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Re: Hui et al., Which Treatment Is Better?

To the Editor:

We noted the article by Hui et al.[1] regarding the hypothetical use of patient preference in crossover trials as a patient-reported anchor to assess the minimal clinically important difference (MCID) in subjective measures such as, in this case, breathlessness.

Blinded patient preference is a useful way of calculating an anchor-based MCID. Researchers in our collaboration have included this measure in double-blind, randomized, placebo-controlled, crossover trials since the late 1990s when evaluating opioids for the reduction of breathlessness. This has enabled us to calculate the patient-anchored MCID for both an absolute and relative change in refractory breathlessness scores by analyzing individual data pooled from three studies in this clinical setting.[2,3]

The distribution method for calculating an MCID for an absolute change that takes into account the underlying variability of the measure also was calculated.[2] This is crucial in understanding the optimal interpretation of the patient-reported anchor estimates. This analysis cannot be done for relative change[3] or using retrospective patient-reported assessment of change without baseline measures. We have recently demonstrated that variability of patients' reports of breathlessness intensity are independent of baseline intensity and, therefore, recommend that absolute values are used for sample size calculations precisely because both methods of MCID calculation can then be used to give robust estimates.[3] Unlike Hui et al., we suggest that both methods have different limitations, and therefore, both should be calculated to optimize the use of data and interpretation of results.[4–7]

As the authors state, patient preference may present a useful and pragmatic way of identifying a clinically relevant outcome as patient preference reflects the net effect of an intervention incorporating benefits and harms. We need to persevere in better understanding the optimal ways to design and report clinical trials that use subjective outcomes in order to continue to develop the best evidence base for our patients at the end of life.

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Choosing a "Yardstick" to Determine the Minimal Clinically Important Difference: Reply to Johnson and Currow

To the Editor:

We appreciate the comments by Johnson and Currow on our recent article that discussed the use of crossover trial designs to estimate the minimal clinically important difference (MCID).[1] We agree that both the anchor-based approach and the distribution-based approach have merits.

One important consideration regarding the anchor-based approach is the selection of an appropriate anchor or gold standard. Perhaps the most intuitive "yardstick" is to ask patients to directly compare control vs. active intervention (in a crossover study) or before vs. after treatment (in a single-arm study) and provide their global impression of change by stating if the symptom of interest was "better," "about the same," or "worse."[2,3] However, this approach is partly limited by its subjective nature.[4]

Importantly, global impression of change should be differentiated from the concept of overall preference, in which the patient indicates a final treatment choice after a trial of all study interventions. Overall preference/choice is unique to crossover designs and is based on not only the perceived benefits but also risks and logistical factors.[5,6] This pragmatic outcome provides different information from global impression of change and MCID. Because of its composite nature, overall preference/choice may be more difficult to interpret as a gold standard for MCID determination.[7]

Other commonly used yardsticks in the anchor-based approach use validated questionnaires or objective outcomes.[8] The two main considerations for these indirect measures are that these anchors themselves should have had predetermined MCIDs or clinically meaningful cutoffs and that they should be assessing the same construct as the instrument for which the MCID is being derived.

MCID has practical implications and remains an elusive concept. More research is clearly needed to determine the MCIDs for many palliative care outcomes, ideally using different approaches that can complement each other.

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