Developing PROMIS-based research and clinical profiles for patients with heart failure
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Objectives
Heart failure (HF) is a common and morbid condition. We previously reported the development of the PROMIS®-Plus-HF Profile Measure, a complete assessment of health that combines generic and HF-specific items. To facilitate patient-centered research and care, we sought to develop research and clinical profiles of the PROMIS-Plus-HF measure with overall, physical, mental, and social summary scores.

Methods
Candidate items (n=31) for the Research and Clinical Profiles were selected from the 86 items in the PROMIS-Plus-HF Profile Measure based on psychometric properties and to ensure coverage of the range of symptoms experienced by HF patients. In a web-based survey, HF clinicians (n=43) rated item importance and clinical actionability. Informed by these results, the study team developed a 27-item Research Profile and 10-item Clinical Profile. Overall, physical, mental, and social health summary scores on a scale of 0 to 100 were calculated. In a cross-sectional (n=600) sample, we measured the reliability: internal consistency with Cronbach’s alpha and test-retest in sample of 100 participants. Known groups validity was assessed using one-way ANOVA, modeling difference in HF score across New York Heart Association (NYHA) Class and Kansas City Cardiomyopathy Questionnaire (KCCQ) summary scores and subscales. Differences in change in Profile scores (responsiveness) by KCCQ change was evaluated using linear mixed regression.

Results
In the 600-person cross-sectional sample, the summary scores for the 27-item PROMIS-Plus-HF Research Profile and 10-item Clinical Profile were normally distributed. Internal consistency for domain scores were excellent (all α >0.8). Test-retest intraclass correlation coefficients for domain and overall scores were ≥0.90. Both profiles demonstrated known groups validity for overall score and physical sub-score based on NYHA Class, and for all scores based on KCCQ groups (p<0.05). In the 75-person longitudinal sample, the Research Profile demonstrated evidence of responsiveness (p<0.05) for the overall and domain scores. For the Clinical Profile, the point estimates for the overall and social and mental health scores reflected responsiveness and the change in physical score reached statistical significance (p<0.05).

Conclusion
The PROMIS-Plus-HF Research and Clinical Profiles demonstrated overall good psychometric characteristics. The PROMIS-Plus-HF Research and Clinical Profiles may be used to facilitate patient-centered research and clinical care.
function PF and pain interference PI data was performed in 248 patients who had a hammertoe correction January 2015-December 2019. Categorical (yes/no) for recurrence and complications was obtained by chart review. Mann-Whitney U, Chi-square test and mixed linear regression models for were used to compare groups for demographic and assess PF and PI differences at final follow up time point for each implant group (k-wire, nextra implant, retrograde fusion screw, Trim it pin) correcting for confounding demographic variables.

Results
Baseline demographics demonstrated implants were used in slightly older aged patients (2 years average). Other confounding variables included BMI (larger had lower PF), Smoking history (past smokers had lower PF and higher PI), insurance (governmental products had lower PF and higher PI). Implants had a higher recurrence rate (OR 1.9) however no increase in other complications. At final follow up when controlling for confounding variables, PF was better with nextra and trim-it pins than k-wire. There was no difference in PI between k-wire and implant groups.

Conclusions
There is variation in the surgical implants used for the commonly performed hammertoe procedure. The choice of implant should be based on patient reported outcomes (function and pain improvement) as well as the risk of recurrence or complications. In this case, the cost differential between the k-wire and the few implants reviewed is nearly 1,000 dollars. Objective assessments of outcomes will aid in determining value, eliminate variation and improve the alignment of provider and health care cost allocation.

105-O.
Methodology for selecting and evaluating items from PROMIS* Item Banks to develop novel short-form questionnaires
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Objectives
PROMIS* measures can be administered via computer adaptive testing or through use of existing short-forms and profile measures. Customized short-forms can be developed by selecting items from PROMIS item banks. We describe a systematic approach for selecting PROMIS items when creating custom short-forms and for generating evidence to support content validity within specific patient populations.

Methods
A modified Delphi process was used to initially evaluate items from the PROMIS and PROMIS-Cancer Physical Function items banks and to reduce the number of items to be further evaluated in qualitative interviews. The Delphi panel (n=10) included both measurement experts and patient representatives who evaluated the items using predefined criteria and voted over three rounds to keep or drop each item. Retained items were subsequently evaluated in combined concept elicitation/cognitive interviews. Interviews (n=150) were planned with patients diagnosed with one of five different cancers (i.e., lung, renal, hepatocellular, melanoma, and head and neck). Interviews were conducted at multiple sites in the United States and incorporated card sorting and rating exercises, which facilitated discussion on the relevance and importance of each item and any difficulty answering the interviews. The interviews were audio recorded, transcribed, and analyzed.

Results
The Delphi panel evaluated 169 PROMIS Physical Function items, voting to drop 93 and retain 76 items for further evaluation in the qualitative interviews. While recruitment is ongoing, preliminary results from the interviews have provided evidence for selecting PROMIS items most relevant to patients with each tumor type. The final deliverables will include a disease-specific short-form for each tumor type and an evidence dossier suitable for submission to regulatory authorities. This methodology can be applied to other measurement systems (e.g., EORTC, PRO-CTCAE) with item banks/libraries to select subsets of items relevant to a specific target population.

Conclusions
Qualitative patient interviews incorporating card sorting and rating exercises can be used to select a subset of items relevant to a specific population, while simultaneously generating additional evidence to support content validity of the novel short-form measures. A modified Delphi process helped to reduce the number of items that needed to be evaluated, thus making the interviews more manageable and efficient.
106-P. PROMIS® Paediatric Self Report Profile-25 distinguishes subgroups of children with two common paediatric knee injuries
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Objective
To test the sensitivity of the generic PROMIS-25 and the child version of the illness-specific measure Knee Injury and Osteoarthritis Outcome Score (KOOS-Child) to two specific knee injuries which involve different symptoms and treatment regimens.

Methods
The qualitative control of treatment of severe knee injuries is followed by the Swedish Paediatric Orthopaedic Quality register (SPOQ). All patients were invited to complete paper versions of the two instruments at predefined follow-ups. Data collected in 2017-2019 are presented. Analyses were made of floor and ceiling effects. Agreement between domains was tested using bivariate correlation. Sensitivity of injury and treatment outcomes was investigated using a receiver operating characteristic (ROC) curve.

Results
Data from 272 paediatric patients (49% female; mean age 13-years at follow-up, range: 9-14) were gathered. Diagnoses: patellar dislocation 43%; anterior cruciate ligament injury (ACL) 22%; other diagnoses 33%; unknown 1%. The missing data rate was negligible: PROMIS 0.4%, KOOS 1.6%. Ceiling effects were found in all KOOS variables. The highest correlations between the domains of PROMIS (p) and the KOOS (k) were between (p)mobility and (k)sport (r=0.717), between (p)pain interference and (k)pain (r=0.634) and between (p)anxiety and (k)QoL (r=0.509). Sensitivity to diagnosis (patellar dislocation and ACL) was more pronounced in PROMIS, where (p)anxiety and (p)mobility had the largest AUC (0.5525 and 0.5461, respectively) of all domains in both instruments.

Conclusions
The expected agreements between similar domains in the two instruments were found. Our results suggest that the PROMIS-25 was more sensitive to differences in anxiety and mobility between different injury locations than the KOOS-Child. Further analysis of the differences between these instruments will help to identify the measure of first choice in registry data collection.

107-P. PROMIS® Paediatric Self Report and Proxy Profile-25 compared to a quality-of-life instrument
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Objective
To compare the generic paediatric PROMIS profile-25 (p) with the multi-dimensional quality-of-life instrument DISABKIDS-31 (d).

Methods
Paper versions were administered to children aged 8-17 years and their parents, and to parents only for younger children, at the orthopaedic outpatient clinic of a university hospital. PROMIS-25 is a six-dimensional PROM profile; DISABKIDS-31 is a five-dimensional quality-of-life measure. Intraclass correlation coefficient assessed agreement between child and proxy. Multiple linear regression was calculated to predict DISABKIDS total Qol from the PROMIS profile for self-report and proxy-report. To visualize the relationships between the variables, multidimensional scaling with PROXSCAL was used.

Results
Data on 35 children (4-17 yrs, 60% girls) were collected, which included 17 child/proxy diads (9-17 yrs), 1 child (10 yrs) and 17 parent-reports without child self-report (4-15 yrs). The most frequent reason for visiting the clinic (77%) was leg or muscle injuries; other diagnoses included injury or deformity to the feet or back. Missing data was negligible: PROMIS 3%, DISABKIDS 4%. There was good to excellent agreement between child and parent DISABKIDS (r=0.673-0.903); poor to excellent for PROMIS (r=0.272-0.975), with (p)eer relationships (r=0.272) having the lowest agreement. Predicting DISABKIDS Qol scores, a significant regression equation was found for PROMIS self-report (F(7,9)=4.931, p=0.015) with an adjusted R² of 0.632, and for proxy-report (F(7,24)=14.608, p<0.001), adjusted R²=0.54, with (p)ysical function, (p)ain and (p)ain intensity being reliable predictors (p<0.001, p=0.040; p=0.020, respectively). Multidimensional scaling revealed a good separation between variables for both instruments, with the possible exception of PROMIS anxiety and depression.

Conclusions
The two questionnaires demonstrated mixed inter-rater reliability, with PROMIS peer relations having the lowest ICC, indicating a possible greater sensitivity to differences in child/proxy reporting in PROMIS. A large part of the variation in DISABKIDS total-Qol can be explained by the PROMIS profile scores, indicating overlap between the instruments. The most reliable predictor of total-Qol was the physical functioning/mobility variable in PROMIS. Multidimensional scaling suggests that PROMIS-25 has a better separation between domains than DISABKIDS, with the possible exception of (p)ain and (p)ain/depression. Further analysis of the differences between these instruments would benefit from a larger and more diverse population.

108-P. Patient-centered approach to response-level missing data
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Objective
To use mixture modelling as a patient-centered method to explain item-level missing data in PROMIS measures. These methods are used to evaluate the presence of item missingness across patient demographics, conditions and treatment, and patient-reported symptom severity and impact. These results inform novel Missing Not at Random models of missingness for PROMIS measures and help guide the clinician’s selection of PROMIS measures to minimize patient non-response.

Methods
Data used in analyses were obtained from HealthMeasures Dataverse, including data collected as a part of the development of the PROMIS Neuropathic and Nociceptive Pain Quality measures. PROMIS measures were scored using IRT item parameters and pattern-response scoring methods. Mixture modelling analyses were conducted with patient demographics, clinical information, number of items missing and PROMIS T scores. All analyses were conducted in R statistical computing software.

Results
Initial results with the PROMIS Neuropathic & Nociceptive Pain Data set show that more item-level missing data is associated with better neuropathic pain scores (as indicated by lower PROMIS Neuropathic Pain Quality T scores) and with patients who have a condition associated with nociceptive pain (rheumatoid arthritis & fibromyalgia). Conversely, less missing item-level data is associated with worse pain.
(indicated by higher PROMIS Neuropathic Pain Quality T scores) and with patients who have conditions associated with neuropathic pain (diabetic neuropathy & cancer chemotherapy induced peripheral neuropathy).

Conclusion
These results provide important guidance for researchers or regulators who may be concerned about the item-level missing data in PROMIS measures: missing data is less likely to occur with patients who have worse health-related quality of life (greater symptom severity and impact). Missing data is also less likely when patients are answering items relevant to their condition or severity. Researchers seeking to model item-level missingness for data imputation methods should focus on missingness in patients with lower symptom severity and impact. These findings reinforce the importance of administering item content relevant to the patient, which is appropriate to either the patient’s condition or severity. Clinical users can incorporate these findings into their practice by administering condition-relevant PROMIS short forms or by administering PROMIS Computer Adaptive Tests to minimize irrelevant items.

109-P.
Measurement of minimal disease activity in psoriatic arthritis using PROMIS-Physical Function or the Health Assessment Questionnaire-Disability Index
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Background
Minimal disease activity (MDA), is a treat-to-target strategy (T2T) objective in psoriatic arthritis (PsA). MDA criteria include physical function, traditionally assessed via the Health-Assessment Questionnaire Disability Index (HAQ-DI). It is of interest to assess the performance of more current physical function instruments such as the Patient-Reported Outcomes Measurement Information System-Physical Function Profile (PROMIS-PF).

Objectives
To assess the interchangeability of the HAQ-DI with the PROMIS-PF in the calculation of MDA in PsA.

Methods
Longitudinal PsA data were collected including HAQ-DI and PROMIS-PF in a PsA cohort. MDA definitions were built substituting the HAQ-DI criterion with the PROMIS-PF short form 4a (PROMIS-PF4a) or with the PROMIS-PF computer adaptive test (PROMIS-PF Bank). We assessed agreement/accuracy between HAQ-DI based and PROMIS-PF based MDA definitions at each visit and longitudinally through the kappa statistic/ROC curve analysis.

Results
One hundred participants contributed 352 observations with up to five visits. Mean (SD) age was 52 (12) years, 60% were female, and 43% were in MDA at baseline. Kappa statistic for PROMIS-PF based MDA reflected almost perfect agreement with HAQ-DI MDA: kappa=0.94 (95% CI 0.90-0.97) for MDA PROMIS-PF Bank and kappa=0.90 (95% CI 0.80-0.95) for MDA PROMIS-PF4a. Higher longitudinal agreement was seen between MDA HAQ-DI and MDA PROMIS-PF Bank versus MDA PROMIS-PF4a between consecutive visits: kappa ranged between 0.81-0.94 versus 0.72-0.84, respectively (Table 1). Area under ROC curve for predicting MDA HAQ-DI was 0.97 for MDA PROMIS-PF Bank and 0.95 for MDA PROMIS-PF4a.

Conclusions
Excellent agreement was seen between HAQ-DI and PROMIS-based MDA definitions statically and longitudinally. The PROMIS-PF Bank and PROMIS-PF4a are accurate replacements for the HAQ-DI in calculating MDA state in PsA.

110-O.
Interpretation of PROMIS Fatigue CAT scores in solid organ transplant recipients
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Objective
Relating PROMIS T-scores to functional impacts can help clinicians and patients to meaningfully interpret T-scores. Here we assess the relationship between T-scores vs the last items and responses in solid organ transplant recipients (kidney (KTRs), kidney-pancreas (KPRs), and liver (LTRs)) using the PROMIS Fatigue Computer Adaptive Test (CAT).

Methods
A cross-sectional, convenience sample of adult KTRs, KPR, and LTRs completed the PROMIS Fatigue CAT on an electronic data capture system (DADOS, TECHNA Institute, UHN). The number of items answered, and the unique last items administered from the PROMIS Fatigue item bank were tabulated. Final T-scores were ordered from low to high, and last questions and responses at different T-scores are reported. Results
Of the 373 participants, the mean (SD) age was 53 (14), 235 (63%) were male, 199 (53%) were KTRs, 46 (12%) were KPRs and 128 (34%) were LTRs. T-scores were <50 (46%), 50-60 (35%), >60 (19%). A total of 18 unique last questions were completed in this study sample. Patients with T-scores ranging from 24-40 had last questions and responses that reflected no to very little fatigue. Unique last questions to this T-score range included questions about strenuous exercise and feeling “sluggish”. Responses to these questions suggested that patients were able to perform strenuous exercises and did not feel tired. Patients with T-scores 60 had last questions and responses reflecting moderate to severe fatigue. Unique last questions administered to patients with T-scores 60 included questions about fatigue interfering with physical functioning, and for patients with T-scores >70, the ability to eat and carry a conversation. Responses to questions in this T-score range suggested that fatigue limited the ability to perform even basic daily activities of living.

Conclusion
We reported a relationship between PROMIS Fatigue CAT T-scores, and the last question and response administered. This relationship can help improve the interpretation of PROMIS Fatigue T-scores and help clinicians and patients understand how PROMIS Fatigue T-scores relate to limitations in daily life.

