The minimal clinically important difference of the Patient-Reported Outcomes Measurement Information System (PROMIS) physical function and upper extremity computer adaptive tests and QuickDASH in the setting of elbow trauma

Dustin J. Randall, BS<sup>a,b,1</sup>, Yue Zhang, PhD<sup>c,1</sup>, Andrew P. Harris, MD<sup>d</sup>, Yuqing Qiu, MS<sup>e</sup>, Haojia Li, MSc<sup>f</sup>, Andrew R. Stephens, BS<sup>a</sup>, Nikolas H. Kazmers, MD, MSE<sup>a</sup>,*  

<sup>1</sup>These authors contributed equally to this work (DJR and YZ).

<sup>*</sup>Corresponding author: Nikolas H. Kazmers, MD, MSE, Department of Orthopaedics, University of Utah, 590 Wakara Way, Salt Lake City, UT 84108, USA.  
E-mail address: nkazmers@gmail.com (N.H. Kazmers).

<sup>a</sup>Department of Orthopaedics, University of Utah, Salt Lake City, UT, USA  
<sup>b</sup>Oakland University William Beaumont School of Medicine, Rochester, MI, USA  
<sup>c</sup>Division of Public Health, University of Utah, Salt Lake City, UT, USA  
<sup>d</sup>University Orthopedic Surgeons, Knoxville, TN, USA  
<sup>e</sup>Weill Cornell Medicine, Department of Population Health Sciences, New York, NY, USA

ARTICLE INFO

Keywords:  
Elbow  
Minimal clinically important difference (MCID)  
Orthopaedic/orthopedic trauma  
PROMIS upper extremity (UE) computer adaptive test  
PROMIS physical function (PF) computer adaptive test (CAT)  
QuickDash

Background: Minimal clinically important difference (MCID) estimates are useful for gauging clinical relevance when interpreting changes or differences in patient-reported outcomes scores. These values are lacking in the setting of elbow trauma. Our primary purpose was to estimate the MCID of the Patient-Reported Outcomes Measurement Information System (PROMIS) physical function (PF) computer adaptive test (CAT), the PROMIS upper extremity (UE) CAT, and the QuickDASH using an anchor-based approach for patients recovering from elbow trauma and related surgeries. Secondarily, we aimed to estimate the MCID using the 1/2 standard deviation method.

Materials & methods: Adult patients undergoing treatment for isolated elbow injuries between July 2014 and April 2020 were identified at a single tertiary academic medical center. Outcomes, including the PROMIS PF CAT v1.2/2.0, PROMIS UE CAT v1.2, and QuickDASH, were collected via a tablet computer. For inclusion, baseline (6 months before injury up to 11 days postoperatively or after injury) and follow-up (11 to 150 days postoperative or after injury) PF or UE CAT scores were required, as well as a response to an anchor question querying improvement in physical function. The MCID was calculated using (1) an anchor-based approach using the difference in mean score change between anchor groups reporting “No change” and “Slightly Improved/Improved” and (2) the 1/2 standard deviation method.

Results: Of the 146 included patients, the mean age was 46 ± 18 years and 67 (46%) were women. Most patients (129 of 146 or 88%) were recovering from surgery, and the remaining 12% were recovering from nonoperatively managed fractures and/or dislocations. The mean follow-up was 157 ± 192 days. Scores for each instrument improved significantly between baseline and follow-up. Anchor-based MCID values were calculated as follows: 5.7, 4.6, and 5.3 for the PROMIS PF CAT, PROMIS UE CAT, and QuickDASH, respectively. MCID values estimated using the 1/2 standard deviation method were 4.3, 4.8, and 11.7 for the PROMIS PF CAT, PROMIS UE CAT, and QuickDASH, respectively.

Conclusions: In the setting of elbow trauma, we propose MCID ranges of 4.3 to 5.7 for the PROMIS PF CAT, 4.6 to 4.8 for the PROMIS UE CAT, and 5.3 to 11.7 for the QuickDASH. These values will provide a framework for clinical relevance when interpreting clinical outcomes studies, or powering clinical trials, for populations recovering from trauma.

© 2021 The Author(s). Published by Elsevier Inc. on behalf of American Shoulder and Elbow Surgeons. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

Over the last two decades, there has been increasing focus on incorporating the patient perspective in the interpretation of treatment outcomes. In addition to traditional methods of grading an outcome such as radiologic and physical evaluations, the creation of patient-reported outcome (PRO) instruments has become a significant part of determining the effectiveness of a treatment.
Many PRO instruments have been developed, with the Patient-Reported Outcomes Measurement Information System (PROMIS) tools designed by the National Institutes of Health receiving increased focus in recent orthopedic literature. These instruments may be delivered using computer adaptive testing (CAT) methods which can limit the time requirement for patient completion by decreasing the number of questions, but floor and ceiling effects have been reported. Three

Well-designed PROs provide the ability to give meaningful interpretations. In clinical research, statistical significance is often calculated, such as to evaluate for a difference in outcomes scores between two treatment strategies. However, when statistically significant differences are observed, it may remain unclear whether these differences are clinically relevant or not. One measure that has helped to assess for clinical relevance is the minimal clinically important difference (MCID). There are two main methods for determining MCID: anchor-based and distribution-based. Although distribution methods have been used across many fields of medicine over time, anchor-based methods are appealing because they query patients directly for a global rating of change which is directly used in calculating the MCID. Both methods have been used to calculate MCIDs in several upper extremity orthopedic populations recently. These include patients undergoing carpal tunnel release, cubital tunnel decompression, ligament reconstruction tendon interposition, and total shoulder arthroplasty and for a general hand and upper extremity cohort or specific cohorts of patients with distal radius fractures or thumb carpometacarpal arthritis.

