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# Estimation of Minimally Important Differences and Patient Acceptable Symptom State Scores for the Patient-Reported Outcomes Measurement Information System Pain Interference Short Form in Rheumatoid Arthritis

Patricia Katz,[1] Carol L. Kannowski,[2] Luna Sun,[2] and Kaleb Michaud[3]

**Objective.** Studies have supported the validity of the Patient-Reported Outcomes Measurement Information System (PROMIS) Pain Interference (PI) scale in rheumatoid arthritis (RA). Here, we characterize minimally important differences (MIDs) and patient acceptable symptom state (PASS) values.

**Methods.** PROMIS PI scores were collected in four periods at 6-month intervals from patients with RA (n > 3200 per period). Both anchor- and distribution-based methods estimated MIDs. Anchors were pain comparisons, pain interference, and general health. Time responses for each anchor-response group (four administrations, each with three change periods) were averaged. The mean changes of the "somewhat worse" and "somewhat better" groups were used as estimates for MID for worsening and improvement, respectively. Distribution-based MID analyses used standardized error of measurement (SEM) and SD. PASS was estimated with the question "If your health was to remain for the rest of your life as it has been in the past 48 hours, would this be acceptable?" MIDs and PASS values were also estimated by baseline pain levels.

**Results.** Anchor-based methods yielded estimates of 1.65 to 1.84 for worsening and –1.29 to –1.73 for improvement. The SEM estimate was 1.84. The PASS estimate for the entire group was 41.6. Substantial differences in MIDs and PASS were noted among baseline pain groups.

**Conclusion.** The best estimate of a group-level MID was approximately 2 points, similar to MIDs suggested in other conditions. The PASS value for the entire group was almost an SD better than the population mean. Results should enhance use of PROMIS PI in RA by facilitating interpretation of scores and changes.

## INTRODUCTION

Clinical care and research in rheumatic diseases rely heavily on patient-reported measures to assess disease activity and progression and treatment effectiveness. The National Institutes of Health Patient-Reported Outcomes Measurement Information System (PROMIS) represents the most comprehensive suite of patient-reported outcome measures available. PROMIS measures were developed using modern psychometric standards methods and include domains important to patients with rheumatoid arthritis (RA) (eg, pain, fatigue, physical functioning) (1).

When asked to identify the PROMIS domains most important to their quality of life, a sample of individuals with RA identified physical function and pain interference (PI) as the most relevant (2). Most work to date has focused on the PROMIS Physical Function scale, showing it to be valid and responsive in RA (3-9). A number of studies have also supported the validity and applicability of the PROMIS PI measure in RA (4,10,11); however, studies examining its responsiveness to clinically measured disease activity have yielded mixed results (10,12,13).

Additional longitudinal analyses needed for informed use of PROMIS measures are identification of criteria for clinically meaningful changes (or minimally important differences [MIDs]) and patient acceptable symptom state (PASS). MIDs represent the smallest changes, positive or negative, considered meaningful to patients (14). PASS defines the level of symptoms at which

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[1]Patricia Katz, PhD: University of California, San Francisco; [2]Carol L. Kannowski, PharmD, Luna Sun, PhD, PharmD: Eli Lilly and Company, Indianapolis, Indiana; [3]Kaleb Michaud, PhD: FORWARD, The National Databank for Rheumatic Diseases, Wichita, Kansas, and University of Nebraska Medical Center, Omaha.

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Address correspondence to Patricia Katz, PhD, Department of Medicine, University of California, San Francisco, 3333 California Street, Suite 270, San Francisco, CA 94143-0920. E-mail: patti.katz@ucsf.edu.

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patients consider themselves well (15). In simpler terms, improvement by MID indicates "feeling better," whereas PASS indicates "feeling well." Studies have estimated MIDs for the PROMIS PI scale in osteoarthritis, low back pain, and cancer (12,16-18), but no similar work has been done in RA. RA represents a major symptom area; however, the lack of validated estimates for MIDs or PASS scores hampers interpretation of the PROMIS PI scale in RA. In these analyses, we estimated the MID and PASS score for the four-item PROMIS PI scale in a large cohort of individuals with RA.

## PATIENTS AND METHODS

**Data sources.** Data were from FORWARD, The National Databank for Rheumatic Diseases (19). Participants in FORWARD are recruited primarily from rheumatologists, who also provide the diagnoses. A minority of participants are enrolled from other sources, in which case diagnoses may be confirmed by participants' physicians or may be self-reported. Data are collected at 6-month intervals by questionnaires. All participants have the option of completing the semiannual questionnaire online, as a mailed paper questionnaire, or by telephone interview. Less than 1% of participants in this analysis responded by telephone; a previous analysis found that scores from the online and paper questionnaires were similar (7). All FORWARD procedures are approved by the Via Christi Institutional Review Board, and all participants provide consent to participate. Data shown in these analyses span four six-month data collection periods (Table 1): A) January to June 2017 (n = 3848), B) July to December 2017 (n = 3648), C) January to June 2018 (n = 3925), and D) July to December 2018 (n = 3248). Recruitment occurred between periods B and C, which explains the increase in sample size. More than 93% of participants in each period had physician-confirmed RA.