111-P.
Reducing questionnaire burden when screening for depressive symptoms in patients with end-stage kidney disease
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Objective
Routine screening for depressive symptoms can be time-consuming and burdensome for patients. However, patients without depressive symptoms can be quickly screened out using ultra-brief screening tools and avoid the need of completing more precise, but longer, questionnaires. In this study we compare the questionnaire burden of completing the Patient Health Questionnaire (PHQ9) or PROMIS Depression Computer Adaptive Test (D-CAT) vs using various two-step screening combinations for depressive symptoms in patients with end-stage kidney disease (ESKD).

Methods
A cross-sectional, convenience sample of adult kidney transplant recipients and patients on maintenance dialysis completed the Edmonton Symptom Assessment Survey-revised (ESASr), PROMIS D-CAT and PHQ9. PHQ9 score ≥10 was used as reference to identify moderate/severe depressive symptoms. ESASr depression (ESASr-D) and PHQ2 score of ≥1 and ≥2 were evaluated for the pre-screening step. In the second step, D-CAT T-score ≥55 was used to identify patients with potentially significant depressive symptoms. The total number of questions completed were calculated for the different scenarios.

Results
Mean(SD) age of the 164 participants was 52(17), 68% were male, 62% Caucasian. Based on PHQ9, 16% (n=26) had depression. In the single step screening scenarios, the sample would complete a total of 1476 PHQ9 or 1020 D-CAT items, respectively (9 or 6 items per participant on average, respectively). All the different 2-step screening combinations would reduce the total number of items completed by the total sample by at least half. A 2-step method combining PHQ2 ≥2 and D-CAT (Sensitivity:65% Specificity:94%), required a total of 510 items (both PHQ2 and D-CAT together; 3.1 per participant on average). A 2-step screening combining ESASr-D ≥1 and D-CAT (Sensitivity:58% Specificity:94%) required a total of 435 items (both ESASr-D and D-CAT together; 2.7 per participant on average).

Conclusion
Compared to administering either PHQ9 or PROMIS Depression CAT to all participants, a 2-step process including an ultra-brief pre-screening tool reduced the number of questions completed by the total sample substantially.

112-P.
Psychometrics of three Swedish pediatric item banks from the Patient-Reported Outcomes Measurement Information System (PROMIS)
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Objective
The Patient-Reported Outcomes Measurement Information System (PROMIS) aims to provide self-reported item banks for several dimensions of physical, mental and social health. Here we investigate the psychometric properties of the Swedish pediatric versions of the item banks for pain interference, fatigue and physical activity.

Methods
12-19 years old participants (n = 681) were recruited in public school settings, at a child- and psychiatric outpatient clinic, and a youth health outpatient clinic confirmatory factor analyses (CFA) were performed to evaluate scale dimensionality and local dependence. Item Response Theory (IRT) analyses were then used to finalize item banks and assure that each item is valid and weighted as a standalone assessment.

Results
CFA results confirmed that pain interference, fatigue and physical activity are separate constructs. Items with low item fit and items with Differential Item Functioning (DIF) were removed resulting in 14 items of pain interference and 15 items of fatigue items, and 6 items of physical activity.

113-P.
Parental caregiver burden and recovery of adolescent Anorexia nervosa after multi-family therapy
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Objective
Parental involvement in the treatment of anorexia nervosa has shown to be extremely important, especially for adolescents. This study investigated whether parental caregiving burden changed during adjunct multi-family therapy of adolescent anorexia nervosa and eating disorders not otherwise specified (EDNOS) and whether caregiver burden at baseline and changes in caregiver burden during treatment were associated with treatment outcome.

Methods
Twenty-four females, 13 to 16 years old, and their parents, participated in the study. Caregiver burden was measured with the Eating Disorders Symptom Impact Scale, by mothers (n=23) and fathers (n=22). Treatment outcome was measured by adolescent body mass index, level of global functioning and self-rated eating disorder symptoms by the Eating Disorders Examination Questionnaire 4.0.

Results
All patient outcomes improved and overall caregiver burden decreased significantly during treatment. When broken down in aspects of caregiver burden the decrease in parental perceived isolation, was found to be associated with improvement of BMI and Children’s Global Assessment Scale. When analyzing fathers and mothers separately, we found that maternal feelings of guilt and paternal perceived burden of dysregulated behaviors at base-line were correlated to treatment outcome.

Conclusions
Multi-Family Therapy shows preliminary effectiveness as an adjunct treatment for anorexia nervosa and eating disorders not otherwise specified. Fathers might be more important than seen before in treatment, especially in the participation of Multi-Family Therapy. Caregiver burden can be a potential mediator of treatment results in the future.

114-P.
Measuring function in a multidisciplinary Osteogenesis Imperfecta clinic
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Objective
Our objective is to report on early results of data collected during multidisciplinary clinic visits using PROMIS, functional mobility scores (FMS), and BMI, identifying relationships between type of Osteogenesis Imperfecta (OI) and function.

Methods
This is a single center retrospective review of OI patients attending a clinic visit including Genetics, Orthopaedics, and Physical Therapy between January, 2016– October, 2019. Demographic, clinical, operative data, PROMIS dimensions including physical mobility, upper extremity function, pain interference, fatigue, and peer relationships (pediatric) or social participation (adult) and FMS were collected.
Individuals’ presentations were sorted by mild, moderate, or severe and by BMI into categories of ideal, overweight, and obese.

**Results**

49 met criteria and were grouped based on OI severity. OI severity was associated with higher BMI and lower levels of function on PROMIS Physical Mobility and Upper Extremity Function dimensions. BMI was negatively associated with PROMIS Physical Function score. Individuals with OI who scored higher on PROMIS Physical Mobility and Upper Extremity Function had lower levels of Pain and Fatigue based on reported scores. Statistical significance between group differences for BMI, and PROMIS scores for Physical Mobility and Upper Extremity Function. Participants with mild or moderate OI had significantly higher BMI than those with severe OI. PROMIS Physical Mobility: participants with mild and moderate OI had significantly higher scores than those with severe OI; individuals with mild OI also scored significantly higher than those with moderate OI severity. PROMIS Upper Extremity Function: participants with mild OI had significantly higher scores than those with moderate or severe OI.

**Conclusions**

Patient reported outcome (PRO) measures are helpful in understanding individuals’ functional levels and identifying needs. Mild OI presentation tend to have lower BMI and greater activity as noted on PROMIS. Fatigue and Pain Interference on PROMIS did not have a significant relationship based on severity of OI or BMI. Severe presentation of OI tend to have higher BMI and less physical activity and upper extremity function on PROMIS. Past year fracture history, surgical intervention, and bisphosphonate use had no statistically significant impact on PRO across this population.

**115-O.**

Cross-walking PROMIS-29 to the Roland-Morris Disability Questionnaire and Oswestry Disability Index for chronic back pain

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**Objective**

There is extensive literature on the effectiveness of pharmaceutical and nonpharmacologic interventions for chronic low back pain (CLBP) based on different samples and outcome measures. The NIH Research Task Force (RTF) on CLBP noted that these differences make it difficult to compare studies of similar or competing interventions. These differences limit the usefulness of the results in answering questions such as ‘Which therapies work best? And for whom?’. This study reports empirical links of the PROMIS-29 with the Roland-Morris Disability Questionnaire (RMDQ) and the Oswestry Disability Index (ODI) to enable comparisons across more studies.

**Methods**

Secondary analyses of three datasets: 1) RAND Center of Excellence for the Appropriateness of Care (CERC) data (n=1677) were collected on chiropractic patients being treated for CLBP and CNP; 2) Assessment of Chiropractic Treatment for Low Back Pain (ACT) data (n=750) were collected on active military personnel participating in chiropractic clinical trials for LBP; and 3) Amazon Mechanical Turk (MTurk) data were obtained from a general population sample (n=5755) that included a subgroup that reported CLBP (n=1444). The PROMIS-29 was administered in all three datasets, the RMDQ in the ACT, and the ODI in the CERC and MTurk datasets. We develop ordinary least squares regression equations to predict the RMDQ and the ODI from PROMIS-29 scales.

**Results**

\[ R^2 \]

values ranged from 54 to 61% with normalized mean absolute error (NMAE) ranging from 0.51 to 0.53 standard deviations in regression models predicting the RMDQ from the PROMIS-29. Physical function, pain interference, and sleep disturbance were consistently retained. \[ R^2 \] values ranged from 65 to 67% in CERC data and 63% in MTurk data with NMAE ranging from 0.43 to 0.47 in CERC and 0.46 in MTurk data for predicting the ODI. Physical function, social function, sleep disturbances, and average pain intensity were consistently retained.

**Conclusions**

The RMDQ and ODI “legacy” scores can be predicted from the PROMIS-29 with sufficient accuracy for group-level comparisons. These crosswalks enable comparisons of studies that use legacy measures with those that administer the PROMIS-29. In addition, these results can be used for the harmonization required for individual patient data meta-analyses.

**116-O.**

Dutch reference values for the PROMIS Scale v1.2 – Global Health

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**Objective**

In order to add context to the health impact of diseases and conditions, it is important to interpret and compare patient-reported outcomes across studies and populations. This study aims to estimate and evaluate Dutch reference values for the Patient-Reported Outcomes Measurement Information System Global Health (PROMIS-GH) scale.

**Methods**

The PROMIS-GH v1.2 was administered through a web-based survey to 4370 Dutch persons, representative for the Dutch general population in 2016. T-scores for the mental health (GMH) and physical health (GPH) subscales, and their shorter two-item subscales, were calculated for the entire population, age groups and gender. T-scores for GMH and GPH were compared to the US reference population, which has a mean T-score of 50 and a standard deviation of 10, and to age-range and gender subpopulation reference scores. US reference population T-scores are representative for the 2000 US general population.

**Results**

The Dutch population had a GMH T-score of 44.7 and a GPH T-score of 45.2, both substantially lower, and thus worse, than the US reference population T-score of 50. Lower T-scores for the Dutch general population were found for both age-range and gender subpopulations compared to US subpopulation reference values. T-scores of the Dutch general population showed a similar pattern compared to US reference values: T-scores worsened with increasing age, but improved again for the oldest age groups; males scored better than females.

**Conclusions**

This study reports reference values for the PROMIS-GH scale for the Dutch general population, including age-range and gender subpopulations. PROMIS can improve the assessment of physical and mental health, but appropriate population reference values are essential for their interpretation. This study provides these values for the Netherlands; they are notably worse from the US reference values of 2000; perhaps the US data is outdated and no longer representative of the current US health status. Nevertheless, this study fuels the discussion on whether or not we should anchor the mean and standard deviation of PROMIS scales on the US population.

**117-P.**

PROMIS in English speaking countries – A systematic review of the evidence for measurement invariance of PROMIS tools

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Objective

Measurement invariance across different populations defined in terms of language and culture must be quantified and confirmed to ensure that Patient Reported Outcome Measures (PROMs) maintain their metric properties. The Patient Reported Outcomes Measurement Information System (PROMIS) was designed and tested on a US reference population. Assumptions of validity and cross-cultural equivalence in other English-speaking countries is based on a universal translation approach, but remains untested and should be confirmed alongside evaluation of other psychometric properties such as reliability and responsiveness. We aimed to investigate the use of PROMIS instruments in non-USA English speaking countries, and the evidence of measurement invariance within these populations.

Methods

We performed a systematic search of MEDLINE and Embase for contemporary literature from 2017 onwards. Articles were included if they provided evidence of use or assessment of metric properties of PROMIS instruments in UK, Australian or New Zealand populations. Secondary searches of published abstracts from conference proceedings and trial registries were also undertaken.

Results

Twenty-two articles met our inclusion criteria and 12 (55%) used a PROMIS instrument as an outcome measure without any evaluation of their metric properties in the target populations. The remaining 10 articles analysed the metric properties of PROMIS tools. Six Australian psychometric analyses focused on mental health metrics for the Depression, Anxiety and Emotional Distress item banks. Three studies provided evidence to support validity, responsiveness to change was confirmed in two and measurement invariance was assessed in one. Only four studies including UK populations studied either the validity, responsiveness or invariance. Sixty-nine registered clinical trials were identified. The majority planned to use PROMIS tools to assess outcomes. There was no evidence of cross-cultural adaptation or testing for cross-cultural equivalence of PROMIS item banks.

Conclusion

Evidence on the measurement properties of PROMIS instruments in populations from English speaking countries outside of the US and Canada is scarce. Lack of confirmation of measurement invariance places the interpretation of PROMIS instruments at risk. There is a pressing need for the evaluation of cross-cultural validation amongst English speaking populations to ensure appropriate interpretation and acceptance of the PROMIS instruments.

118-O.

Monotonic polynomials to model flexible item response curves for PROMIS Physical Function

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Objective

The PROMIS Instrument Development and Validation Scientific Standards suggest to investigate each items’ measurement properties by inspecting initial probability functions from non-parametric IRT models. Typically, items are excluded when their response function is misfitting a parametric model. Monotonic polynomials allow to parametrically model aberrant response curves and therefore to retain such items in the measurement model. We investigated suitability of this approach in the PROMIS Physical Function item bank.

Methods

Using PROMIS Wave 1 data (N = 15,725) for Physical Function, we fitted a monotonic polynomial model as well as the standard graded response model. We compared both models in terms of overall model fit, latent trait estimates, and item as well as test information. We investigated item-level differences between both models using common measures of differential item functioning and simulated the impact of model differences on scoring of 5 and 10 item tests.

Results

The monotonic polynomial showed better fit to the data indicated by a significant likelihood ratio test and a lower AIC (but higher BIC) compared to the graded response model. The difference of theta estimates between both models was less than 0.12 in 95% of the cases, but the monotonic polynomial model had higher information in the lower ranges of the construct. The high concordance between both models could be due to the fact that items with aberrant response curves have not been included in the PROMIS Physical Function itembank.

Conclusions

Monotonic polynomials as flexible intermediates between parametric and non-parametric models appear to be a useful addition to PROMIS developers’ toolbox.
Introduction

Surveys are one of the basic and commonly used measuring tools to describe the phenomenon of interest to us. A quick and straightforward to implement online form facilitates and shortens the time of the entire process. Tests and research instruments must meet the criterion of reliability. The study aimed to determine the difficulties that should be considered in conducted surveys among children and adolescents based on questionnaires about body posture, physical activity, back pain, and symptoms of depression.

Aim of the study

The research was carried out at randomly selected schools in Warsaw and Tczew. The study involved 85 teenagers attending elementary school classes.

Material and methods

The study was conducted in 2 groups (32 participants - average age 12.3 years and 53 participants average age 11.8 years). The study was conducted using the internet "mini-questionnaire" http://mini-anikieta.azurewebsites.net/ with the consent of the Bioethics Committee. In both groups, the study was conducted twice, with the second one after a one-week break, as recommended for the reliability studies. The questionnaire consisted of 53 items. Questions include data on age, weight, and height as well as on carrying a backpack/school bag, school and sports activity, and the presence of posture defects (Korovessis, Glinkowska). Besides, the PROMIS Ped SF v2.0 – Depressive Symptoms 8b (eight items) was used to assess the participants’ mood for back and neck pain. The groups differed in information resources during the procedure of signing informed consent (standard vs. enriched with additional instructions and introduction to the problem of back and neck pain and problems with posture). Retest test reliability testing was performed, and Cronbach’s alpha values were calculated using Medcalc version 19.1 software.

Results

In both groups, reliability in the questions asked sex, body build, and basic data from everyday life (e.g., backpack weight, number of hours spent on various school activities and outside school) showed good Cronbach’s alpha results (> 0.7). In the group in the standard procedure, Cronbach’s alpha values were insufficient (from 0.1 to 0.56), especially questions about sadness, weakness, fatigue, and exhaustion. Student information about themselves was highly consistent (Height - alpha 0.97; Weight 0.86). In the second group, data from 53 students about themselves were good - Cronbach’s alpha > 0.7.

