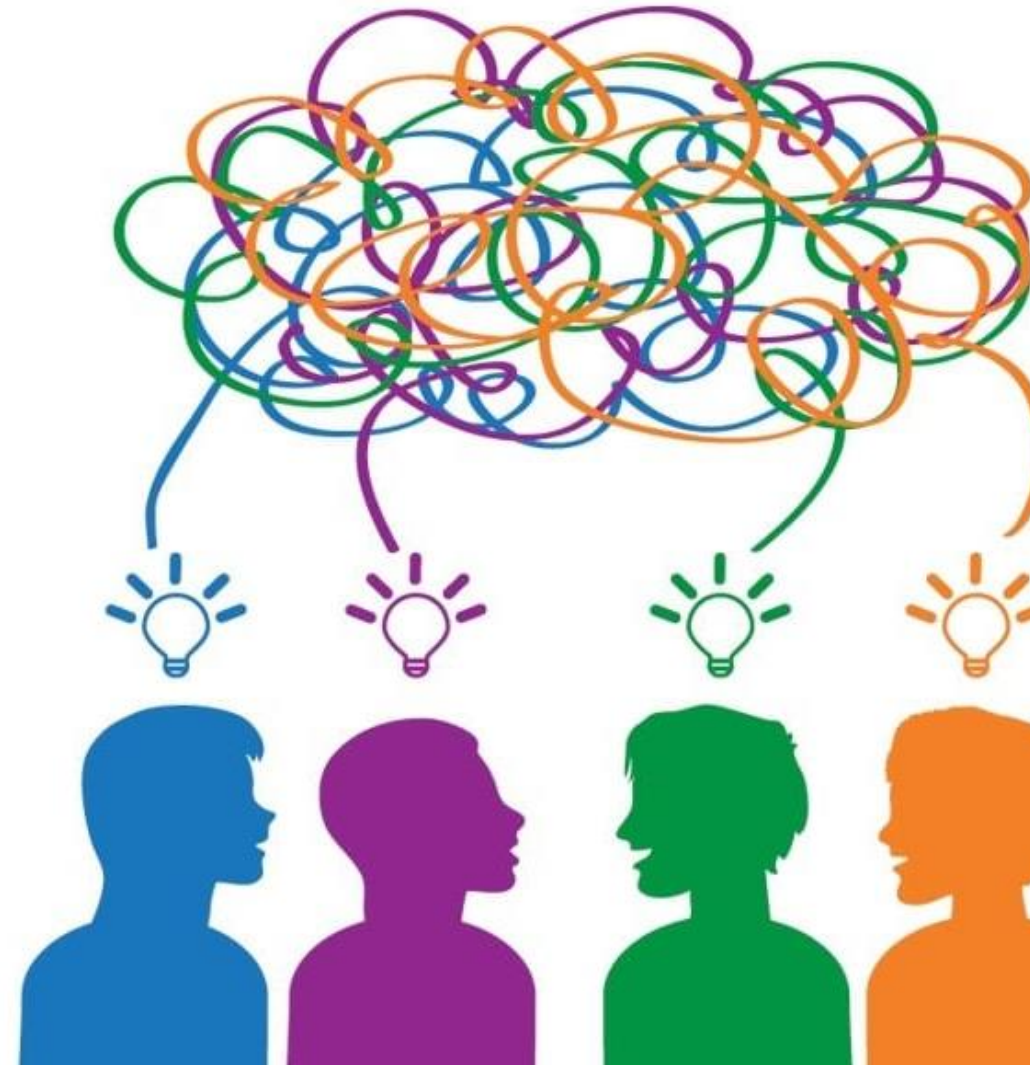
Study objective

To explore current and future health systems opportunities and challenges associated with the transition to DTG among women of child bearing potential in South Africa and Uganda.

Methodology: study participants

***Participant category	# Participants		
	South Africa	Uganda	International
MoH officials	2	2	0
Regulators	4	1	0
Researchers	6	3	1
Activists	0	3	2
Pharmacists/clinicians	0	3	0
HIV development Partners	1	2	1
Total	13	14	4

***Some participant categories overlap due to multiple roles



Key findings



Acceptability & uptake of dolutegravir at community level

- Difficulty in meeting community expectations.
- Potential resistance to transition feared among women who are stable on their current regimen.
- Birth defects risks of DTG a significant barrier to DTG uptake in communities.

“I think the challenge is managing expectations...We expect that many people are going to come in asking to be switched, and meeting this demand is going to be difficult because of the huge numbers involved in our ART programme.” (South Africa KII 6).