**Measures.** *Patient-Reported Outcomes Measurement Information System*. The four-item PROMIS PI short form was administered in each data collection period. For scoring, PROMIS scales are converted to T scores, with a population mean of 50 and SD of 10 based on the general US population (20). PROMIS scoring documentation provides the crosswalk between raw scores and T scores and is available at http://assessmentcenter.net. Higher PI scores reflect greater pain interference with daily life.

*Measures used to estimate MID and PASS.* For MID anchor-based analyses, changes in the measure under study (ie, PROMIS PI) were calculated for groups that reported improvement, worsening, or no change in relevant comparison measures, referred to as "anchors." We examined three anchor items: comparisons of pain, pain interference with daily activities, and health in general with that of 6 months before. Each item used a five-point response scale that consisted of the following responses: much better now, somewhat better now, about the same, somewhat worse, and much worse. All correlations between the two pain-specific anchors and PROMIS PI scores were greater than (0.30), the criterion suggested for an appropriate anchor measure (14) (see Appendix Table (1)).

To estimate PASS scores, the following question, specified for the PASS methodology, was asked: "If your health was to remain for the rest of your life as it has been during the last 48 hours, would this be acceptable or unacceptable to you?" (21,22). Because the PASS question was asked in only one of the four questionnaire administrations, we also examined an item that was available in all questionnaires ("How satisfied are you with your health now? Very satisfied, somewhat satisfied, neither satisfied nor dissatisfied, somewhat dissatisfied, or very dissatisfied?"), similar to a method used by Connelly et al (23).

*Other variables.* Participants self-reported demographic characteristics (eg, age, race, education) and other health and disease characteristics (eg, comorbidities, functioning, current pain). Current pain was rated on a 0 (no pain) to 10 (severe pain) numeric rating scale allowing for ratings at 0.5 increments at each administration.

**Analysis.** *Minimally important differences*. Both anchor- and distribution-based methods were used to estimate MIDs, as recommended (14). For the anchor-based estimates, differences in PROMIS scores were calculated for each pair of consecutive administrations, yielding three change periods (period A to period B, period B to period C, and period C to period D). The mean changes in PROMIS scores for individuals falling into each of the five response categories of the anchor items (much worse,

**Table 1.** Sample sizes for each data collection period and each change period

| | Data Collection Periods | | | | Change Periods | | |
|---|---|---|---|---|---|---|---|
| | A | B | C | D | A-B | B-C | C-D |
| Total | 3848 | 3648 | 3925 | 3248 | 3232 | 3055 | 2499 |
| By baseline pain level[a] | | | | | | | |
| Low | 1849 | 1768 | 1909 | 1540 | 1634 | 1529 | 1280 |
| Moderate | 1071 | 1000 | 1083 | 912 | 895 | 838 | 668 |
| High | 917 | 863 | 918 | 788 | 698 | 675 | 543 |

[a]Respondents' pain levels, on a 0-10 numeric rating scale, were categorized as low (0-2.5), moderate (3.0-5.5), and high (≥6.0) in the year prior to the administration of the comparison questions (for minimally important difference) or the year that the PASS question was administered. Values by baseline pain level may not sum to the total for each period because of missing data for baseline pain level.

**Table 2.** Characteristics of study sample (2017, period A, N = 3848)

| | Results |
|---|---|
| Sociodemographic | |
| Age, mean ± SD, y | 64.9 ± 12.0 |
| Female sex, % (n) | 83.1 (3129) |
| White, % (n) | 91.3 (3313) |
| Education level, mean ± SD, y | 14.6 ± 2.3 |
| General health | |
| Ever smoker, % (n) | 42.9 (1650) |
| Rheumatic Disease Comorbidity Index, mean ± SD | 2.17 ± 1.70 |
| RA specific, mean ± SD | |
| RA duration, y | 20.8 ± 12.7 |
| HAQ II (range 0-3) | 0.87 ± 0.64 |
| Fatigue rating (range 0-10) | 3.8 ± 2.9 |
| Pain, mean ± SD | |
| Pain rating (range 0-10) | 3.5 ± 2.7 |
| PROMIS Pain Interference score | 56.3 ± 9.5 |

Abbreviation: HAQ, Health Assessment Questionnaire; PROMIS, Patient-Reported Outcomes Measurement Information System; RA, rheumatoid arthritis.

somewhat worse, etc) were then calculated for each change period and averaged over the three change periods.

Effect sizes (mean change divided by SD of baseline) were calculated for each group at each change period (6,24). Mean changes in PROMIS scores and effect sizes were averaged over the three change periods for each response category. Effect sizes between 0.2 and 0.50 were considered small; between 0.50 and 0.80, moderate; and greater than 0.80, large (25). Effect sizes less than 0.20 were considered negligible. The mean change of individuals responding "somewhat worse" was used as the estimate for the MID for worsening; the mean change of individuals responding "somewhat better" was used as the estimate for the MID for improvement (26).

For the distribution-based calculations, we used 1) the standard error of measurement (SEM), which reflects the precision of measurement and can be interpreted as the smallest difference likely to reflect a true difference rather than measurement error, and 2) 0.5 and 0.35 SD (17,27). Distribution-based estimates were then averaged over the four administrations.

*Patient acceptable symptom state.* PASS is usually defined as the 75th percentile score of those who consider their current state of health acceptable (22); however, because higher scores of the PROMIS PI reflect worse status, the 25th percentile was used. Secondary analyses also considered the 75th percentile of those who were somewhat or very satisfied with their health. These latter estimates were averaged over the four questionnaire administrations.

