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Study conducted at the Johns Hopkins Bloomberg School of Public Health

Introduction

The **interpretability** of Patient-Reported Outcomes Measurement Information System (PROMIS) measures in the **orthopaedic trauma population** is limited as the **distributions and MCIDs of these measures are unknown.**

Objectives

1. Establish a range of MCIDs for **10 PROMIS measures** in patients with lower extremity fractures.
2. Identify if those MCIDs were broadly applicable across **sex, age, and follow-up timepoints.**

Materials and Methods

- Conducted under the **Streamlining Trauma Research Evaluation with Advanced Measurement (STREAM) Study:**
 - Implemented PROMIS tools in a large orthopaedic trauma clinical trials consortium (METRC)
 - Goal: evaluate psychometric properties of PROMIS in this population for use in future clinical trials.
- **1000 patients with lower extremity fractures** from 7 multicenter orthopaedic trauma trials
 - Mean±SD age was 42±13 years and 69% patients were male.
 - Computerized adaptive testing
 - Collected at 3 months, 6 months, and 12 months
- **PROMIS Domains:**
 - **Physical health:** Physical Function (PF), Pain Interference (PI), Sleep Disturbance (SLD)
 - **Mental health:** Anxiety, Depression, Psychosocial Illness Impact (PII), Applied Cognition (AC)
 - **Social health:** Ability to Participate in Social Roles and Activities (APSRA), Satisfaction with Social Roles and Activities (SSRA), and Emotional Support (EMS)
- **MCIDs:**
 - One-half standard deviation (½SD)
 - Twice the Standard Error of Measurement (2SEM)
 - Minimum Detectable Change (MDC)
- Effect sizes (ES)
 - Cohen's d: small (0.2), medium (0.5), and large (0.8)