Although the inception of PROMIS instruments took place back in 2004, and descriptions of the QuickDASH date back to a similar time frame, we are unaware of any current studies that report MCID values using these instruments for patients recovering from elbow trauma. Therefore, our primary study purpose was to establish MCID estimates for the PROMIS physical function (PF) CAT, PROMIS upper extremity (UE) CAT, and QuickDASH using a the mean-change anchor-based and distribution-based methods for patients after treatment in the setting of elbow trauma. Secondly, we aimed to establish the MCID using the 1/2 standard deviation (SD) method for these three instruments among a patient population recovering from elbow trauma.

Materials and methods

Before initiating data collection for this retrospective cohort study, institutional review board approval was received. All included patients were adults (≥18 years of age) and sought care for their baseline visit between July 2014 and April 2020 and were evaluated by one of five fellowship-trained orthopedic hand surgeons, or one of four fellowship-trained orthopedic trauma surgeons, at a level-one tertiary academic medical center with capture of 10% of the US land mass. Patients were identified by one of 55 current procedural terminology codes pertaining to treatment of a spectrum of traumatic elbow conditions (all codes are listed in Supplementary Appendix S1). Manual chart review of clinical and operative notes was performed to verify the accuracy of coding, to collect demographic data, and to exclude patients without a history of elbow trauma. Patients with additional ipsilateral and/or contralateral upper extremity injuries, injuries to the spine, or abdominal and/or thoracic injuries were excluded. Patients with concomitant lower extremity injuries were excluded from the PROMIS PF CAT MCID analysis but not from the upper extremity—specific analyses (PROMIS UE CAT or QuickDASH).

As part of standard care, all patients seeking care for elbow trauma at our university orthopedic clinic are routinely given a hand-held tablet and instructed to complete the following PRO instruments at each clinic visit: the PROMIS PF CAT, PROMIS UE CAT, and QuickDASH. Notably, both the PROMIS PF and UE CATs have undergone an update from version 1.2 (v1.2) to version 2.0 (v2.0) during the study period. For the PROMIS PF CAT, scores between versions may be interchanged, whereas scores for the PROMIS UE CAT are not interchangeable between versions. The resulting PRO data, which are collected prospectively and integrated into each patient's medical record, were electronically pulled for each included patient for retrospective review.

For study inclusion, baseline scores (defined as 6 months preoperatively or before injury to 11 days postoperatively or after injury) and follow-up scores (11 to 150 days postoperatively or after injury) were required for at least one of the three instruments under study (PROMIS PF CAT, PROMIS UE CAT, QuickDASH). In addition, inclusion required a response to the following anchor question at the follow-up visit: “Compared to your first evaluation at the University Orthopaedic Center, how would you describe your physical function level now?” Likert response choices to the anchor question included “Much worse,” “Worse,” “Slightly Worse,” “No change,” “Slightly improved,” “Improved,” and “Much improved.” For patients with multiple pretreatment visits that could potentially be included within the specified time period relative to the surgery/injury date for baseline data, scores from the visit closest to the surgery/injury date was used. For patients with multiple postoperative/postinjury visits, the scores from the visit closest to 6 weeks after the surgery/injury were used. Each patient only accounted for one data point for the anchor-based and 1/2 SD MCID calculations.

Basic descriptive statistics for patient baseline characteristics were calculated. Normally distributed continuous variables were compared using the Student’s t-test, and non-normal data were compared using the Wilcoxon rank-sum test. Among the several existing methods for calculating MCID (anchor-, distribution-, opinion-, ½ SD-based methods, and so on), we opted to use the anchor-based and ½ SD methods. We calculated anchor-based MCID values by calculating the difference in score change between the anchor group reporting “No change” and the combined group reporting low levels of improvement (“Slightly improved” plus “Improved”) as previously performed. We also used the 1/2 SD distribution method to estimate the MCID using the score change among anchor groups. Formulae used to calculate MCID using both methods are provided in Supplementary Appendix S2. All pertinent statistical tests were two-sided, and a significance level of 0.05 was used throughout.

Results

A total of 447 patients had eligible elbow surgeries and/or injuries. Figure 1 summarizes the attrition of patients included in analysis based on study selection criteria. Of these, 101 were excluded owing to lack of data for all three outcomes instruments under study. An additional 198 patients were excluded owing to lack of both baseline and follow-up scores, and two additional patients with concomitant lower extremity injuries were excluded.
Included Patients

Records identified for patients with traumatic elbow conditions
(n=447)

Screened records for associated responses to all three outcomes instruments under study
(n=447)

Records excluded due to lack of data for any of the three outcomes instruments under study
(n=101)

Screened records for both baseline and follow-up scores
(n=346)

Records excluded due to lack of both baseline and follow-up scores
(n=198)

Screened records to confirm isolated elbow trauma
(n=148)

Records excluded due to concomitant lower extremity injuries
(n=2)

Patients included in analysis
(n=146)

Figure 1 Attrition of patients included in analysis based on study selection criteria.

from the PROMIS PF CAT analysis but not the PROMIS UE CAT or QuickDASH analyses. This left a total of 146 patients for analysis of which 70 patients had includable responses to the anchor question (“No change,” “Slightly improved,” or “Improved”).