*Analysis by pain level.* Because both MIDs and PASS scores may differ according to current health states (21,28), we categorized respondents' pain levels on a 0 to 10 numeric rating scale as low (0-2.5), moderate (3.0-5.5), and high (greater than or equal to 6.0) in the year prior to the administration of the comparison questions (for MID) or the year that the PASS question was administered. Definitions of pain level categories were based on previous studies (29,30). We then repeated the MID and PASS analyses separately for low, moderate, and high pain levels.

**Table 3.** Minimum important change: anchor-based analyses[a]

| | Mean Change in PROMIS Pain Interference Scores | | | | | Effect Sizes of Mean Change in PROMIS Pain Interference Scores | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Comparison[b] | Much Worse | Somewhat Worse | Same | Somewhat Better | Much Better | Much Worse | Somewhat Worse | Same | Somewhat Better | Much Better |
| Total | | | | | | | | | | |
| Pain | 4.03 | **1.65** | −0.30 | **−1.60** | −2.95 | 0.43 | 0.18 | −0.03 | −0.17 | −0.32 |
| Pain interference | 3.44 | **1.76** | −0.24 | **−1.73** | −2.77 | 0.37 | 0.19 | −0.03 | −0.19 | −0.30 |
| General health | 3.69 | **1.84** | −0.32 | **−1.29** | −2.87 | 0.40 | 0.20 | −0.03 | −0.14 | −0.31 |
| By baseline pain level | | | | | | | | | | |
| Low | | | | | | | | | | |
| Pain | 10.97 | **4.24** | 0.25 | **−0.45** | −1.44 | 1.47 | 0.57 | 0.03 | −0.06 | −0.19 |
| Pain interference | 12.20 | **5.00** | 0.39 | **−0.43** | −1.44 | 1.64 | 0.67 | 0.05 | −0.06 | −0.19 |
| General health | 10.59 | **4.43** | 0.21 | **−0.28** | −0.79 | 1.42 | 0.59 | 0.03 | −0.04 | −0.11 |
| Moderate | | | | | | | | | | |
| Pain | 3.95 | **1.32** | −0.55 | **−2.03** | −4.70 | 0.68 | 0.23 | −0.10 | −0.35 | −0.80 |
| Pain interference | 4.38 | **1.71** | −0.65 | **−2.17** | −4.77 | 0.75 | 0.29 | −0.11 | −0.38 | −0.82 |
| General health | 3.52 | **1.64** | −0.60 | **−1.58** | −4.31 | 0.60 | 0.28 | −0.11 | −0.27 | −0.74 |
| High | | | | | | | | | | |
| Pain | 1.53 | **−0.47** | −1.89 | **−3.61** | −7.33 | 0.26 | −0.08 | −0.32 | −0.61 | −1.24 |
| Pain interference | 0.81 | **−0.37** | −1.83 | **−4.05** | −9.31 | 0.14 | −0.06 | −0.31 | −0.68 | −1.56 |
| General health | 0.82 | **−0.35** | −1.72 | **−3.13** | −7.73 | 0.14 | −0.06 | −0.29 | −0.53 | −1.30 |

Abbreviation: PROMIS, Patient-Reported Outcomes Measurement Information System.
Bolded values show the change in PROMIS PI scores for the 'somewhat worse' and 'somewhat better' groups, which were used to estimate MIDs.
[a]Values are mean changes averaged over three change periods.
[b]In each case, respondents compared their pain, pain interference, and health to 6 months before, ie, the pain rating at time B compared current pain with pain at time A, 6 months before, and the corresponding Δ in PROMIS T scores reflect the change in the score from time A to time B.

**Table 4.** Minimum important change over four six-month periods in individuals with RA: distribution-based methods[a]

| | Total, Mean (Range) | | |
|---|---|---|---|
| | SEM[b] | 0.5 SD | 0.35 SD |
| Total | 1.84 (1.77-1.90) | 4.61 (4.43-4.74) | 3.23 (3.10-3.32) |
| By baseline pain level | | | |
| Low | 1.55 (1.54-1.57) | 3.89 (3.86-3.93) | 2.72 (2.70-2.75) |
| Moderate | 1.24 (1.18-1.30) | 3.11 (2.96-3.24) | 2.18 (2.07-2.27) |
| High | 1.24 (1.15-1.31) | 3.10 (2.87-3.28) | 2.17 (2.01-2.30) |

Abbreviation: RA, rheumatoid arthritis; SEM, standardized error of measurement.
[a]Values are averaged over four administrations.
[b]Calculated as SEM = SD × square root (1 − reliability).

## RESULTS

Characteristics of the sample at the first questionnaire administration are shown in Table 2 and were relatively consistent across the four periods. The mean age was 65 ± 12 years. The sample was predominantly female and white. Mean pain levels on the numeric rating scale were moderate (mean 3.5; SD 2.7) but spanned the entire 0 to 10 range (median 3.0; interquartile range 1-5.5). The mean PROMIS PI score was approximately 0.5 SD higher (worse) than the population mean of 50.

