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## Although not consistently superior, the absolute approach to framing the minimally important difference has advantages over the relative approach

Yuqing Zhang<sup>a</sup>, Shiyuan Zhang<sup>a</sup>, Lehana Thabane<sup>a</sup>, Toshi A. Furukawa<sup>b</sup>, Bradley C. Johnston<sup>c,d,e</sup>, Gordon H. Guyatt<sup>a,f,\*</sup>

<sup>a</sup>Department of Clinical Epidemiology and Biostatistics, McMaster University, 1280 Main St West, Hamilton, Ontario, Canada L8S 4K1

<sup>b</sup>Departments of Health Promotion and Human Behavior and Clinical Epidemiology, Kyoto University Graduate School of Medicine/School of Public Health, Yoshida Konoe-cho, Sakyo-ku, Kyoto 606-8501, Japan

<sup>c</sup>Department of Anaesthesia and Pain Medicine, The Hospital for Sick Children, University of Toronto, 555 University Avenue, Toronto, Ontario, Canada M5G 1X8 <sup>d</sup>Institute of Health Policy, Management and Evaluation, Dalla Lana School of Public Health, University of Toronto, 4th Floor, 155 College St, Toronto, Ontario, Canada M5T 3M6

<sup>e</sup>Child Health Evaluative Sciences, The Hospital for Sick Children Research Institute, 555 University Ave, Toronto, Ontario, Canada M5G 1X8 <sup>f</sup>Department of Medicine, McMaster University, 1280 Main St West, Hamilton, Ontario, Canada L8S 4K1

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#### Abstract

**Objectives:** Using studies that established minimal important difference (MID) using anchor-based methods, we set out to address the relative merits of absolute and relative changes in establishing an instrument's MID.

**Study Design and Setting:** In seven data sets, we calculated correlations between global change ratings and absolute and relative score changes and conducted meta-analyses. We considered that the measure with the higher correlation represented the more valid approach.

**Results:** The meta-analyses showed no significant difference between pooled correlations of absolute and relative difference on healthrelated quality of life instrument with global transition scores of symptoms, emotional function, physical function, and cognitive function. In four of five domains, there was at least one study in which the absolute was significantly superior to the relative; in one of these four, one study showed statistically significant superior performance of the relative. In an analysis restricted to patients with low baseline scores for the domain of cognitive function, the relative approach showed higher correlation with global rating than did the absolute approach.

**Conclusion:** Although we found no consistent superiority of either approach to establishing the MID, when differences existed they usually favored the absolute, which also has advantages of simplicity and ease of pooling across studies. Researchers may consider the absolute as a default but also compare both methods on an instrument by instrument basis. © 2015 Elsevier Inc. All rights reserved.

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#### 1. Introduction

Health-related quality of life (HRQOL), one type of patient-reported outcome, is a multidimensional concept that includes domains related to physical, mental, emotional, and social functioning [1].

One of the challenges in using HRQOL is interpreting the magnitude of apparent intervention effects. Clinicians and policy maker audiences unfamiliar with an instrument are likely to have difficulty deciding whether treatment effects are trivial, small, or large when presented only with differences in natural units without further help in interpretation.

One aid to interpretation is the minimal important difference (MID), which is defined as the smallest difference in score in the outcome of interest that informed patients or proxies perceive as important, either beneficial or harmful, and leads the patient or clinician to consider a change in the management [2]. Commonly used approaches to establishing the MID include "anchor-based" [3,4] and "distribution-based" methods [5]. The most widely used anchor-based approach, first introduced in 1985 [4], relies on a global transition question as the "anchor" or "external reference." Typically, the change in the instrument of interest corresponding to a small but important change in the global rating of change represents the MID.

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E-mail address: guyatt@mcmaster.ca (G.H. Guyatt).

### What is new?

- When establishing minimal important difference (MID), neither the absolute change in score nor a relative change is consistently superior in interpreting patient-reported health-related quality of life (HRQOL) outcomes.
- Individual study results did, however, suggest that in particular populations and instruments, one approach or the other may be preferable—more often, the absolute.
- All else being equal, the absolute approach is more simple and straightforward.
- When establishing MID for HRQOL, researchers should consider comparing both methods on an instrument by instrument basis to identify whether there is a superior approach.