Of the 146 included patients, the mean age was 46 ± 18 years, and 46% were female. Additional baseline characteristics are provided in Table I, including a breakdown of these data by each PRO instrument. The majority (88%) of patients were recovering from surgery, whereas 12% were recovering from nonoperatively managed fractures and/or dislocations (Table II). The most common surgical procedures were distal biceps repair (24 of 146 or 16% of the cohort), olecranon open reduction internal fixation (15 of 146 or 10%), and distal humerus open reduction internal fixation (11 of 146 or 8% when considering 2 patients undergoing additional ligament repair or open fracture débridement). Mean follow-up was 157 ± 192 days.

Scores on the PROMIS PF CAT, PROMIS UE CAT, and QuickDASH are summarized for baseline and follow-up visits for all included patients and for patients included in anchor-based MCID analyses (Table III). Scores for each of the three instruments improved significantly for the entire cohort of 146 patients (P < .05 for each comparison). The summary of score change by anchor group is outlined for each PRO instrument in Table IV.

Anchor-based MCID values were calculated as 5.7 for the PROMIS PF CAT, 4.6 for the PROMIS UE CAT, and 5.3 for the QuickDASH (Table V). MCID values calculated using the 1/2 SD method were 4.3 for the PROMIS PF CAT, 4.8 for the PROMIS UE CAT, and 11.7 for the QuickDASH (Table V).

Discussion

Our main study finding pertains to defining estimates of the MCID for the PROMIS PF CAT v1.2/2.0, the PROMIS UE CAT v1.2, and the QuickDASH for a cohort of patients recovering from elbow trauma. Specifically, we propose MCID values in the range of 4.3 to 5.7 for the PROMIS PF CAT, 4.6 to 4.8 for the PROMIS UE CAT, and 5.3 to 11.7 for the QuickDASH.

As patient-reported outcomes continue to be implemented in clinical practice, effective interpretation of these scores has become increasingly important. PROMIS instruments, as well as legacy
Baseline patient characteristics.