Discussion

The too-short range of information provided before testing among children and adolescents may result in low compliance of the responses in the test-tester, which could affect the reliability of the research instrument. Analysis of potential causes suggests that among the reasons there may have been motivational problems for the scrupulous and faithful answering of questions by children and adolescents.

Conclusions

Research confirms the need to inform children accurately and young people about issues related to surveys; otherwise, there is a risk of unreliable research.
Methods
This was a multi-center, prospective; single-blind randomized clinical trial comparing PT to DETA. A total of 60 patients prescribed PT were randomly assigned. The PT groups were assigned to therapy twice a week for 8 weeks. The DETA group was assigned to 15-25 minute videos 3 times a week for 8 weeks that were tailored based on the patient’s disability and health status. The DETA’s algorithm adjusted the intensity of DETA’s program progression based on results from a 4-week interim follow-up measuring changes in PROMIS® scores. The primary outcome was change in PROMIS® scores. Patients were reviewed at baseline and at 8 weeks.

Results
Thirty patients completed the 8 week intervention (17 control, 13 treatment) at the time of submission. No differences existed between the groups in age or gender (p>0.05). Preliminary analysis suggests changes in PI (control: -1.8±7.8, Limber app: -6.3±6.7) and PF (control: 0.46±6.6, Limber app: 5.7±7.0). Independent t-tests revealed absolute changes in PROMIS Physical Function were significantly greater in the DETA group compared with control, indicating a greater improvement in function; a large effect size was noted (p<0.05, Hedge’s g = 0.77). Changes in Physical Function and Pain Interference surpassed MIDC in the Limber group, but not in the control group.

Conclusion
An 8-week DETA program was superior to the standard of care of PT at the time of submission. The study supports that a DETA could have similar outcomes with respect to pain and function compared to PT. This study describes an innovative approach to risk stratify patients to appropriate exercise based off of their disability.

123-P.
PROMIS and PROs in the Symptoms System - Visualizing health in clinical care
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OBJECTIVES
This presentation will explore means to: Equalize asymmetry between needs and expectations in health care using patients’ perceptions about symptoms, functions and quality of life; Balance knowledge and preferences in point-of-care interactions, leading to better outcomes and enhanced value in health care; Empower patients to take responsibility for quality of care with scientifically based methods to contribute to safer, more efficient and equal care; Implement PROMIS and other PROM instruments in a patient-driven digital system, where the combination and visualization of PROMIS measures together with other PROs facilitates usage, with benefits for both clinical care and patients.

METHODS
An evaluation protocol designed according to universal and co-design principles will be described. This will explore how to visualize results and combine PROMIS measures with other PROs, facilitate long-term implementation, support patient empowerment, self-management, and improve clinical care. A mixed-methods approach will be used to explore patient and multidisciplinary perspectives on the visualization of data, and the feasibility of implementation in clinical care and for patient self-management.

RESULTS
Measuring patient reported outcomes (PROs) with standardized questionnaires is a scientifically sound method to gain insight into patients’ symptoms, functions and quality of life. In certain contexts, PRO collection has been linked to increased survival, improved symptom management, and good treatment results in randomized studies. PROMIS provides a set of person-centered measures that evaluates and monitors physical, mental, and social health. With its generic approach, and possibilities for modern methods of administration, it offers great advantages over historical paper questionnaires and facilitates use at many stages both for clinical care and patients. This protocol will explore how to combine and visualize PROMIS measures together with legacy questionnaires.

Processes to visualize data for patients as well as clinicians, while upholding the quality of the data collected, will be explored. In the presentation we will illustrate the visualizations tested.

CONCLUSIONS
Equalizing asymmetry between needs and expectations of PROs visualization for clinicians and patients requires careful consideration of the overall purpose of the data and health management.

124-P.
Do PROMIS measures correlate with fitness and satisfaction with social roles in participants of a university wellness clinic?
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Objective
Studies determining the concurrent validity of patient reported outcomes and performance outcomes are useful for application to clinical care. To determine the correlation (bivariate and multivariate) between PROMIS measures of physical health (PF) and mental health (depression and SE of emotions) and social roles (SSR) and short forms (SF8) in addition to psychologic testing (i.e. VO2 Max). Univariate correlations and multivariate linear analysis were used to assess the convergence of age, gender, and different PROMIS measures with 1) VO2 max and 2) PROMIS SSR.

Results
Age (r= -0.31, p=0.02), PF (r=0.46, p<0.01) and fatigue (r=0.40, p<0.01) showed significant univariate convergence with VO2 max. Younger age, higher physical function and lower fatigue correlated with higher VO2 max values. A multivariate model including age (p=0.05), PROMIS PF (p=0.05), fatigue (p=0.01), and PI (p=0.04) resulted in a r-value of 0.62 for predicting VO2 max. Age (r= -0.40, p<0.01), PROMIS PF (r=0.44, p<0.01), PI (r=0.44, p<0.01) and SE daily activities (r=0.35, p=0.02) showed significant convergence with SSR. Younger age, higher physical function, lower PI and higher SE with daily activities correlated with higher SSR values. A multivariate model including PROMIS PF (p<0.01), depression (p=0.05), and SE of emotions (p=0.02) resulted in a r-value of 0.65 for predicting SSR.

Conclusions
Perceptions of function detected by PROMIS measures associated with physical health rather than psychosocial health show better convergence with fitness in mostly younger people attending a Wellness Clinic. In contrast, measures of physical health (PF) and mental health (depression and SE emotions) showed convergence with satisfaction with social roles. These outcomes support the use of PROMIS measures of physical health to counsel young participants seeking to improve fitness and a combination of physical and mental health measures when focusing on social roles.

125-P.
Is unacceptable self-efficacy associated with unacceptable physical health domain function and symptoms?
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Journal of Patient-Reported Outcomes 2020, 4(Suppl 2):125-P.
Objective

Interpretation and application of the Patient-Reported Outcomes Measurement Information System (PROMIS) Self-Efficacy for Managing Symptoms (SEsx) for orthopedic physical therapy patients is unclear. Self-efficacy is theorized to mediate PROMIS physical domain measures such as pain interference (PI), physical function (PF) and fatigue. However, no current studies document the association between acceptable levels of physical domain measures and self-efficacy. Although there are several self-efficacy measures, managing symptoms is thought to be the most applicable to orthopedic patients. The purpose of this analysis was to evaluate the associations between unacceptable SEsx with physical health domain measures (PF, PI, and Fatigue).

Methods

PROMIS computer adaptive tests (PF, PI, Fatigue, SEsx) were administered at initial evaluation (n=199) for spine (44.7%), lower extremity (35.7%), upper extremity (17.6%) and other reasons (2.0 %) in physical therapy. Unacceptable T-scores were coded (0.1): PF < 40, PI > 60, Fatigue > 55, SE < 45. Odds ratios (OR) and 95% confidence intervals (CI) were calculated to examine the associations of unacceptable SEsx with other unacceptable PROMIS measures. A logistic regression model including age, gender, unacceptable PROMIS PF, SEsx, and Fatigue was evaluated for ability to independently predict unacceptable PROMIS PI.

Results

Patient (age=42.5 (19.5), 60% female). The proportion of patients with unacceptable symptoms were: PF 33.5%; PI 52.5%; Fatigue 40.7%, and SEsx 46.7%. The proportion of patients with any unacceptable symptoms was 69.7%. A total of 14.6% reported all symptoms at unacceptable levels. Unacceptable SEsx was significantly associated with: unacceptable PI (OR = 8.3, CI 4.4 to 15.7), unacceptable PF (OR=7.5, 95%CI 3.8 to 14.9), and unacceptable Fatigue (OR= 3.5, CI 1.9 to 6.2). Logistic regression showed that unacceptable PF (OR 8.20, CI 2.23 to 30.86) and unacceptable SEsx (OR = 4.5, CI 2.2 to 9.3) were independent predictors of unacceptable PI.

Conclusion

The strong association of SEsx with PF and PI, and prevalence of unacceptable SEsx measures suggests providers should develop methods to address SEsx in patients with physical health measures indicating unacceptable function and symptoms. This finding supports the theory that addressing patient confidence and beliefs (SEsx) may enhance care directed at physical health.

127-O.

Validation of PROMIS measure of itch impact and intensity in pediatric patients with Atopic Dermatitis

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Background

Itch is the most common symptom of pediatric skin diseases, including atopic dermatitis (AD), and greatly affects patient quality of life (QOL). Assessments of itch exist, but lack comprehensiveness and psychometric validity. To fill this gap, we have developed the new PROMIS Itch Questionnaire (PIQ-C). The PIQ-C was developed using mixed-methods approaches and consists of 45 unidimensional items, calibrated using a graded response model based on item responses from 600+ children with itch conditions. Here, we report clinical validity of the PIQ-C using cross-sectional and longitudinal data.

Methods

Children aged 8-17 were recruited from Chicago-area dermatology clinics. Children completed the PIQ-C and additional clinical assessments of disease severity/QOL (Itch NRS, EASI, POEM, IGA, CDLQI) at baseline and 6-month follow-up. Severity measures were categorized as mild/moderate/severe and change in severity from baseline to 6- and 12-months were calculated and categorized as improved/same/worse change. Convergent validity was assessed by evaluating correlations of PIQ-C and an itch-related clinical measure at baseline. Known groups validity was assessed using one-way Analysis of Variance (ANOVA), modelling difference in PIQ-C score across severity group at baseline. Responsiveness to change was assessed using mixed linear regression: differences in change in PIQ-C score from baseline to six months was evaluated for differences between clinical change groups.

Results

181 patients aged 8-17 completed baseline PIQ-C; 59 completed the 6-month follow-up. At baseline, PIQ-C was highly correlated with CDLQI (0.73), POEM (0.64), and moderately correlated with Itch NRS (0.54). Significant increase in PIQ-C was found as severity of AD increased across all clinical measures used to define severity (p<0.05 for all). The PIQ-C was responsive to change across time; patients with improved clinical score also had a significantly improved PIQ-C, and the change in PIQ-C differed across improved/same/worse change groups in the expected direction (p<0.0001 for all).

Conclusion

The PIQ-C measure includes aspects of itch important to assessing overall symptoms and impact. Correlations with known measures, ability to distinguish among severity groups, and responsiveness across time suggest clinical validity. Next steps include evaluating replicability of results in patients from other clinics and validation in children with other itch conditions.
128-P. Investigating parameter stability in the presence of high slopes
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Journal of Patient-Reported Outcomes 2020, 4(Suppl 2):128-P.

Objective
There is a growing recognition that large slopes in IRT models are not as desirable as a trait as originally believed. Larger slopes suggest greater information and thus higher reliability and a shorter computer adaptive testing experience; however, slopes may be inflated when the IRT model fails to account for locally-dependent item subsets, or when there is a preponderance of individuals at the floor or ceiling of the domain. The objective of this study was to investigate the sampling distribution of the PROMIS® Pain Interference 8-item short form (where slope inflation may be occurring) using data from PROMIS 1 Wave 1, using both a standard normal latent distribution and when estimating the latent distribution using Davidian curves.

Methods
We utilized general population data from PROMIS 1 Wave 1, for participants with item-level data on at least 5 of the 8 items from the Pain Interference short form. In order to investigate the effect of sample size on parameter stability, we conducted a bootstrap resampling of sample size 500, 750, and 1259 (i.e., the total eligible number of participants). The primary outcome was the slope estimates across replications. We utilized factorial analysis of variance to investigate whether the slopes were significantly different by latent density, sample size, and their interaction. Each item was analyzed separately.

Results
There was a main-effect for sample density in all 8 items, with higher slopes with DC-IRT models. The difference by sample size was less consistent, with only 3 items showing a difference in slopes by sample size. The interaction was nonsignificant for all items.

Conclusions: Contrary to expectations, slopes were larger when the latent density was estimated using Davidian Curves. Additionally, there was a higher frequency of nonconvergence (even with 10,000 cycles) with DC-IRT models. The lack of significance for sample size was encouraging, insofar as it suggests the parameters are robust to sampling conditions. However, while the means were similar across sample sizes, the range varied more widely with the smaller sizes (as would be expected). Future research should evaluate whether a zero-inflated model would also provide consistent slope estimates as here.

129-P. Comparing PROMIS® Global Health-10 and EQ-SD: sensitivity to clinical cut-off scores for anxiety and depression
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Journal of Patient-Reported Outcomes 2020, 4(Suppl 2):129-P.

Objective
To investigate the psychometric properties of the Swedish translation of the GH-10 questionnaire.

Methods
PROMIS GH-10, EQSD, GAD7 and PHQ9 were electronically collected from consecutive attendees of an emergency clinic from Sept 2018 to May 2019. Confirmatory factor analysis evaluated the two-factor structure of the GH-10; physical (PCS) and mental (MCS). Goodness-of-fit was defined as comparative fit index above .9 and standardized root mean square residual (SRMR) above 0.08. Internal consistency and discriminant validity were assessed. Analyses were repeated, stratified by cutoffs for clinical treatment, and sensitivity analysis was conducted using receiver operating characteristic (ROC) curves.

Results
Of 164 patients (58% female) aged 18–88 (mean: 49 years), 58% were in full-time employment; 56% were overweight or obese. The two-factor solution indicated acceptable CFI .935, but the SRMR was .0567, thus below goodness-of-fit levels. Pain had the lowest factor score on PCS. Internal consistency for the two sub-domains was good; Cronbach’s alpha for PCS was 0.730, for MCS 0.862 and for the whole instrument 0.906. Hypothesized relationships between GH-10 subdomains and the other instruments were confirmed and in line with previous published reports. Pearson’s correlations showed strong correlations of the mental health subscale to the PHQ-9 (r=0.702) and the GAD-7 (r=0.704). Moreover, the physical subscale of the GH-10 showed a good correlation with the EQ-SD index (r=0.550) and with the EQ-SD VAS (r=0.565). The area under the curve (AUC) of the MCS and PCS was higher than for EQ-SD against the GAD-7 PHQ-9 cutoffs.

Conclusions
Taking into account the sample size, the Swedish version of the GH-10 has good psychometric properties. The less well performing item concerning pain should be investigated further.

130-O. A Comparison of the measurement properties of the PROMIS-Fatigue (MS) 8b against legacy fatigue questionnaires
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Objective
Amidst the growing number of patient-reported outcome (PRO) measures of fatigue being used in MS clinical trials and clinics, evidence-based consensus on generalizable and the most appropriate measures across different settings would be beneficial for clinical research as well as patient care.

To compare the validity and responsiveness of the PROMIS SF v1.0 - Fatigue (MS) 8b with the Fatigue Severity Scale (FSS) and the Modified Fatigue Impact Scale (MFIS), across US and UK populations

Methods
Two observational studies were performed in MS populations, as part of a PRO measure development project, including a cross-sectional study in two tertiary MS centers in the US (n=296) (US sample) and a 96-week longitudinal study in the UK MS Register cohort (still ongoing) (n = 384) (UK sample). Analyses included examination of: 1) relative validity based on ability to discriminate across patient subgroups according to fatigue or functional status at baseline (i.e. ANOVA-F PRODx ANOVA-F PROMIS-F(MS)8b); and 2) relative responsiveness, based on baseline-to-week-52 score change (Effect size) across fatigue or functional status response groups (UK sample only).

Results
The mean age was 44.5±11.2 / 50.7±9.4; and 74 %/ 75.9% were female (US /UK Samples). The mean PROMIS-F(MS)8b T-score at base-line was 57.4±10.5 / 59.9±9.4 (US sample / UK sample). Compared with the PROMIS-F (MS8b, relative validity (anchor: GHS fatigue global question) was 86% for MFIS symptom score, 87% for MFIS total line was 57.4±10.5 / 59.9±9.4 (US sample / UK sample). Compared with the Fatigue Severity Scale (FSS) and the Modified Fatigue Impact Scale (MFIS), across US and UK populations

2020, 4(Suppl 2):T93
These differences have practical implications on the application of these questionnaires in both clinical practice and research settings e.g. in sample size estimation in clinical trials.

