

Abstracts Listed Numerically

1. Clinical Utilization of Patient Reported Outcome (PROMIS) Scores for Surgical Reconstruction of Posterior Tibialis Tendon Dysfunction

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Objective: To evaluate the ability of PROMIS scales to predict improvement following surgery for posterior tibial tendon deficiency (PTTD).

Methods: PTTD patients who underwent surgical reconstruction were identified using CPT data. Inclusion criteria required complete PROMIS PI, PF, and depression scores at baseline and follow up. 41 patients met inclusion criteria. Two-way ANOVA was used to assess change from pre- to postoperative PROMIS scales. MCIDs were calculated using the distributive method. Receiver operating characteristic (ROC) curves were obtained and area under the curve (AUC) was measured to determine if pre-operative PROMIS scores could predict achieving or failing to achieve MCID. Cutoff values were compared to a previous study. Chi-square analysis was used to test what proportions of patients preoperative classified as achieving MCID, ambiguous to achieving MCID, or failing to achieve MCID using previous published values.

Results: At mean 7.7 months follow-up, PROMIS PF was marginally improved (2.6, $p=0.08$), whereas PI (-4.2) and Depression (-4.3) were significantly improved. The AUC for PF (0.76), PI (0.72), and Depression (0.73) were significant. The PF, PI, and Depression nearest cutoffs for 95% specificity of exceeding MCID were 33.4, 74.3, and 59.1, respectively. The PF, PI, and Depression nearest cutoffs for 95% sensitivity for failing to achieve MCID were 46.8, 53.4, and 37.7 respectively. Chi-square analysis suggested that previously published cut offs predicted majority of patients preoperatively classified as achieving MCID, MCID ambiguous, and failing to achieve MCID for PF and PI, but not for Depression.

Conclusions: Preoperative PROMIS scores can predict postoperative outcome for PTTD. PF scale was only slightly improved, whereas more significant improvements noted for the PI and Depression scales after surgical reconstruction. PF scale below 33.4, PI score above 74.3, and Depression scales above 59.1 are likely to improve after surgery, whereas PF above 46.8, PI below 53.4, and Depression below 37.7 are unlikely to improve.

2. The ability of PROMIS Scales to Predict Patient Acceptable Symptom State (PASS) at an average of 14 Month Follow Up after Foot and Ankle Surgery

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Objective: To evaluate the ability of PROMIS scales to predict patient acceptable symptom state (PASS) after foot and ankle surgery.

Methods: This retrospective cohort study contacted 106 patients following one of four foot and ankle surgeries (mean=14.2±7 months). The selected codes represent the most common surgeries at an academic practice. Each patient completed PROMIS PF, PI, and depression CATs, PASS question, global rating of function, and a question of whether their surgery was a success/failure. When available, prospectively collected preoperative PROMIS scores were retrospectively reviewed (76/106). Receiver operator curve (ROC) analysis was used to calculate the area under the curve (AUC) and specific cutoffs (near 95% sensitivity/specificity) for predicting PASS Yes/No based on preoperative and follow up PROMIS data. A chi-square analysis evaluated the association of PASS Yes/No and patients grading surgery as a success/failure.

Results: The association between patients' judgement of whether their surgery was a success/failure and PASS Yes/No was strong (chi-square 32.6/ $p<0.001$). ROC demonstrated a significant AUC for the ability of preoperative PROMIS to predict PASS Yes/No. Preoperative cutoffs (95% sensitivity) of PASS No at the time of phone follow were PI>69.5, PF<27.2, and D>64 while cutoffs for PASS Yes were PI<49.9 and PF>47.7. Data was insufficient to establish a cutoff for depression. The ROC yielded higher AUC for PROMIS following surgery. Cutoffs (95% sensitivity) of PASS No were PI>65.2, PF<33.5, and D>58.0 while cutoffs for PASS Yes were PI<46.9, PF>49.5 and D<33.2.

Conclusions: The selected PROMIS scales were accurate in both predicting and determining PASS Yes/No status. The highest predictor of PASS however was GRF with 7.5/10 or higher indicating a PASS yes and <4.5 a PASS No. PASS Yes scores approximated a t-score of 50 for PROMIS PI and PF scales, indicating approximately average for the US population is PASS Yes for many patients.

3. Evaluating the Impact of Orthopaedic Resident Participation and Postgraduate Year on Patient-Reported Outcomes Using PROMIS-10

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Objective: The impact of resident participation and their level of training on patient care in orthopaedic surgery is unclear. Current literature in patients undergoing elective total knee arthroplasty (TKA) relies primarily on short-term perioperative clinical outcomes, hence we aimed to investigate this question using validated patient-reported metrics.

Methods: We evaluated a prospective cohort of 1626 surgeries at a single tertiary academic institution. Both PROMIS-10 and VR-12 surveys were used to determine patient-reported physical function (PCS) and mental function (MCS), prioritizing the PROMIS-10. Multivariate regression was used to assess outcomes in surgeries accounting for postgraduate year (PGY) and number of residents. Outcomes included postoperative PCS, clinically significant (≥ 5 points) PCS improvement, operative time, length of stay, and facility discharge, after adjusting for previously described preoperative factors.

Results: 95% of cases were conducted with resident assistance. Compared to attending-only surgeries, no PGY level or number of residents at surgery were associated with postoperative PCS or PCS improvement. Higher odds of PCS improvement were associated with better preoperative MCS, and was inversely related to preoperative PCS. Longer operative times were associated with all PGY levels except for PGY5 (PGY1 8.44 minutes ($P=0.024$), PGY2 11.63 minutes ($P<0.001$), PGY3 9.68 minutes ($P<0.001$), PGY4 4.19 minutes ($P=0.011$)) or the presence of multiple residents (4.39 minutes, $P=0.024$). However, the individual attending surgeon had the greatest impact on length of surgery more so than resident participation and year of training. There were no statistically significant differences in length of stay or facility discharge.

Conclusions: The presence of residents in the operating room, regardless of relative experience, was not associated with clinically meaningful changes in postoperative patient-reported physical function, length of stay, and facility discharge among primary TKA patients. Resident participation and training level were associated with longer operative time, but individual surgeons had stronger associations.

4. Show Me the Money: How Can Patient Reported Outcomes (PRO) Result in Health Cost Savings?

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Objective: To determine the financial impact of procedure reduction to the Health Care System by using pre-procedure PROMIS threshold scores for patient selection in Orthopedics. The use of patient reported outcomes continues to expand beyond the scope of clinical research to involve standard of care assessments across orthopaedic practices. Publications have determined minimal clinical important differences for these values using the Patient Reported Measurement Information System (PROMIS) and determined that these pre-operative threshold values were predictors of improvement or failure to improve a minimal clinical important difference (MCID) after operative intervention in joint replacement, discectomy as well as spinal injection procedures. The purpose of this study was to determine the financial impact to a healthcare system by reducing orthopaedic procedures based on patient selection using previously validated pre-procedure PROMIS threshold values.

