

Publication

Impact of the diagnostic test Xpert MTB/RIF on patient outcomes for tuberculosis (Review)

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Background The World Health Organization (WHO) recommends Xpert MTB/RIF in place of smear microscopy to diagnose tuberculosis (TB), and many countries have adopted it into their diagnostic algorithms. However, it is not clear whether the greater accuracy of the test translates into improved health outcomes. **Objectives** To assess the impact of Xpert MTB/RIF on patient outcomes in people being investigated for tuberculosis. **Search methods** We searched the following databases, without language restriction, from 2007 to 24 July 2020: Cochrane Infectious Disease Group (CIDG) Specialized Register; CENTRAL; MEDLINE OVID; Embase OVID; CINAHL EBSCO; LILACS BIREME; Science Citation Index Expanded (Web of Science), Social Sciences citation index (Web of Science), and Conference Proceedings Citation Index - Social Science & Humanities (Web of Science). We also searched the WHO International Clinical Trials Registry Platform, ClinicalTrials.gov, and the Pan African Clinical Trials Registry for ongoing trials. **Selection criteria** We included individual- and cluster-randomized trials, and before-and-after studies, in participants being investigated for tuberculosis. We analysed the randomized and non-randomized studies separately. **Data collection and analysis** For each study, two review authors independently extracted data, using a piloted data extraction tool. We assessed the risk of bias using Cochrane and Ejective Practice and Organisation of Care (EPOC) tools. We used random effects meta-analysis to allow for heterogeneity between studies in setting and design. The certainty of the evidence in the randomized trials was assessed by GRADE. **Main results** We included 12 studies: eight were randomized controlled trials (RCTs), and four were before-and-after studies. Most included RCTs had a low risk of bias in most domains of the Cochrane 'Risk of bias' tool. There was inconclusive evidence of an effect of Xpert MTB/RIF on all-cause mortality, both overall (risk ratio (RR) 0.89, 95% confidence interval (CI) 0.75 to 1.05; 5 RCTs, 9932 participants; moderate-certainty evidence), and restricted to studies with six-month follow-up (RR 0.98, 95% CI 0.78 to 1.22; 3 RCTs, 8143 participants; moderate-certainty evidence). There was probably a reduction in mortality in participants known to be infected with HIV (odds ratio (OR) 0.80, 95% CI 0.67 to 0.96; 5 RCTs, 5855 participants; moderate-certainty evidence). It is uncertain whether Xpert MTB/RIF has no or a modest effect on the proportion of participants starting tuberculosis treatment who had a successful treatment outcome (OR) 1.10, 95% CI 0.96 to 1.26; 3 RCTs, 4802 participants; moderate-certainty evidence). There was also inconclusive evidence of an effect on the proportion of participants who were treated for tuberculosis (RR 1.10, 95% CI 0.98 to 1.23; 5 RCTs, 8793 participants; moderate-certainty evidence). The proportion of participants treated for tuberculosis who had bacteriological confirmation was probably higher in the Xpert MTB/RIF group (RR 1.44, 95% CI 1.29 to 1.61; 6 RCTs, 2068 participants; moderate-certainty evidence). The proportion

of participants with bacteriological confirmation who were lost to follow-up pre-treatment was probably reduced (RR 0.59, 95% CI 0.41 to 0.85; 3 RCTs, 1217 participants; moderate-certainty evidence). Authors' conclusions We were unable to confidently rule in or rule out the effect on all-cause mortality of using Xpert MTB/RIF rather than smear microscopy. Xpert MTB/RIF probably reduces mortality among participants known to be infected with HIV. We are uncertain whether Xpert MTB/RIF has a modest effect or not on the proportion treated or, among those treated, on the proportion with a successful outcome. It probably does not have a substantial effect on these outcomes. Xpert MTB/RIF probably increases both the proportion of treated participants who had bacteriological confirmation, and the proportion with a laboratory-confirmed diagnosis who were treated. These findings may inform decisions about uptake alongside evidence on cost-effectiveness and implementation.

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