131-P. Validation of the PROMIS® Pediatric Item Banks Anxiety and Depressive Symptoms in a general Dutch population
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Objective
This study aims to validate the Dutch-Flemish PROMIS pediatric item banks v2.0 Anxiety and Depressive Symptoms in a general Dutch population.

Methods
Participants (N = 2,893, aged 8 - 18), recruited by two certified internet panel agencies, completed the PROMIS pediatric item banks v2.0 Anxiety and Depressive Symptoms online. Both item banks were assessed on unidimensionality, local dependence, monotonicity, Graded Response Model (GRM) item fit, and differential item functioning (DIF) across gender, age groups, region, ethnicity, and language. The PROMIS pediatric Anxiety and Depressive Symptoms short forms 8a and simulated computerized adaptive testings (CATs) were assessed on reliability and construct validity compared to the Revised Child Anxiety and Depression Scale short version (RCADS-22) subscales.

Results
The PROMIS pediatric item banks v2.0 Anxiety and Depressive Symptoms showed sufficient unidimensionality (Omega H = 0.83, 0.95; ECV = 0.79, 0.93, respectively), local independence (residual correlations < 0.2), and monotonicity (H = 0.61, 0.69, respectively). Both item banks showed sufficient GRM item fit (S-X2 p-value < 0.001), except for the Depressive Symptoms items 2697R1r “I wanted to be by myself”, 7010 “I felt sad for no reason”, and 9001r “I felt too sad to eat”. No DIF was found for gender, age groups, region, ethnicity, and language, except for the Depressive Symptoms items 2697R1r “I wanted to be by myself” and 488R1r “I could not stop feeling sad” that showed uniform DIF for language (McFadden pseudo R2 change > 2%). Based on U.S. parameters, the PROMIS pediatric Anxiety and Depressive Symptoms short forms 8a showed a reliability of > 0.90 in 2% and 34%, and the CATs in 26% and 41% of the participants, respectively. Both short forms and CATs revealed high positive correlations (r > 0.70) with the corresponding RCADS-22 subscales and slightly lower correlations with the non-corresponding RCADS-22 subscales (r ≤ 0.70).

Conclusions
The Dutch-Flemish PROMIS pediatric item banks v2.0 Anxiety and Depressive Symptoms show sufficient psychometric properties, except for four Depressive Symptoms items that show DIF for language or poor GRM item fit; the short forms 8a and CATs seem valid, but reliable for a small percentage of children.

132-P. Evaluation of a patient-reported frailty tool in Systemic Lupus Erythematosus
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Objective
Frailty is associated with disability in systemic lupus erythematosus (SLE). To our knowledge, no phenotypic frailty tool including objective/subjective domains has been compared to a validated point-of-care frailty measure in SLE. We evaluated the point-of-care self-reported FRAIL scale (FS) versus the standard Fried phenotype (FP) by comparing the prevalence of frailty as measured by both tools in a cohort of women with SLE. We also evaluated the association of each frailty measure with several patient-reported outcomes (PROs), comparing associations in frail versus non-frail women.

Methods
Adult women <70 years old with validated SLE and mild/moderate disease enrolled from one center. Measures included: frailty (FP/FS); disease activity/damage; and PROs (PRO Measurement Information System (PROMIS) computerized adaptive tests (CATs) and Valued Life Activities (VLA) disability). Differences between frail and non-frail participants were evaluated using Fisher’s exact or Wilcoxon rank sum tests and the association of frailty with disability using logistic regression. Correlation between the FP and the FS was determined using Spearman’s correlation.

Results
72 women enrolled; 67 (93%) completed the FS. 17% (FP) and 27% (FS) were frail. Frail women according to either definition had greater disease damage (FP: p=0.002; FS: p=0.0006) and worse PROMIS CATs, including mobility, physical function, pain behavior and interference, and fatigue (FP and FS: all p<0.01). Compared with non-frail women, frail women classified by the FS had greater comorbidity (p=0.02); when classified by the FS, frail women were older (p=0.04) with worse PROMIS CAT depression (p=0.02). Frailty according to either definition was associated with VLA disability after adjustment for age, comorbidity, and disease activity (FP: p=0.02; FS: p=0.0003), but this relationship was attenuated for the FP after adjustment for disease damage (p=0.08). There was moderate correlation between the FS and the FP (r = 0.48; p < 0.0001).

Conclusions
Prevalence of patient-reported frailty was high in this cohort of women with SLE. Frailty, measured with either metric, was associated with worse PROs, providing face validity for both definitions. The FS was associated with disability even after adjustment for multiple confounders. These data suggest that the FS may be an informative point-of-care tool to identify frail women with SLE.
Introduction

Patient-reported outcomes and listening to the true feelings of the patient are the hot spot in cancer research both in China and abroad recently. Given the increase in misuse and abuse of prescription opioids, clinicians clearly benefit from a standardized tool to screen screening opioid overdose. In 2009, the International Society for Pharmacoeconomics and Outcome Research (ISPOR), FDA, the Health-related quality of Life Working Group and the International Association for quality of Life Research (ISQOL) jointly put forward that incorporating patient self-reporting data into the evaluation system of clinical decision-making. Combined with the patient self-reporting measurement system, it can help clinicians to better detect and screen abnormal drug use behavior, and lay the foundation for early intervention.

Objectives

The present study developed a Chinese version of the Severity of Substance Use, and incorporated into the Patient-Reported Outcomes Measurement Information System to promote domestic opioid abuse screening, improve drug evaluation and promote clinical nursing and drug management.

Methods

After applying for authorization from the American PROMIS data management center, the translation method of FACIT (Functional Assessment of Chronic Illness Therapy) was adopted. After simultaneous forward translations, reconciliation, back-translation, expert review and proofreading, the first translation draft was formed and submitted to the PNC-China center for quality review. On the basis of the review, cognitive interviews were conducted among 5 cancer patients (at least 5 patients in each item) who were eligible for inclusion, and the interviewees pointed out the items and phrases that were difficult to understand, as well as the possible difficulties in the answer process. The interviews with each patient were recorded and recorded with their consent. The head of the translation team will sort out the patient’s feedback, and the cultural mediator will provide the appropriate translation plan with reference to the patient’s opinion. After cultural debugging, the final Chinese version of the drug use severity scale was formed.

Results

A Chinese version of the severity scale of drug use was formed.

Conclusion

We provide a culturally adjusted Chinese version of screening tool to screen drug abuse in China, and the translation has gone through a standardized process and cultural debugging, which can be used to screen drug abuse in China.

134-P.

A PROMISing prospect of measuring pediatric general health: A comparison of the PROMIS® pediatric Global Health scale (PGH-7) and the Pediatric Quality of Life Inventory (PedsQLTM).

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Objective

On February 18th 2020 the International Consortium for Health Outcomes Measurement (ICHOM) announced the release of the Standard Set for overall pediatric health. This outcome set contains the Patient-Reported Outcomes Measurement Information System (PROMIS) Pediatric Scale v1.0 Global Health (PGH-7-2) for measuring overall physical, mental and social health. Our aim was to assess the psychometric properties of the PGH-7 in the Dutch population and to compare the performance of the PGH-7 with the Pediatric Quality of Life Inventory (PedsQLTM).

Methods

Children aged 8-18 years (n=2654), representative of the Dutch population on key demographics were asked to complete the PGH-7 (nitems=7) and the PedsQL (nitems=23). To assess structural validity of the PGH-7 a graded response model (GRM) was fitted to the data after assessing the following assumptions: Unidimensionality through CFA (CFI>.95, TLI>.95, RMSEA<.10), local independence by residual correlations (r<.20) and monotonicity by Mokken analysis (H>50, H>30). Item fit of the GRM model was inspected with S-X2, where p<.001 indicates misfit. Additionally, convergent validity of the PGH-7 T-score with the PedsQL total score was assessed. A moderately strong correlation (>0.50) was expected, as both instruments measure physical, mental and social domains. Percentage of participants reliably measured was assessed using the standard error of measurement (SEM) <.032 as a criterion (which equals a reliability of 0.90). Relative efficiency was calculated (1- SEM2/Sem2) to compare how well both instruments perform relative to the amount of items administered.

Results

In total 1082 (response rate = 40.8%) children completed both questionnaires. All GRM assumptions were met. PGH-7 displayed good structural (no misfit) and convergent (r=65) validity. Both questionnaires measured reliably (PGH-7=.74-5, PedsQL=.76-6) at the mean and 2SD in clinically relevant direction. The relative efficiency of the PGH-7 was 2.6 in comparison to the PedsQL indicating that, on average, the items in the PGH-7 are 2.6 times more informative than PedsQL items.

Conclusions

The PGH-7 displays sufficient reliability and validity in the general Dutch pediatric population. The scale measures more efficiently than the most commonly used legacy instrument (PedsQL).

135-P.

How the COVID-19 pandemic impacts the psychosocial well-being of children and adolescents in the Netherlands

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Objective

Recent measures of implementing social isolation and physical distancing as governmental reactions to the COVID-19 outbreak profoundly impact daily life, including that of children and adolescents. Suddenly children and adolescents were not allowed to go to school or participate in sports or other socializing activities anymore. It is therefore relevant to investigate the impact of these measures on psychosocial outcomes in children and adolescents in the general population. In this study we surveyed how the COVID-19 outbreak impacts the psychosocial functioning in a sample of Dutch children and adolescents during the first months of lockdown in one of the largest public health crisis of our time.

Methods

In April 2020, children and adolescents aged 8-18 years, representative of the Dutch population on key demographics, were asked to complete the following Patient-Reported Outcomes Measurement Information System (PROMIS®) computerized adaptive tests (CATs); anger, anxiety, depressive symptoms, peer relationships, sleep-related impairment and the global health scale, online using the KLIK PROM portal (www.hetklikkt.nl). In addition, parents were asked to complete sociodemographic questions about themselves (age, ethnicity, education level) and their child (age, gender, education level and presence of chronic conditions). Finally, both children and...
parents answered COVID-19 specific questions such as consequences for employment, school and the atmosphere at home. Using independent sample T-tests, PROMIS COVID-19 T-scores were compared to normative data that were collected in the general population pre-COVID (2018; n=1098). Additionally, the same data was gathered simultaneously in a sample of chronically ill children/adolescents and a sample of pediatric psychiatric patients.

**Results and Conclusion**

In total, 902/90/265 children and parents completed all questionnaires for respectively the general population/chronically ill/psychiatric samples. Preliminary results indicate that during the COVID quarantine, children scored significantly (p < 0.001) lower on all domains measured by the PROMIS CATs when compared to pre-quarantine normative data. Children and families experience the quarantine differently, as some children indicate that the atmosphere at home has improved, while others indicate a decline in atmosphere. However, further analyses are required to compare groups on background characteristics and to determine possible relevant covariates that may impact psychosocial functioning. These results will be shown at the conference.

### 136-O.
**Integrating PROMIS CAT collection into Epic: tips for success**

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*Journal of Patient-Reported Outcomes* 2020, 4(Suppl 2):136-O.

**Objective**

There are many significant challenges in implementing PROMIS CAT collection for effective and efficient population health applications. One of the biggest challenges is in effectively integrating this platform with daily clinical operations through the electronic medical record. While third-party platforms offer numerous advantages with regards to customization that may be appealing to medical providers, they can be costly and do not fully integrate into the electronic medical record. The purpose of this presentation is to highlight technical and practical key steps to effectively developing a PROMIS CAT platform within a widely used electronic medical record (Epic, Verona, WI, USA).

**Methods**

A PROM platform was designed with the following objectives: 1) electronic questionnaire assignment fully integrated through the native EHR on a 2) population basis through the orthopedic department, such that all ambulatory patients (and not just surgical patients) received questionnaires. The primary outcome was questionnaire completion rate during an initial pilot implementation. Secondary outcomes included completion rates by questionnaire type, patient age (<45 years, 45-64 years, and 65+ years), and visit type (new or follow-up patient), along with psychometric data of included questionnaires.

**Results**

An automated PROM platform was created through the native workflow and EHR, without the hiring of any additional personnel, utilizing National Institutes of Health (NIH) Patient-Reported Outcomes Measurement Information System (PROMIS) computer adaptive test (CAT) questionnaires. Among the first 1,930 ambulatory encounters and 8,383 questionnaires administered, there was an overall completion rate of 86%, with no questionnaire type completed less than 80% of the time. Questionnaire completion rate among the two youngest age groups (<45 and 45-64 years) was 87%, compared to 83% among patients 65 and older. New patient questionnaire completion rate was 91%, compared to 81% for follow-up patients. There were favorable floor and ceiling effects for all PROMIS questionnaires, with the exception of PROMIS Depression, which had a high floor effect.

**Conclusions**

The results of this pilot study demonstrate feasibility of administering PROMs on a population basis through an EHR. The questionnaire completion rate of (86%) exceeded the target for this pilot phase (60%) and for steady-state implementation (80%). This methodology can serve as a model for effective PROM collection.

### 137-P.
**Design, development, and implementation of an integrated and automated patient reported outcome measure platform through a native electronic health record:**

Results from the first 2,000 ambulatory encounters and 8,400 questionnaires administered to patients who had PROMIS computer adaptive test (CAT) questionnaires. Among the first 1,930 ambulatory encounters and 8,383 questionnaires administered, there was an overall completion rate of 86%, with no questionnaire type completed less than 80% of the time. Questionnaire completion rate among the two youngest age groups (<45 years, 45-64 years, and 65+ years), and visit type (new or follow-up patient), along with psychometric data of included questionnaires.

**Background**

Patient reported outcome measures (PROMs) represent the gold standard for reporting patient-centric health state measures in orthopedics. However, routine collection of PROMs in the busy ambulatory setting is challenging due to a number of constraints. The purpose of this study was to design and implement a successful PROM platform through a native electronic health record (EHR).

**Methods**

A PROM platform was designed with the following objectives: 1) electronic questionnaire assignment fully integrated through the native EHR on a 2) population basis through the orthopedic department, such that all ambulatory patients (and not just surgical patients) received questionnaires. The primary outcome was questionnaire completion rate during an initial pilot implementation. Secondary outcomes included completion rates by questionnaire type, patient age (<45 years, 45-64 years, and 65+ years), and visit type (new or follow-up patient), along with psychometric data of included questionnaires.

**Results**

An automated PROM platform was created through the native workflow and EHR, without the hiring of any additional personnel, utilizing National Institutes of Health (NIH) Patient-Reported Outcomes Measurement Information System (PROMIS) computer adaptive test (CAT) questionnaires. Among the first 1,930 ambulatory encounters and 8,383 questionnaires administered, there was an overall completion rate of 86%, with no questionnaire type completed less than 80% of the time. Questionnaire completion rate among the two youngest age groups (<45 and 45-64 years) was approximately 87%, compared to 83% among patients 65 and older. New patient questionnaire completion rate was 91%, compared to 81% for follow-up patients. There were favorable floor and ceiling effects for all PROMIS questionnaires, with the exception of PROMIS Depression, which had a high floor effect.

**Conclusions**

The results of this pilot study demonstrate feasibility of administering PROMs on a population basis through an EHR. The questionnaire completion rate of (86%) exceeded the target for this pilot phase (60%) and for steady-state implementation (80%). This methodology can serve as a model for effective PROM collection.

### 138-P.
**Role of pre-operative PROM scores in predicting post-operative outcomes and likelihood of achieving MCID following arthroscopic rotator cuff repair**

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*Journal of Patient-Reported Outcomes* 2020, 4(Suppl 2):138-P.

**Background**

The Patient-Reported Outcomes Measurement Information System (PROMIS) has emerged as a valid and efficient means of collecting outcomes in patients with rotator cuff tears. The purpose of this study was to examine the role of pre-operative PROMIS computer
adaptive test (CAT) scores in predicting post-operative PROMIS CAT scores, as well as likelihood of achieving minimal clinically important difference (MCID) following rotator cuff repair. We hypothesize that pre-operative PROMIS CAT scores will directly impact both post-operative PROMIS CAT scores and likelihood of achieving MCID.