Methods: The University of Rochester PROMIS registry currently documents PROMIS PF and PI on approximately 80% of all orthopedics patients since April 2015. The PROMIS registry was searched to determine the number of new patients seen in the last 12 months in the spine and joint replacement orthopaedic clinics that had threshold t-score values indicating patients would not achieve MCID improvement for joint replacement, discectomy and spinal injection procedures. The previously published physical function (PF) and pain interference (PI) pre-procedure threshold t-scores (95% accuracy) used to identify patients unlikely achieve MCID improvement were: spinal injection (CPT code: 64483) were PF >40.3 ; PI <62.1 , discectomy (CPT code 63030) PF >42.8 ; PI <61.9 , and joint replacement (CPT code: Knee 27447 and Hip 27130) PF >48.3 ; PI <51.5 were used. This produced an annualized percentage of patients per CPT code. A range of cost was used (high/low) per procedure to take into account variation across payers. The cost per procedure was multiplied by the number of procedures documented. This value was divided by 12 months to estimate the annual cost change if the pre-procedural PROMIS threshold scores were successfully applied to clinical decisions.

Results: The annual percentage of patients who were determined not to benefit from surgery based on the annual cost decrease by applying the PROMIS threshold values for each procedure are: Spinal Injection - 1,069/3,814 (28.0%),

\$123k-\$718k, Discectomy- 618/2,436 (25.4%) 319k-415k; Knee and Hip Joint Replacement- 304/3,289 (9.2%) 122k-164k.

Conclusions: The goal of orthopaedic surgeons is to improve patient care by operating on patients who would benefit from procedures and just as importantly counsel patients on other treatments when surgery is not indicated. Patient reported outcomes (PROMIS) demonstrated 95% accuracy in identifying patients who may not benefit from surgery. Using this selection process can lead to significant healthcare savings annually. Examining alternative care pathways for patients not meeting PROMIS pre-procedural threshold values for specified orthopedic problems may yield important cost efficiencies and improve the value of patient care.

5. **Bookmarking PROMIS Physical Function t-scores to Improve Clinical Interpretation and Application**

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Objective: To generate a validated “snapshot” of patient perceived ability matched to performance based tests and translate t-score to clinical meaning for individualized care.

Methods: Forty-six community dwelling individuals over 65 years old (77+/- 4.6 years) participated in a single data collection. The session included completion of the PROMIS PF v1.0 CAT using Assessment Center (www.assessmentcenter.net) and completion of the modified Physical Performance Test (mPPT). The mPPT is a battery of 7 tests including gait speed, 5 times sit to stand (5xSTS), stair climbing, picking up a penny, putting on a coat, placing a book on a shelf, and turning in place. Tests are timed with a stop watch. The mPPT is used to classify elderly individuals' frailty level based on physical function. This sample included patients ranging from moderate to not frail on the mPPT. Analysis included univariate correlation between PROMIS PF CAT t-scores and mPPT total score (as well as with each test). Multivariate analysis modeled age and mPPT tests as the best predictor(s) of PROMIS PF CAT t-scores. In an additional analysis, PROMIS PF model parameters were also obtained for items that matched selected mPPT battery tests (gait speed - PFC38, PFM23, PFB5r1; stair climbing - PFA21, PFC32, FM21; 5xSTS - PFA15, PFC41, PFA41). Significant univariate correlations and multivariate correlations were examined between mPPT test items and PROMIS PF CAT t-scores and regression lines plotted (Figure 1). For significant univariate correlations for individual mPPT items, there correspondence to the categorical “no difficulty” model parameter for each PROMIS PF item was also documented.

The validated PROMIS PF bank items were then graphically displayed in a “snapshot” tool to assist with clinical decision making.

Results: Of the 6 tests on the mPPT, 5 of 6 showed significant univariate correlations with PROMIS PF CAT t-scores (r^2 values ranged from 0.22 to 0.41), with gait speed showing the highest significant correlation. The best multivariate model that predicted PROMIS PF was age ($p=0.03$), gait speed ($p<0.01$), and stair climbing ($p=0.02$). The lowest t-score was 40.5 which corresponded to a timed stair task of 14 s. The highest t-score of 57.8 corresponded to a gait speed of 2.0 m/s. Using the equations of the line for gait speed and 5xSTS, a 1.6 m/s gait speed and 14 second 5xSTS corresponded to a t-score of 52.9 and 49.8, respectively. This corresponded to “no difficulty” for the selected PROMIS items. For stair climbing, a 9 second time corresponded to a t-score of 47.3 and a “no difficulty” ranking for the most similar item (PFA21 ‘normal pace stairs’). However, a 5 second time corresponded to a t-score of 52.7 and a “no difficulty” for a more difficult item (PFC32 ‘5 flights of stairs’), but an even more difficult item (PFM21 ‘10 story building’) resulted in an unrealistic estimate of stair climbing time (i.e. < 1 second).

Conclusions: Understanding how PROs (PROMIS) translates to physical function is pivotal in providing pertinent information to the patient as well as interpreting the success or failure of treatments. This data ($r^2=0.22-0.41$) suggests sufficient alignment between performance based tests and PROMIS PF CAT t-scores for clinical evaluation and goal setting of perceived function. Correspondence was highest for PROMIS PF CAT items that showed similarity in task to gait speed, stair climbing or 5xSTS. Overall these findings improve the clinical application of PROMIS PF CAT by anchoring t-scores to performance based tests of function. These PROMIS PF items were then used to generate a “snapshot” tool for quick reference. The “snapshot” tool links a PROMIS PF t-score to specific physical performance tasks for goal setting and to guide clinical assessment of the patient. This application may aid in injury or fall prevention. Further, “snapshots” of other sets of PROMIS PF items may be useful for different diagnoses and settings. This “snapshot” methodology can be used with other PROs and has utility as a shared decision making tool to increase patient engagement.

6. **Barriers to Provider Adoption of Patient Reported Outcomes for Clinical Use by Orthopaedic Surgeons**

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Objective: To determine barriers to provider adoption of patient reported outcomes in consistent with models of technology adoption and scales of provider burnout.

Methods: The PRO Provider Adoption Survey was developed, administered, and analyzed in providers (n=107) from orthopedics and cardiology. The PRO Provider Adoption Survey was developed from the Unified Theory of Acceptance and Use of Technology (UTAUT) model which includes: performance expectancy (PE) (what benefit the provider expects), effort expectancy (EE) (how easy or difficult it is to use), social influence (SI) (whether influential people encourage providers to use PROMIS), and other influential factors (i.e. age, gender). The modified 2-item Maslach Burnout scale (M-MBI) captures the domains of emotional exhaustion and depersonalization to estimate burnout. Principal component analysis and internal reliability were calculated for the PRO Provider Adoption Survey. Subsequently, PE, EE, SI, burnout, and age were used in a logistic regression model to estimate providers 'Yes' answers to using PRO's for clinical use.