**Minimally important differences.** Anchor-based methods yielded estimates of 1.65 to 1.84 for worsening and –1.29 to –1.73 for improvement (Table 3). Effect sizes were small. When we considered the full range of response options to the anchor items, however, PROMIS PI scores for the somewhat worse and somewhat better categories showed incremental mean changes compared with those for the same, much worse, and much better categories. Data for each change period are shown in Appendix Table 2.

In the distribution-based estimation, the SEM method, using the mean over four administrations, yielded an estimate similar to those from the anchor-based methods (1.84; Table 4). SD estimates of 0.5 and 0.35 were similar to changes seen in the much worse and much better groups. Distribution-based estimates for each of the four six-month periods are shown in Appendix Table 3.

When we examined anchor-based analyses by baseline pain levels, substantial differences were seen by group (Table 3). Among individuals with low pain, relatively large changes in PROMIS scores were associated with "somewhat worse" comparisons (4.24-5.00), whereas very small changes were associated with "somewhat better" comparisons (–0.28 to –0.45). For the high pain group, the pattern was reversed, with relatively large changes in PROMIS scores associated with "somewhat better" comparisons (–3.13 to –4.05) and very small changes associated with "somewhat worse" comparisons (–0.35 to –0.47). In the moderate pain group, PROMIS scores for somewhat worse and somewhat better groups were similar (1.32 to 1.71 and –1.58 to –2.03, respectively). Figure 1 illustrates the distribution of comparisons for each pain group. As pain increased, a smaller proportion of respondents rated their pain the same as 6 months before, and a higher proportion rated pain as somewhat or much worse. Data for each year are shown in Appendix Tables 4 to 6.

In contrast to results from the anchor-based analyses, distribution-based methods yielded similar results across baseline pain groups (Table 4). Data for each year are shown in Appendix Table 3.

**Patient acceptable symptom state.** By using the established PASS question, the PASS estimate was almost 1 SD below the population mean (41.6; Table 5). Estimates derived from the satisfaction with health item were closer to the population mean of 50. When examining the baseline pain groups separately, there were large differences in estimated PASS values (Table 5). The proportion of individuals who considered their state of health acceptable decreased from 84% of the low pain group to 59% of the moderate pain group to 30% of the high pain group. The estimated PASS value for the low pain group was 41.6, compared with 55.6 for the moderate pain group and 59.9 for the high pain group.

## DISCUSSION

The goal of these analyses was to estimate values for MIDs and PASS for the PROMIS PI scale in individuals with RA. Results suggest that the best estimate of MIDs for the entire group is approximately 2 points for both improvement and worsening. This estimate is within the range suggested by analyses in other conditions (Appendix Table 7). In general, whereas an analysis in patients with cancer suggested MIDs in the range of 4 to 6 points (18), MIDs recommended by other analyses in rheumatic or musculoskeletal conditions range from 2 to 3 points (12,16,17), suggesting a convergence of the evidence supporting these MID values. It is important to note that our analyses, as well as those cited previously, provided group-level estimates. At the individual level, an important change may be greater. This remains for further study.

As suggested by others, however, the baseline value of pain affected the MID. Individuals who had low pain levels appeared to have a ceiling on improvement so that ratings of improvements