Methods

Patients undergoing arthroscopic rotator cuff repair by one of three fellowship-trained surgeons were identified over a 12-month period. Only patients that completed both pre- and post-operative PROMIS CAT assessments were included in this cohort. PROMIS CAT forms for upper extremity physical function (PROMIS-UE), pain interference (PROMIS-PI), and depression (PROMIS-D) were utilized. MCID was calculated according to both distribution-based (db) and anchor-based (ab) methodology, and receiver operating characteristics (ROC) were utilized to determine if pre-operative scores were predictive of post-operative outcomes, with 95% specificity.

Results

One hundred and seventeen rotator cuff repair patients were included for statistical analysis with surveys completed an average of 29±36 days before and 243±117 days after surgery. PROMIS-UE improved from 30.3 to 38.7 (p<0.05), PROMIS-PI improved from 62.7 to 75.4%, and PROMIS-D improved from 47.4 to 44.3. The average change from pre-operative scores to post operative scores in PROMIS-UE and PROMIS-PI exceeded their dbMCIDs of +3.3+ and -2.8, respectively. PROMIS-UE, PROMIS-PI, and PROMIS-D exceeded their abMCIDs of 27+3.1, -4.7, and -3.1, respectively. The percent of patients who met dbMCID for PROMIS-UE, PROMIS-PI, and PROMIS-D was 67.8%, 75.4%, and 37.5%, respectively. After introduction of 95% specificity cutoffs, percentage of patients achieving dbMCID for PROMIS-UE, PROMIS PI, and PROMIS-D increased to 86.7%, 88.9%, and 50.0%, respectively. Similarly, the cohort’s probability of achieving abMCID for PROMIS-UE, PROMIS-PI, and PROMIS-D was 66.7%, 64.7%, and 48.2%, respectively. When prognostic cutoffs were introduced, probability of achieving abMCID for PROMIS-UE, PROMIS-PI, and PROMIS-D all increased to 86.7%, 83.3%, and 66.7%, respectively.

Conclusion

Arthroscopic rotator cuff repair is an effective surgery for symptomatic patients with rotator cuff tears, resulting in improvements of PROMIS-UE, PROMIS-PI, and PROMIS-D. Pre-operative PROMIS CAT domain scores can be utilized to predict likelihood of achieving or failing to achieve significant improvement across all three health domains.

139-P. Presence of preoperative clinical depression does not hinder recovery after anterior cruciate ligament reconstruction

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Background

Current literature suggests a link between psychosocial factors and poor surgical outcomes in patients with musculoskeletal complaints. However, there is a limited body of literature examining the effect of depression on outcomes after anterior cruciate ligament reconstruction (ACLR). The goal of this study is to determine the prevalence of depression in ACLR patients and evaluate its effect on patient-reported outcomes postoperatively.

Methods

In this single center retrospective cohort study, 121 pediatric and adult patients who underwent ACLR were included. PROMIS Physical Function (PF), Pain Interference (PI) and Depression (D) scores collected preoperatively and six months postoperatively were reviewed. A PRS of D ≥ 55 served as a validated threshold for clinical depression. Patients were separated into clinical depression (CD) and no clinical depression (NCD) groups based on preoperative PROMIS D score.

Results

121 patients undergoing ACLR were included in this study. 24 (20%) patients met criteria for clinical depression. Preoperatively, the CD group reported lower mean PROMIS PF (34.6 vs. 40.2, p < 0.01), higher PROMIS PI (65.1 vs. 59.1, p < 0.01) than those in the NCD group. Postoperatively, the mean PROMIS PF scores for the CD and NCD group were 48.7 and 51.0, respectively (p = 0.2). Mean postoperative PROMIS PI scores for the CD and NCD cohorts were 52.3 and 48.1, respectively (p = 0.04). After ACLR, there was substantial improvement in PROMIS PF, PROMIS PI in both the CD (+14.1 and -12.8, respectively) and NCD cohorts (+10.8 and -10.4, respectively).

Conclusion

Prevalence of preoperative depression in ACLR patients could be as high as 20%. Despite high prevalence of depression preoperatively, there is a significant increase – which exceeds currently accepted MCID values - in PROMIS PF scores after ACLR regardless of presence of preoperative clinical depression. This data suggest that high scores on PROMIS-D pre-operatively do not significantly hinder a patient’s recovery after ACLR.

140-P. Establishing and comparing reference pre-operative PROMIS scores in patients undergoing shoulder surgery

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Background

The Patient-Reported Outcomes Measurement Information System (PROMIS) has become increasingly popular amongst orthopaedic surgeons treating shoulder pathology. Despite this, there have been few studies that describe and compare preoperative reference scores for specific shoulder surgeries. The primary purpose of this study was to establish and compare baseline preoperative PROMIS scores for three common types of shoulder surgery: rotator cuff repair (RCR), total shoulder arthroplasty (TSA) and labrum repair (LR). The authors hypothesized that PROMIS scores would be sensitive enough such that each surgical group would have a different score compared to the other groups.

Methods

In this retrospective cohort study, adult and pediatric patients who underwent surgery for either RCR, TSA, or LR were included. PROMIS-Upper extremity (UE), Pain Interference (PI), and Depression (D) scores that were collected at each patient’s preoperative visit were reviewed. Continuous and categorical variables were compared between operative groups using analysis of variance (ANOVA) and chi-square or Fisher’s exact tests, respectively. Multivariable general linear models were used to identify significant independent predictors of PROMIS scores when controlling for age, sex, and BMI.

Results

413 patients were included in the study. 272 were in the RCR group, 84 in the TSA group, and 57 in the LR group. The average LR PROMIS-UE was 39.8 compared to the RCR group (29.9, p < 0.001) and the TSA group (29.6, p < 0.001). There was no difference between the mean RCR and TSA PROMIS-UE (p = 0.93). The average LR PROMIS-PI was 56.6 compared to the RCR group (62.8, p < 0.001) and the TSA group (63.9, p < 0.001). There was no difference between RCR and TSA PROMIS-PI (p = 0.09). The average LR PROMIS-D was 43.5 compared to the RCR group (47.7, p = 0.004) and the TSA group (50.3, p < 0.001). The TSA group also had higher mean PROMIS-D than the RCR group (p = 0.03). For PROMIS-UE and PI, age, BMI, and gender were not found to be significant independent predictors (p = 0.00, 0.88; p = 0.31, 0.48, respectively).

Conclusion

Patients undergoing shoulder labrum repair had higher preoperative functional scores and lower pain interference and depression scores than those undergoing TSA and RCR. These baseline PROMIS scores should be taken into consideration when tracking a patient’s
outcomes after surgery, as a certain score could mean drastically different functional and pain outcomes depending on the underlying pathology.

141-P. Withdrawn

142-O. Clinically relevant thresholds and meaningful differences for PROMIS Physical Function and I-RODS: patient survey in CIDP

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Objective
To identify clinically relevant thresholds for PROMIS Physical Function (PF) T-scores and Inflammatory Rasch-built Overall Disability Scale (I-RODS) scores to distinguish disability levels, based on a novel approach in patients with chronic inflammatory demyelinating polyneuropathy (CIDP).

Methods
Online global GBS/CIDP Foundation survey data from 426 adults with self-reported CIDP were used to classify two patient-reported outcomes (PROs; PROMIS PF T-scores from the Short Form-4 and I-RODS Rasch-transformed centile scores for social activity/participation) in three disability measures: work impairment, residential changes and need for assistive devices. Chi-square automatic interaction detection (CHAID) was used to identify range of clinically relevant thresholds, meaningful group differences and associated effect sizes (differences/SD) in scores based on most substantial shifts in proportion of patients at highest levels for each disability measure.

Results
Mean (SD) PROMIS PF T-score was 36.5 (7.9) (tertiles: 23–33, 34–39, 40–57), and mean I-RODS centile score was 56.2 (16.9). PROMIS PF T-scores of 34–40 (median: 36) and in the highest tertile (41–57; median: 44) were associated with only 5% and 2%–2% of patients needing a wheelchair (highest of three levels of need for assistive devices), respectively. By contrast, among those in the highest PROMIS PF T-score tertile, 29% had retired or claimed disability pay (highest level of work impairment) and 15% moved to a single-story home, with family or assisted-living facility (highest level of residential changes). Findings were similar for I-RODS. A group median difference of 6 (23 to 29; effect size: 0.76) in PROMIS PF T-score was associated with greatest shift (39%) in wheelchair dependency from 66% to 27%. By contrast, a group median difference of 11 (23 to 34; effect size: 1.39) was needed to shift highest level of work impairment from 84% to 56%, and a group median difference of 10 (34 to 44; effect size: 1.26) was needed to shift highest level of residential changes from 31% to 15%.

Conclusions
Clinically relevant thresholds (range: 36–44) and meaningful differences (range: 6–11; effect size: 0.76–1.39) of PROMIS PF T-scores varied with the underlying cross-sectional anchor (specific disability measure) and physical function trait levels in CIDP patients. Interpretation of meaningfulness of between-group PROMIS PF T-scores may be better informed by realistic assessment of limits in terms of change on an underlying anchor in the context of this high-burden disease.

143-P. Development and validation of the Pediatric PROMIS Pain Quality Scale

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Objective
The primary objective of this study is to evaluate the dimensionality and validity of the Pediatric PROMIS Pain Quality Scale.

Methods
The data used in this study included pediatric patients with chronic widespread musculoskeletal pain (fibromyalgia), juvenile idiopathic arthritis, or sickle cell disease ages 8 to 18 treated at three academic medical centers in Ohio, Pennsylvania, and Georgia for a total sample size of N = 447. Initial pools of the pediatric PROMIS pain-related items were developed based on literature reviews, clinician interviews, and qualitative research with patients with chronic pain conditions. Our prior research has focused on the development of three constructs related to pain (pain interference, pain intensity, and pain behavior). The current project focused on the development of a pain quality item bank. A total of 59 candidate items were developed. The pediatric pain quality item bank assesses the specific physical sensations and affective components associated with pain. Because pain can be felt and described in so many ways, this category of pain contains a variety of attributes, such as perceived temperature (e.g., cold), sensations (e.g., throbbing), and perceived affective qualities of pain (e.g., uncomfortable). We conducted confirmatory factor analysis (CFA) to assess dimensionality of the 59 items for pain quality. Of these, 23 items measured “affective” aspects of pain quality and were in the format of “In the past 7 days, did your pain ever feel (e.g., miserable, unpleasant), with dichotomous response options (yes/no). The remaining items assessed the “sensory” aspect of pain quality and were in the format “In the past 7 days, did your pain ever feel (e.g., sharp, achy), with a 5-point response option scale (“not at all” to “very much”). Additionally, we developed both sensory and affective pain quality 8-item short forms based on feedback from pain management clinicians.

Results
The 59-item unidimensional model fit the data well: comparative fit index (CFI) = .93, Tucker-Lewis index (TLI) = .93, and root mean square error of approximation (RMSEA) = 0.056. The IRT discrimination parameters ranged from 1.05 to 3.81. Three items were excluded due to discrimination parameters less than 1.0. The category threshold parameters for the remaining 56 items ranged from -1.02 to 3.66.
Conclusions
The 56-item pediatric PROMIS pain quality item bank includes both sensory and affective pain quality 8-item short forms that can be used in research and clinical practice. This information may be useful for understanding the condition-specific experiences of pain as well as outcome evaluations.

144-O.
Agreement between child and caregiver reports across five PROMIS scales in a pediatric burn population
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Objective
To examine the agreement between self- and proxy-report on pediatric PROMIS scales of physical function, depression, peer relationships, pain interference, and anger in children and youth who have sustained a burn injury.

Methods
Data were collected from children ages 8-17 years who have sustained a moderate to severe burn injury and their caregivers during Burn Model Systems (BMS) National Longitudinal data collection. Self- and proxy-report scales were completed at the same timepoint between 6 months and 15 years after burn injury at regular intervals. The PROMIS-25 and Anger Short Form v1.0 were completed by pediatric burn participants. Caregivers completed either custom (depression, pain) or standard (Physical Function 8a, Peer 7a, Anger 5a) PROMIS proxy short forms. Self- and proxy-report were compared using paired t-tests, effect size (d), Cohen’s weighted Kappa, and intraclass correlation coefficients (ICC(2,1) individual measures). Concordance rates by severity groups were generally high with 9% (pain) to 19% (peer relationships) of pairs discordant.

Results
A total of 274 child-caregiver pairs completed the PROMIS measures. Mean child age was 13.0 (SD:3) years. Caregivers reported worse scores than the child across all domains, though differences were only significant for physical function, pain interference, and anger (all p<0.01). Physical function and anger had the largest mean differences at 2.5 and 2.6 points, respectively. Effect sizes ranged from 0.03 (depression) to 0.29 (physical function), with most domains displaying small bias. Kappa values showed moderate to substantial agreement and ranged from 0.52 (pain interference) to 0.69 (depression). Concordance rates by severity groups were generally high with 9% (pain) to 19% (peer relationships) of pairs discordant.

Conclusions
This study provides support for the use of proxy PROMIS physical function, depression, peer relationships, pain interference, and anger scales in pediatric burn populations. Mean differences between self- and proxy-reports were generally small across all domains and agreement was moderate to substantial. Providers need to be aware that caregivers typically report slightly worse symptoms across all domains compared to child reports.

146-P.
Is PROMIS a useful outcomes tool for children with Arthrogryposis?
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Objective
Arthrogryposis is a potentially disabling congenital condition characterized by contractures of the extremities due to lack of muscle development. Our objective was to determine whether Patient Reported Outcome Measurement Information System (PROMIS) scores would discriminate between children with arthrogryposis and the general pediatric population. We hypothesized that children with arthrogryposis would report impaired Upper Extremity Function and Mobility, but normal Pain Interference and Peer Relationships scores compared to the reference population.

Methods
This is a retrospective cohort study of children with arthrogryposis aged 5-17 years who responded to four pediatric PROMIS domain questionnaires (Mobility, Upper Extremity (UE) Function, Pain Interference, and Peer Relationships) during outpatient visits to Shriners Hospitals Northern California between April 2017 and May 2019. Responses were converted to a T-score for comparison to a reference
pediatric population (mean reference score = 50, standard deviation = 10). For Mobility, UE Function, and Peer Relationships, a T-score ≥ 50 is within normal limits; 40-49 = mild impairment; 30-39 = moderate impairment, and 0-29 = severe impairment. For Pain Inteference, a T-score ≤ 49 is within normal limits; 50-59 = mild, 60-69 = moderate, and 70-78 = severe impairment.

Results
PROMIS questionnaires were administered to 68 children with arthrogryposis (34 boys, 34 girls) with a mean age of 9.8 years (S.D. 3.8 years). They reported moderately impaired Mobility (38.0±8.9) and UE Function (31.8±12.2), both significantly different than the reference population (p<0.0001). 66% reported moderate or severe impairment with Mobility, and 74% rated their UE Function impairment as moderate or severe. Participants’ Peer Relationship scores were high (54.0±8.3). 97% reported excellent or good Peer Relationships, and 3% reported them as fair. Participants reported normal Pain Interference (49.3±10.0), which was not significantly different than the general population (p<0.00001). 66% reported moderate or severe impairment, and 70-78 = severe impairment.

Conclusions
PROMIS Pain interference scores and Health-Related Quality of Life with activity.

Mean (SD) age (n=523) was 57 (17) years. Fifty-seven percent were male, 49% were White (251), 40% were on dialysis, 37% had diabetes. Higher PROMIS pain interference scores were significantly associated with lower HRQoL as measured by the EQ-SD-5L [β = -0.008, 95% CI [-0.010, -0.006], p < 0.001] after adjusting for age, sex, marital status, education, income, ethnicity, comorbidity, diabetes, renal replacement therapy and additional PROMIS domains such as sleep disturbance and depression. Pain interference was also significantly associated with worse physical (-0.663 [-0.805, -0.521], p<0.001) and mental (-0.184 [-0.291, -0.077], p<0.001) HRQoL in similar multivariable analytic quantile regression models.