Results: The PRO Provider Adoption Survey showed high Cronbach's alpha(>0.9) and appropriate factor loadings for PE and EE but not SI. A total of 62% of orthopedic providers and 10% of providers in cardiology identified as users of PRO's clinically. M-MB was higher, EE and PE lower in orthopedics as compared to cardiology. The logistic regression analysis identified the key barrier to adoption as EE rather than PE, M-MB, and age. The logistic regression analysis shows the primary barrier to adoption as EE (OR = 0.44; p = 0.005), NOT PE (OR= 1.03; p = 0.74) or M-MB (OR =0.93; p =0.67).

Conclusions: A key barrier to provider adoption is effort expectancy or how easy or difficult the PRO is to use. EE expectancy may be addressed through IT enabled strategies, appropriate training, and design of PRO instruments.

7. Generalizability and Validation of PROMIS Scores to Predict Surgical Success in Foot and Ankle Patients: A Tale of Two Academic Centers

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Objective: To determine the degree of concordance of previously determined pre-operative PROMIS physical function (PF) and pain interference (PI) t-scores as a predictor of post-operative success from a large, independent orthopaedic surgery practice.

Methods: Prospective consecutive patient visits to a multi-surgeon tertiary F/A clinic were obtained between 1/2014-11/2016 resulting in 18,565 unique visits and 1,408 new patients. Patients undergoing elective operative intervention for F/A were identified by ICD-9/10; CPT code. PROMIS PF and PI were assessed at initial and follow-up visits (minimum 6 months, mean 7.8 months). Two-way ANOVA was used to determine differences in PROMIS PF and PI from pre to post surgery with age and gender as co-variables. The distributive method of estimating a minimal clinically important difference (MCID) was used. Receiver operator curve (ROC) analysis was used to determine cut offs for achieving and failing to achieve MCID. To determine the validity of previously published cut offs, 1) they were compared to cut offs for this data set and 2) the percentage of patients achieving and failing to achieve MCID based on previous cut offs were evaluated using a chi-square analysis.

Results: There were significant improvements in PROMIS PF scores (mean=6.0; sd=11.6;p<0.01) and PI scores (mean=-7.0; sd=8.4;p<0.01) over the episode of care. The AUC for PROMIS PF (0.77) was significant (p < 0.01) and the cut offs for achieving MCID (current data = <23.8 versus previous study= <29.7) and failing to achieve MCID (current data=>41.1 versus previous study=>42) were comparable (Figure 1). Of the patients identified as **unlikely** to achieve MCID, a significant proportion (88.9 %) failed to achieve an MCID ((Chi square=4.7;p=0.03). Of the patients identified as **likely** to achieve MCID, a significant proportion (84.2 %) achieved MCID (Chi square=17.8;p<0.01). This validates the prior preoperative PROMIS PF thresholds for patients undergoing F/A surgery who will and will not demonstrate MCID improvement in PROMIS PF. The AUC for PROMIS PI was not significant.

Conclusions: PROMIS PF cut offs from published data were successful in classifying patients who would improve in PF with surgery from a different geographic area and academic institution with a broad unique array of surgical procedures, diagnoses, and a diverse patient population. This study provides validation evidence to support using the PROMIS PF as a potential tool for surgical selection to help identify patients who would benefit from surgery as well as those who would not. This can allow for appropriate utilization of healthcare dollars and manpower resources to benefit our patients.

8. PROMIS Functional and Pain Scores in Surgically Treated Patients with Metastatic Bone Disease: Early Results

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Objective: Approximately 20% of cancer related US health care dollars (12 billion \$) are spent managing skeletal related events. Much has been published regarding the benefits of surgical treatment of metastatic bone disease (MBD) including improved function, decreased in hospital morbidity, and significant cost savings. Using PROMIS instruments, we sought to determine if patients' function and pain scores improve after surgical treatment for MBD.

Methods: This is an IRB approved, multicenter, prospective study involving patients treated surgically for MBD. Basic demographic and disease related data were recorded as well as the PROMIS instruments for Pain Interference and Physical Function. Descriptive analysis of all data was performed. PROMIS scores were collected longitudinally and summarized at each point of time to evaluate average change in score over period of time.

Results: A total of 43 records of 13 patients at 9 possible periods of time were recorded: baseline, 1, 2, 4, 6, 10 weeks, 3, 5 and 6 months. Regarding change in physical function score from baseline, the average change at week 1 was -2.5 (SD=5.4), at 2 weeks 1.7 (SD=7.6), after 4 weeks 6.9 (SD=10), after 6 weeks 6.4 (SD =10.9), after 10 weeks 15.3 (SD=3.1), and after 3 months 8.6 (SD=7.6). Regarding change in pain inference score from baseline, the average change at week 1 was -1.2 (SD=7.3), at 2 weeks -2.1 (SD=9.5), after 4 weeks -12.6 (SD=4.5), after 6 weeks -8.3 (SD =10.2), after 10 weeks -16.6 (SD=4.3), and after 3 months -11.4 (SD=8.2).

Conclusions: This study demonstrated trends of increasing physical function and decreasing levels of pain interference after surgery for metastatic bone disease, demonstrating proof of concept that collecting PROMIS data on this population is feasible. Continuing our multicenter, prospective enrollment will hopefully elucidate more information regarding pain and function in surgically treated patients with metastatic bone disease.

9. PROMIS Captures Variability in Physical Function Across Hand Conditions

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Objective: To determine whether PROMIS Physical Function, Pain Interference and Quick DASH scores varied similarly across conditions receiving hand specialty care.

Methods: This cross-sectional evaluation analyzed 1,491 consecutive outpatient clinic visits of adult patients presenting to a tertiary hand clinic for an upper extremity condition from 7/1/2015-11/30/2016. All patients completed electronic PROMIS Physical Function, and Pain Interference modules at their visit. Quick DASH scores were recorded in 30 patient subsets from each of 5 diagnoses. Differences in patient-reported outcome measures were statistically analyzed between conditions and correlations between PROMIS scores and QuickDASH scores were calculated.

Results: PROMIS scores varied significantly between diagnostic groups. Patient-reported Physical Function, and Pain Interference, were worst among patients with carpal tunnel syndrome followed by thumb arthritis, while the least pain, and best function were reported by those with ganglion cysts or Dupuytren's contracture. Statistical differences persisted after accounting for differences in patient demographics across diagnoses (i.e., age, sex, race). QuickDASH scores varied similarly as patients with carpal tunnel syndrome or thumb arthritis reported worse upper extremity function than patients with ganglion cysts or Dupuytren's contracture. A strong correlation was seen between QuickDASH scores with both PROMIS Physical Function scores ($r = -0.66$) and Pain Interference scores ($r = 0.79$).

