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Surveillance of adverse events in the treatment of drug-resistant tuberculosis: first global report

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Previous evidence on adverse events is available from single studies. This global project (658 patients from 26 countries) demonstrates aDSM is feasible and serious adverse events of recommended drugs are reasonably low (overall 57 out of 504, 11.3%). http://bit.ly/2kzvbqe

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ABSTRACT The World Health Organization (WHO) recommends that countries implement pharmacovigilance and collect information on active drug safety monitoring (aDSM) and management of adverse events.

The aim of this prospective study was to evaluate the frequency and severity of adverse events to anti-tuberculosis (TB) drugs in a cohort of consecutive TB patients treated with new (*i.e.* bedaquiline, delamanid) and repurposed (*i.e.* clofazimine, linezolid) drugs, based on the WHO aDSM project. Adverse events were collected prospectively after attribution to a specific drug together with demographic, bacteriological, radiological and clinical information at diagnosis and during therapy. This interim analysis included patients who completed or were still on treatment at time of data collection.

Globally, 45 centres from 26 countries/regions reported 658 patients (68.7% male, 4.4% HIV co-infected) treated as follows: 87.7% with bedaquiline, 18.4% with delamanid (6.1% with both), 81.5% with linezolid and 32.4% with clofazimine. Overall, 504 adverse event episodes were reported: 447 (88.7%) were classified as minor (grade 1–2) and 57 (11.3%) as serious (grade 3–5). The majority of the 57 serious adverse events reported by 55 patients (51 out of 57, 89.5%) ultimately resolved. Among patients reporting serious adverse events, some drugs held responsible were discontinued: bedaquiline in 0.35% (two out of 577), delamanid in 0.8% (one out of 121), linezolid in 1.9% (10 out of 536) and clofazimine in 1.4% (three out of 213) of patients. Serious adverse events were reported in 6.9% (nine out of 131) of patients treated with amikacin, 0.4% (one out of 221) with ethionamide/prothionamide, 2.8% (15 out of 536) with linezolid and 1.8% (eight out of 498) with cycloserine/terizidone.

The aDSM study provided valuable information, but implementation needs scaling-up to support patient-centred care.