

Patient and Provider Experience of Using Dolutegravir in Resource Limited Settings: Acceptability Findings from Uganda and Nigeria

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Background

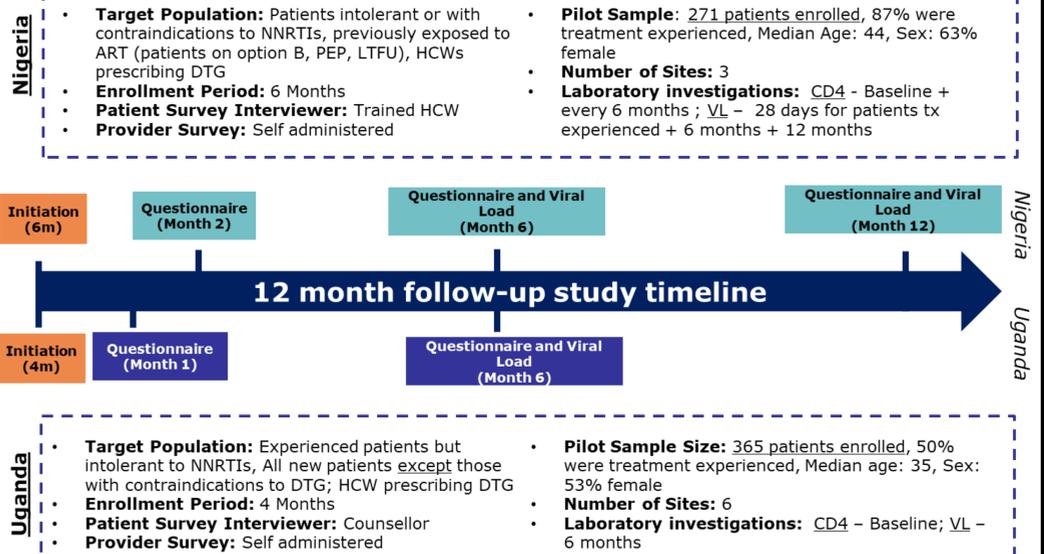
In 2016, Dolutegravir (DTG) was recommended as an alternative regimen from the World Health Organization (WHO) and as preferred in 2018. However, there is limited experience with DTG in low- and middle-income countries (LMICs) and in combination with the preferred nucleoside reverse transcriptase inhibitor (NRTI) backbone of tenofovir (TDF) with lamivudine (3TC). Beginning July 2017, CHAI partnered with the Ministries of Health (MOH) in Uganda and 3 high volume sites in Nigeria, two early DTG adopter countries, as part of a pilot study.

The objectives were to:

1. Understand barriers to scale-up and potential areas of concern which may inhibit the successful future roll out of DTG;
2. Understand the experience and acceptability of using DTG as part of a first-line regimen from the ART patient's perspective; and
3. Understand the experience and acceptability of prescribing DTG instead of an NNRTI, as part of a first-line regimen from the ART providers' perspective.

We are presenting 6 month findings from this study intended to facilitate the national rollout in Uganda and Nigeria, as well as other LMICs looking to use DTG.

Methods



Results: Patient Acceptability, Side Effects, and Viral Load

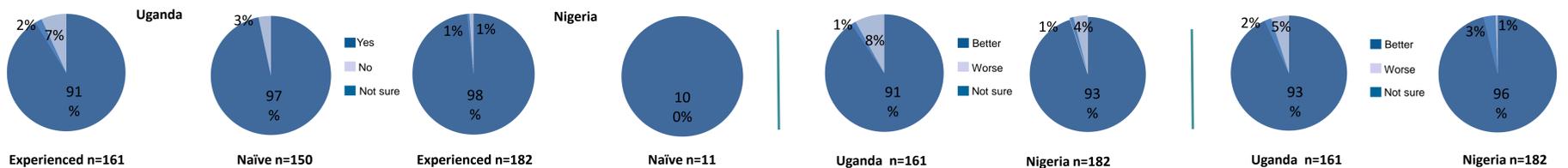
Patient Acceptability

Three questions were asked of experienced patients who had switched to DTG and one question of treatment naïve patients newly initiating treatment using DTG. The results demonstrated a high acceptability to a DTG-based regimen across both patient groups in both countries.

