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 NRTI, 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.

Results: Patient Acceptability, Side Effects, and Viral Load

Patient Acceptability

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

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

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 gave 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-naive 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 patients (n=131) and 100% of treatment-naive patients (n=16). There were no reported cases of IRIS, <1% reported insomnia and muscle or joint aches.

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 weight 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 limited to patients experienced exposed to ART (patients on option B, PEP, LTU), HCW prescribing DTG;

Provider Acceptability was measured by a series of questions that were asked to healthcare workers on prescribing DTG and their perceived acceptability of their patients' perspectives. 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.

Methods

- Target Population: Experienced patients but intolerant to NNRTIs, All new patients except those with contraindications to DTG, HCW prescribing DTG
- Enrollment Period: 6 Months
- Patient Survey Interviewer: Counsellor
- Provider Survey: Self administered
- Pilot Sample Size: 365 patients enrolled, 90% were treatment experienced, Median age: 44, Sex: 63% female
- Number of Sites: 3
- Laboratory investigations: CD4 – Baseline; Vl at 6 months
- Number of日子: 6 months

Results: Prescriber Acceptability

- Target Population: Patients intolerant or with contraindications to NNRTIs, previously exposed to ART (patients on option B, PEP, LTU), HCW prescribing DTG
- Enrollment Period: 6 Months
- Patient Survey Interviewer: Trained HCW
- Provider Survey: Self administered
- Pilot Sample: 273 patients enrolled, 87% were treatment experienced, Median Age: 44, Sex: 65% female

Limitations:

- Understanding 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.

Background

Naïve

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- 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 weight 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.

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