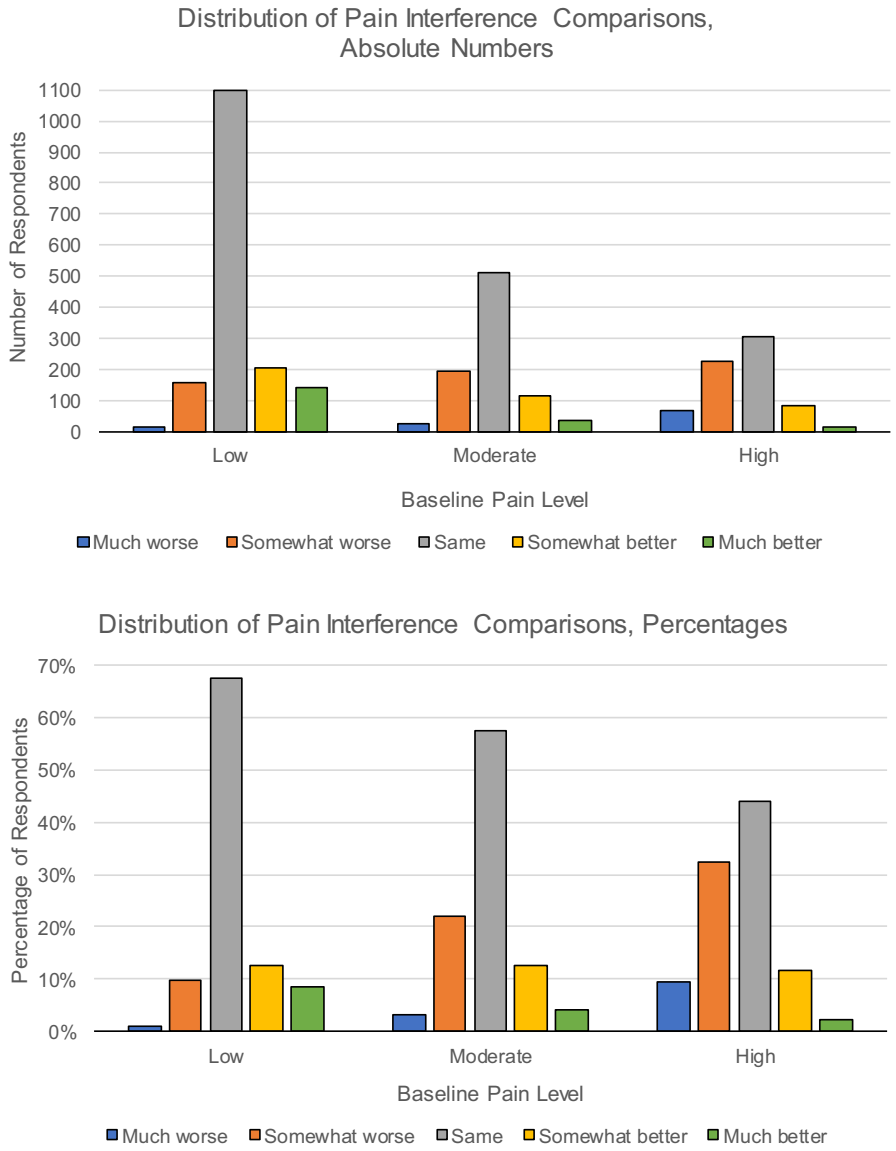


**Figure 1.** Sample distribution of comparison ratings for minimally important difference estimation. These graphs show data from period B. Other periods were similar.

were associated with small changes in PROMIS PI scores. In contrast, this group appeared to require a larger change to experience worsening of pain or health such that ratings of worsening were associated with fairly large increases in PI scores. The converse was true for individuals with high pain levels at baseline. This group appeared to have a floor on worsening so that ratings of worsened status were associated with small decrements in PROMIS PI scores. For this group, larger changes were needed for improvement, indicated by relatively large changes in PROMIS PI scores. These findings may reflect the boundaries (ie, floor and ceiling) of the scale as well as the perceptions of individuals at various baseline pain levels.

PASS analyses have not previously been estimated for any of the PROMIS measures. Our analyses showed that to meet the PASS criterion overall, PROMIS scores needed to be considerably better than the general US population mean of 50. PASS values were also associated with baseline pain, however. Among those with low pain at baseline, the PASS estimate was almost a full SD below the population mean, suggesting that this group aspires to PI levels equivalent to or better than population averages. More than 80% of this group also rated their current health state as acceptable. In contrast, as baseline pain increased, the proportion of individuals who felt their current state was acceptable decreased, whereas the degree of pain interference that was acceptable increased. For both the moderate and high pain groups, however, the level of acceptable pain interference was slightly lower than the mean pain level of that group.

Strengths of these analyses include its large sample size, the repeated assessments over administrations allowing for three change periods, the ability to examine MIDs and PASS

**Table 5.** PASS estimates[a]

| | Mean Pain Interference Score | Based on Established PASS Item ("Last 48 h")[b] | Based on Satisfaction With Health Question |
|---|---|---|---|
| Total | | 41.6 | 51.4 |
| By baseline pain level | | | |
| Low | 51.3 | 41.6 | 41.6 |
| Moderate | 57.6 | 55.6 | 55.2 |
| High | 61.9 | 59.9 | 58.5 |

Abbreviation: PASS, patient acceptable symptom state.
[a]Rated current health state as acceptable (n/N): total, 2341/3611; low pain, 1483/1753 (84.6%); moderate pain, 586/985 (59.5%); high pain, 260/857 (30.3%).
[b]The established PASS question was only asked in the period B questionnaire.

scores by baseline pain levels, and the availability of appropriate items as anchors for the MID analyses and to estimate PASS scores. It is possible that estimates of MIDs and PASS scores may vary in clinical cohorts or according to race/ethnicity, age, or disease duration. We were not able to examine these potential differences in this cohort because of the characteristics of the sample (ie, a preponderance of respondents were white, older, and had relatively long-standing disease), which means that additional studies are needed to determine how generalizable these values are in cohorts with more diversity in, for example, age, race/ethnicity, and disease duration. We did, however, determine that baseline levels of pain affect both MIDs and PASS scores. Because the participating individuals agreed to respond to surveys online or by mail, there may also be unmeasured biases in this cohort for which we were unable to account. It is also possible that the computer-adapted version of the PI score may yield slightly different results.

Overall, in this first estimation of MIDs and PASS scores for the PROMIS PI short form in RA, we found MIDs that were in the range of those identified in other studies of rheumatic and musculoskeletal conditions. PASS estimates reveal that individuals generally aspire to less pain interference than they currently experience. Those with low baseline pain aspire to levels better than population averages. These results should enhance use of the PROMIS PI score in RA by facilitating interpretation of scores and changes.

## AUTHOR CONTRIBUTIONS

All authors were involved in drafting the article or revising it critically for important intellectual content, approved the final version to be published, and take responsibility for the integrity of the data and the accuracy of the data analysis.

**Study conception and design.** Katz, Michaud.
**Acquisition of data.** Katz, Michaud.
**Analysis and interpretation of data.** Katz, Kannowski, Sun, Michaud.

## ROLE OF THE STUDY SPONSOR

Eli Lilly and Company had no role in the study design or in the collection, analysis, or interpretation of the data, the writing of the manuscript, or the decision to submit the manuscript for publication. Publication of this article was not contingent upon approval by Eli Lilly and Company.