Conclusions: PROMIS Physical Function, and Pain Interference scores vary significantly according to the diagnosis prompting presentation for specialty hand care. The differences in PROMIS scores were consistent with the variability in QDASH scores across common atraumatic hand conditions. Our data indicate the PROMIS scores, although not anatomic region specific, detect differences between upper extremity conditions similar to the Quick DASH.

10. Utilization After Carpal Tunnel Release PROMIS Predicts Increased Resource

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Objective: To determine if patient mental health, preoperative experience with pain, and pre-operative opioid usage could predict resource consumption postoperatively.

Methods: This retrospective cohort study evaluated all adult patients undergoing isolated unilateral (68%) or bilateral carpal tunnel release (32%) at a tertiary orthopaedic center from 6/1/2015-6/30/2016. All patients completed the PROMIS Pain Interference and Depression Computer

Adaptive Testing (CATs) at their pre-operative visit. Postoperative encounters were quantified as a summation of postoperative office visits, phone calls, or electronic messaging related to their carpal tunnel syndrome. Pre-operative opioid use was determined by patient report and prescriptions recorded within 90 days preoperatively. Independent t-tests and chi square testing assessed differences in initial PROMIS scores between patients who had one versus more than one postoperative encounter as well as differences in age, sex, race, and opioid use between groups.

Results: 219 patients who underwent carpal tunnel release were eligible for the study. 59% of patients had a single postoperative encounter while 41% had multiple postoperative encounters (25% had two, 8% had three, and 8% required four or more). Patients who required multiple post-operative encounters had significantly higher pre-operative PROMIS Depression scores (average difference 3 points, 95%CI 0.1-5.5). There was no difference in PROMIS Pain Interference scores or opioid use (each $p>0.05$). There was also no difference between groups by unilateral versus bilateral surgery, average age, sex, or race (all $p>0.05$).

Conclusions: While depressive symptoms are thought to influence ultimate patient-reported outcomes, our data now indicate that greater depressive symptoms are also associated with more postoperative encounters after carpal tunnel release. If considering care within a bundled reimbursement model for carpal tunnel syndrome, preoperative PROMIS Depression scores may predict variability in postoperative resource consumption. Although disproportionate pain and narcotic use preoperatively are concerning, these factors did not predict the need for more postoperative encounters.

11. In Sweden we PROMIS

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Objective: To translate and validate core PROMIS item banks and short forms into Swedish.

Methods: The project team has established and support a series of projects to validate and implement different PROMIS item banks and short forms. The project continues to host seminars demonstrating PROMIS to different stakeholders. This is part of a long-term strategy for full implementation of item banking in Sweden.

Results: The following initiatives have been taken: 1) translation of all child and most adult item banks together

with the hospitals in Gothenburg, Lund, and Stockholm, 2) translation and validation of the core pediatric PROMIS item banks for use in the pediatric cancer registry, 3) validation of four pediatric item banks in a population of children with asthma, 4) validation of the pediatric Profile-25 in the child orthopedic quality register, 5) translation & validation of the adult profile-29

Conclusions: PROMIS core item banks have good potential for inclusion in the data collection procedures of the national quality registries; however, there are technical difficulties in the implementation that need to be resolved before full operation. The best solution will be a national option where all registries will be able to link to the item banks and use the CATs. This means that the system must integrate with several different computer platforms used by the quality registries. One solution is to use the national electronic health platform – 1177, which is a telephone and text support system for the whole of Sweden. It consists of information, inspiration, and e-services for health and healthcare.

Patients register in the system using their electronic bank id and access aspects of their healthcare records, make appointments, etc. Clinicians can communicate with the patient via text messaging, informing them when they should complete a PROM and sending a unique access code.

12. A Swedish protocol for PROMIS validation and feasibility

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Objective: To design a protocol for the assessment of the psychometric properties of PROMIS core item banks in Sweden and to identify its usefulness in the national health care quality registries and in clinical settings.

Methods: Baseline and follow-up data will be collected over two years in different chronic adult populations. Internal reliability and convergent and divergent validity will be tested against currently used outcome measures in the registries. Responsiveness will be examined over the study period. Mapping from PROMIS to the EQ-5D and other generic measures will be undertaken.

Conclusions: PROMIS core item banks must demonstrate good psychometric properties, acceptability to patients as a means of expressing their subjective quality-of-life outcomes, as well as acceptance as a valid outcome measure by the healthcare professionals. Many quality

registries have established (legacy) PROM measures already and the project needs to demonstrate that these can be mapped to the PROMIS system reliably and without loss of data integrity. We must show that PROMIS provides information within the same health domains as existing measures, but with higher precision and relevance and less burden to patients and in administration. Clinicians are keen to adopt a new and better way to collect patient data, but concerns remain over how PROMIS will integrate into a national electronic data collection strategy and local clinical routines so that data is used to improve health care at both group and individual levels.

14. Validity of the PROMIS Pain Behavior and Pain Interference item banks across diverse clinical samples and a general population

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Objective: To examine the generic (non-disease-specific) nature of the PROMIS Pain Behavior (PROMIS-PB) and Pain Interference (PROMIS-PI) item banks as a prerequisite for comparing different clinical samples and the general population.

Methods: Patients with rheumatoid arthritis (RA, n=1.917), chronic pain (CP, n=2.623), or osteoarthritis (OA, n=1.049), and individuals from the Dutch general population (n=1.030) completed the full Dutch-Flemish (DF)-PROMIS-PB (39 items) or DF-PROMIS-PI (40 items). Differential Item Functioning (DIF) across the diverse clinical samples and the general population was evaluated with use of the R-package Lordif, using ordinal logistic regression models with a McFadden's pseudo R^2 change of 2% as critical value. When items were flagged for DIF, it was examined whether the DIF was uniform or non-uniform. Furthermore, the impact of the DIF was examined by plotting item characteristic curves (ICC) and test characteristic curves (TCC).

Results: The results are shown in Table 1. For the DF-PROMIS-PB three items were flagged for DIF; two items (PAINBE24 and PAINBE25) between RA and the general population and one item (PAINBE45) between CP and the general population. For the DF-PROMIS-PI two items were flagged for DIF; one item (PAININ20) between CP and the general population and one item (PAININ42) between OA and the general population. The R^2 values were just above

the critical value of 2% and the ICC and TCC (not shown) showed very little impact of DIF on the item scores and test T-scores.

Conclusions: The impact of DIF across populations was negligible. This study provides evidence for the generic nature of the PROMIS-PB and PROMIS-PI, and indicates that the item banks and their T-scores can be used to compare different clinical samples and the general population.

