Assessment of Patient Sociodemographic Variables in Clinical Trials—Can Patient Characteristics Make a Difference?

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Abstract

Introduction: The recruitment of patients into clinical trials is often thought to be a selective process whereby non-biological variables such as education, occupation, family/social support, and socioeconomic status are often found to be predictive of patient volunteers. This paper considers whether the susceptibility of trials to recruit non-representative patient populations may impair the extrapolation of results to diverse sociodemographic patient groups and/or hinder operational trial efficiency. Method: A review of the Embase and Medline databases was conducted using Subject Headings (clinical trial or randomised-controlled trial) combined with Keywords (sociodemographic, education, occupation or socioeconomic). References presenting patient sociodemographic characteristics in relation to trial recruitment or impact on measured trial data points were reviewed. Results: Both quantitative and qualitative reports suggest clinical trials are prone to recruit biased sociodemographic cohorts. This review suggests three trial cohort analyses that may enhance the interpretation of trial results and provide insight into the operational efficiency of clinical trials. Assessments include: (1) comparing recruited trial cohort with source population; (2) assessing trial data points across sociodemographic groupings irrespective of treatment; (3) assessment of patient dropouts based on sociodemographic characteristics. Conclusion: In view of the known sociodemographic disparities found in trial recruitment, a methodology is suggested which may provide valuable information regarding the external validity of trial results and/or assessing operational trial efficiency. The challenge to those undertaking clinical trials should be to firstly determine whether recruitment biases may exist, and secondly whether trial integrity may be compromised by the presence of such biases.

Key words: Compliance, Generalisability, Randomised-controlled trial, Recruitment, Socioeconomic status (SES)

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