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**Appendix Table 1.** Correlations between PROMIS Pain Interference scores and anchor measures[a,b]

| PROMIS Pain Interference | Compared With 6 mo Before | | |
|---|---|---|---|
| | Pain | Pain Interference | General Health |
| Period B | −0.35 | −0.42 | 0.32 |
| Period C | −0.33 | −0.41 | 0.30 |
| Period D | −0.33 | −0.38 | 0.31 |

Abbreviation: PROMIS, Patient-Reported Outcomes Measurement Information System.
[a]Differences in PROMIS scores were calculated for each pair of consecutive administrations, yielding three change periods (period A to period B, period B to period C, and period C to period D). As an example, data labeled as period B refer to the change period from period A to period B.
[b]Anchor variables used in correlations were all from the later year in each pair of years (ie, period B in the above example).

**Appendix Table 2.** Minimum important change: anchor-based analyses, mean changes in PROMIS Pain Interference scores, and effect sizes for each category of comparison measures (all responses)[a]

| | Mean Change in PROMIS Pain Interference Scores | | | | | Effect Sizes of Mean Change in PROMIS Pain Interference Scores | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Comparison | Much Worse | Somewhat Worse | Same | Somewhat Better | Much Better | Much Worse | Somewhat Worse | Same | Somewhat Better | Much Better |
| Pain | | | | | | | | | | |
| Period B | 5.07 | 1.93 | −0.09 | −1.57 | −3.71 | 0.53 | 0.20 | −0.01 | −0.17 | −0.39 |
| Period C | 3.53 | 0.84 | −0.57 | −1.65 | −2.75 | 0.37 | 0.09 | −0.06 | −0.17 | −0.29 |
| Period D | 3.49 | 2.19 | −0.23 | −1.59 | −2.39 | 0.39 | 0.25 | −0.03 | −0.18 | −0.27 |
| **Mean** | **4.03** | **1.65** | **−0.30** | **−1.60** | **−2.95** | **0.43** | **0.18** | **−0.03** | **−0.17** | **−0.32** |
| Pain interference | | | | | | | | | | |
| Period B | 4.27 | 2.14 | −0.08 | −1.64 | −3.40 | 0.45 | 0.23 | −0.01 | −0.17 | −0.36 |
| Period C | 2.44 | 1.20 | −0.50 | −2.09 | −2.48 | 0.26 | 0.13 | −0.05 | −0.22 | −0.26 |
| Period D | 3.61 | 1.93 | −0.14 | −1.47 | −2.43 | 0.41 | 0.22 | −0.02 | −0.17 | −0.27 |
| **Mean** | **3.44** | **1.76** | **−0.24** | **−1.73** | **−2.77** | **0.37** | **0.19** | **−0.03** | **−0.19** | **−0.30** |
| General health | | | | | | | | | | |
| Period B | 5.16 | 2.01 | −0.09 | −1.59 | −2.79 | 0.54 | 0.21 | −0.01 | −0.17 | −0.29 |
| Period C | 3.11 | 1.65 | −0.74 | −1.31 | −3.24 | 0.33 | 0.17 | −0.08 | −0.14 | −0.34 |
| Period D | 2.81 | 1.86 | −0.12 | −0.96 | −2.58 | 0.32 | 0.21 | −0.01 | −0.11 | −0.29 |
| **Mean** | **3.69** | **1.84** | **−0.32** | **−1.29** | **−2.87** | **0.40** | **0.20** | **−0.03** | **−0.14** | **−0.31** |

Abbreviation: PROMIS, Patient-Reported Outcomes Measurement Information System.
Bolded values highlight the mean values of mean changes and mean effect sizes.
[a]Differences in PROMIS scores were calculated for each pair of consecutive administrations, yielding three change periods (period A to period B, period B to period C, and period C to period D). As an example, data labeled as period B refer to the change period from period A to period B.

**Appendix Table 3.** Minimum important change over four six-month periods in individuals with RA: distribution-based methods total and by baseline pain level

| | Total Group | | | Low Pain (0-2.5) | | | Moderate Pain (3.0-5.5) | | | High Pain (≥6.0) | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Period | SEM | 0.5 SD | 0.35 SD | SEM | 0.5 SD | 0.35 SD | SEM | 0.5 SD | 0.35 SD | SEM | 0.5 SD | 0.35 SD |
| A | 1.90 | 4.74 | 3.32 | 1.56 | 3.91 | 2.73 | 1.28 | 3.21 | 2.25 | 1.24 | 3.10 | 2.17 |
| B | 1.89 | 4.72 | 3.30 | 1.54 | 3.86 | 2.70 | 1.21 | 3.02 | 2.11 | 1.26 | 3.15 | 2.20 |
| C | 1.77 | 4.43 | 3.10 | 1.54 | 3.86 | 2.70 | 1.18 | 2.96 | 2.07 | 1.15 | 2.87 | 2.01 |
| D | 1.82 | 4.56 | 3.19 | 1.57 | 3.93 | 2.75 | 1.30 | 3.24 | 2.27 | 1.31 | 3.28 | 2.30 |
| Mean | 1.84 | 4.61 | 3.23 | 1.55 | 3.89 | 2.72 | 1.24 | 3.11 | 2.18 | 1.24 | 3.10 | 2.17 |

Abbreviation: RA, rheumatoid arthritis; SEM, standardized error of measurement.