Conclusions
PROMIS pain interference score was strongly associated with HRQoL. Future research should assess if PROMIS guided screening may improve pain management and HRQoL in patients with ESKD.

Objective
Patient-Reported Outcomes (PROs) can elevate the patient voice, but given their more recent introduction into clinical care, it is unclear how patients view PRO questionnaires and why patients often fail to complete them. This presentation will share the patient view of PROs, identified challenges, and a prioritized list of recommendations.

Methods
The Electronic Health Record (EHR) Access to Seamless Integration of PROMIS (EASI-PRO) consortium consists of nine universities integrating PROMIS into EHRs. EASI-PRO researchers conducted 23 patient interviews across four clinics at one site. Transcripts were reviewed to examine patient experiences regarding PRO completion, reactions to PRO questions, and physician interaction.

Results
Barriers to completion included lack of patient portal access, email overload, confusion between PROs and healthcare satisfaction surveys, challenging physical health, and technical factors. Patients described their experience interpreting email prompts and advised how to make PRO requests more likely to be answered. Patients expressed confusion regarding the purpose of PROs and how they would be used and voiced a desire to learn how results would impact their clinical care. Patients reported that PRO measures themselves were generally understandable but could sometimes be unclear. Their length and content were appropriate. Comments demonstrated the importance of selecting PRO measures that are highly relevant to the patient population, and that completing PRO measures can result in feelings of introspection and gratitude. Patients expressed a strong desire for quick communication of concerning scores and hope that physicians would utilize PRO results to enhance their care. Many patients assumed that the physician would take their PRO results into account and use results to prepare for their medical appointments.

Conclusions
In our study, most patients were quite willing to complete PROs, but barriers to completion hampered their response. We will present practical recommendations to address barriers, such as revising the call center script, setting tablets at maximum time-out, communicating expected PRO completion time, informing patients about the purpose of PROs, and refraining from using the word “survey.” Recommendations also focus on patient desires concerning use of PROs in patient care, encouraging clinicians to acknowledge PRO completion and use in the clinical setting.
Objective
Depression is a common symptom of multiple sclerosis (MS) that has been predicted by a variety of demographic and clinical variables and other symptoms. However, it is unclear if depression is a premorbid symptom prior to diagnosis of MS and its role in clinical decision making. We utilized a large clinical database to enable cross linkage with PROMIS scales and clinical variables of MS.

Method
The data network of a large academic center was evaluated to extract PROMIS and other identified variables in both inpatient and outpatients with MS. Keywords were PROMIS, Pain Interference, Anxiety, Depression, and Physical Function with clinical variables of medications for fatigue, year of diagnosis, and diagnosis code for MS (ICD 9 240/ICD 10 G35).

Results
Data were available from 260 visits on 66 patients with MS. Patients were predominantly female (61%) and white (90 %) with an average age of 51. PROMIS core item banks were completed by all patients. The year of diagnosis ranged from 1 to 23 years. PROMIS Depression assessment score ranged from 34 to 60 t score.

Conclusions
The current work highlights the possible role of premorbid depression as a precursor for disease onset in patients with MS. Additional research is necessary related to the use of PROMIS Depression and other symptom measures in medical decision making for treatment modalities.

Objective
Fatigue is a prevalent symptom in patients with multiple sclerosis (MS). Complementary therapies such as mindfulness-based art therapies (MBAT) has potential to minimize fatigue and improve global health. Information is lacking on the patient’s perspective using patient reported outcomes. To determine the patient perspective related to use of mindfulness-based art therapy to improve patient reported outcomes of fatigue and global health.

Method
Community dwelling participants with multiple sclerosis (MS) completed two measures at one time point (i.e., PROMIS Fatigue SF and Global Health were completed). Mean population scoring on each module is defined at 50. Participants also completed a demographic survey that included clinical variables. Bivariate Spearman correlation analysis defined the association between the PROMIS modules and other symptom measures in medical decision making. We utilized a large clinical database to enable cross linkage with PROMIS scales and clinical variables of MS.

Results
Twelve participants with MS took part in the study. All the participants were white, women, average age 48 years, and married, with some college (ranged from 13 to 21 years); and employed. Mean SF and Global scores were similar to values found for MS participants in other studies (39, 30 respectively). The PROMIS Fatigue Scale SF correlated with time since diagnosis (p < .04). There was no correlation between the PROMIS Global LE score and PROMIS Fatigue (p < .57).

Conclusions
The PROMIS Fatigue SF and global health is a useful tool in participants with MS to provide their perspective of symptoms and global health who used MBAT. Further research is needed for follow up the effectiveness of MBAT on fatigue and global health using patient reported outcomes.

Objective
Fixed-precision between-item multidimensional computerized adaptive testing by aligning item selection and stopping rules

Method
In this presentation, aforementioned selection-stopping asymmetry and its consequences will be discussed, and alternative item selection approaches will be introduced and evaluated. An empirical multidimensional item bank of 194 polytomous items, designed to measure different aspects of quality of life was used as a basis for the simulation study. Four dimensions were measured, using three PROMIS item banks and an additional disease-specific item bank: fatigue (50 items), COPD-specific complaints (46 items), physical function (63 items), and social roles and activities (35 items). The bank was calibrated using a between-item multidimensional graded response model. Higher scores were indicative of higher quality of life for all dimensions. All dimensions were highly positively correlated, and items had high discrimination parameters. The threshold parameters covered a wide range for each dimension.

Results
For all but two selection rules, the CAT algorithm reached a proper stop for 100% of the N = 10000 simulees. The longest average total test length was found for the traditional D-rule (12 items), the shortest test length was found for “restricted” and “filtered” item selection rules (7 items); here, items from dimensions for which the required fixed-precision threshold was already met were no longer selected. The traditional rules did not outperform unidimensional CAT in terms of efficiency. For extreme theta values, bias was larger for selection rules that were associated with the shortest tests. Results regarding item usage will be presented as well.

Conclusions
Using selection rules which incorporate knowledge on which of the dimensions already meet the required fixed-precision threshold can be expected to result in shorter test lengths for fixed marginal precision MCATs.

Objective
Culture in play: spotlighting the universal French translation and linguistic validation of PROMIS item banks

Method
In this presentation, aforementioned selection-stopping asymmetry and its consequences will be discussed, and alternative item selection approaches will be introduced and evaluated. An empirical multidimensional item bank of 194 polytomous items, designed to measure different aspects of quality of life was used as a basis for the simulation study. Four dimensions were measured, using three PROMIS item banks and an additional disease-specific item bank: fatigue (50 items), COPD-specific complaints (46 items), physical function (63 items), and social roles and activities (35 items). The bank was calibrated using a between-item multidimensional graded response model. Higher scores were indicative of higher quality of life for all dimensions. All dimensions were highly positively correlated, and items had high discrimination parameters. The threshold parameters covered a wide range for each dimension.

Results
For all but two selection rules, the CAT algorithm reached a proper stop for 100% of the N = 10000 simulees. The longest average total test length was found for the traditional D-rule (12 items), the shortest test length was found for ‘restricted’ and ‘filtered’ item selection rules (7 items); here, items from dimensions for which the required fixed-precision threshold was already met were no longer selected. The traditional rules did not outperform unidimensional CAT in terms of efficiency. For extreme theta values, bias was larger for selection rules that were associated with the shortest tests. Results regarding item usage will be presented as well.

Conclusions
Using selection rules which incorporate knowledge on which of the dimensions already meet the required fixed-precision threshold can be expected to result in shorter test lengths for fixed marginal precision MCATs.
Objectives
The purpose of this study was to translate and linguistically validate 20 PROMIS® adult item banks into Universal French and highlight cultural nuances arising during the translation process.

Methods
We translated nearly 600 PROMIS items using the FACIT universal methodology – a standardized iterative process of forward- and back-translation, expert review, harmonization and cognitive interviewing. All members of the translation team were native French-speakers from Belgium, Canada, France, and Switzerland. French-speaking community participants in Canada assessed the relevance, understandability, and appropriateness of the translations. A pragmatic qualitative analyses of cognitive interviews of each translated item was used to identify conceptual and linguistic differences between cultures.

Results
The study sample consisted of native French-speaking adults (57 women, 23 men) in Montreal, Canada with a mean age of 37 (20-72). Conceptual and linguistic differences were evident for specific physical ("achy" Pain Quality—Nociceptive; "bushed" and "wiped out" Fatigue; and "do a pull-up" Physical Function); emotional ("angry" Depression); and social ("I have trouble" Ability to Participate; "people are around me but not with me" Social Isolation and "sense of purpose" Psychosocial Illness Impact – Positive) items. Interview data revealed that 580 items of the 593 considered items required no revisions. Of the concepts discussed here, only 11 items required iterations to improve conceptual equivalence and two items were revised to accurately reflect the English source.

Conclusions
Translating complete PROMIS items banks reveals that while most PROMIS domains are conceptualized and described similarly across cultures, a few items require additional exploration to ensure equivalence. PROMIS universal French item banks in this study are conceptually equivalent to the English source and acceptable for use in international research and clinical trials. Cognitive interviewing in other French-speaking regions is planned. Structured qualitative interviews are essential to assuring the validity of translated items.

153-P.
Responsiveness of PROMIS short forms among adult cancer patients
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Objective
The ability of a patient reported outcome measure to reflect changes in health is necessary to support its use in trials and clinical patient monitoring. Though PROMIS measures are commonly used among cancer patients, the responsiveness of some commonly-used PROMIS short forms has not been established among this population.

Methods
We used data from a prospective, observational study of 1828 cancer patients. Each participant was surveyed at a baseline timepoint and 6 weeks later on several PROMIS domains, including several short forms of differing lengths within some domains: Physical Function (10a), Anxiety (4a, 6a, 8a), Depression (4a, 6a, 8a), Ability to Participate in Social Roles and Activities (4a, 6a, 8a), Sleep Disturbance (4a, 6a, 8a), Fatigue (7a), Pain Intensity (3a), and Pain Interference (7 item custom short form). Each was scored on a T score metric (mean = 50, SD = 10). We used mixed effects models to estimate the squares mean change for each short form. Domain specific ratings of change were assessed (e.g., change in physical function over past 6 weeks) and used to categorize change as "better," "same," or "worse." For these groups, we calculated PROMIS change scores. Then we calculated standardized response means (SRM) for each group. SRMs of 0.30 or above were considered evidence of responsiveness.

Results
Participants were on average 56 years of age, most often had an ECOG performance status rating of 0 or 1 (71%), and the most common cancer types were breast (26%) and lymphoma/myeloma (21%). Estimated changes in PROMIS scores were most often between 1 and 2.5 T score points. While SRMs for the "better" and "same" change groups were small, those for the "worse" group always exceeded the 0.30 (range: 0.69-0.94). Notably, for domains with multiple short forms, scale length did not affect responsiveness (e.g., Anxiety 4a SRM = 0.69; 6a SRM = 0.69; 8a SRM = 0.70).

Conclusions
PROMIS short forms for multiple domains were highly responsive to change in health among a diverse sample of cancer patients. Instruments with more items were not more responsive, indicating the utility of even brief PROMIS assessments.

154-O.
PROMIS-29 domains associated with dissatisfaction in spine surgery patients who improve in pain and functioning
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Objective
Patient satisfaction is important when evaluating the success of spine surgery. A subset of patients have clinically relevant improvements in disability/pain but report being dissatisfied with surgery. The aim was to evaluate whether changes in mental health (depression and anxiety) and social (ability to participate in social roles [SR]) domains of the PROMIS-29 were associated with dissatisfaction 1 year after spinal surgery for patients who achieve clinical improvement in disability or extremity pain.

Methods
The study was a retrospective analysis of data collected between 2018-2019 from a prospective spine surgery registry, Quality Outcomes Database. Participants completed the PROMIS-29, ODI, and back/leg NRS pain rating outcomes preoperatively and 1 year after surgery. Patient demographic and clinical characteristics were collected from medical records and patient interviews. Satisfaction was assessed at 1-year with 1-item from the NASS lumbar spine outcome assessment. Participants (N=369) undergoing elective surgery for degenerative spine conditions and having a successful outcome (achieving at least 30% improvement in disability or leg pain) 1-year after surgery were included. Logistic regression predicted dissatisfaction at 1-year from PROMIS-29 domain T-scores (SR, anxiety, depression) at 12 months. Covariates included demographic, clinical, surgical characteristics, preoperative PROMIS scores and disability, and postoperative complications and revision surgery after surgery.

Results
A total of 116 participants (31%) with clinical improvement in disability or leg pain reported being dissatisfied at 1-year after surgery. When controlling for baseline scores, ability to participate in social roles (OR=0.87, 95%CI=0.84-0.90, p<0.001), depression (OR=1.09, 95%CI=1.06-1.13, p<0.001), and anxiety (OR=1.05, 95%CI=1.02-1.07, p<0.001) at 12 months were all significantly associated with dissatisfaction at 1-year post surgery. None of the preoperative PROMIS domains were associated with dissatisfaction at 1-year (p < 0.05).

Conclusions
12-month PROMIS scores were significantly associated with dissatisfaction indicating that patients with who had less improvement in
social activities, depression, and anxiety tend to report being dissatisfied even after having a clinically relevant improvement in disability/pain. Preoperatively, none of these PROMIS scores were associated with dissatisfaction at 1-year. The results indicate that improvements in social and mental health factors play a role in patient satisfaction after lumbar spine surgery along with improvements in disability and pain.

155-O. Withdrawn

156-P. Patient reported outcomes after risk-reducing gynecologic surgery for hereditary breast and ovarian cancer syndromes
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Objective
To determine the impact of risk-reducing gynecologic surgery (RRGS) on the health-care quality of life (QOL) on women with hereditary breast and ovarian cancer syndromes (HBOCS) and to compare these outcomes to patients with benign and malignant ovarian disease.

Methods
Patient reported outcome (PRO) collection was implemented at our gynecologic oncology clinic in January 2018. At serial visits, patients were administered general and disease specific PRO measures (PROMs) based on patient disease status. Cohorts of patients with ovarian cancer (OC), HBOCS or benign ovarian masses (BOM) were identified and additional clinical and surgical characteristics were collected prospectively. Specific PROM questions reflecting important physical and psychosocial outcomes were selected a-priori from questionnaires for analysis. Over the study period, both first and last and pre- and post-operative PROM responses were described and compared between cohorts.

Outcomes
Between January 2018 and October 2019, 150 HBOCS patients, 209 BOM patients and 329 OC patients were identified. In the HBOCS cohort, PROM responders were similar to non-responders, however, were significantly younger than OC responders (p<0.001). During the study period, 24.7% of HBOCS patients had RRGS. Post-operatively, patients reported feeling less tense (p=0.034) and less worried about future health (p=0.020) but did report more difficulty sleeping (p=0.011), less interest in sex (p=0.025) but no changes in body image. Patients did not report feeling burdened by their treatment. When first and last PROM responses were compared in the HBOCS patients who did not have RRGS, no significant changes were noted. When first PROM responses were compared between cohorts, HBOCS and BOM patients were similar however HBOCS patients reported better QOL (p=0.015) and overall health (p=0.008). OC patients reported the worst QOL (p=0.008), highest levels of worry (p=0.048) and treatment burden (p<0.001), lowest overall health (p=0.003) and highest disease interference in their family life (p=0.003), social life (p<0.001) and finances (p=0.008). When last PROM responses were compared between groups, a similar trend was noted.

Conclusion
Patients with HBOCS report overall good QOL after RRGS and better QOL than patients with ovarian malignancies. These results can help to guide counselling for patients with HBOCS and to address their unique health-care needs.

