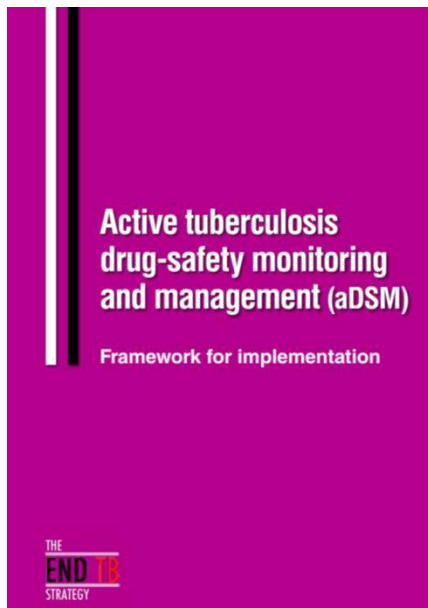


Active TB drug-safety monitoring and management (aDSM)



<http://www.who.int/tb/publications/aDSM/en/>

The document outlines how active monitoring and management for possible drug toxicities can be implemented within the unique context of a national tuberculosis programme, involving all relevant stakeholders including technical and funding agencies and experts in drug safety, to help determine causality, make decisions and improve knowledge about new and repurposed drugs.

Rationale

- Adverse drug reactions can lead to a tuberculosis (TB) patient interrupting treatment before completion, and can thus contribute to avoidable morbidity, drug-resistance, treatment failure, reduced quality of life, or even death.
- It is important that adverse events, especially serious ones, be monitored in TB patients on treatment. This is particularly relevant in the care of patients with drug-resistant TB, who often take regimens combining new or repurposed medicines for which the safety profile is incomplete.
- In 2015, in collaboration with partners and national TB programmes, WHO released a framework for the implementation of active TB drug-safety monitoring & management (aDSM)
- aDSM is defined as the active and systematic clinical and laboratory assessment of patients on treatment with new TB medicines, novel MDR-TB regimens or XDR-TB regimens to detect, manage and report suspected or confirmed drug toxicities.



aDSM Implementation Framework

- All adverse events detected in a patient require appropriate clinical management. In terms of recording and reporting, however, the core package of aDSM is focused on serious adverse events. Serious adverse events are those which lead to death or a life-threatening experience; to hospitalization or prolongation of hospitalization; to persistent or significant disability; to a congenital anomaly; or require an intervention to prevent them from leading to one of these outcomes. Treatment sites may also include adverse events which are not serious in aDSM.
- aDSM is now becoming an integral component of the programmatic management of drug-resistant TB (PMDT). Its rationale is underpinned by recent developments in MDR-TB treatment, particularly the conditional approval of new medicines ahead of the completion of Phase III trials, the increased use of repurposed drugs for XDR-TB treatment and the development of novel second-line TB regimens. Such approaches need careful monitoring for drug-related harms, some of which may not yet have been described.
- aDSM is not meant to replace or duplicate the efforts of national pharmacovigilance systems (NPV) but to complement their capacity, address gaps in safeguarding patient safety and help increase the knowledge base about novel treatment regimens.
- For national TB programmes to undertake aDSM effectively, a series of activities need to be coordinated to ensure that the right expertise is developed through interaction with local and external drug-safety experts; sufficient funds are made available for clinical monitoring activities, data collection and analysis; and decisions are made on the basis of new knowledge gained.
- Countries and technical partners that have successfully implemented aDSM within their TB programmes are encouraged to share the data to increase global knowledge about drug safety. Since 2016, the WHO Global TB Programme and the Special Programme for Research and Training in Tropical Diseases (TDR) have run a global aDSM database. More information about how to contribute to this database and how to download aDSM training resources can be accessed via http://www.who.int/tdr/research/tb_hiv/adsm/ and www.who.int/tb/areas-of-work/drug-resistant-tb/treatment/pharmacovigilance/.

The screenshot displays the WHO Global TB Programme and TDR website. The top navigation bar includes links for 'About us', 'Health topics', 'News', 'Countries', and 'Emergencies'. The main content area is titled 'Tuberculosis (TB)' and features a sidebar with a 'Tuberculosis' menu. The central text describes the 'Active TB drug-safety monitoring and management (aDSM)' as a health programme component for monitoring patient safety and managing adverse drug reactions (ADRs). It mentions the WHO's role in developing aDSM and its use in TB treatment. To the right, there is a section for the 'WHO global database for TB active drug safety monitoring home page', which provides information on the database's purpose, access, and data collection. The bottom of the page includes a footer with the text '© WHO May 2018'.