European Respiratory Society
Annual Congress 2013

Abstract Number: 2571
Publication Number: 189

Abstract Group: 10.2. Tuberculosis
Keyword 1: MDR-TB **Keyword 2:** Monitoring **Keyword 3:** Treatments

Title: Getting the best possible evidence from observational studies of treatment of multidrug-resistant tuberculosis patients

Dr. Dennis 4772 Falzon falzond@who.int MD [1], Dr. Richard (Dick) 4773 Menzies dick.menzies@mcgill.ca MD [2], Dr. Charles L. 4774 Daley DaleyC@njhealth.org MD [3], Dr. Christian 4777 Lienhardt lienhardtc@who.int MD [1], Dr. Aamir 4776 Khan aamir.khan@irdresearch.org MD [4], Dr. Michael L. 4778 Rich mrich@pih.org MD [5], Dr. Mohammed A. 4779 Aziz azizm@emro.who.int MD [6], Dr. Catharina S.B. 4780 van Weezenbeek vanweezenbeekc@who.int MD [7] and Dr. Carole D. 4781 Mitnick carole_mitnick@hms.harvard.edu [5,8]. [1] Stop TB Department, World Health Organization, Geneva, Switzerland ; [2] Montreal Chest Institute, McGill University, Montréal, Canada ; [3] Division of Mycobacterial and Respiratory Infections, National Jewish Health, Denver, United States ; [4] Interactive Research and Development, The Indus Hospital, Karachi, Pakistan ; [5] Partners in Health, PIH, Boston, United States ; [6] Regional Office for the Eestern Mediterranean, World Health Organization, Cairo, Egypt ; [7] Regional Office for the Western Pacific, World Health Organization, Manila, Philippines and [8] Department of Global Health & Social Medicine, Harvard Medical School, Boston, United States .

Body: Background: The development of clinical recommendations by the World Health Organization (WHO) requires the systematic review of evidence and the grading of its quality. There is no high-quality evidence on treatment for multidrug-resistant tuberculosis (MDR-TB) patients using only standard second-line anti-TB drugs, as results of randomized controlled trials are not available. Well executed observational studies can meanwhile provide useful information that is applicable to clinical practice. For observational data to provide the best possible guidance, measures need to be taken to limit bias, imprecision, and heterogeneity. Intervention: WHO has established an expert Working Group to develop principles that national TB control programmes and other implementers could use to ensure the quality of observational study data. Results: Based on past experience, the group identified a number of critical points that need to be improved upon. Patient and programme-related data should be captured and reported in a standardized manner. These include bacteriological endpoints, proxies of disease severity, information on adverse drug reactions, the duration of current and past use of individual drugs, reason for change of regimen, use of accompanying medications, costs, hospitalization, patient support and type and extent of surgery. Conclusions: The Working Group recommends that programmes undertaking observational studies record most of these parameters, that they register data electronically, that they strive to publish their work, and that they share anonymous, individual patient data so as to update the knowledge base on MDR-TB patient outcomes.