15. Reference values and measurement invariance of the Profile 29 in the UK, France and Germany

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Objective: Comparability of Patient-Reported outcome measures over different languages is essential to allow cross-national research. We investigate the comparability of the PROMIS Profile 29, a generic health-related quality of life measure, in general population samples in the UK, France and Germany and present general population reference values.

Methods: A web based survey was simultaneously conducted in the UK (n = 1,509), France (1,501) and Germany (1,502). Along with the PROMIS profile 29, we collected sociodemographic information as well as the EQ-5D. We tested measurement invariance by means of multi-group confirmatory factor analysis. Differences in the health-related quality of life between countries were modeled by linear regression analysis. We present general population reference data for the included PROMIS domains utilizing plausible value imputation and quantile regression.

Results: Multi-group confirmatory factor analysis of the PROMIS Profile 29 indicated strong measurement invariance between different languages (CFI = 0.952, TLI = 0.950, RMSEA = 0.049, SRMR = 0.041). We observed significant differences in patient-reported health between countries, which could be partially explained by differences in overall ratings of health. The physical function and pain interference scales showed considerable floor effects in the normal population in all countries.

Conclusions: Scores derived from the PROMIS Profile 29 can be readily compared across the UK, France and Germany. Due to the use of plausible value imputation, the presented general population reference values can be compared to data collected with other PROMIS short forms or computer-adaptive tests.

16. Validity and Clinical Utility of the PROMIS Family Relationships Measure in Children with Chronic Conditions

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Objective: To determine the content validity and clinical utility of the PROMIS Pediatric Family Relationships measure in children with asthma, sickle cell disease, and type 1 diabetes.

Methods: Individual semi-structured interviews were conducted with children with asthma, sickle cell disease, or type 1 diabetes, and their parents. The interview guide included probes about facets of the Family Relationships instrument, the impact of chronic disease on family relationships, and the acceptability of healthcare providers asking about family relationships. Interviews were fully transcribed and double-coded.

Results: Participants included 16 sociodemographically diverse children (8-16 years old) and 16 parents. Interviews lasted 8-46 min (median: 26 min). Youth with chronic conditions and their parents endorsed facets of family relationships in a manner consistent with the facets included in the PROMIS measure. Support was the most commonly coded facet overall. Parents spontaneously raised the child's chronic illness as influencing family relationships more than youth did. Many respondents expressed no concerns about healthcare providers asking about family relationships or requesting that families complete the PROMIS family relationship measure in clinical practice. Those who did have concerns raised questions about the appropriateness of the topic in general or specialist care and about what a provider could and/or would do with the information. If a survey uncovered family relationship issues, youth expected providers to act as an advocate and source of advice, whereas parents expected resources and/or referrals to resources.

Conclusions: The PROMIS Family Relationship measure appears to adequately capture the facets of family relationships for youth with chronic conditions and their parents. The use of the measure in clinical care is

acceptable to many patients.

However, family relationships can be a particularly sensitive issues for some families, and this needs to be taken into account when integrating the measure into clinical care.

17. PROMIS Global Health Scale in Patients Undergoing Total Joint Arthroplasty

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Objectives: To explore baseline and follow-up scores of the PROMIS global health 10 scale in patients undergoing orthopaedic hip and knee procedures.

Methods: Patients undergoing primary THA or TKA, with completed PROMIS surveys pre- and 6 weeks post-operatively were included in. Patients who underwent re-operation on their primary joint, had prosthetic infection, revision surgeries, intra-operative surgical complications, contralateral hip or knee replacement for either THA or TKA were excluded.

Results: 524 patients from one clinical practice were included. The mean pre-operative mental score was 43.63 and post-operative score 45.40 (Mean change = 1.79, CI: 1.29 to 2.30). The mean pre-operative physical score was 36.92 and the post-operative score 41.99 (Mean change = 6.04, CI: 5.54 to 6.54). Linear regression analysis of four predictors – baseline PROMIS, procedure (TKA, THA, anterior THA), side, and satisfaction with surgery) was carried out on change in PROMIS scores. Higher baseline PROMIS scores were associated with a decreased change in PROMIS scores. Patients satisfied with their surgery had an increase in mental PROMIS scores of 2.23 (CI: 1.64 to 2.81) and physical scores of 7.03 (CI: 6.44 to 7.61), while patients with poor satisfaction scores did not change. For TKA's, the mean change in physical score was 5.37 (CI: 4.63 to 6.11) and mental score was 0.99 (CI: 0.28 to 1.7). For posterior THA's, the mean change in physical score was 6.41 (CI: 5.70 to 7.11) and mental score was 2.17 (CI: 1.43 to 2.91). For anterior THA's the mean change in physical score was 5.7 (CI: 0.86 to 10.54) and change in mental score was 4.42 (CI: -4.62 to 13.46).

Conclusions: The PROMIS global health 10 survey is a useful tool in assessing pre- and post-operative mental and physical well-being in TKA and THA patients. Patient satisfaction predicts changes in PROMIS scores.

18. Development of Patient-Reported Outcome Instrument for Social Determinants of Health

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Objective: To evaluate a patient-reported outcome instrument designed to assess perceived stress associated with social determinants of health. Perceived stress related to adverse events is strongly related to poor emotional and physical health but few short validated instruments are available for use in clinical practice.

Methods: Our 15 item questionnaire was based on pilot work documenting the prevalence of adverse life events reported by parents of children less than 5 years of age receiving care in an urban community health center. Predictive validity was determined by comparing the individual items to results of other validated instruments that measure depression, anxiety, stress, and stress management. Exploratory factor analysis was run on the results of the 15-item questionnaire administered to prenatal patients and caregivers of children <2 years (N=560).

Results: EFA identified 3 eigenvalues >1. The EFA was conducted for 1 to 4 factor models, and the 3-factor model proved to have the best fit (RMSEA=0.000, CFI=1.000, TLI=1.006) while maintaining a parsimonious structure. The three factors identified were determined to represent subscales relating to different forms of stressful experiences: 1) Requiring concrete social services, 2) Relationship difficulties, and 3) Daily family function. Predictive validity was demonstrated for all items on at least one criterion measure, such as increased rates of depression and anxiety as measured by the PHQ-4, higher scores on a two-item stress scale, or lower scores on the stress-management scale.

Conclusions: These results demonstrate that a short but comprehensive screen for social determinants of health is valid and illustrates the complex nature of stress related to social determinants of health. However, in the interest of brevity, conceptual clarity, and low endorsement for some items, we revised the wording and decreased the number of items to 11. Further work is needed to confirm the validity and reliability of this revised questionnaire.