There are, however, two ways to apply the anchor-based method. Consider an instrument with possible scores from 0 to 10 in which higher numbers represent poorer function. One patient has a decrease in score from 10 to 9 and second patient from 2 to 1. Using absolute measures of change, both patients have had a one-point improvement. Using relative measures of change, however, the first patient has had a 10% improvement and the second patient a 50% improvement.

One could argue for either of these two approaches to expressing the MID—as a relative or absolute change, depending on what one believes is the patient's experience. Do the two patients depicted above both experience a small reduction in an adverse experience or does the first experience a small reduction and the latter a large reduction? There is no consensus on the matter, and indeed, investigators have used both absolute [3,6,7] and relative [8] approaches.

How might one establish which of these interpretations is correct—or at least, more correct—for it is possible that both relative and absolute changes to some extent reflect patients' experience? The anchor-based method of establishing the MID relies on the global transition score providing an accurate representation of the patient's experience of change [8,9]. Therefore, whichever of the relative or absolute change correlates more highly with the transition rating is likely to be the superior approach.

Using studies that established MID using anchor-based methods, we set out to address the relative merits of absolute and relative changes in establishing an instrument's MID.

#### 2. Method

We reviewed 320 original data sets from studies conducted in the Department of Clinical Epidemiology and Biostatistics at McMaster University from 1987 to 2004. Studies were eligible if they met the following criteria: (1) randomized control trials or cohort studies in which patients completed one or more disease-specific HRQOL instruments; (2) at follow-up visits, patients also completed a global transition questionnaire separate from the target instrument that corresponded to one or more domains of the target instrument; (3) data allowed calculation of Pearson correlation coefficients between the global transition scores and scores change on the target instrument(s) for both absolute and relative changes; and (4) the study had relevant information available for data analysis.

#### 2.1. Data abstraction

Two reviewers (Y.Z. and S.Z.) independently applied eligibility criteria to the data sets and corresponding articles with information needed and extracted data from eligible studies. Reviewers resolved discrepancies by discussion and an arbitrator adjudicated unresolved disagreements.

### 2.2. Data analysis

We examined data from each follow-up visit separately. In each case, the data included the previous (which we will call "pre") and follow-up (which we will call "post") questionnaire scores and the corresponding global transition scores.

We made assumptions for our analysis: (1) existence of a linear relationship between the transition score and the post – pre scores and (2) both transition scores and the post – pre variables are approximately bivariate normally distributed.

We calculated the absolute difference of scores changes using post – pre and relative scores changes using post – pre then divided by pre. For each study: *x* represents absolute score difference, *y* represents global transition scores difference, *z* represents relative score difference, and *n* represents the sample size. Let  $r_{xy}$ ,  $r_{zy}$ , and  $r_{xz}$  are the Pearson correlation coefficient between *xy*, *zy*, and *xz*, respectively. This translates to estimating difference between  $r_{xy}$  and  $r_{zy}$  and testing the null hypothesis that  $r_{xy} - r_{zy} = zero$ .

For each study, for our pooled analysis, we chose the follow-up time point in which the mean of  $r_{xy}$  and  $r_{zy}$  showed the highest value. We performed data analyses in two levels: individual patient analyses and then study-level analyses.

We determined estimates  $r_{xy}$  and  $r_{zy}$ , respectively, for each study based on patient-level data. We examined the corresponding scatter plots to evaluate the plausibility of a linear relationship between the two variables. Lastly, we determined the  $r_{xy} - r_{zy}$  with a 95% confidence intervals (CIs) for each study.

We then conducted analyses at the study level. The estimation of the difference  $D_i = r_{xy} i - r_{zy}$  i and the corresponding standard error (SE<sub>i</sub>) for each study *i* have been calculated. We then pooled the difference D<sub>i</sub> with SE<sub>i</sub>

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