157-P. Validation after translation of PROMIS-57 Profile Norwegian with factor analysis, IRT and DIF analysis
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Objective
Cross-sectional reliability and validation after translation of seven PROMIS® Short forms in a Norwegian general population, n=408.

Methods
Anonymous, voluntary online collection of demographics, RAND36 and PROMIS57 (including 8-item short forms for physical function, anxiety, depression, fatigue, sleep disturbance, ability to participate in social roles and activities, and pain interference). Analysis: Correlations against similar/dissimilar domains in PROMIS57 and RAND36, bi-factor, EFA, CFA and Mokken analysis checking factor structure and IRT assumptions. IRT Graded Response model: Item and model fit, ICC, TIF and SE plots. DIF analysis in lrdif (R) with ChiSquare and McFadden R2 methods for language DIF against Wave1 and Profile-shUI datasets, and demographic DIF.

Results
Reliability=.9, concurrent validity correlations .7-.9 and discriminant correlations .4-.7. CFA 7-factor with WLSMV estimator results in scaled model fit indices of: RMSEA=.05, CFI=.99, TLI =.99 supporting the structural validity. First factor eigenvalue ratios from bi-factor analysis between 41 (Sleep) and 32.1 (Social), and Estimated Common Variance (ECV) per domain between 86 and 96 (>60 supports unidimensionality). Local Dependence: 4 or less out of 196 possible item pairs flagged with CFA residuals >.2, or IRT Chen&Tthisen LD index >.3. Only two misfitting items (Sleep 44 and 72), based on s-x2. Graded Response model fit: RMSEA=.13, SRMSR: .14, TLI and CFI: .96., and acceptable IRT plots. Scores in this general population sample are skewed and zero-inflated. Sample: 74% women, mean age 52.

Conclusions
For each domain (=short form) excellent reliability, and concurrent and discriminant validity. Factor structure of PROMIS 57 seven domains confirmed. IRT assumptions are met for unidimensionality, local independence, monotonicity and invariance (=no language DIF, age, gender or education DIF). Issues: very high discrimination parameters may be related to skewed/zero-inflated distribution, sub-threshold LD/dimensionality issues, and sample size. Lessons learned: obtain a larger and more diverse sample for IRT and DIF. Translate and assess entire item banks at once, rather than profiles and short forms.

158-P. Word selection for translating PROMIS® Fatigue items, using a lay person panel
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Journal of Patient-Reported Outcomes 2020, 4(Suppl 2):158-P

Objective
To systematically translate words indicating varying degrees of fatigue in the PROMIS Item bank with the help of lay person input.

Methods
Comparing the rank order of available words expressing different degrees of fatigue in Norwegian by asking a small cognitive debriefing panel, n=5, to rate each expression on a 10-point NRS scale. The rank order and standard deviation for each expression
helps indicate which words should match the severity of each English language counterpart in the PROMIS Fatigue Item Bank.

Results

14 words/expressions tested. Agreement among blinded participant, median SD 1.3 on a 10point scale. Useful supplement to expert and translator opinion. The resulting ranking could not be used directly for word selection, as the semantic meaning not always matched. Also some words are already translated by FACITrans in FACT or NeuroQol items.

Conclusions

Many PROMIS fatigue items hinge the severity onto a single word or expression, to a greater degree than other short forms and item banks. While translating the Fatigue short form, we wished to avoid making word choices that would “use up” words that would be a better fit later for other items in the bank. This ranking by a panel helped inform the process, though the panel perhaps should have had more respondents.

159-P.

PROMIS sleep disturbance and sleep-related impairment item banks in the Dutch general population

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Objective

The Patient-Reported Outcomes Measurement Information System (PROMIS®) v1.0 item banks ‘Sleep Disturbance’ (SD, 27 items) and ‘Sleep-Related Impairment’ (SRI, 16 items) were developed to measure self-reported aspects of sleepiness, sleep quality, and functional impact of sleep problems more efficiently and precisely than current instruments, by using Computerized Adaptive Testing (CAT). We validated these item banks in a Dutch general population.

Methods

Participants in an internet panel completed both item banks. Unidimensionality, local dependence, monotonicity, Graded Response Model (GRM) item fit, Differential Item Functioning (DIF) for age, gender, education, region, ethnicity, and language (Dutch compared to US Wave 1 data), and reliability were assessed.

Results

A representative Dutch sample of 1006 people participated. We found sufficient unidimensionality for the both item banks (SD: CFI=0.93, TLI=0.92, RMSEA=0.13, Omega H=0.80, ECV=0.69; SRI: CFI=0.96, TLI=0.95, RMSEA=0.17, Omega H=0.85, ECV=0.76). Some local dependence was found (SD: 4.8%; SRI: 0.8% item-pair correlations>0.20), sufficient monotonicity (SD: H=0.60; SRI: H=0.65), and good IRT item fit (SD: zero out of 27 items with S-X² p-value <0.001; SRI: two out of 16 items). For SD DIF for age was found for four items; younger persons report more sleep problems compared to older persons with similar levels of sleep disturbances. No DIF was found for SRI. We found a reliability of at least 0.90 with simulated CATs (based on US item parameters) in 96% of the participants with on average 4.5 (range 2-12) items for SD and 75% of the participants with on average 6.2 (range 3-12) items for SRI.

Conclusion

The PROMIS sleep item banks showed sufficient psychometric properties in a general Dutch population and can be used as CAT. PROMIS CATs allow reliable and valid measurement in an efficient and user-friendly way with limited administration time.

160-O.

Reducing patient and provider burden: methodology for automated collection of PROMIS CAT in EPIC

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Objective

Stakeholder burden is an obstacle to patient reported outcomes (PROs) data collection across the continuum of spine care. The objective is to describe methods to automate administration of 8 PROMIS domains via computer adaptive testing (CAT) within the Epic electronic health record (EHR) throughout a high volume, multisite regional spine care practice to improve patient response rates and unbiased outcome assessment.

Methods

Collaborative efforts between 11 Mayo spine care provider specialties (representing over 1,000 providers), project managers, and EPIC data architects provided the architect team an understanding of clinical and research requirements for data collection. Iterative builds and testing of code ensued.

Results

Consensus was achieved among all spine care providers to move from legacy instruments to 8 PROMIS domains assessed via CAT. Anchor events (EPIC defined visit types, procedure and surgical codes) were used as triggers to initiate a predefined cadence (baseline, 3, 6, 12, 24, 60 months) of PROMIS CAT assignments. EHR logic was developed to automatically cease data collection and re-initiate the baseline and cadence collection as the patient traversed diverse spine care trajectories potentially including primary care, spine specialty care, interventional pain procedures, and surgery. PRO collection modes include: electronic patient portal > on-site tablet > interactive voice response > manual phone contacts. Epic reports were parameterized to assess patient response rates on a clinical site-specific basis for quality assurance and to direct efforts to improve response rates. An Epic registry and dashboard were created to display longitudinal patient-level and aggregated data. Epic’s registry function integrated clinical, laboratory, imaging and surgical data with the PROMIS data. Artificial intelligence and conventional analytic efforts are planned to identify and validate patient phenotypes that predict care trajectories and may be used to inform shared and clinical decision making.

Conclusions

A system was created in the Epic EHR for automated CAT assessment of PROMIS domains in order to measure the effectiveness of intensity and sequence of spine care in a quaternary, regional health system. Patient response rates distinguished by site of care, mechanism of data collection, and follow up interval will be presented, along with Epic display and analysis tools.

161-O.

Incorporating PROMIS into the CIBMTR hematopoietic cell transplant outcomes registry

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Objectives

Hematopoietic cell transplantation (HCT) is an established therapy to treat many hematologic diseases. The Center for International Blood and Marrow Transplant Research (CIBMTR) is an outcome registry that has been collecting clinical outcome data for HCT recipients for over 45 years. There are >540,000 unique patients represented in the registry with longitudinal data collected, including demographics, exposures, clinical outcomes and late effects, linked to bio-repository samples. Important clinical questions using this CIBMTR data are proposed by the community and facilitated by CIBMTR scientific and statistical experts. However, to date there is no routine collection of Patient-Reported Outcomes (PROs). Our objective was to incorporate routine PRO collection into the CIBMTR registry.

Methods

CIBMTR performed two studies to assess the feasibility of centralized PRO collection. The first used pen-and-paper methodology and local consenting, the second used a bespoke electronic (ePRO) system through which consent was obtained by CIBMTR. Both required local institutional review board (IRB) approval (in the second for sites to provide patient contact details to CIBMTR). The ePRO system incorporates a patient-friendly interface in Qualitracs, an API link to the PROMIS measures delivered using CAT technology, links to a contact management system to track and trigger PROs, and links to the CIBMTR database to store PROs and link them to the clinical data.

Results

The first study confirmed feasibility and acceptability of centralized PRO data collection, but highlighted barriers imposed by pen-and-paper methodology. The second study showed successful implementation of the ePRO system with logistic efficiencies, ease of electronic consenting and PROMIS data collection (with an average of 4.2-7.4 questions completed in 0.7-1.2 minutes per domain), and successful linkage with clinical data, but delays related to local IRB approvals. To address this CIBMTR developed a mechanism to collect patient contact details and operate the PRO collection under a single centrally IRB-approved protocol.

Conclusions

Using these strategies, CIBMTR can now incorporate routine PROMIS PROs for HCT recipients whose clinical data is included in the registry. This has enormous potential for future uses of these data to answer important research questions in a real-world data setting.

163-P

Measurement properties of PROMIS short forms for pain and function in three samples of orthopaedic patients

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Objective

The aim of this study was to evaluate the measurement properties of the German PROMIS- short forms (SF) for pain intensity 3a (PAIN), pain interference 4a (PI) and physical function 4a (PF) in patients undergoing total knee arthroplasty (TKA), total hip arthroplasty (THA) or foot/ankle surgery (F/A).

Methods

PROMIS-SF data were taken from our clinic registries for the respective patient groups pre-, 6 and 12 months post-surgery (THA, TKA only). Higher PROMIS-SF scores indicate more PAIN, higher PI and better PF. Main reference measures were the Oxford Knee Score (OKS), Oxford Hip Score (OHS) and Foot Function Index (FFI-D). A subsample completed pre-surgery or 6-month PROMIS-SF twice within 14 days to test reliability.

Results

Baseline (and longitudinal) sample sizes were: TKA, 144 (120); THA, 132 (116); F/A, 748 (202). Test-retest sample sizes ranged from 45 to 65. Correlations with reference measures were r≥0.7 for TKA and THA, and r≥0.6 for F/A. Cronbach’s α indicated appropriate internal consistency for all SF [0.84-0.93] in all groups. Intraclass correlation coefficients were best for TKA (0.9-0.97), good for F/A (0.81-0.91) and acceptable for THA (0.69-0.81). Standard errors of measurement represented the following percentages of the mean score change: TKA, 14-23%; THA, 16-21%; F/A, 30-60%. Smallest detectable change thresholds (SDC90) were: PAIN, 7 points (all groups); PI, 7-8 points (all groups); PF, 8-9 points (THA, F/A); PF, 4 points (TKA). Minimal important changes could be calculated for TKA and F/A, and moderately impaired UEF (30.2±3.5; P=0.003); 8-12 year-olds (13) reported normal PR and Mobility and moderately impaired UEF (42.7±8.0). 13-17 year-olds (10) reported normal outcomes on all three domains.

Conclusions

1. A limitation of PROMIS is similar to previous studies for children with UCBED.
2. 5-7 year-olds reported lower UEF scores; short Form UEF tasks may be too difficult, and/or parents may under-report function (4). A study of typically developing 5-7 year-old is underway to determine whether the UEF Short Form questions have a floor effect for this age group.
3. PROMIS UEF may have a ceiling effect for older children with UCBED.
4. Children with UCBED have a potentially stigmatizing UE difference, but do not report challenges with peer relationships.

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were around 8-9 and 4-5 points, respectively. All three groups showed follow-up ceiling effects (best score) in the PF scale: TKA, 30%; THA, 66%; F/A, 41%. Correlations of PROMIS change scores with the main reference instruments’ change scores were good for TKA \( [0.52 \leq r \leq 0.65] \) and THA \( [0.73 \leq r \leq 0.8] \), but limited for F/A \( [0.42 \leq r \leq 0.56] \).

**Conclusions**

PROMIS-SF of pain and function could be used in orthopaedic patients. However, the standard error of measurement showed one to two thirds of the mean change for F/A patients, which limits the interpretation of change. Furthermore, improvement of PF in THA patients might be underestimated, as the follow-up PF score showed large ceiling effects.

**164-P.**

**Predicting scores for the EORTC QLQ C-30 using linear modeling of PROMIS Global Health responses**

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**Background**

Translation of data between patient reported outcome (PRO) tools allows for pooling and comparison of data between similar patient populations. To date there exists no established method for prediction of European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ C-30) scores from the Patient Reported Outcomes Measurement Information System Global Health questionnaire (PROMIS GH). This study’s aim was to create a prediction method for the EORTC QLQ C-30 based on PROMIS GH responses.

**Methods**

The EORTC QLQ C-30 (Version 3.0) and PROMIS GH (Version 1.2) were administered prospectively at the University of Pittsburgh Medical Center to self-described healthy subjects who were control volunteers for a study on pancreatic pain. These subjects had neither pancreatic disease or abdominal pain. Multivariable regression models were completed with EORTC QLQ C-30 subscores (Quality of Life (QOL), physical, role, emotional, cognitive, and social functioning) as dependent variables and the PROMIS items as independent variables. Adjusted \( R^2 \) and model \( p \)-value were reported for EORTC QLQ C-30 subscales.

**Results**

A total of 220 subjects (Mean age 43.8 ± 18 years, males n= 90 (41%)) were analyzed. Mean composite PROMIS Mental Health T-score was 53.68 ± 9.08, and composite Physical Health T-score was 55.68 ± 7.45, confirming healthy status of the population. Range of mean scaled composite scores for EORTC QLQ-C30 was 84.2 ± 15.79 to 95.83 ± 12.6. EORTC QLQ C-30 QOL score showed the highest correlation with between actual and predicted values (adjusted \( R^2 = 0.638 \); \( p<0.001 \)). The emotional functioning subscore also showed close correlation between observed and predicted values (adjusted \( R^2 = 0.623 \); \( p<0.001 \)). Modest to poor correlation was seen for physical (adjusted \( R^2 = 0.480 \)), social (adjusted \( R^2 = 0.372 \)), role (adjusted \( R^2 = 0.292 \)), and cognitive functioning scores (adjusted \( R^2 = 0.289 \); all \( p<0.001 \)). Higher correlations between actual and predicted values were seen with items containing direct content overlap between the two PRO tools.

**Conclusion**

PROMIS-GH can be used to predict EORTC QLQ C-30 QOL and emotional functioning subscore values using linear regression modeling. Additional subscores cannot be predicted with more than moderate correlation to actual scores due to lack of content overlap between the PRO tools.

**165-P.**

**Common patient-reported outcomes across ICHOM standard sets – The value of PROMIS**

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**Objective**

The International Consortium for Health Outcomes Measurement (ICHOM) develops condition-specific Standard Sets of outcomes to be measured in clinical practice for value-based healthcare evaluation. There are, however, large differences and inconsistencies between sets in selected patient-reported outcomes (PROs), terms and definitions used, and recommended patient-reported outcome measures (PROMs), even for the same PROs, which threatens the validity and practical applicability of the ICHOM Standard Sets. It would be ideal if common PROs would be named and defined similarly and measured with the same PROMs across conditions. PROMIS® offers an evidence-based conceptual framework of commonly relevant PROs and validated PROMs that are applicable across patient populations and medical specialties. The aim of this study was to identify shared PROs across ICHOM Standard Sets and to examine to what extent these PROs can be measured with PROMIS.

**Methods**

All individuals PROs and recommended PROMs were extracted from all available ICHOM Standard Sets in January 2020. Similar PROs were categorized into unique PRO concepts. Subsequently, it was examined which of these PRO domains can be measured with PROMIS.