| Variable                      | Stats/Subgroups        | All included patients (N = 146) | PROMIS PF CAT v1.2/2.0 (N = 131) | PROMIS UE CAT v1.2 (N = 87) | QuickDASH (N = 110) |
|-------------------------------|------------------------|---------------------------------|----------------------------------|----------------------------|---------------------|
| **Age**                       | Mean (SD)              | 45.5 (18)                       | 44.5 (18)                        | 45.7 (17.7)                | 46.4 (17.5)         |
| **Median (IQR)**              | 47 (30.2, 60)          | 46 (29.2, 58)                   | 46 (30.5, 58)                    | 48 (31.5, 59)              |                     |
| **Range**                     | (11, 86)               | (11, 86)                        | (11, 86)                         | (11, 86)                   |                     |
| **Sex**                       | F                      | 67 (46%)                        | 58 (44%)                         | 41 (47%)                   | 52 (47%)            |
| **M**                         | 79 (54%)               | 73 (56%)                        | 46 (53%)                         | 58 (53%)                   |                     |
| **BMI**                       | Mean (SD)              | 28.6 (7.4)                      | 28.8 (7.4)                       | 29.5 (8.2)                 | 29.2 (7.8)          |
| **Median (IQR)**              | 27.1 (23.4, 32)        | 27.1 (23.6, 32.4)               | 28.1 (23.3, 33.3)                | 27.6 (23.5, 33.2)         |                     |
| **Range**                     | (17.4, 56)             | (17.9, 56)                      | (18.3, 56)                       | (17.9, 56)                 |                     |
| **Race**                      | White or Caucasian     | 103 (87%)                       | 96 (87%)                         | 57 (85%)                   | 71 (86%)            |
| **Asian**                     | 3 (3%)                 | 3 (3%)                          | 1 (1%)                           | 1 (1%)                     |                     |
| **Choose not to disclose**    | 1 (1%)                 | 1 (1%)                          | 1 (1%)                           | 0 (0%)                     |                     |
| **Native Hawaiian and Other Pacific Islander** | 3 (3%) | 2 (2%) | 1 (1%) | 3 (4%) |                     |
| **Other**                     | 8 (7%)                 | 8 (7%)                          | 6 (9%)                           | 8 (10%)                    |                     |
| **Insurance**                 | Commercial             | 66 (56%)                        | 63 (57%)                         | 39 (58%)                   | 49 (59%)            |
| **Government Other**          | 11 (9%)                | 11 (10%)                        | 6 (9%)                           | 7 (8%)                     |                     |
| **Medicaid**                  | 8 (7%)                 | 8 (7%)                          | 5 (7%)                           | 5 (6%)                     |                     |
| **Medicare**                  | 18 (15%)               | 15 (14%)                        | 9 (13%)                          | 11 (13%)                   |                     |
| **Self-pay**                  | 7 (6%)                 | 6 (5%)                          | 4 (6%)                           | 5 (6%)                     |                     |
| **Worker’s compensation**     | 8 (7%)                 | 7 (6%)                          | 4 (6%)                           | 6 (7%)                     |                     |
| **Smoking**                   | Yes                    | 17 (12%)                        | 17 (13%)                         | 8 (9%)                     | 10 (9%)             |
| **Quit**                      | 22 (15%)               | 18 (14%)                        | 13 (15%)                         | 16 (15%)                   |                     |
| **Unknown**                   | 72 (50%)               | 64 (50%)                        | 42 (48%)                         | 53 (49%)                   |                     |
| **Alcohol use**               | Yes                    | 58 (40%)                        | 54 (42%)                         | 36 (41%)                   | 43 (39%)            |
| **No**                        | 59 (46%)               | 55 (46%)                        | 59 (68%)                         | 73 (67%)                   |                     |
| **Unknown**                   | 59 (40%)               | 44 (35%)                        | 39 (52%)                         | 42 (37%)                   |                     |
| **ASA class**                 | 0                      | 17 (12%)                        | 14 (11%)                         | 12 (14%)                   | 16 (15%)            |
| **1**                         | 52 (36%)               | 48 (37%)                        | 30 (34%)                         | 39 (35%)                   |                     |
| **2**                         | 50 (34%)               | 45 (34%)                        | 29 (33%)                         | 36 (33%)                   |                     |
| **3**                         | 62 (41%)               | 62 (41%)                        | 44 (51%)                         | 50 (45%)                   |                     |
| **4**                         | 41 (27%)               | 41 (27%)                        | 33 (39%)                         | 38 (34%)                   |                     |
| **Hand dominance**            | Left                   | 7 (5%)                          | 6 (5%)                           | 5 (6%)                     | 7 (6%)              |
| **Right**                     | 65 (45%)               | 62 (47%)                        | 44 (51%)                         | 50 (45%)                   |                     |
| **Unknown**                   | 74 (51%)               | 63 (48%)                        | 38 (44%)                         | 53 (48%)                   |                     |
| **Injury to dominant hand**   | Yes                    | 26 (18%)                        | 24 (18%)                         | 17 (20%)                   | 22 (20%)            |
| **No**                        | 35 (24%)               | 34 (26%)                        | 26 (30%)                         | 25 (23%)                   |                     |
| **Left**                      | 15 (10%)               | 12 (9%)                         | 8 (9%)                           | 13 (12%)                   |                     |
| **Right**                     | 17 (12%)               | 13 (10%)                        | 12 (14%)                         | 16 (15%)                   |                     |
| **Unknown**                   | 53 (36%)               | 48 (37%)                        | 24 (28%)                         | 34 (31%)                   |                     |

BMI, body mass index; IQR, interquartile range; SD, standard deviation.

Instruments, can make notable contributions to clinical practice by improving our understanding of how to gauge, interpret, and compare improvement for different treatments. Substantial progress has been made in recent years in regards to collecting and interpreting PROMIS scores, including prior studies reporting MCID estimates, for a variety of orthopedic procedures. However, we are unaware of prior literature that has focused on patients with elbow trauma.

Although MCID studies are limited in the setting of elbow trauma, our proposed MCID values are consistent with previous studies. Our estimates of 4.3 to 5.7 for the PROMIS PF CAT are in line with values reported among patients undergoing treatment of distal radius fracture (3.6 to 4.6) and for patients undergoing elective foot and ankle surgery (4.2). Although the instrument is different and scores may not be directly interchangeable, our PROMIS PF CAT MCID estimate is also subjectively comparable to that defined in a cohort of patients with an advanced-stage cancer using the PF 10-item questionnaire (range, 4.0-6.0, depending on the method used). Although we were unable to identify published studies reporting the MCID for the PROMIS UE CAT v1.2 in the setting of elbow trauma, our estimates of (4.6 to 4.8) were similar to those reported by Kazmers et al for patients recovering from carpal tunnel release (3.6) but subjectively greater than estimates for a general nonshoulder hand and upper extremity population (2.1). It is noteworthy that our estimates are comparable with a gross estimate of 5.0 for the MCID of PROMIS instruments in general, which can be obtained using the 1/2 SD method based on an intended SD of 10 in a normative population. Finally, our Quick-DASH MCID value of 5.3 to 11.7 also falls within the range of previously reported values for upper extremity patients (6.8 to 19). There are several limitations to our study. In general, the MCID may be calculated using anchor-, distribution-, or opinion-based methods, with no consensus on a gold standard. For this reason, we reported both the 1/2 SD and anchor-based values. The triangulation method is an option for calculating the mean of MCID values estimated across a range of different techniques. However, one downside is that the estimation uncertainty in each technique is not typically considered in the triangulation. The qualitative interview-based MCID calculation is typically included in the triangulation, but we did not conduct this in our study (similar to most MCID studies across all orthopedic subspecialties that we identified in the literature over the past decade). Qualitative interview-based MCID calculation may, however, appear in future work. When using the anchor-based methods, MCID values may be influenced by the anchor question chosen for the analysis, and no
Table II
Summary of surgeries performed.