“People are going to take the neural tube defects news serious and because of that they will reject DTG...even if the woman likes it the man will tell her not to use it.” (Uganda, KI7)

Difficult to operationalise Informed choice

- Choice would promote adherence and equity.
- Difficult to ensure 'choice' in a context of deep-rooted patriarchy and paternalism.
- High illiteracy among women a major barrier to them making rational choices on ART.
- Weak counselling services in public health facilities would undermine effective treatment literacy and choice.

"... if you give them choice they will feel part of the decision about their treatment and are likely to adhere...." (South Africa KII 4).

"if a woman has not been to school it will be difficult for her to understand the risks.... Most of them end up doing what their husbands tell them to do... So as much as it is a good thing I don't this choice thing will work in our settings" (Uganda KII 5).

'Effective' contraception difficult to achieve

- Potential expansion of contraceptive options and improved family planning services.
- Deficient family planning services and lack of integration between family planning and HIV care.
- Difficult to operationalise 'reliable' or 'effective' contraception.
- Low uptake of long-acting contraception and challenges in contraception adherence.
- Challenge over how to deal with women who become pregnant while on DTG.

“What they [WHO] say ‘reliable method of contraception’? what does it mean in practice? Is it someone saying that they are not sleeping with anyone? Are condoms a reliable method of contraception? is it injectables? is hormonal contraception? So understanding community perspective is important” (South Africa KII 6).

“We need to make sure that contraception services are available in the ART clinics. That has been a weakness because in our health facilities the family planning clinic is usually on its own and ART clinic is on its own.” (Uganda KII 1).

Frequent stockouts predicted

- Concern about potential stockout of contraception commodities, especially long acting contraceptives.
- Low funding for contraception.
- Widespread concern about potential stockout and wastage of ART drugs.

“over the years we’ve been relying a lot on PEPFAR and Global fund money for our national programme but now the money is dwindling...They [PEPFAR] don’t like funding anything that is related to contraception.”
(Uganda KII 2)

“...how do you quantify choice? How do you say that for every 5 women who come into the facility 5 of them will chose to have dolutegravir, so it is difficult to plan to ensure that the right commodities are available?”
(Uganda KII 1)

Limited data on DTG use in pregnancy

- Limited data on the safety of DTG in pregnancy, especially in periconception stage.
- Paucity of data switching during pregnancy a hindrance to DTG use in late pregnancy.

“The issue of neural tube defect is making life difficult for us as we develop the guidelines. We need more data especially on whether it is safe in the peri-conception period and other stages of pregnancy. What we currently have does not give us the certainty that we need.”

(South Africa KII 7)

Lack of pharmacovigilance in pregnancy

- Greater recognition for DTG rollout to be accompanied with effective pharmacovigilance in pregnancy.
- Weak pregnancy pharmacovigilance.
- Underreporting and inadequate data.
- Pregnancy registry onerous, expensive and difficult to scale up.
- Pregnancy registries in South Africa rarely analysed and have limited feedback mechanisms.

“I don’t think our pharmacovigilance system in this country is efficient enough to follow up the roll-out” (Uganda KII 1).

“Spontaneous reporting, I don’t think is likely to provide too much robust evidence..... I don’t have too much confidence in being able to really properly address the question at hand” (South Africa KII 4).

“So that programmatic pharmacovigilance [pregnancy registry] side is weak, and the data are not coming out of that to be able to inform policy decisions” (South Africa KII 5).

Limited health worker capacity

- Limited health worker capacity to deliver a 'nuanced' ART services.
- Concern that a nuanced approach would lead to poor quality ART services.
- Limited application of lessons from previous transitions.

"... with our client load, low staffing norms, limited motivation of health workers, it will be hard for us to implement the counselling they [WHO] are asking for.... This is a big problem for the quality of ART service and the roll-out" (Uganda KII 3).

"There hasn't been training for about 11 or 12 years within the South African programme. We have just kind of been bashing along.... The switches we have had have not been particularly complicated. This one is going to be much more complicated. But it is also an opportunity to again re-emphasise the training that, as I say, hasn't really been happening for ages." (South Africa KII 2).

Conclusions

- Rapid change with limited evidence
 - DTG safety in pregnancy
 - ART switching in pregnancy
- Multi-sectoral effort to DTG transition
- Extensive community engagement
- Improved individual and institutional capacity
 - pharmacovigilance in pregnancy
 - counselling and family planning services
 - Training for health workers
- Learning from previous transitions



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