1. *Would you recommend this drug to a friend starting ART if you were given the chance to?*

2. *Compared to the HIV medication you were taking before, how well do you think this medicine might be working?*

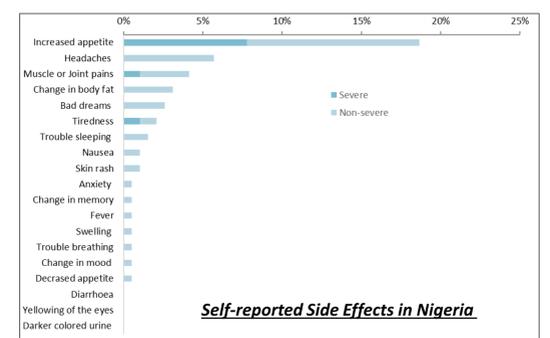
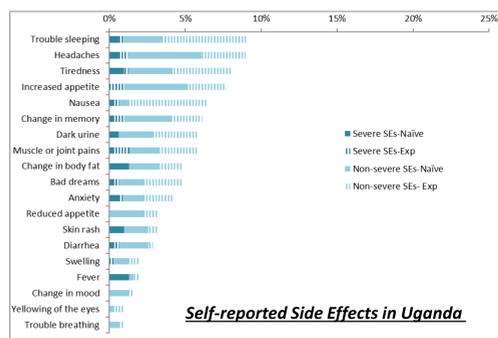
3. *Given the choice between the two: do you prefer your current regimen or your last regimen?*



Side Effects:

Patients were asked if they had experienced any of 20 pre-listed side effects, and to rank this by level of severity out of 5.

- Frequency of side effects (SEs) was similar in both sites
 - In Nigeria, 30% of the interviewed patients reported SEs perceived to be due to DTG, and 8% for severe SEs
 - In Uganda, 33% of the interviewed patients reported SEs perceived to be due to DTG, and 7% for severe SEs
- Most common side effects reported among patients were similar in both countries: Increased appetite, Tiredness, Headache, Muscle ache (Uganda #8/Nigeria #3), Insomnia



"The previous medication used to give me headache all the time which is not the case with the current. I used to miss doses because of getting home late. The current medicine is so small. It cannot be identified as ARV medication. It is so good."
"Drug is easy to swallow because it is small in size, has no side effects and I no longer feel feverish like before."
 Uganda patients for reasons they preferred DTG over their previous regimen.

Viral Load and health records:

In **Uganda**: At 6 months, 94% had a suppressed viral load (VL)<1000 copies/mL (n=312), 95% of treatment-experience patients (n=154) and 89% of treatment-naïve patients (n=158). The most common SE reported were change in body fat (12%) and nausea and headaches (8%). In **Nigeria**: At 6 months, 94% had vl < 1000 copies/mL (n=137), 94% of treatment-experience (n=131) and 100% of treatment-naïve patients (n=6). There were no reported cases of IRIS, <1% reported insomnia and muscle or joint aches.

Results: Prescriber Acceptability

Provider Acceptability was measured by a series of questions that were asked to healthcare works on prescribing DTG and their perceived acceptability of their patients. Overall, among the providers interviewed, there was a high acceptability of DTG. Supply security was expressed as a concern at the beginning of the study.

Reasons for high acceptability of DTG among prescribers include:

- DTG is more effective than NNRTIs
- DTG causes fewer side effects than efavirenz and nevirapine
- DTG has a lower pill burden than nevirapine
- Their adequate training gave them the ability to properly administer dolutegravir

"More information and fantastic patient outcomes" was said to be a reason a provider in Nigeria became more comfortable prescribing DTG over the 6 months of the study.

Discussion and Limitations

- There was high acceptability of DTG in both countries in over 90% of patients, with most patients noting improvements in side effects. Neuropsychiatric side effects and IRIS were not a barrier and were uncommon;
- Increase in appetite is the only side effect affecting >9% of patients at 6 months, this previously unreported finding needs further investigation to determine if this a positive or negative result and recommend further studies on associations with weight gain;
- 6 month viral load suppression results were more favorable than the national averages (78% in Uganda, 82% in Nigeria)
- With adequate training HCWs were comfortable prescribing DTG due to favorable patient outcomes. The main concern expressed was for supply security and the importance of adequate training for providers to feel comfortable prescribing a new regimen.

Limitations: Treatment experience patients were only included if they had NNRTI intolerance, which could lead to a bias in acceptability. Also, patient interviews were administered by HCWs that could result in desirability responding. We used DTG singles where national rollouts will use a triple FDC.

