

Reply to author: Standardized methods for enhanced quality and comparability of tuberculous meningitis studies

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In reply:

The comments made by doctors Dhawan and Sankhyan confirm the need for standardized methodological approaches to enhance the quality and comparability of tuberculous meningitis (TBM) studies (1). However, achieving consensus on which data points should be included in a standardized core dataset can be challenging. We adhered to four guiding principles in drafting this framework:

- 1) Restrict the core dataset to the minimal number of elements necessary for enhanced study quality and comparability. The dataset should encourage TBM research that meets minimal quality standards, without presenting a cumbersome hurdle that could discourage research.
- 2) Differentiate “essential” from “desirable” datapoints to assist agreement on a core or ‘must have’ data, whilst retaining flexibility and acknowledging that different settings and studies will have different data requirements.
- 3) Focus on data that are available in most tuberculosis endemic settings, or are considered of fundamental importance for the conduct meaningful TBM research.
- 4) Include the data points necessary for accurate case characterization and disease description, according to a previously published uniform case definition for TBM research (2).

Dhawan and Sankhyan raise a number of important issues with respect to the diagnosis and management of TBM, many of which were discussed by the consortium when defining the core dataset. We respectfully believe that the suggested variables are “desirable”, rather than “essential”. We maintain that it is important to retain the simplest core dataset possible, in order to encourage wide

uptake and strict adherence to the essential core dataset. We emphasize, however, that although we do not wish to make changes to the currently published version, we will consider future changes and additions to the dataset as experience grows of its use and when new research technologies or questions arise.

References

- 1) Marais BJ, Heemskerk AD, Marais SS, van Crevel R, Rohlwink U, Caws M, et al. Standardized methods for enhanced quality and comparability of tuberculous meningitis studies. *Clinical Infectious Diseases* 2017;64(4):501-509.
- 2) Marais S, Thwaites GE, Schoeman J, Torok E, Misra UK, Prasad K, et.al. Tuberculosis Meningitis: defining a uniform case definition for use in clinical research. *Lancet Infect Dis* 2010; 10: 803-12