| Surgery/Injury type                                                | Count (% of all included patients)* |
|-------------------------------------------------------------------|-------------------------------------|
| Distal biceps repair                                              | 24 (16.4)                           |
| Nonoperative                                                      | 17 (11.6)                           |
| Olecranon ORIF                                                     | 15 (10.3)                           |
| Distal humerus ORIF                                                | 11 (7.5)                            |
| Radial head ORIF                                                   | 6 (4.1)                             |
| Total elbow arthroplasty                                          | 6 (4.1)                             |
| Radial head excision                                              | 5 (3.4)                             |
| Terrible triad ORIF                                               | 5 (3.4)                             |
| Elbow manipulation closed reduction under anesthesia               | 3 (2.1)                             |
| Olecranon ORIF with open fracture debridement                     | 3 (2.1)                             |
| Radial head arthroplasty                                          | 3 (2.1)                             |
| Contracture release with hardware removal                         | 2 (1.4)                             |
| Ligament reconstruction                                           | 2 (1.4)                             |
| Monteggia ORIF                                                     | 2 (1.4)                             |
| Radial head arthroplasty with ligament repair                     | 2 (1.4)                             |
| Removal of loose body                                             | 2 (1.4)                             |
| Total elbow arthroplasty with cubital tunnel decompression        | 2 (1.4)                             |
| Brachial artery and median/unlar nerve repair with distal biceps repair | 1 (0.7)                     |
| Capitellum ORIF                                                   | 1 (0.7)                             |
| Chronic dislocation ORIF with capsulectomy and cubital tunnel release | 1 (0.7)                     |
| Closed reduction of elbow dislocation                             | 1 (0.7)                             |
| Contracture release with cubital tunnel release and radial head excision | 1 (0.7)                     |
| Contracture release with exostectomy                              | 1 (0.7)                             |
| Contracture release with ligament reconstruction                  | 1 (0.7)                             |
| Contracture release with loose body excision                      | 1 (0.7)                             |
| Contracture release with radial head excision                     | 1 (0.7)                             |
| Contracture release with synovectomy                              | 1 (0.7)                             |
| Contracture release with ulnar nerve decompression and synovectomy | 1 (0.7)                             |
| Coronoid ORIF with external fixator removal and ligamentous repair | 1 (0.7)                             |
| Coronoid ORIF with ligamentous repair                             | 1 (0.7)                             |
| Distal humerus ORIF with ligament repair                          | 1 (0.7)                             |
| Distal humerus ORIF with open fracture debridement                | 1 (0.7)                             |
| Distal triceps tendon repair                                       | 1 (0.7)                             |
| Elbow arthrodesis                                                  | 1 (0.7)                             |
| Hardware removal                                                   | 1 (0.7)                             |
| Heterotopic ossification excision with ligamentous repair and radial nerve neurolysis | 1 (0.7)                     |
| Heterotopic ossification excision with revision cubital tunnel release | 1 (0.7)                     |
| Ligament reconstruction with coronoid ORIF                         | 1 (0.7)                             |
| Ligament repair                                                    | 1 (0.7)                             |
| Olecranon and radial head ORIF with ligamentous repair             | 1 (0.7)                             |
| Olecranon ORIF revision with hardware removal                      | 1 (0.7)                             |
| Radial head arthroplasty with ligament repair                      | 1 (0.7)                             |
| Radial head arthroplasty, ulnar shortening osteotomy, interosseous membrane reconstruction | 1 (0.7)                             |
| Radial head excision with hardware removal                         | 1 (0.7)                             |
| Radial head excision with ulna nonunion repair and removal of hardware | 1 (0.7)                     |
| Radial head excision with ulnar shortening osteotomy               | 1 (0.7)                             |
| Radial head nonunion repair with ligament repair                   | 1 (0.7)                             |
| Radial head ORIF with ligament repair                              | 1 (0.7)                             |
| Removal of loose body with ligament repair                         | 1 (0.7)                             |
| Ulna malunion correction with open reduction of the radiocapitellar joint | 1 (0.7)                     |
| Uln malunion repair with radial head excision                      | 1 (0.7)                             |
| Ulnar nerve decompression                                          | 1 (0.7)                             |
| Ulnar nerve decompression with elbow manipulation                  | 1 (0.7)                             |

ORIF, open reduction internal fixation.

* N = 129 for surgical patients. N = 17 for nonoperative patients.