**Appendix Table 4.** Minimum important change: anchor-based analyses, mean changes in PROMIS Pain Interference scores, and effect sizes for each category of comparison measures (low pain)

| | Mean Change in PROMIS Pain Interference Scores[a] | | | | | Effect Sizes of Mean Change in PROMIS Pain Interference Scores | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Much Worse | Somewhat Worse | Same | Somewhat Better | Much Better | Much Worse | Somewhat Worse | Same | Somewhat Better | Much Better |
| Pain | | | | | | | | | | |
| Period B | 13.74 | 4.56 | 0.19 | −0.64 | −2.05 | 1.83 | 0.61 | 0.03 | −0.09 | −0.27 |
| Period C | 12.59 | 4.04 | 0.24 | 0.03 | −0.6 | 1.69 | 0.54 | 0.03 | 0.00 | −0.08 |
| Period D | 6.59 | 4.11 | 0.33 | −0.75 | −1.67 | 0.89 | 0.55 | 0.04 | −0.10 | −0.23 |
| **Mean** | **10.97** | **4.24** | **0.25** | **−0.45** | **−1.44** | **1.47** | **0.57** | **0.03** | **−0.06** | **−0.19** |
| Pain interference | | | | | | | | | | |
| Period B | 13.35 | 5.33 | 0.44 | −0.72 | −2.11 | 1.78 | 0.71 | 0.06 | −0.10 | −0.28 |
| Period C | 15.37 | 5.01 | 0.38 | −0.2 | −0.51 | 2.07 | 0.67 | 0.05 | −0.03 | −0.07 |
| Period D | 7.88 | 4.65 | 0.36 | −0.38 | −1.69 | 1.06 | 0.63 | 0.05 | −0.05 | −0.23 |
| **Mean** | **12.20** | **5.00** | **0.39** | **−0.43** | **−1.44** | **1.64** | **0.67** | **0.05** | **−0.06** | **−0.19** |
| General health | | | | | | | | | | |
| Period B | 11.63 | 4.34 | 0.29 | −0.9 | −0.62 | 1.55 | 0.58 | 0.04 | −0.12 | −0.08 |
| Period C | 11.26 | 5.47 | 0.03 | 0.16 | −0.42 | 1.52 | 0.74 | 0.00 | 0.02 | −0.06 |
| Period D | 8.87 | 3.48 | 0.31 | −0.11 | −1.32 | 1.20 | 0.47 | 0.04 | −0.01 | −0.18 |
| **Mean** | **10.59** | **4.43** | **0.21** | **−0.28** | **−0.79** | **1.42** | **0.59** | **0.03** | **−0.04** | **−0.11** |

Abbreviation: PROMIS, Patient-Reported Outcomes Measurement Information System.
Bolded values highlight the mean values of mean changes and mean effect sizes.
[a]Changes in PROMIS Pain Interference scores were calculated as the difference between scores in the period shown in the first column and the previous period; for example, mean changes for period B are differences between scores at period A and period B.

**Appendix Table 5.** Minimum important change: anchor-based analyses, mean changes in PROMIS Pain Interference scores, and effect sizes for each category of comparison measures (moderate pain)

| | Mean Change in PROMIS Pain Interference Scores | | | | | Effect Sizes of Mean Change in PROMIS Pain Interference Scores | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Much Worse | Somewhat Worse | Same | Somewhat Better | Much Better | Much Worse | Somewhat Worse | Same | Somewhat Better | Much Better |
| Pain | | | | | | | | | | |
| Period B | 4.95 | 1.67 | −0.13 | −1.94 | −6.3 | 0.78 | 0.26 | −0.02 | −0.30 | −0.99 |
| Period C | 2.89 | 0.25 | −1.08 | −2.53 | −5.48 | 0.52 | 0.05 | −0.20 | −0.46 | −0.99 |
| Period D | 4.02 | 2.04 | −0.44 | −1.62 | −2.31 | 0.73 | 0.37 | −0.08 | −0.30 | −0.42 |
| **Mean** | **3.95** | **1.32** | **−0.55** | **−2.03** | **−4.70** | **0.68** | **0.23** | **−0.10** | **−0.35** | **−0.80** |
| Pain interference | | | | | | | | | | |
| Period B | 5.9 | 2.19 | −0.45 | −1.77 | −5.2 | 0.92 | 0.34 | −0.07 | −0.28 | −0.82 |
| Period C | 3.48 | 1.01 | −1.2 | −3 | −5.73 | 0.63 | 0.18 | −0.22 | −0.54 | −1.04 |
| Period D | 3.75 | 1.94 | −0.29 | −1.74 | −3.39 | 0.69 | 0.35 | −0.05 | −0.32 | −0.62 |
| **Mean** | **4.38** | **1.71** | **−0.65** | **−2.17** | **−4.77** | **0.75** | **0.29** | **−0.11** | **−0.38** | **−0.82** |
| General health | | | | | | | | | | |
| Period B | 4.71 | 2.14 | −0.31 | −1.63 | −4.94 | 0.74 | 0.34 | −0.05 | −0.26 | −0.77 |
| Period C | 3.77 | 0.82 | −1.31 | −1.88 | −5.59 | 0.68 | 0.15 | −0.24 | −0.34 | −1.01 |
| Period D | 2.08 | 1.95 | −0.17 | −1.24 | −2.39 | 0.38 | 0.36 | −0.03 | −0.23 | −0.44 |
| **Mean** | **3.52** | **1.64** | **−0.60** | **−1.58** | **−4.31** | **0.60** | **0.28** | **−0.11** | **−0.27** | **−0.74** |

Abbreviation: PROMIS, Patient-Reported Outcomes Measurement Information System.
Bolded values highlight the mean values of mean changes and mean effect sizes.

