The Severe Asthma Questionnaire: sensitivity to change and minimal clinically important difference

To the Editor:

The Severe Asthma Questionnaire (SAQ) is a validated measure of the health-related quality of life of people living with severe asthma [1]. The minimal clinically important difference (MCID) of the SAQ has not been calculated. The MCID is useful for representing clinical as opposed to statistical significance. There are two main ways of calculating the MCID. Distribution methods define the MCID in terms of the relationship between the distribution of scores and mean change score. These methods are purely statistical and the relationship and formulae that constitute the MCID is determined by convention. By contrast, the anchor method [2] defines the MCID in terms of an independent anchor or criterion. When the anchor is the patient's perception of a just noticeable difference in their condition, then the anchor method has two advantages over the distribution method. First, the MCID is defined by a criterion and, therefore, has criterion validity rather than being only a convention. Second, the MCID is defined in terms of the patient's perception of treatment, and the patient's perception of their treatment is recognised as being an important outcome for clinical decision-making [2]. In this letter we present the MCID of the SAQ using the anchor method.

110 patients were recruited from six UK specialist asthma centres who were initiating a National Institute of Health and Care Excellence approved biologic treatment as part of usual care (62% female, mean age 49 years, mean forced expiratory volume in 1 s 67% of predicted). Participants completed the SAQ at baseline and completed the SAQ and a Global Rating of Change (GRoC) questionnaire [3] at 4, 8, 12 and 16 weeks after starting treatment. Patients responded to the 16 items of the SAQ using a 7-point scale, and responses were scored to produce an overall SAQ score from the mean of 16 items, and three subscale scores (My Life, My Mind, My Body) from the means of subsets of those 16 items [4]. In addition, patients provided a single response to a 100-point Borg-type rating of global quality of life, the SAQ-global. Questionnaires with >10% missing items were deemed invalid. Baseline mean±SD scores demonstrated significant health-related quality of life impairment across all aspects of the SAQ: 3.65±1.49 for the SAQ, 3.74±1.62 for My Life subscale, 3.78±1.78 for My Mind subscale, 3.34±1.51 for My Body subscale and 45.50±23.67 for the SAQ-global. Questionnaire change scores were calculated by subtracting the baseline score from the follow-up score, so that positive change scores indicated improvement in quality of life. There was a significant ($p<0.01$) improvement between baseline and 4 weeks for the SAQ, the subscales of the SAQ and the SAQ-global, and improvement was maintained for subsequent weeks.

Patients were asked to rate the GRoC in terms of improvement by circling a statement "which best describes how you feel since starting your new treatment for your asthma". We analysed GRoC responses into any one of six categories: 1) "any degree of deterioration", 2) "no change", 3) "a little better", 4) "somewhat better" or 'moderately better", 5) "a good deal better" and 6) "a great deal better". Perceived change of "a little better" was defined as the point of the MCID following normal practice. In order to take full advantage of the repeated measures design, we used all available data where a GRoC rating was accompanied by a valid questionnaire change score over the 16-week study but excluded scores where the GRoC category was the repeat or deterioration of the previous week, as such scores could be less reliable due to increased recall bias caused by the intervening experiences. The study received ethical approvals

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The Severe Asthma Questionnaire (SAQ) is sensitive to change and clinically significant improvement was detected within 4 weeks of starting biologic therapy. The MCID of the SAQ is 0.5 and of the SAQ-global is 11. https://bit.ly/3poJqcG

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TABLE 1 Change scores for those reporting different degrees of global rating of change

Description of change (GRoC scale 0–5)	SAQ	SAQ My life	SAQ My mind	SAQ My body	SAQ-global
Any degree of deterioration (−5 to −1)	−0.41±1.15 (4)	0.06±0.88 (4)	−1.23±1.45 (4)	−0.50±1.50 (4)	−5.00±15.81 (4)
No change (0)	−0.32±0.97 (34)	−0.30±1.04 (35)	−0.42±1.21 (35)	−0.25±1.32 (35)	0.95±16.78 (37)
"A little better" (1) (MCID)	0.54±0.94 (28)	0.67±0.90 (28)	0.43±1.11 (28)	0.45±1.38 (28)	10.89±14.91 (28)
"Somewhat better" and "moderately better" (2 or 3)	0.92±1.04 (34)	0.90±1.01 (33)	0.90±1.00 (33)	0.84±1.82 (33)	17.41±16.96 (34)
"A good deal better" (4)	1.23±1.10 (33)	1.11±1.27 (33)	1.20±1.22 (33)	0.99±1.27 (33)	19.18±20.38 (33)
"A great deal better" (5)	2.19±1.05 (27)	2.19±1.19 (26)	2.32±1.52 (26)	2.15±1.70 (26)	31.83±19.00 (29)

Data are presented as mean±SD (n). GRoC: Global Rating of Change; SAQ: Severe Asthma Questionnaire; MCID: minimal clinically important difference.

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The coronavirus disease 2019 pandemic reduced data collection at later time points. Of the 110 patients recruited, 107 provided valid change scores at week 4, 74 at week 8, 30 at week 12 and 49 at week 16. Of the 28 judgements that were used to assess the MCID of the SAQ, 18 and 10 came from weeks 4 and 8, respectively. No additional judgements for MCID calculations were provided at weeks 12 or 16. The 110 patients recruited provided a total of 799 judgements that are presented in table 1.

These data show that the MCID for the SAQ is 0.5 and for the SAQ-global is 11. The MCID for the subscales of the SAQ are similar to that of the SAQ. Based on data reported elsewhere [1], the standard error of measurement [5] gives an MCID of 0.5 for the SAQ and 6.0 for the SAQ-global. The standard error of measurement method provides an estimate of statistical discrimination and should not normally be greater than that provided by the anchor method. An MCID of 0.5 is reported by the authors of another asthma questionnaire, the Asthma Quality of Life Questionnaire (AQLQ) [6] that, like the SAQ, asks patients to rate on a 7-point scale. However, the similarity in results should be interpreted cautiously as there are some differences in the anchor methodology, and the assessment of the MCID of the AQLQ was based on the mean of only 10 judgements. Other asthma questionnaires, such as the St George's Respiratory Questionnaire [7] have other forms of response format and are therefore not comparable.

In addition to providing the MCID for the SAQ, our data provide information about the multiples of the MCID that are equivalent to larger degrees of perceived change. A "great deal better" is approximately four times the MCID for the SAQ and three times the MCID for the SAQ-global. A "good deal better" is approximately twice the MCID for the SAQ and twice the MCID for the SAQ-global. These additional values can be used to assess the clinical significance of changes that are much greater than the MCID, such as in super-responders.

The SAQ was developed with patients who contributed as partners to the content, wording and format of the questionnaire [8, 9]. The 16 items are validated to be used as a single scale (SAQ) [1] or as three subscales (My Life, My Mind, My Body) [4], and the questionnaire also provides a global estimate of quality of life (SAQ-global). In this paper we have presented the MCID for all scoring methods.

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