19. Consensus of the Utility of a "Snapshot" Tool to Interpret PROMIS Physical Function T-Scores

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Objective: To reach consensus on the utility of a "snapshot" tool of PROMIS physical function to aid in interpretation of t-scores for clinical decision making

Methods: A Delphi panel of 9 expert physical therapists (PTs) (5 board certified, 6 faculty) practicing in geriatrics, neurology, orthopedics, hospital, post-acute, and home health specialties/settings were recruited to participate. PROMIS PF bank items were categorized using WHO-ICF Activities & Participation coding (e.g. Self-care, Transferring, Walking, Housework). Item Response Theory (IRT) model parameters were used to scale items to a specific T-score. Stacked, clustered columns were graphically displayed for each item (n=36) within ICF categories, resulting in a one-page "snapshot," benchmarking tasks to the PF T-score for online decision making. The Delphi panel considered 8 questions (5-point Likert scale) related to understandability, importance of categories/items, and helpfulness in evaluation and plan of care. Aggregate were shared through two rounds of consensus development. Consensus converged after round 2 when >70% on each Likert scale (e.g. >70% rating "4-Very" or "5-Extremely helpful") was reached.

Results: Consensus was achieved for 8 of 9 questions. Questions achieving consensus at the 4-Very/5-Extremely level were: ease of understanding (89% of panelists, 4.0±0.5 [mean ± standard deviation]); importance of items (78%, 4.0±0.71); and helpfulness for recommending community interventions (78%, 4.11±1.05). Questions achieving consensus at the 3-Somewhat/4-Very level were: importance of categories (89%, 3.78±0.67); and helpfulness in understanding a patient's level of PF (78%, 3.89±0.78), goal setting (78%, 3.67±0.87), and determining plan of care (100%, 3.22±0.44). Five panelists (56%) endorsed comments around the desire to select which PROMIS PF bank items are included on the snapshot.

Conclusions: Panelists reached consensus on the clinical utility of the "snapshot" approach to interpreting PROMIS PF T-scores and applying them to clinical decisions. Suggested further improvement included the option to customize which items were included in the "snapshot" was strongly endorsed.

20. The PROMIS Physical Function: A review of development, usage and collaboration 2006-2017

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Objective: Conduct a review of the use and application of the PROMIS physical function (PF) instruments in research and clinical practice with attention to the locations and populations of its use, the reasons for its use and trends in collaboration, nature and use over time.

Methods: A literature search was conducted with three databases, including PubMed, Web of Science, and SCOPUS between January 2006 and May 2017. This comprehensive search strategy searched the term 'PROMIS PF' and defined criteria for article inclusion and exclusion based on the use or application of PROMIS instruments related to physical function in clinical or research arenas. A network analysis and visualization of the research efforts and collaborations were also constructed to understand PROMIS in action.

Results: The PubMed search provided 207, Web of Science returned 267 articles, and SCOPUS identified 173 articles. Across the three search engines there were 319 unique articles were identified. A total of 232 articles met our inclusion criteria. The articles content dealt with test development, validation, and predictive use in psychosocial determinants of health. Some focused specifically on aging populations, on children and on the development of language translations. Knowledge hubs within researcher networks identified opportunities for collaborations.

Conclusions: Initial research on the PROMIS PF between 2006 and 2008 focused on test development and by 2009 there was the beginning of research applying the instrument to specific clinical populations. The number of publications referencing the PROMIS PF have increased each year from 1 article in 2006 to 53 published articles in 2016. The PROMIS PF has been increasingly used to assess physical function in specific health conditions and has moved from research based to clinical based utilization.

21. Relevance and Utility of PROMIS® Instruments in Systemic Lupus Erythematosus (SLE): A Qualitative Study

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Objective: To evaluate SLE patient perspectives on the relevance and potential utility of PROMIS computerized adaptive tests (CATs) and PROMIS10.

Methods: Adult SLE patients were recruited from an SLE Center of Excellence. Subjects completed 12 PROMIS CATs, the PROMIS10, and participated in focus groups (women) or structured interviews (men). Focus groups and interviews explored the relevance of PROMIS domains, the potential value of PROMIS instruments in routine medical care, and identified missing domains. Transcripts were analyzed for recurring themes and concepts using grounded theory.

Results: Twenty eight women and 4 men with SLE participated in 4 focus groups and structured interviews. Participants reported that PROMIS instruments, especially CATs, reflected their experience with lupus, with women prioritizing domains of fatigue, pain interference, physical function, sleep disturbance, and cognitive abilities as most relevant, and men selecting fatigue, sleep disturbance, anxiety, pain interference, and pain behavior. Subjects identified body image, intimate relationships, pregnancy, and relationships with providers as important areas not addressed by PROMIS. Participants were enthusiastic about using PROMIS in their medical care, citing utility in validating their experience, tracking symptoms and disease progression, facilitating communication with providers, and guiding treatment plans. A recurring theme in the focus groups and interviews was the importance of doctors reviewing the survey results.

Conclusions: SLE patients endorse PROMIS instruments as relevant, valuable, and potentially useful in improving clinical care. These data identify domains of importance to SLE patients, including men's greater emphasis on mental health, and areas where there is a need to develop PROMIS instruments. Further longitudinal studies are essential to explore how to most effectively integrate PROMIS measures in routine clinical care.

22. The Physical Function and Upper Extremity Patient-Reported Outcomes Measurement Information Systems in Glenohumeral Osteoarthritis

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Objective: The NIH's Patient-Reported Outcomes Measurement Information Systems (PROMIS) assessment of musculoskeletal function includes both general Physical Function and Upper Extremity function Computer Adaptive Tests (PF CAT and UE CAT). Although validated in the general population, it is unclear how the PF CAT and UE CAT compare to legacy patient-reported outcome measures in patients with symptomatic glenohumeral osteoarthritis.

Methods: This cross-sectional study enrolled 98 patients undergoing an anatomic total shoulder arthroplasty for glenohumeral osteoarthritis at a tertiary center. All patients completed the American Shoulder and Elbow Surgeons (ASES) score, Simple Shoulder Test (SST), PF CAT, and UE CAT preoperatively. The total and functional subscale ASES scores were analyzed. Statistical analysis quantified correlations between instruments, ceiling effects, and floor effects for each outcome measure.

Results: The UE CAT was moderately correlated with the ASES function score ($r=0.541$) and had low-moderate correlation with the total ASES score ($r=0.489$). There was low correlation between the UE CAT and SST ($r=0.386$), the PF CAT and functional ASES ($r=0.377$), PF CAT and total ASES ($r=0.361$), and PF CAT and SST ($r=0.322$). None of the instruments demonstrated substantial ceiling effects (1.02% for UE CAT, ASES, SST and 2.04% for PF CAT). The SST demonstrated a floor effect in 10.2% of responses whereas a floor effect was seen in only 1.02% of response for the ASES, PF CAT, and UE CAT.

Conclusions: The UE CAT correlated moderately well with the functional portion of the ASES and appears to be a reasonable measure of assessing shoulder function in patients with glenohumeral arthritis. The low correlations seen between the UE CAT and the SST are likely related to the substantial floor effect seen with the SST. The PF CAT poorly correlates with established legacy scores and we do not recommend using this instrument to assess patients with glenohumeral arthritis.

