

What is a minimally important difference or ‘MID’?

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WHAT IS A MINIMALLY IMPORTANT DIFFERENCE?

There are a number of related but subtly different definitions and terms, summarised by King (2011). A simple definition based on their key features is:

The minimally important difference (MID) is the change in score of a patient-reported outcome (either beneficial or harmful) that is important from the patient's or clinician's perspective and would warrant a change in the patient's management.

There is no global MID that will suffice for all patient-reported outcome (PRO) instrument or scale, although an effect size of between 0.2 and 0.5 may provide a useful ballpark guideline (King, 2011). For a particular patient-reported outcome (PRO) instrument or scale, the MID is not an immutable characteristic, but may vary by population and context (Revicki, Hays, Cella, & Sloan, 2008).

WHAT IS THE MID USEFUL FOR?

The MID is useful for making treatment decisions at both the individual patient and group levels. Such decisions at the individual level involve a patient (or their clinician, acting as their agent) choosing among treatment options or deciding to cease or reduce treatment. At the group level, the decision may relate to clinical research conducted to test the relative effectiveness of treatments, often testing a promising new treatment against a current best practice – here the decision is whether one treatment is better than another, with the MID used as the decision threshold. When taken into the policy arena, this decision becomes “what is the recommended treatment”. MIDs can also be used for determining sample sizes for clinical trials.

ARE THERE OTHER TERMS FOR THE MID OR SIMILAR QUANTITIES TO THE MID?

Other concepts that have very similar definitions to that of the MID are the minimal clinically important difference, subjectively significant difference, clinically important difference, clinical significance or clinically significant change, minimally detectable difference/change, smallest real difference and smallest statistically detectable difference. King (2011) summarises their definitions, differences/similarities and evolution.

HOW ARE MIDS DETERMINED?

There are two broad classes of method for determining MIDs. They are the *anchor-based approach* and the *distribution-based approach*. Revicki et al (2008) recommend that the *anchor-based approach* be used to produce primary evidence for the MID of any particular PRO scale and the *distribution-based approach* be used to provide secondary or supportive evidence for that MID.

WHAT IS THE ANCHOR-BASED APPROACH TO DETERMINING MIDS?

The anchor-based approach involves using an external indicator, or *anchor*, to classify individuals into groups according to degree and direction of change. That is, using an appropriate anchor, individuals are classified as having experienced either no change, small change (positive or negative) or large change (positive or negative). The MID is estimated as the mean difference in the patient-reported outcome score that is derived from patients in the small change groups.

WHAT MAKES AN APPROPRIATE ANCHOR TO ESTIMATE THE MID?

The external indicator used as an anchor can be either clinical, e.g., physiological variables, clinician ratings, or patient-reported, e.g., global ratings of change. The global rating of change is the most commonly used anchor, and involves the patient-reported outcome being assessed prospectively at two time points, at the second of which the subject is also asked to think back to the first time point and judge the degree of change in that particular outcome, using a single item with five options, usually 'much worse', 'a little worse', 'the same/ no change', 'a little better', 'much better'. It is important that the anchor is at least moderately correlated (at least .3) with the patient-reported outcome for which the MID is being calculated (Revicki et al., 2008).

WHAT IS THE DISTRIBUTION-BASED APPROACH TO DETERMINING MIDS?

The distribution-based approach involves estimation of MIDs based on the distribution of the patient-reported outcome for which the MID is being calculated. The MID is not anchored to a relevant clinical or patient-based external anchor, and for this reason is considered an easily calculable proxy for the MID, so is at best an indirect method of estimating MIDs and is typically used when the anchor-based approach is not possible.

WHAT ARE SOME DIFFERENT DISTRIBUTION-BASED METHODS FOR ESTABLISHING MIDS?

There are several distribution-based quantities used to establish MIDs, the two most prominent being the standard error of measurement (SEM) and the standardised mean difference.

The SEM is calculated as the standard deviation of the sample multiplied by the square root of 1 minus the reliability of the scale, where the reliability is usually operationalised as test-retest reliability or internal consistency (Cronbach's alpha).

The standardised mean difference, also known as Cohen's *d*, is a signal-to-noise ratio in which the mean difference or change is divided by an index of variability, usually the standard deviation either pooled over groups or at baseline. As this is a form of effect size (Cohen, 1988), this form of the MID is often called an effect size.

Other distribution-based methods are the minimum detectable change and the smallest real difference. Both of these are functions of the SEM (see King 2011 for details).

WHAT EVIDENCE IS REQUIRED FOR A MID TO BECOME ESTABLISHED?

Ideally, MIDs are established using both anchor-based (with multiple clinical and patient-based anchors) and distribution-based methods. A point estimate of the MID if any particular PRO scale and/or a range of values should be determined using this triangulation of methods. Revicki et al (2008) recommend that the *anchor-*

based approach be used to produce primary evidence for the MID of any particular PRO scale and the *distribution-based approach* be used to provide secondary or supportive evidence for that MID.

Furthermore, MIDs for a given patient-reported outcome measure may vary across populations, so the specific context in which the MID was established should be considered. Empirical estimates are known to differ by domain and by which method is used (particularly with clinical anchors). Therefore, specific estimates of MIDs should not be over interpreted. For a given PRO scale, all available MID estimates and ranges should be considered and applied judiciously to any particular clinical or research context.

There is also convergent evidence from a large number of studies using different methods to establish MIDs that a standardised mean difference of about 0.5 (i.e., a half standard deviation) is likely to be at least the minimally important difference (Norman, Sloan, & Wyrwich, 2003). This corresponds to the widely-accepted criterion of a *medium* effect size (Cohen, 1988).

FURTHER READING

Cohen, J. (1988). *Statistical power analysis for the behavioral sciences* (2nd ed.). Hillsdale, NJ: Lawrence Erlbaum Associates.

Authoritative text on power analysis for a range of statistical methods. Includes detailed guidance for the calculation and interpretation of a range of effect size measures.

King, M. T. (2011). A point of minimal important difference (MID): a critique of terminology and methods. *Expert Review of Pharmacoeconomics & Outcomes Research*, 11(2), 171-184.

Provides a history and catalogue of the various ways MIDs have been conceptualised and operationalised. Includes a catalogue of definitions and methods (classified as either patient rating of change clinical anchors, standard error of measurement or effect size) for estimating MIDs, and a guide for their interpretation. Although there is no universal MID, the nuances in definition are often not important.

Norman, G. R., Sloan, J. A., & Wyrwich, K. W. (2003). Interpretation of changes in health-related quality of life: the remarkable universality of half a standard deviation. *Medical Care*, 41, 582-592.

Reports a systematic review of literature on MIDs for quality of life outcomes and finds that 32 out of 38 studies reviewed reported MIDs close to .05. The MID did not depend on number of response options or whether the instrument was disease-specific or generic. This consistency is attributed to the limit of people's ability to discriminate over a wide range of tasks; about 1 in 7, which is close to half a standard deviation.

Revicki, D., Hays, R. D., Cella, D., & Sloan, J. (2008). Recommended methods for determining responsiveness and minimally important differences for patient-reported outcomes. *Journal of Clinical Epidemiology*, 61(2), 102-109.

Provides a summary of recommendations on methods for evaluating MIDs (and responsiveness) for patient-reported outcome measures. Concludes that: MID estimation should be based on multiple approaches and triangulation of methods; anchor-based methods provide meaningful MID estimates; distribution-based methods are useful when anchor-based methods are unavailable, and; MIDs may vary by population, context and application.