**Results**

In 28 ICHOM Standard Sets, 182 PROs were identified. A total of 96 different PROMs are recommended for measuring these PROs. The 182 PROs were categorized into 21 unique PRO concepts. More than half (12/21) of these PRO concepts (covering 74% of the 182 PROs and 79% of the 96 PROMs) can be measured with a PROMIS measure. Furthermore, inconsistencies were found in the selected PROs and PROMs across Standard Sets. It is unclear why some PROs are included in some Standard Sets, but not in others.

**Conclusion**

Considerable overlap was found in PROs across ICHOM Standard Sets, and large differences in terms used and recommended PROMs, even for the same PROs. Inconsistencies in the selected PROs and PROMs across Standard Sets questions the validity of the Standard Sets. We recommend a more universal and standardized approach to PRO and PROM selection, using a common measurement system such as PROMIS, to improve the validity of outcome measurements in clinical practice, and facilitate benchmarking, learning and improve quality of care across patient groups.

**166-P.**

**Smallest Detectable Change (SDC) and Minimal Important Change (MIC) of PROMIS instruments – A systematic review**

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Objective
To summarize available evidence on Smallest Detectable Change (SDC, smallest change in score that is not due to measurement error) and Minimal Important Change (MIC, smallest change that patients, on average, consider important) of PROMIS measures and provide method recommendations.

Methods
A systematic PubMed search was performed to identify all studies that evaluated test-retest reliability or estimated a MIC value of any PROMIS measure in any population. The quality of reliability studies was assessed with the COSMIN Risk of Bias checklist and SDC was extracted or calculated from test-retest reliability standard error of measurement or limits of agreement. Anchor-based MIC values were extracted (which are preferred over distribution-based methods).

Results
Twenty-five studies examined test-retest reliability. Only five studies provided evidence on SDC, of which three were rated as doubtful or adequate quality. These three studies reported SDC values between 7.7-16.3 T-score points for 16 PROMIS measures. Twenty-two studies evaluated the MIC of one or more PROMIS measures, of which 16 used anchor-based methods. MIC was most often defined as a mean change in PROMIS T-score in patients who slightly improved on an anchor. Anchors, however, did not always measure the same construct as the PROMIS measure and sample sizes were often small. Most MIC values were found for adult Pain Interference (14 studies, MIC values 0.7-12.4), Physical Function (13 studies, MIC values 0.1-12.0), Anxiety (6 studies, MIC values 0.2-8.0), Depression (5 studies, MIC values 2.1-5.8), Fatigue (5 studies, MIC values 1.5-7.6), Satisfaction with Social Roles and Activities (4 studies, MIC values 0.6-6.2), and Sleep Disturbance (3 studies, MIC values 1.2-6.6). Only two studies estimated MIC values for pediatric item banks, MIC values ranged from 0.1-12.7 T-score points, SDC and MIC values could not directly be compared for the same PROMIS measure but SDC values were mostly lower than MIC values.

Conclusion
Limited evidence is available on the SDC and MIC of PROMIS measures. More high quality evidence is needed. Data from test-retest reliability studies was not optimally used and should be re-analysed to estimate the SDC. Higher quality anchors and larger sample sizes are needed in MIC studies.

167-O.
Effectiveness of automated EMR notification for prompting provider intervention for severe depression
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Objective
Although there is good evidence that patient-reported outcome measures can be used to improve patient-doctor communication, and can uncover unrecognized problems, they are only useful if physicians use them. The purpose of this study was to determine if simple EMR notifications would prompt providers to address severe depression when present in their patients. In March of 2018 we initiated the routine collection of PROMIS, Physical Function, Pain Interference, and Depression/Mood CATS in our orthopaedic clinics. By May of 2018 we noticed that 2% of patients had Depression CAT scores consistent with severe depression. To address this, we worked with EIS to prepare a Best Practice Alert for patients with severe depression. An automated in-basket message was sent to the nursing triage pool for patients with depression scores greater than 70. The triage nurse forwarded the note to the visit provider notifying the physician of the high score and provided resources for referring the patient to their PCP or a mental health provider. No other notification was provided.

Methods
Between October 2018 and March 2020, 282 patients were identified as having severe depression (PROMIS Depression CAT >70), and the responsible physician was made aware as noted above. A retrospective quality review of progress notes to determine if providers documented the high score and provided some intervention.

Results
The physicians documented the high score in 63 cases (22%). No mention was made of the depression in 219 cases (78%). Interventions noted for the 63 patients, where the physician documented the high depression score, are noted in table 1.

Discussion
A simple Best Practice Alert was not adequate to prompt physicians to document some intervention to address their patient’s depression. Nevertheless, this simple intervention was effective in 22% of cases. In addition, it may be possible that the physician did indeed address the patient’s depression and just did not document it in the chart. The mechanism to provide notification does not disrupt clinic flow in any way, and physician education along with standard macros for documentation may greatly increase the numbers of patients whose depression are being addressed.

Table 1 (abstract 167-O). See text for description
| Referred to | Count of MRN | %     |
|-------------|--------------|-------|
| Mental Health Provider | 27 | 42.86% |
| Not specified | 25 | 39.68% |
| Social Worker | 5 | 7.94% |
| PCP | 3 | 7.94% |
| Program or Resource | 1 | 1.59% |
| Grand Total | 63 |       |

168-P.
Progress in clinical application of patient reported outcomes
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Objective
Patient-Reported Outcomes (PROs) refer to the subjective evaluation of the patient’s own health status directly from the patient. With the rapid development of medical treatment in recent years, people are becoming more aware of the importance of patient self-reports in clinical evaluation. The research of PROs is more and more clinically carried out. This article is about the progress of clinical research of PROs at home and abroad.

Methods
Search domestic and foreign databases to summarize and evaluate relevant literature.

Results
A total of 1 958 related documents were retrieved. PROs are widely used in patients with various diseases, such as leukemia patients, lung cancer patients, breast cancer patients, pelvic floor dysfunction patients, femoral head necrosis hip preservation patients, lumbar disc herniation patients, Patients with chronic obstructive pulmonary disease complicated with pulmonary heart disease in Chinese medicine, patients with anatomical total shoulder replacement, patients with hip replacement, and knee replacement. Pay attention to the health-related outcomes reported by patients, listen to the true feelings of patients, provide patients with an understanding of their own health status, adverse reactions that occur during treatment, the impact of physical functions and the impact of different environments on personal and family life. Research hotspots in the field of chronic diseases for several years.

Conclusions
With the continuous development and improvement of PROs, its high reliability and simplicity of measurement have been recognized by more and more researchers and clinical practitioners, but the current development and application in China is still in its infancy and requires higher quality research to justified.
169-P. Evaluating multiple domains of health in high school athletes with sport-related concussion
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Objective
The objective of this study was to evaluate patient-perceived health-related quality of life (HRQOL) using the Patient-Reported Outcomes Measurement Information System (PROMIS) Pediatric-25 subscale in adolescent patients throughout concussion recovery and to describe the impact of sport-related concussion history on HRQOL.

Methods
This study included a convenience sample of male and female inter-scholastic students from nine high school athletic training facilities who were participating in sports. Patients who sustained isolated medically diagnosed concussions from sports participation were administered the PROMIS Pediatric-25 scale at days 3 and 10 post-concussion and at return-to-play (RTP). The following subscales were used for analysis: Physical Function Mobility (PFM), Anxiety (ANX), Depression (DS), Fatigue (FTG), Pain Interference (PI), and Peer Relationships (PR). Self-reported concussion history (yes/no) was collected. Generalized estimating equations were used for primary PROMIS analysis (p<.05) and summary statistics were reported as means and 95% CI. Ceiling and floor effects (more than 15% of patients reporting the highest or lowest score on the subscale, respectively) are reported.

Results
Seventy patients completed the study (51 males, 7 females, 12 unreported, age=15.7±0.9 years, height=174.6±8.4cm, mass=72.8±14.8 kg, grade=10.0±0.9 level). For the Pediatric-25 subscales, the severity of problems associated with PFM, ANX, DS, FTG, and PI were highest 3 days post-concussion, decreasing at 10 days post and RTP (all p<.05). No differences were found between days 3 and 10 for PR scores, but improvements were identified at RTP (p<.05). Pediatric-25 subscale scores at the three measurements were not statistically associated with concussion history (all P>0.5). Ceiling and floor effects were present in all subscales throughout each time point, except for PFM (14.7%) and PI (11.8%) at day 3 post-injury.

Conclusions
Patients who suffered a concussion improved from day 3 through RTP on multiple health domains including function, anxiety, depression, fatigue, and pain. Importantly, HRQOL improved with time since injury; with between 41-79% of patients reaching the instruments’ best score by day 10 post-injury. Serial assessment of health domains is needed to ensure recovery occurs, interventions are provided when deficits exist, and clinicians can use that information to inform clinical decisions.

170-P. Psychometric proprieties of PROMIS Anxiety and Depression Short Forms among breast cancer patients in China
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Objective
The patient-reported outcomes measurement information system (PROMIS) are developed to assess patient-reported health outcomes for adults and children living with chronic conditions. The adult PROMIS anxiety and depression short forms (SF) have been translated into Chinese and applied in women with breast cancer in China. This study aimed to evaluate the PROMIS anxiety and depression short forms SF among patients with breast cancer in China.

Methods
Internal reliability was evaluated using Cronbach’s alpha coefficient. Besides, scale dimensionality was examined using confirmatory factor analysis (CFA). In addition, concurrent validity was evaluated using correlations between PROMIS anxiety and depression short forms and breast cancer quality of life scores (assessed by Functional Assessment of Chronic Illness Treatment- Breast). Both classical (CTT) and modern (IRT) psychometric methods were used to evaluate the items following the PROMIS validation scientific standards. Known-groups validity was evaluated by comparing T-score differences among patient groups regarding early cancer stage and later cancer stage. In addition, the differential item functioning (DIF), item parameters and scale information curve were analyzed.

Results
A final sample comprised 975 breast cancer patients. The Chinese version of PROMIS anxiety-SF and depression-SF both demonstrated good internal consistency reliability. Unidimensionality of the two measures were supported by CFA. The anxiety and depression T-scores across patient group with later cancer stage were significantly higher than those in the early group, which indicated good known-groups validity. According to the IRT item parameters, the item discrimination parameters for anxiety-SF ranged from 1.00-6.32, and the item threshold parameters ranged from -1.39-2.38. As for depression-SF, the item discrimination parameters and item threshold parameters ranged from 1.00-8.63, and -1.39-2.60, respectively.

Conclusions
The Chinese version of adult PROMIS anxiety-SF and depression-SF showed satisfactory psychometric proprieties among breast cancer patients. Additional research in a more diverse sample is necessary to verify the results of this study.
internal consistency reliability and validity in this study. Unidimensionality and good known-groups validity of the short forms were supported by the results. In addition, the IRT item parameters further demonstrated the item discrimination parameters for Emotional Support ranged from 1.00-5.27, and the item threshold parameters ranged from -1.76-1.39. With regard to Informational Support, the item discrimination parameters and item threshold parameters ranged from 1.00-6.66, and -1.91-1.39, respectively. As for Instrumental Support, the data ranged from 1.00-4.47, and -2.03-1.39 accordingly.

Conclusions

Adult PROMIS Social Relationships short forms 4a of Chinese version are demonstrated to be feasible, valid, and reliable in breast cancer patients in China. Further research in a more diverse sample and with different study design are encouraged to verify the results in the current study.

172-P.

Using cognitive interviewing to adapt PROMIS® Measure Items of Self-efficacy for managing chronic conditions in Chinese cross-cultural translation

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Objective

To use cognitive interviewing techniques to evaluate the comprehensiveness, wording and format of PROMIS® Self-efficacy items among Chinese living with chronic conditions after FACIT forward-backward translation and then to revise items based on subjects’ feedback.

Methods

We conducted 25 cognitive interviews of native Chinese speakers with diversity range of chronic conditions (e.g., diabetes, hypertension, obesity, inflammatory bowel disease, hepatitis sclerosis, peptic ulcer, and cardiovascular disease) on 137 items of self-efficacy. retrospective probing was chosen due to the self-administered questionnaire. Audio recordings were used to cover the gaps in the handwritten comments and were not transcribed verbatim. Questionnaire Appraisal System (QAS-99) was used to code the text data. A series of feedback from subjects were compiled. Then the experts and translation group reviewed the data and decided whether to revise or rewrite each potential item.

Results

The appraisal from the cognitive interviews identified most items were easy understanding. Meanwhile, some issues were encountered in the lengthy, awkward, syntax of the wording. 5 out of 25 motions items, 8 out of 35 daily activities items, 6 out of 26 medicine and treatment items, 2 out of 23 social interaction items and 4 out of 28 symptoms items were found to have poor comprehension mainly for the reason of wording. And 7 of 137 items had to rewritten because of culturally inappropriate. All these items were revised base on the subjects’ feedback, linguistic rules and the expert suggestions.

Conclusions

Cognitive interviewing is a useful method in conducting quality assessment of already developed questionnaire and adapting items in the context of simplified Chinese. Results showed that the revised version of PROMIS self-efficacy items is conceptually, culturally and semantically equivalent to the original. Future work related to Chinese version psychometric properties validation of PROMIS self-efficacy for managing chronic conditions can now be initiated.

173-P.

Development of a Pediatric PROMIS mini-program based on Wechat application for children and adolescents

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Objective

This study was to develop a smartphone application Wechat-based mini-program to enable children and adolescents aged 5-17 years old and their proxies to assess pediatric patients’ quality of life-related symptoms and functions using Pediatric PROMIS profile-25.

Methods

A multidisciplinary team including researchers, clinical professionals and software engineers was formed to discuss the contents, structures, and functions of the program and its administrative portal, to make longitudinal assessment and data management more efficient, and the interface more user-friendly. Several rounds of joint sessions and modifications were performed among the team to assure the quality of the program during the development.

Result

The Wechat mini-program ‘PROMIS Assessment’ for pediatric patients aged 8-17 years old and proxies of all 5-17 year-old children was created. Pediatric PROMIS profile-25 involving seven dimensions (depressive symptoms, anxiety, fatigue, physical activity-mobility, peer relationship, pain interference, and pain intensity) was used for QoL assessment. Demographic information of both children and proxies and patients’ clinical information were also included. Outcomes were shown with graphs to users in the ‘Disease Management’ and ‘Symptoms Management’ parts. Voice assistant, cartoon interface, and virtual animal raise system were used to help increase children’s understanding and compliance.

Conclusion

The smartphone mini-program based on Wechat and its administration portal were developed to assess and collect quality of life outcomes of pediatric patients using brief items. It helps parents self-monitor their children’s disease progress and tendency of symptoms and functions, as well as giving medical professionals patient-reported outcomes to help make more targeted medical decisions.

174-P.

The Patient-Reported Outcomes Measurement Information System (PROMIS®) Physical Function measures in adults – A systematic review of measurement properties

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Objective

This study aims to systematically review and critically appraise the measurement properties of Patient-Reported Outcomes Measurement Information System (PROMIS®) Physical Function (PF) measures in adults.

Methods

MEDLINE and EMBASE were searched for studies on PROMIS-PF measurement properties. Studies were included if the aim of the study was to evaluate at least one measurement property of a PROMIS-PF measure in adults. No restrictions were made with...
respect to language, study design and the type of application of the
measure. Following the COnsensus-based Standards for the selection
of health Measurement InStruments (COSMIN) methodology, Risk of
bias was assessed using the COSMIN Risk of Bias checklist. The results
per measurement property were quantitatively or qualitatively
pooled and the quality of evidence was determined.

Results
The database searches identified 1086 unique studies. After title and
abstract screening by two independent reviewers, 284 studies were
deemed eligible for full-text screening.

Conclusions
This study will systematically summarize, pool and appraise the
measurement properties of all PROMIS-PF measures that are cur-
rently available.

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