Application of the Médecins Sans Frontières clinical trial transparency policy: cost analysis of TB-PRACTECAL, a multicentre phase 2–3 trial in drug-resistant tuberculosis

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Introduction

Clinical trials are a cornerstone of medical innovation. Nonetheless, little information on the cost of conducting clinical trials is available, especially for clinical trials in the global south. This lack of data and transparency hinders the creation of reliable cost estimates and adequate funding of clinical trials in resource-limited settings. Following the recent adoption of the Médecins Sans Frontières (MSF) Clinical Trial Transparency Policy, we present a detailed cost report for TB-PRACTECAL.

Methods

TB-PRACTECAL was an open-label, phase 2–3, multicentre randomised trial of all-oral regimens for the treatment of drug-resistant tuberculosis. Trial planning began in 2013 and work on publications continued into 2023. The trial took place in six sites across Belarus, South Africa, and Uzbekistan, and enrolled 552 patients. We analysed accounting data for the TB-PRACTECAL project, comprehensively including different costs, presented into 27 categories, by site, and by year, and at the per-patient level.

Ethics

This study received permission from the Research Committee of MSF, Operational Centre Amsterdam. It did not require ethics approval, as it did not include data from participants.

Results

Total costs for TB-PRACTECAL were €33.9 million, of which 26% were at central level (costs incurred by the UK clinical trial team including trial planning, management, quality assurance, and analysis of results), while 72% were at the trial site level (across all six sites) and 2% were uncategorisable. At trial sites, the largest cost category was staff (43%), followed by external diagnostic services (11%), medicines (9%), other medical consumables (7%), external non-medical services (6%), and transport and travel (6%). Among medicines, the costliest were bedaquiline (46% of medicine costs), linezolid (16%), imipenem/cilastatin (10%), and delamanid (9%). The mean cost per patient enrolled was €61,460 across the whole trial (including trial management overhead). When only site-level costs were considered, per-patient costs ranged between €19,998 and €45,942 across the six sites.

Conclusion

The costs of TB-PRACTECAL were similar to previously reported estimates for comparable clinical trials. However, TB-PRACTECAL included additional costs that would not typically be incurred in a commercial trial, such as investments in clinical research infrastructure and purchase of investigative medical products. To our knowledge, this is the first time MSF, or any other entity, published and analysed the disaggregated costs of a specific clinical trial. These data could help generate reliable predictions for future clinical trials and support planning and involvement, particularly in low-resource settings. Additionally, this study highlights the role of clinical trial cost disclosure in supporting both practical and policy discussions around the development of a more equitable system of biomedical R&D and fairer medicine pricing. Additionally, we developed a financial reporting template to facilitate future reporting of clinical trial cost by MSF and other entities investing in research.

Conflicts of interest

All authors declare no competing interests.