Minimally Important Differences Do Not Identify Responders to Treatment

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The minimally important difference (MID) is "the average change in the domain of interest on the target measure among the subgroup of people deemed to change a minimal (but important) amount according to an 'anchor'" [1]. The MID is used to determine if statistically significant group change is also large enough to be clinically meaningful. It is an additional consideration when interpreting group differences because very trivial differences can be statistically significant when the sample size is large.

It has been suggested that the MID be used to identify "responders" to treatment [2]. For example, the 2009 FDA guidance document recommended identifying responders using empirical evidence from anchor-based methods and suggested that the "difference in the PRO score for persons who rate their condition the same and better or worse can be used to define responders to treatment" [3]. Using group-level change to identify responders would lead to misclassification of patients as responders when they have not actually changed. In comparison to group change, much larger change is needed for statistically significant change in an individual's score, because of the much larger standard errors for estimates of individual change [1, 4]. Thus, responders need to be identified based on the significance of individual change using indices such as the reliable change index (RCI) or the equivalent coefficient of repeatability (CR) [5] = 1.9* SQR (2)*SEM = 2.77*SEM, where SEM = standard error of measurement = SD (SQR (1 – reliability)).

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