Nonoperative patients had injuries including radial head fracture (N = 17), elbow dislocation closed reduction (N = 2), coronoid fracture (N = 1), non-displaced distal humerus extra-articular fracture (N = 1), and closed reduction of a recurrent elbow dislocation (N = 1).

universal or gold standard anchor question exists at this time. There is also potential for recall bias when patients are answering anchor questions.11 In comparison to the anchor-based methods, the distribution-based methods seek to define a threshold of random noise in the instrument that establishes the floor for the magnitude of potential meaningful change. Distribution-based calculations are limited by the lack of patient-reported input pertaining to improvement. In regard to our anchor-based calculations, we were able to demonstrate statistically different score change on the PROMIS PF CAT between anchor groups but not for the PROMIS UE CAT or QuickDASH. Despite this limitation, statistically significant differences in score change between anchor groups is not an absolute requirement to estimating MCID. It should also be noted that when using these MCID values to evaluate treatment response, meeting the MCID does not equal patient satisfaction and vice versa. Furthermore, these MCID values are not intended to be used at the level of individual patients but rather applied for populations of patients. Another limitation of our study was the small sample size of patients meeting inclusion criteria of isolated elbow trauma in addition to completing preoperative and postoperative scores. Of the 447 patients initially identified for potential inclusion by one of 55 CPIT codes, only 146 patients ultimately met inclusion criteria. This limitation parallels our retrospective study design, which has potential to introduce selection bias, as the effect of certain patients completing vs. not completing PRO questionnaires is uncertain. However, this is commonly observed in prior MCID studies.20,22,23,30 Finally, our study population was heterogeneous in terms of operative procedures and inclusion of nonoperative patients (12% of the cohort). Although it may seem appealing to focus on specific surgeries when reporting MCID, we believe our estimates should be widely generalizable to patients recovering from a spectrum of traumatic elbow conditions.

Conclusion

In summary, we have derived MCID estimates for patients with elbow trauma using two commonly used methods (anchor-based and 1/2 SD). When interpreting outcomes for these patients on a population level, we propose the following MCID estimate ranges: 4.3 to 5.7 for the PROMIS PF CAT, 4.6 to 4.8 for the PROMIS UE CAT, and 5.3 to 11.7 for the QuickDASH. These values will aid in the interpretation of clinically relevant clinical outcomes and in the powering of prospective clinical trials in the setting of elbow trauma.

Disclaimers:

Funding: This investigation was supported by the University of Utah Population Health Research (PHR) Foundation, with funding in part from the National Center for Research Resources and the National Center for Advancing Translational Sciences, National Institutes of Health, through grant no. UL1TR002538 (formerly 5UL1TR001067-05, 8UL1TR000105 and UL1RR025764). This investigation was supported by the University of Utah Focusing on specific patient populations, and 5.3 to 11.7 for the QuickDASH. These values will aid in the interpretation of clinically relevant clinical outcomes and in the powering of prospective clinical trials in the setting of elbow trauma.

Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jseint.2021.06.005.
Table III
Summary of scores.

| Statistic                                | Baseline score | Follow-up score | P value |
|------------------------------------------|----------------|-----------------|---------|
| All included patients                    |                |                 |         |
| PROMIS PF CAT v1.2/2.0 (N = 131)         | Mean (SD)      | 38.4 (9.8)      | 42.5 (9.4) | <.001*  |
|                                          | Median (IQR)   | 36.6 (15.3)     | 42.9 (13.7) |         |
|                                          | Range          | (19.3, 67.3)    | (22.2, 66.8) | -       |
| PROMIS UE CAT v1.2 (N = 87)              | Mean (SD)      | 28.3 (8.5)      | 32.1 (9.2)  | <.001*  |
|                                          | Median (IQR)   | 28.2 (11.4)     | 32.3 (13.1) | -       |
|                                          | Range          | (14.7, 56.4)    | (14.7, 56.4) |         |
| QuickDASH (N = 110)                      | Mean (SD)      | 54.0 (22.8)     | 41.1 (24.2) | <.001*  |
|                                          | Median (IQR)   | 56.8 (31.3)     | 40.9 (41.8) | -       |
|                                          | Range          | (0, 95.5)       | (0, 95.5)   | -       |

Patients included in anchor-based calculations

|                                 | Statistic                                | Baseline score | Follow-up score | P value |
|---------------------------------|------------------------------------------|----------------|-----------------|---------|
|                                 | PROMIS PF CAT v1.2/2.0 (N = 61)          | Mean (SD)      | 37.7 (10.4)     | 40.8 (9.7) | <.001*  |
|                                 | Median (IQR)                             | 35.1 (15.1)    | 41.0 (14.8)     | -       |
|                                 | Range                                    | (23.2, 67.3)   | (23.5, 61.1)    | -       |
| PROMIS UE CAT v1.2 (N = 42)     | Mean (SD)                                | 27.9 (9.1)     | 29.9 (8.1)      | .13     |
|                                 | Median (IQR)                             | 27.1 (14.0)    | 29.3 (10.9)     | -       |
|                                 | Range                                    | (14.7, 47.6)   | (14.7, 49.0)    | -       |
| QuickDASH (N = 56)              | Mean (SD)                                | 55.0 (22.9)    | 44.8 (22.3)     | <.001*  |
|                                 | Median (IQR)                             | 59.1 (31.8)    | 43.2 (36.4)     | -       |
|                                 | Range                                    | (0, 95.5)      | (0, 81.8)       | -       |

CAT, computer adaptive test; IQR, interquartile range; PF, physical function; PROMIS, Patient-Reported Outcomes Measurement Information System; SD, standard deviation; UE, upper extremity.