**Appendix Table 6.** Minimum important change: anchor-based analyses, mean changes in PROMIS Pain Interference scores, and effect sizes for each category of comparison measures (high pain)

| | Mean Change in PROMIS Pain Interference Scores | | | | | Effect Sizes of Mean Change in PROMIS Pain Interference Scores | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Much Worse | Somewhat Worse | Same | Somewhat Better | Much Better | Much Worse | Somewhat Worse | Same | Somewhat Better | Much Better |
| Pain | | | | | | | | | | |
| Period B | 1.36 | −0.33 | −1.1 | −3.1 | −8.3 | 0.22 | −0.05 | −0.18 | −0.51 | −1.36 |
| Period C | 0.86 | −1.65 | −2.56 | −4.38 | −7.25 | 0.14 | −0.28 | −0.43 | −0.73 | −1.21 |
| Period D | 2.38 | 0.57 | −2.00 | −3.36 | −6.45 | 0.42 | 0.10 | −0.35 | −0.59 | −1.14 |
| **Mean** | **1.53** | **−0.47** | **−1.89** | **−3.61** | **−7.33** | **0.26** | **−0.08** | **−0.32** | **−0.61** | **−1.24** |
| Pain interference | | | | | | | | | | |
| Period B | 1.24 | −0.20 | −1.28 | −3.79 | −10.72 | 0.20 | −0.03 | −0.21 | −0.62 | −1.76 |
| Period C | −1.14 | −1.09 | −2.47 | −4.83 | −11.9 | −0.19 | −0.18 | −0.41 | −0.81 | −1.98 |
| Period D | 2.32 | 0.18 | −1.73 | −3.53 | −5.32 | 0.41 | 0.03 | −0.31 | −0.62 | −0.94 |
| **Mean** | **0.81** | **−0.37** | **−1.83** | **−4.05** | **−9.31** | **0.14** | **−0.06** | **-0.31** | **−0.68** | **−1.56** |
| General health | | | | | | | | | | |
| Period B | 2.03 | −0.24 | −1.07 | −3.06 | −8.34 | 0.33 | −0.04 | −0.18 | −0.50 | −1.37 |
| Period C | −0.08 | −1.24 | −2.48 | −3.82 | −7.91 | −0.01 | −0.21 | −0.41 | −0.64 | −1.32 |
| Period D | 0.51 | 0.43 | −1.61 | −2.52 | −6.94 | 0.09 | 0.08 | −0.28 | −0.45 | −1.23 |
| **Mean** | **0.82** | **−0.35** | **−1.72** | **−3.13** | **−7.73** | **0.14** | **−0.06** | **−0.29** | **−0.53** | **−1.30** |

Abbreviation: PROMIS, Patient-Reported Outcomes Measurement Information System.
Bolded values highlight the mean values of mean changes and mean effect sizes.

**Appendix Table 7.** Previous determinations of PROMIS Pain Interference MIDs in rheumatic and musculoskeletal conditions

| Reference | PROMIS Scale | Condition | Treatment Intervention Study? | SEM | 0.35 SD | 0.5 SD | Anchor Based | Suggested MID | Notes |
|---|---|---|---|---|---|---|---|---|---|
| Amtmann et al 16 | Pain Interference | Low back pain | Yes | Time 1: 2.3; time 2: 2.5 | … | … | … | 3.5-5.5 | Suggested MID is IQR of estimates. Corresponding effect sizes are 0.34-0.54 SD |
| Chen et al 17 | Pain Interference | Low back pain | Yes, 6-mo follow-up | 1.97 | 2.40 | 3.43 | Prospective: one category improved: −2.31, one category worsened: 3.78; retrospective: same to a little better: −2.14, same to a little worse: 1.63; retrospective: average 1-point better: −2.40, average 1-point worse: 1.63 | 2-3 points, average 2.5 | Prospective: subtracting the follow-up score from baseline score; retrospective: participants rate change on 7-point scale from very much worse to very much better |
| | … | Back pain or hip/knee OA | Yes, 3-mo follow-up | 1.71 | 1.85 | 2.64 | Prospective: one category improved: −3.83, one category worsened: 3.82; retrospective same to a little better: −0.66, same to a little worse: 1.11; retrospective: average 1-point better: −2.43, average 1-point worse: 2.37 | … | … |
| Lee et al 12 | Pain Interference (6b) | Knee OA | … | Time 1: 1.7; time 2: 1.8 | Time 1: 2.49; time 2: 2.91 | Time 1: 3.5; time 2: 4.15 | 2.35-2.4 | 2.35-2.4 | MIDs corresponded to 26%-39% of normalized SD units |

Abbreviation: IQR, interquartile range; MID, minimally important difference; OA, osteoarthritis; PROMIS, Patient-Reported Outcomes Measurement Information System.