Results

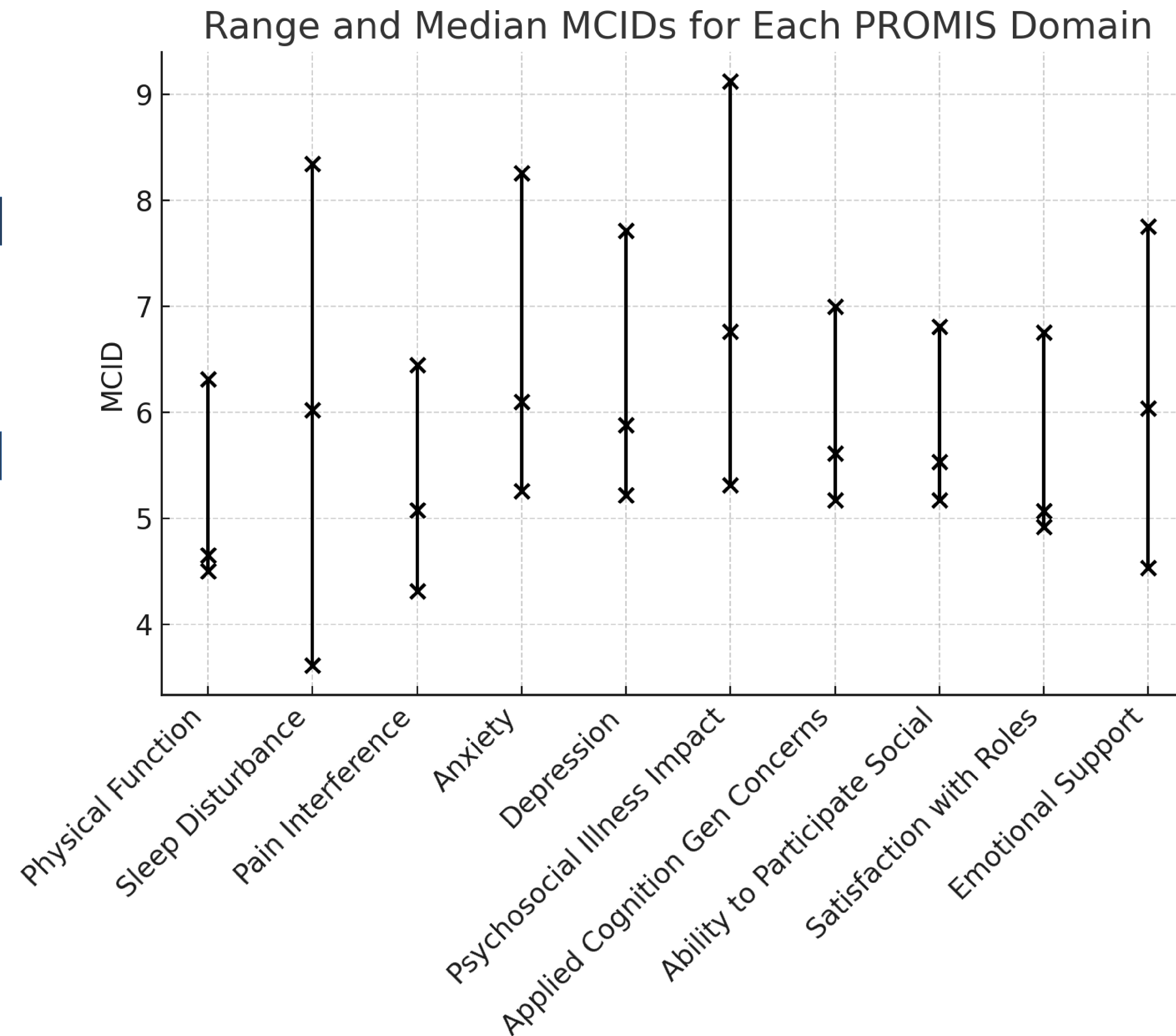


Figure 1. Tie-Fighter plot of median and range of MCIDs for PROMIS domains. These ranges include MCIDs for sex, age, and follow-up timepoint subgroups.

| Domain | Number of assessments | Mean | SD | ½ SD | 2SEM | MDC | Small ES (0.2) | Medium ES (0.5) | Large ES (0.8) |
|---|-----------------------|-------|-------|------|------|------|----------------|-----------------|----------------|
| Physical function | 2546 | 36.62 | 9.01 | 4.50 | 4.65 | 6.31 | 1.80 | 4.50 | 7.21 |
| Pain interference | 2541 | 58.89 | 8.62 | 4.31 | 5.08 | 6.45 | 1.72 | 4.31 | 6.90 |
| Sleep disturbance | 1776 | 55.54 | 7.23 | 3.61 | 6.02 | 8.34 | 1.45 | 3.61 | 5.78 |
| Anxiety | 2536 | 54.50 | 10.53 | 5.26 | 6.10 | 8.26 | 2.11 | 5.26 | 8.42 |
| Depression | 2532 | 51.76 | 10.44 | 5.22 | 5.88 | 7.71 | 2.09 | 5.22 | 8.35 |
| Psychosocial illness impact | 2515 | 48.09 | 10.61 | 5.31 | 6.76 | 9.12 | 2.12 | 5.31 | 8.49 |
| Applied cognition | 1783 | 33.55 | 11.22 | 5.61 | 5.17 | 7.00 | 2.24 | 5.61 | 8.97 |
| Ability to Participate in Social Roles and Activities | 2529 | 44.75 | 11.06 | 5.53 | 5.17 | 6.81 | 2.21 | 5.53 | 8.85 |
| Satisfaction with social roles and activities | 1780 | 42.52 | 9.83 | 4.92 | 5.07 | 6.75 | 1.97 | 4.92 | 7.87 |
| Emotional support | 1774 | 52.69 | 9.07 | 4.53 | 6.04 | 7.75 | 1.81 | 4.53 | 7.25 |

Table 1. MCIDs and ES of PROMIS domains.

Conclusions

- MCIDs were between **3.51 to 9.23 T-score points.**
- MDC provided the greatest MCIDs, consistent with prior studies.
- **MCIDs varied little across sex, age, and follow-up,** suggesting each domain can be applied broadly
- **These values provide a basis for interpretation of PROMIS for future orthopaedic trauma clinical trials.**