1 Statistical significance was based on the Wilcoxon rank-sum test.

2 Statistical significance was based on the Student's t-test.

Table IV
Summary of score change by anchor group.

| Instrument                  | Score change by anchor question group mean ± SD (N) | P value |
|-----------------------------|---------------------------------------------------|---------|
| PROMIS PF CAT v1.2/2.0      | −1.9 ± 6.7 (10)                                   | .014*   |
| PROMIS UE CAT v1.2          | −1.5 ± 6.74 (10)                                  | .061†   |
| QuickDASH                   | −6.6 ± 9.4 (12)                                   | .225†   |

CAT, computer adaptive test; PF, physical function; PROMIS, Patient-Reported Outcomes Measurement Information System; UE, upper extremity.

1 Statistical significance was based on the Wilcoxon Rank-Sum test.

2 Statistical significance was based on the student’s t-test.

Table V
MCID estimates.

| 1/2 SD method | Anchor-based |
|---------------|--------------|
| PROMIS PF CAT v1.2/2.0 | 4.3 (N = 136) | 5.7 (N = 62) |
| PROMIS UE CAT v1.2     | 4.8 (N = 91)  | 4.6 (N = 43)  |
| QuickDASH              | 11.7 (N = 114)| 5.3 (N = 57)  |

CAT, computer adaptive test; PF, physical function; PROMIS, Patient-Reported Outcomes Measurement Information System; UE, upper extremity.

References

1. Beaton DE, van Eerd D, Smith P, van der Velde G, Cullen K, Kennedy CA, et al. Minimal change is sensitive, less specific to recovery: a diagnostic testing approach to interpretability. J Clin Epidemiol. 2011;64:487-96. https://doi.org/10.1016/j.icep.2010.07.012.
2. Beaton DE, Wright JG, Katz JN. Upper Extremity Collaborative Group. Development of the QuickDASH: comparison of three item-reduction approaches. J Bone Joint Surg Am. 2005;87:1038-46. https://doi.org/10.2106/JBJS.D.02060.
3. Beckmann JT, Hung M, Voss MW, Cram AB, Bousanga J, Tyrer AR. Evaluation of the patient-reported outcomes measurement information system upper extremity computer adaptive test. J Hand Surg Am. 2016;41:739-744.e4. https://doi.org/10.1016/j.jhsa.2016.04.025.
4. Belecenas CM, Padovano A, Guattary J, Chamberlain AM, Keener JD, Calfee RP. Performance of Patient-Reported Outcomes Measurement Information System (PROMIS) upper extremity (UE) versus physical function (PF) computer adaptive tests (CATs) in upper extremity clinics. J Hand Surg Am. 2017;42:867-74. https://doi.org/10.1016/j.jhsa.2017.06.012.
5. Bernstein DN, Houck JR, Mahmood B, Hammert WC. Minimal clinically important differences for PROMIS physical function, upper extremity, and pain interference in carpal tunnel release using region- and condition-specific PROM tools. J Hand Surg Am. 2019;44:635-40. https://doi.org/10.1016/j.jhsa.2019.04.004.
6. Cella D, Riley W, Stone A, Rothrock N, Reeve B, Yount S, et al. The Patient-Reported Outcomes Measurement Information System (PROMIS) developed and tested its first wave of adult self-reported health outcome item banks: 2005-2008. J Clin Epidemiol. 2010;63:1179-94. https://doi.org/10.1016/j.jclinepi.2010.04.011.
7. Cella D, Yount S, Rothrock N, Gershon R, Cook K, Reeve B, et al. The Patient-Reported Outcomes Measurement Information System (PROMIS): progress of an NIH Roadmap cooperative group during its first two years. Med Care 2007;45:33-11. https://doi.org/10.1097/01.mlr.0000258591.42478.55.
8. Chowdhury NL, Mace JC, Bodner TE, Alt JA, Decode AS, Levy JM, et al. Does medical therapy improve SinoNasal outcomes test-22 domain scores? An analysis of clinically important differences. Laryngoscope 2019;129:31-6. https://doi.org/10.1002/lary.27470.
9. Cook CE. Clinimetrics corner: the minimal clinically important change score (MCID): a necessary pretense. J Man Manip Ther 2008;16:82E-3. https://doi.org/10.1179/jmt.2008.16.4.82E.
10. Copay AG, Subach BR, Glassman SD, Polly DW Jr, Schuler TC. Understanding the minimum clinically important difference: a review of concepts and methods. Spine J 2007;7:541-6. https://doi.org/10.1016/j.spinee.2007.01.008.
11. Crosby RD, Kolotkin RL, Williams GR. Define clinically meaningful change in health-related quality of life. J Clin Epidemiol. 2003;56:395-407. https://doi.org/10.1016/S0895-4356(03)00044-1.
12. Franchignoni F, Vercelli S, Giordano A, Sartorio F, Bravini E, Ferriero G. Minimal clinically important difference of the disabilities of the arm, shoulder and hand outcome measure (DASH) and its shortened version (QuickDASH). J Orthop Sports Phys Ther 2014;44:30-9. https://doi.org/10.2519/jospt.2014.4893.
13. Ho B, Houck JR, Flemister AS, Ketz J, Oh I, DiGiovanni BF, et al. Preoperative PROMIS scores predict postoperative success in foot and ankle patients. Foot Ankle Int 2016;37:911-8. https://doi.org/10.1177/1071100716650113.
14. Hossain FS, Konan S, Patel S, Rodriguez-Merchan EC, Haddad FS. The assessment of outcome after total knee arthroplasty: are we there yet? Bone Joint J 2015;97-B:3-9. https://doi.org/10.1302/0301-620X.97B1.34434.
15. Ido Y, Uchiyama S, Nakamura K, Itsubo T, Hayashi M, Hata Y, et al. Post-operative improvement in DASH score, clinical findings, and nerve conduction velocity in patients with cubital tunnel syndrome. Sci Rep 2016;6:27497. https://doi.org/10.1038/srep27497.

