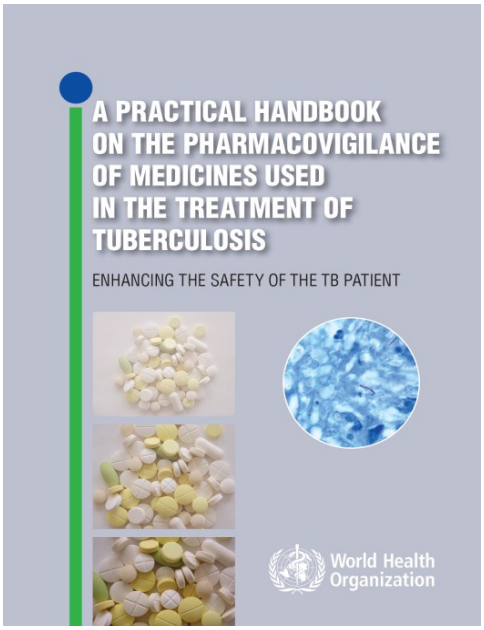
World Health Organization

www.who.int/tb/

Pharmacovigilance in tuberculosis care



www.who.int/medicines/publications/Pharmaco_TB_web_v3.pdf

The handbook explains how pharmacovigilance can be effectively implemented in a tuberculosis programme through key stakeholders, including regulators and manufacturers, and provides a step-by-step approach on how to identify signals, assess relationships between an event and a drug, determine causality, make decisions and communicate findings.

- Pharmacovigilance is defined by the World Health Organization (WHO) as the "*science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem.*"
- Adverse drug reactions (ADRs) 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 death
- It is important that ADRs, especially serious ones, be routinely monitored for in TB patients on treatment in national TB programmes. This is particularly relevant in the care of patients with drug-resistant TB and HIV/TB.
- In 2012, WHO produced a handbook on pharmacovigilance for TB. WHO offers technical assistance to countries to introduce and strengthen pharmacovigilance in their programmes

For more information: www.who.int/tb/challenges/pharmacovigilance/

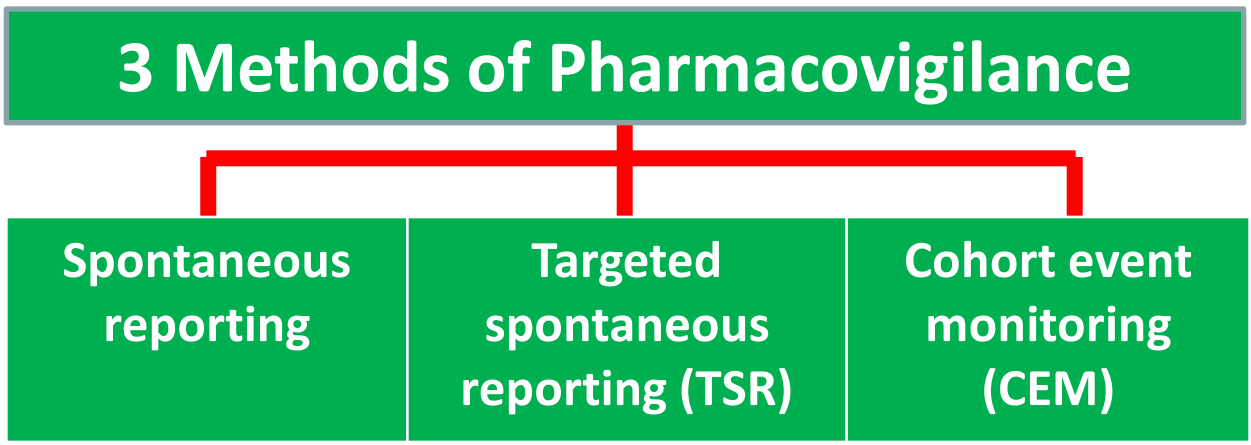
Pharmacovigilance for TB is needed now more than ever

• National TB programmes that systematically monitor harms associated with anti-TB medication are better placed to safeguard patient safety, especially when introducing new anti-TB drugs and regimens

• New TB drugs such as bedaquiline, and others in the pipeline, will be used in combination with existing anti-TB drugs, creating a potential for previously unrecognised drug interactions. Pharmacovigilance will thus be an important part of global and national policy for addressing the safety of current and new anti TB drug regimens. Dialogue with drug developers, regulators and national pharmacovigilance centres will be needed to ensure appropriate mechanisms are in place to report safety concerns alongside the monitoring of effectiveness

• The progressive global scale-up of treatment for multidrug-resistant TB (MDR-TB) is exposing more populations with diverse age, sex and ethnic profile to complex combinations of drugs, increasing the potential for serious ADRs. The long treatment – generally 20 months or more – for MDR-TB increases this likelihood

• Risk of serious ADRs in patients on TB treatment may be increased if they also have HIV, diabetes, alcohol-use disorders, or other co-morbidities. Furthermore, therapy for these comorbidities may increase risk of ADRs



Three distinct methodologies exist in pharmacovigilance :

• Spontaneous reporting involves the reporting of an ADR – e.g. ototoxicity associated with aminoglycosides - to the national pharmacovigilance centre

• Targeted spontaneous reporting is an extension of spontaneous reporting which can be focused on the surveillance of serious adverse events in specific patient groups, such as MDR-TB patients

• Cohort event monitoring (CEM) is an active form of surveillance, similar in design and management to an epidemiological cohort study. CEM would be particularly well suited to the post-marketing surveillance of new drugs

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