Results on Adverse Drug Event Reports on DTG containing ARV regimens

BACKGROUND

- TDF+3TC+DTG (TLD) isfirst-line ART regimen for adults, adolescents and pregnant women.
- The presence of adverse events (AEs)canlimit effectiveness and treatment outcomeof ARVs.
- Drug toxicity is the main reason for treatment change.
- DTG has relatively fewer side effects and is well tolerated but large size post marketing data is limited.
- EFDA in collaboration with development partners (such as GHSC-PSM) has been workingon safety monitoring of DTG.
- Though not as expected, health facilities have been sending ADE reports to EFDA since the introduction of DTG.
- This report examines these ADE reports to identify the most common AEs and serious AEsrelated to DTG containing regimens.

Objective

- To present adverse eventsreported from Addis Ababa and the regionsexperienced by patients taking DTG based ART from 2019-2021.

METHODOLOGY

- The national data regarding AEs were collected using spontaneous reporting to EFDA from 2019 to 2021.
- AEs fromhealth facilities inAddis Ababa were obtained during routine program support
- After thorough data cleaning, data analysis was performed using SPSS version 25

RESULTS

- From the national data 127 ADEs were reported from a total of 67 patients.
- The predominant AEs reported were hyperglycemia accounting for 28.4% followed by hypersensitivity skin reaction (25.4%), CNS side effects most commonly insomnia (20.9%), GI side effects (19.4%) and musculoskeletal (16.4%).
- Equal cases (50%) of AEs were observed in males and females.
- Most of the patients who have reported ADEs are from 31-45 years (57.1%) and with BMI <18 (53 cases).

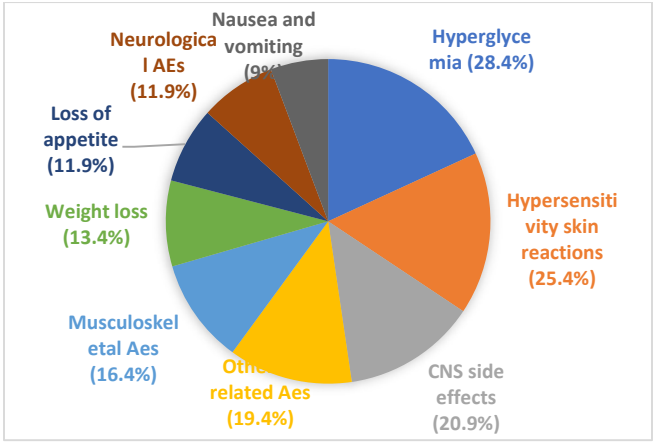

Fig 1: Reported AEs on DTG based ART

- 13 (19.4%) of the patients have also reported the use of other concomitant drugs like cotrimoxazole and metronidazole.
- Other clinical conditions like type II diabetes were reported in 4 (6%).
- Most of the ADE cases were observed early before 15 days (49

cases) after starting the DTG based ART therapy.

- Regimen change (19.5%) and discontinuation of suspected drug (6%), symptomatic management were used asmanagement strategies for the AEs.
- More than half (52.2%) of the reports came from Addis Ababa and pharmacist were the top ADE reporters (45%) compared to other health professionals.

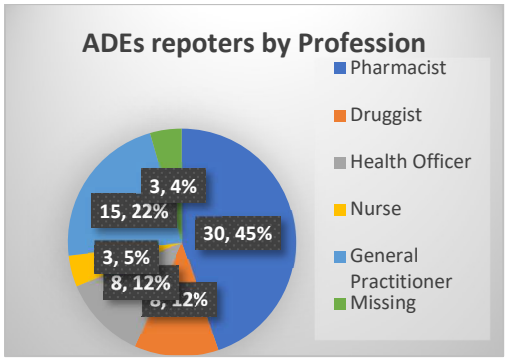

Figure 2. ADE reporters by profession

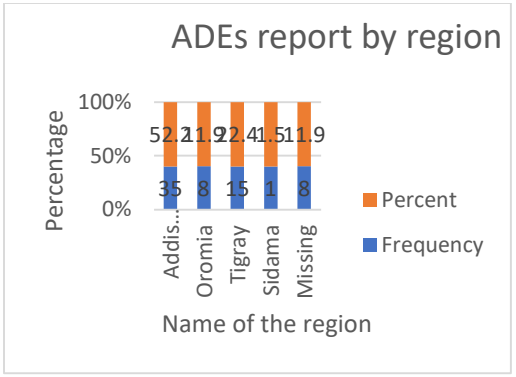

Fig 3. ADE reports by region

Adverse effect report from Addis Ababa

- 290 cases of AEs were also reported from different health facilities of Addis Ababa.

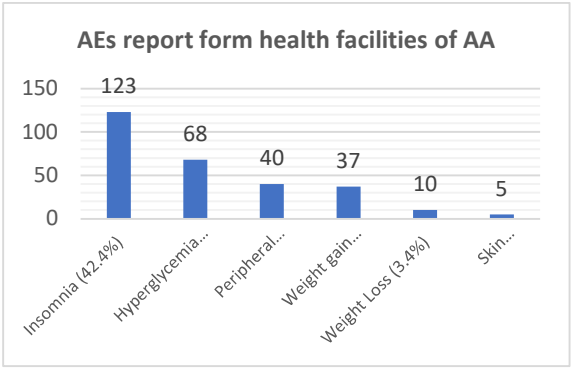

Fig. 4. Type of AEs reported from AA health facilities

- Poorlibido, polyphagia, hypersomnia, edema, gastritis, renal dysfunction, and fetal diffuse edema were also reportedin addition to the above AEs,

Conclusion

- Only 17 health facilities reported through the national pharmacovigilance system.
- 127 cases of ADEs were reported from 67 HIV patients receiving DTG based ART.
- Hyperglycemia and hypersensitivity skin reaction were the most common adverse effects reported
- In addition, 290 ADEs were also reported from health facilities of Addis Ababa where insomnia, hyperglycemia and peripheral neuropathy were the most common ADEs reported.

Recommendations

- EFDA, RHBs, and development partners should support health facilities to increase reporting rate

and quality through site level support, and close-follow-up.

- Strengthen the ADE data management system at EFDA
- Generate information for clinical and supply chain decision making using the ADE reports collected.