16. Jaeschke R, Singer J, Guyatt GH. Measurement of health status. Ascertaining the minimal clinically important difference. Control Clin Trials 1989;10:407-15.

17. Jones IA, Togashi R, Heckmann N, Vangsness CT Jr. Minimal clinically important difference (MCID) for patient-reported shoulder outcomes. J Shoulder Elbow Surg 2020;29:1484-92. https://doi.org/10.1016/j.jse.2019.12.033.

18. Katz P, Morris A, Trupin L, Yazdany J, Yelin E. Disability in valued life activities among individuals with systemic lupus erythematosus. Arthritis Rheum 2008;59:460-73. https://doi.org/10.1002/art.23536.

19. Kazmers NH, Hung M, Bounsanga J, Voss MW, Howenstein A, Tyser AR. Minimal clinically important difference after carpal tunnel release using the PROMIS platform. J Hand Surg Am 2019;44:947-953.e1. https://doi.org/10.1016/j.jhsa.2019.03.006.

20. Kazmers NH, Qiu Y, Pea Z, Presson AP, Tyser AR, Zhang Y. Minimal clinically important difference of the PROMIS upper-extremity computer adaptive test and QuickDASH for ligament reconstruction tendon interposition patients. J Hand Surg Am 2021;46:516-516.e7. https://doi.org/10.1016/j.jhsa.2020.11.007.

21. Kazmers NH, Qiu Y, Yoo M, Stephens AR, Tyser AR, Zhang Y. The minimal clinically important difference of the PROMIS and QuickDASH instruments in a Nonshoulder hand and upper extremity patient population. J Hand Surg Am 2020;45:399-407.e6. https://doi.org/10.1016/j.jhsa.2019.12.002.

22. Kazmers NH, Qiu Y, Yoo M, Stephens AR, Zeidan M, Zhang Y. Establishing the minimal clinically important difference for the PROMIS upper extremity computer adaptive test version 2.0 in a non–shoulder hand and upper extremity population. J Hand Surg Am 2021. https://doi.org/10.1016/j.jhsa.2021.01.023.

23. Lee DJ, Calfee RP. The minimal clinically important difference for PROMIS physical function in patients with thumb carpometacarpal arthritis. Hand (N Y) 2019; 1558944719880025. https://doi.org/10.1177/1558944719880025.

24. Matheson LN, Melhorn JM, Mayer TG, Theodore BR, Gatchel RJ. Reliability of a visual analog version of the QuickDASH. J Bone Joint Surg Am 2006;88:1782-7. https://doi.org/10.2106/JBJS.F.00406.

25. Mintken PE, Glynn P, Cieland JA. Psychometric properties of the shortened disabilities of the arm, shoulder, and hand questionnaire (QuickDASH) and Numeric Pain Rating Scale in patients with shoulder pain. J Shoulder Elbow Surg 2009;18:920-6. https://doi.org/10.1016/j.jse.2008.12.015.

26. Norman GR, Sloan JA, Wyrwich KW. Interpretation of changes in health-related quality of life: the remarkable universality of half a standard deviation. Med Care 2003;41:582-92. https://doi.org/10.1097/01.MLR.0000062554.74615.4C.

27. Northwestern U. HealthMeasures - Transforming how health is measured - interpret scores: PROMIS; 2021. Available at: https://www.healthmeasures.net/score-and-interpret/interpret-scores/promis. Accessed May 26, 2021.

28. Pickard AS, Neary MP, Cella D. Estimation of minimally important differences in EQ-5D utility and VAS scores in cancer. Health Qual Life Outcomes 2007;5:70. https://doi.org/10.1186/1477-7525-5-70.

29. Polson K, Reid D, McNair PJ, Larmer P. Responsiveness, minimal importance difference and minimal detectable change scores of the shortened disability arm shoulder hand (QuickDASH) questionnaire. Man Ther 2010;15:404-7. https://doi.org/10.1016/j.math.2010.03.008.

30. Sandvall B, Okoroafor UC, Gerull W, Guaterry J, Calfee RP. Minimal clinically important difference for PROMIS physical function in patients with distal radius fractures. J Hand Surg Am 2019;44:454-459.e1. https://doi.org/10.1016/j.jhsa.2019.02.015.

31. Sorensen AA, Howard D, Tan WH, Ketchersid J, Calfee RP. Minimal clinically important differences of 3 patient-rated outcomes instruments. J Hand Surg Am 2013;38:641-9. https://doi.org/10.1016/j.jhsa.2012.12.032.

32. Wright A, Hannon J, Hegedus EJ, Kavchak AE. Clinimetrics corner: a closer look at the minimal clinically important difference (MCID). J Man Manip Ther 2012;20:160-6. https://doi.org/10.1179/2042618612Y.0000000001.