23. Different Perceptions of Hip and Knee Arthritis Burden: A Study of Patients and Their Significant-Others

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Objective: Patient reported outcomes may vary substantially based on patient perception. It may be helpful to utilize patient's spouse/significant-other (SSOs) to gain insight into the burden of illness and impact of treatment. Our objective was to evaluate patient outcomes after total hip arthroplasty (THA) and total knee arthroplasty (TKA) as reported by their SSO, and compare them to patient self-

reported outcomes utilizing the same outcome metrics.

Methods: This prospective cohort study involved patients undergoing primary elective THA or TKA. Patients and SSOs were provided outcome metrics at the pre-operative, and initial post-operative follow-up visit. SSOs completed surveys as they pertained to the patient, patients completed surveys as they pertained to him or herself. The primary outcome metric utilized was the Global Health Patient Reported Outcomes Measurement Information System (PROMIS), which has both physical (PS) and mental (MS) domains. Analysis was performed on our aggregate sample using paired t-tests and kappa.

Results: Our sample included 28 patients (21 THAs and 7 TKAs). Pre-operative visits occurred 1-3 weeks prior to surgery, post-operative visits occurred 4-6 weeks after surgery. Pre- and post-operative scores were moderately to strongly correlated between patients and SSOs for PROMIS-PS and PROMIS-MS. Patient's mean PROMIS-PS and PROMIS-MS scores improved significantly between pre- and post-operative time points ($p < 0.05$). SSOs scores improved significantly on the PROMIS-PS ($p = 0.03$), but not the PROMIS-MS ($p = 0.45$). There was moderate agreement between change in patient and SSO reported scores for the PROMIS-PS ($k = 0.459$, $p = 0.014$), but no significant agreement for the PROMIS-MS ($k = 0.330$, $p = 0.06$).

Conclusions: There are differences in the way patients and their SSOs perceive the mental/emotional impact of these procedures. SSOs may underestimate the mental/emotional benefits that patients report after surgery.

24. Trends in PROMIS Scores in the Early Post-Operative Period Following Lateral Ankle Ligament Reconstructive Techniques

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Objective: Lateral ankle ligament injuries are common conditions that can progress to chronic instability requiring operative treatment. Though surgical outcomes are generally good following lateral ankle ligament reconstruction, current scoring systems for evaluating outcomes and monitoring progression have deficiencies. Patient Reported Outcomes Measurement Information System (PROMIS) scores has been established as a method of monitoring patient outcomes. The purpose of this study was to evaluate trends in post-operative PROMIS physical function (PF), pain interference (PI), and

depression scores in patients undergoing lateral ankle ligament reconstruction.

Methods: PROMIS scores were prospectively obtained from all patients evaluated in our foot and ankle clinic. A total of 55 patients who underwent lateral ankle ligament reconstruction were included. PROMIS PF, PI, and depression were evaluated at each post-operative visit. Changes in scores were calculated as compared to baseline pre-operative scores and compared at each follow-up time point using two-way ANOVA. Differences in reconstruction type in patients undergoing allograft (A), modified Broström-Gould (BG), or modified Broström-Gould augmented with fibertape (BG+FT) were also evaluated.

Results: The average follow-up was 27.05 weeks. Changes in PF were significantly different from baseline at all time-points except for 8-12 week follow-up. PF worse at 2 and 4-6 week follow-up, and significantly better at >12 weeks follow-up ($p<0.01$). PI improved from baseline beginning at 8-12 week follow-up ($p=0.02$). Depression was unchanged from baseline at 2 weeks and 4-6 week follow-up, then improved thereafter ($p<0.01$). Though not significant, when comparing reconstruction types, there was a trend towards slower improvement in PF in those with BG+FT, compared to A ($p=0.07$) and BG ($p=0.051$) at 8-12 weeks.

Conclusions: Though longer follow-up is needed, the trends in PF, PI, and depression following lateral ankle ligament reconstruction in our study provides data that can be used for pre-operative counseling and monitoring progression post-operatively.

25. The Value of PROMIS® Physical Function for Predicting Physical Performance in Patients with Various Conditions

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Objective: To investigate the association of PROMIS® Physical Function (PF) T-scores with observed physical performance in several clinical settings.

Methods: Adult patients from three inpatient clinics (rheumatology, cardiology, psychosomatic medicine; $n=78$) completed the full German PROMIS v1.2 PF item bank. PROMIS PF T-scores were derived from different item subsets (full bank, SF-20a, Mobility bank, Upper Extremity bank). Physical performance was observed by administering

the Physical Performance Test (PPT) which consists of nine tasks that simulate activities of daily living, thereby representing a broad range of physical abilities. In addition, patients completed the Brief Illness Perception Questionnaire, the Patient Health Questionnaire-2 measuring depression severity, and a single item from the PROMIS Pain Intensity scale asking for average pain in the past week. We used Pearson's correlation and multiple linear regression to determine the association between PROMIS PF T-scores and PPT sum scores.

Results: Correlations between PPT sum scores and PROMIS PF T-scores were strong for most PROMIS PF measures in each clinical sample, ranging from $r=0.72$ to $r=0.88$. However, the correlation between PPT and PROMIS Upper Extremity was lower in cardiology and psychosomatic medicine patients ($r=0.53$ and $r=0.57$, respectively). Regression analyses identified PROMIS T-scores derived from the full bank ($R^2=55.7$, $\beta=.75$, $p<.001$), the SF-20a ($R^2=55.2$, $\beta=.74$, $p<.001$), and the Mobility bank ($R^2=61.5$, $\beta=.78$, $p<.001$) as strong predictors of physical performance as observed by the PPT. In contrast, the predictive value of PROMIS Upper Extremity was lower ($R^2=32.2$, $\beta=.57$, $p<.001$). The inclusion of further potential predictors (illness perception, mood, pain) to the individual regression models did not result in any additional predictive value.

Conclusions: Several PROMIS PF measures can be used to predict functional physical performance in different clinical settings. An exception was PROMIS Upper Extremity that appeared to be strongly associated with overall physical performance in rheumatology patients only.

26. PROMIS-29 in Crohn's Associated Peripheral Spondyloarthritis

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Objective: PROMIS-29 has never been validated in Crohn's associated spondyloarthritis (SpA).

Method: PROMIS-29 was administered to consecutive patients with Crohn's disease (CD) who were seeking care at an IBD center of excellence. Detailed history of peripheral joint disease, inflammatory back pain and a physical examination were performed. Bath Ankylosing Spondylitis Metrology Index (BASMI), a measure of spinal mobility, Harvey-Bradshaw index (HBI), a measure of CD activity were administered. Patients were assessed to see if they met Assessment of SpA (ASAS) criteria for Crohn's Associated SpA.

