Results of Adverse Drug Events Reported to EFDA from TICs through aDSM

Background

- Multidrug-Resistant Tuberculosis (MDR-TB) has become a major public health problem in developing countries.
- Due to the complexity and length of treatment, MDR-TB management poses a significant challenge to the healthcare system.
- Ethiopia has been using newer and repurposed drugs as well as novel MDR-TB regimens that require active pharmacovigilance system.
- As part of this, Ethiopia implemented Active Drug Safety Monitoring and Management (aDSM).
  - All National TB program sites (TB Treatment Initiation Centres (TICs) use aDSM to track, manage, record, and report adverse drug events (ADEs) experienced by patients taking MDR-TB treatments.
- It became critical to examine the ADE reports received by the EFDA to identify the most common AEs and serious AEs (SAEs), regimens/drugs suspected of causing ADEs since the adoption of aDSM.

Objective

- To present the national ADEs data experienced by patients taking MDR-TB drugs in TB-TICs of Ethiopia from 2017-2020.

Methodology

- An excel data aggregation form was created using the monthly AE line listing form to manage ADE reports received by EFDA from 2017 to May 2020.
- Excel and SPSS were used for data analysis, and simple descriptive statistics were used to display the data.

Results

- EFDA has received 392 valid ADE reports since 2017.
- 43.4% of the reported ADEs were experienced by men, while 53.3% were by females, and the remaining 3.3% had missing data on sex.
- Average age of patients was 34 years (range 7-80 years); the most common age group for patients who suffered ADE was 18-35 years, accounting for 59.7% of all instances.
- From 13 TICs, two hospitals, namely ALERT and St.Peter Hospital, contributed to 77.8% of ADE reports.
- Nurses were the top ADE reporters (34%) and pharamcists are among the least reporters of ADEs in this program.
- Majority 138 (35.2%) of ADEs were associated with GI problems **(Figure-1)**.

- Based on ADEs of special interest, peripheral neuropathy was the leading ADE reported (10.5%) followed by ototoxicity (7.2%) (**Figure-2**).

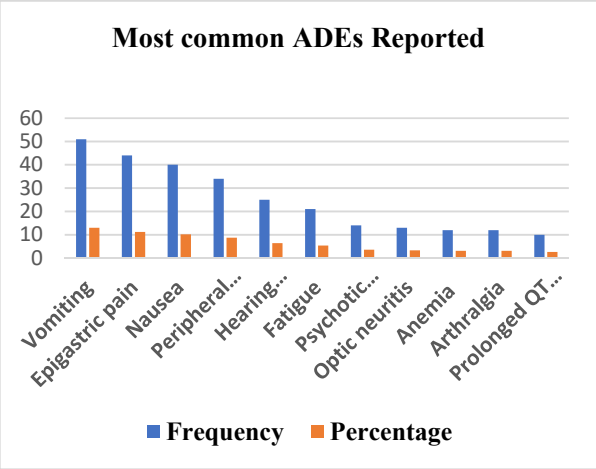

Figure 1: Common reported ADEs (top 10) with MDR-TB treatment

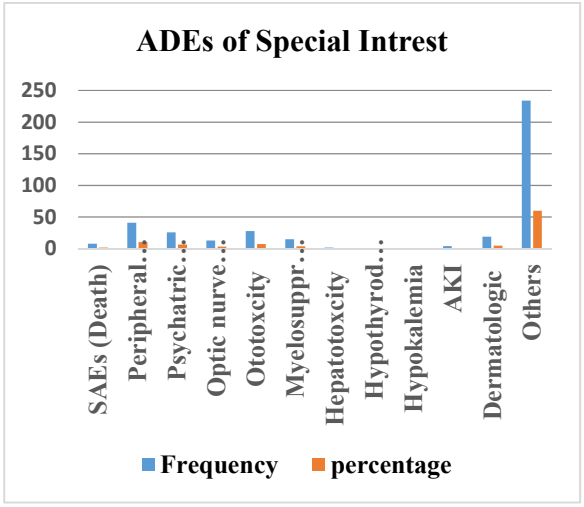

Figure 2: List of ADEs of special interest

- HIV was found to be the most frequently reported comorbid condition.
- HAART with TMP/SMX was the dominant regimen in comorbid patients.
- More than half (55.6%) of the reported cases received LTR (Fully Oral Longer (RR/MDR-TB) regimens
- Linezolid was the most common suspected medicines causing ADEs followed by Cycloserine.
- Majority (48%) of the reported cases were mild and 3.8% of them were life threatening.

Conclusion

- ALERT and St. Peter-TB specialized hospitals were found to be the highest contributors of ADE reports.
- The most common ADEs reported were nausea and vomiting.
- Majority of the reported cases were mild in severity, with prolonged hospitalization being the most common SAE followed by death.
- The most common comorbid medical condition was HIV, and the most commonly prescribed concomitant regimen was HAART.
- Linezolid and Cycloserine were discovered to be common suspect drugs in the reported ADEs.

Recommendations

- Patients on MDR-TB therapies should be closely monitored and aDSM should be strengthened at TICs.
- Enhance training and supervision to improve rate and quality of reporting.
- There should be consistent use of ADE reporting forms (e.g., AE line listing)
- Data management system should be strengthened at TICs and EFDA.