## Minimal Clinically Important Difference

### A Review of Outcome Measure Score

### Interpretation

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#### **KEYWORDS**

- Reproducibility of results Minimal important change Change Difference
- Outcomes assessment Methodology Important

#### **KEY POINTS**

- Standardized health-related outcome measures require evidence for change and a way to interpret change within individuals or difference between groups.
- Values for the minimal clinically important difference (MCID) provide an option for the interpretation of meaningful change/difference.
- There are many methods for developing MCID values, but values can be influenced by sample characteristics and methods used for MCID quantification.
- Anchor-based methods using sensitivity and specificity analysis, such as receiver operating characteristic curve analysis, are recommended in the derivation of MCID to minimize misclassification of those who importantly change.

#### INTRODUCTION

Has the patient changed an important amount? How many people improved or deteriorated from an intervention? Did the intervention make a difference in the study? What value of change on a given measure is meaningful? These questions have challenged clinicians, researchers, funders, policymakers, and other health care stakeholders since the beginning of health-measurement science,<sup>1</sup> and before that in the education and psychology measurement fields.<sup>2</sup> The increase of standardized

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health-related outcome measures has increased the ability of clinicians and researchers to reliably and validly measure and evaluate outcomes.<sup>3</sup> Nevertheless, the issue of interpreting scores, or changes in scores, is an ongoing debate, although with more convergence appearing in recent years.<sup>4,5</sup> The idea of a minimal clinically important change (MCIC) or difference (MCID) is essential in understanding outcomes, both longitudinal change within individuals or cross-sectional difference between individuals, but there is continued questions regarding its development, interpretation, and application. Knowing the elements that create this controversy and then how to move through it will help readers to make the best use of this important threshold. Therefore, the *aim* of this review is to provide clinicians and researchers an overview and guidance on developing, reporting, interpreting, and applying values of MCID.

#### Minimal Clinically Important Difference Definition

In their seminal 1989 paper, Jaeschke and colleagues<sup>6(p408)</sup> defined MCID as "the smallest difference in score in the domain of interest which patients perceive as beneficial and which would mandate, in the absence of troublesome side effects and excessive cost, a change in the patient's management." Since its original definition, many variations have been proposed (Table 1), and variants now include concepts of important change to patients only, important change to other outcome stakeholders (eg, clinicians or researchers), worthwhile importance, risk reduction, or mean score differences between patients with ideal and less than ideal results.<sup>7–9</sup> The term minimal important difference (MID) is now often used to avoid a focus on the "clinical" importance of change. The authors use the term MCID because MCID terminology persists and is recognized. Furthermore, as seen in **Table 1**, polysemy (varying meanings for same term) and synonymy (same meaning for varying terms) complicate MCID literature.<sup>9,10</sup> Despite the variations in the name and the operational definitions, the general gist of MCID definitions is that it defines the lower threshold for change that is important to or valued by someone (eg, patients, health care providers, researchers conducting the study, funders, policymakers, or other stakeholders in the intervention outcomes), and ideally this change should surpass the boundaries of measurement errors/measurement variation to be interpreted as change.<sup>7</sup> Importantly, the concept has evolved to make a distinction between beneficial (improvement) and harmful (deterioration) change.<sup>1,3,11,12</sup>

Values of MCID can be determined for different settings or applications. Sometimes they are designed to offer insights for the interpretation of results in longitudinal evaluative observation studies and clinical trials (group-level applications), and in others, for clinical care and intervention decisions for patients (individual-level application). The values may differ depending on the application (discussed in more detail later). However, which level of application depends on how the MCID value is derived (ie, methods).<sup>7,13,14</sup>

For group-level applications, the MCID has been identified as a metric of clinical significance of the change, quite different from the statistical significance of group difference alone. In this application, it allows for interpretation of intervention efficacy and calculation of sample sizes for future evaluative studies or trials. Therefore, the MCID can offer important insights in situations where sample size and characteristics have driven the statistical significance to be too high, or too low, offering a means to interpret the change.<sup>8,14–17</sup>

In both individual and group-level applications, the MCID can be used to guide the threshold for meaning, rather than any statistical magnitude or significance of the change. It is a far more important threshold used to classify someone as improved (or responding to intervention), not improved (not responding to intervention), or harmed by an intervention (clinically important deterioration).

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