Results: 32/33 enrolled patients completed all instruments: 76% females, 80% white, a median age 36.4 years (IQR 27.2 – 49). Patients had moderate CD activity (mean HBI $8.8 \pm$ SD 4.5) and those with higher HBI activity had worse physical function (median 36.4 vs. 46.9), worse fatigue (median 63.7 vs. 55.1), less social satisfaction (mean 43.3 vs. 50.7), pain VAS (median 6 vs 2.0), and interference from pain (median 62.5 vs. 55.6) compared to patients in remission/low HBI (all $p < 0.05$). In addition, CD patients who met ASAS criteria for peripheral SpA reported worse physical function (median 38.2 vs. 56.9), worse depression (median 54.8 vs. 41) and less social satisfaction (mean 44.7 vs. 50.6) after adjusting for CD activity ($p < 0.05$). There was moderate inverse correlation with BASMI and PROMIS function domain ($r = -0.4$; p -value = 0.01). No PROMIS domains differed between patients with and without inflammatory back pain.

Conclusions: PROMIS-29 provides a valid assessment of physical health domains and some mental health domains and is able to differentiate between CD patients with and without peripheral SpA after controlling for CD bowel disease activity. This underscores the additional burden arthritis places on CD patients, which is often overlooked, especially when there is active bowel disease.

27. Detecting Change in PROMIS Scores: Reliable Change Index (RCI) versus Minimal Important Difference (MID) in an Acute Pediatric Asthma Cohort

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Objective: Unlike the MID, the RCI accounts for varying test reliability across the latent variable by computing the precision of each test estimate. The purpose of this study was to contrast how the two definitions of meaningful change identify responders in a cohort of children experiencing an acute asthma episode.

Methods: We analyzed the parent-proxy edition of the Pediatric Asthma Impact Scale (PAIS) measured during an acute asthma Emergency Department visit and again 3 weeks later. We computed RCI as the individual change in PAIS divided by the individual-level SEMs computed from IRT-based marginal reliability at both time points. The pooled SEM for the change was calculated from the square root of $[SEM_1^2 + SEM_2^2]$. Patients' asthma was classified as controlled based on the Asthma Control Test. We

compared $RCI \leq -1.68$ as a threshold for responders, representing a false-positive rate of 5%, between groups achieving and failing control. For comparison, we also identified patients achieving an MID of -4 on the PAIS, based on 0.5 times the SD of the baseline PAIS for the data set.

Results: For the 59/166 patients becoming controlled, the average improvement in PAIS was -16 (SD 11) on the PROMIS T-scale. 88% had improvements of -4 points or more, compared with 85% with RCI of -1.68 or less. For the 107 remaining uncontrolled, the average PAIS improvement was -9 (SD 12). 66% had improvement of -4 points PAIS, versus 64% with RCI 1.68. Patients not detected by RCI were within one point of MID.

Conclusions: For extremes of the latent trait, where reliability is less robust, assessments of PROMIS responsiveness should consider imprecision arising from measure reliability. The RCI represents a conservative and generalizable way to detect responders. RCI can be calculated using classical test theory or IRT, and can be used to compare tests from different scales.

28. PROMIS-29 in Elderly Hip Fracture Patients

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Objective: To evaluate the validity of PROMIS-29 in assessing physical function and social isolation in patients over 65 undergoing surgical repair of low-trauma hip fractures.

Methods: PROMIS-29 was administered to 109 cognitively intact patients 65yo with no active cancer 2-4 days after surgical repair of hip fracture. Also administered were the Lower Extremity Activity Scale (LEAS), corresponding to physical function, and the Lubben Social Networks Scale-18 (LSNS-18). The LSNS-18 is a validated instrument specifically designed to measure social isolation in the elderly. Patients answered all instruments in reference to the week prior to the unexpected hip fracture. Grip strength was also measured 2-4 days after surgery. Associations were evaluated using Spearman correlations.

Results: Subjects were mostly female (72.5%), Caucasian (92.7%), college-educated (78%) with a mean age of 80.7 ± 8.5 years. 45% were socially isolated based on LSNS-18. The median PROMIS Physical Function t-score was clinically and statistically significantly lower in those who were socially isolated (41.4 vs. 48.2; $p = 0.003$). Those who were socially isolated also had a significantly lower PROMIS-29 Ability to Participate in Social Roles score,

(55.5 vs. 64.2 ; $p=0.077$). LEAS scores showed strong and significant correlations with PROMIS Physical Function, ($r=0.53$; $p<0.001$) and significant but weaker correlations with PROMIS Fatigue ($r=-0.34$, $p<0.001$), Pain Interference ($r=-0.27$, $p<0.005$) and Visual Analogue Pain Scale ($r=-0.28$, $p<0.005$). PROMIS-29 Physical Function showed a significant but only moderate correlation with dominant hand grip strength ($r=0.31$; $p<0.005$). PROMIS-29 Ability to Participate in Social Roles showed a significant but weak correlation with LSNS-18 scores ($r=0.23$, $p<0.017$).

Conclusions: The PROMIS-29 Physical Function domain appears to perform better than the Social Participation domain in this cognitively intact but frail elderly population. Future studies should further evaluate the validity and performance characteristics of PROMIS-29 in this growing and clinically challenging population.

29. The Road to Recovery for Bunion Surgery: Data Analytic Plots to Target Patient Progress

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Objective: Patient reported outcomes (PROs) can be used to generate data analytic curves to serve as a recovery road map for patients and allow surgeons to identify those who are deviating positively or negatively from the expected course. The purpose of this study was to determine if PROMIS PROs can be used to construct data analytic curves for hallux valgus (HV) surgery, a common procedure in foot and ankle surgery.

Methods: PROMIS scores were prospectively obtained from patients evaluated in a specialty foot and ankle clinic. A total of 34 patients who underwent a bunionectomy were included. Using a previously described method, bunionectomy-specific pre-operative cut-off values to achieve and fail to achieve minimally clinically important differences (MCID) in PF with 95% specificity and 95% sensitivity were determined. Patients were stratified based on their pre-operative PF T-scores as above or below the MCID cut-off. PF was evaluated using two-way ANOVA at 4 follow-up time periods to establish data analytic curves based on pre-operative scores.

Results: Bunionectomy-specific PF cut-off for exceeding MCID was 39.6 and 50.2 for failing to achieve MCID. Patients were stratified based on PF T-scores above or below the MCID cut-off of 50.2. Data analytic curves were generated for above the PF cut-off and below PF cut-off. Those starting with a T-score above the bunionectomy specific cut-off had significantly better PF pre-operatively

($p<0.01$) and again at 6-12 week follow-up ($p=0.02$). There were no differences at 1 week or 3-4 week follow-up time points.

Conclusions: Although longer term follow-up is desirable, this short term follow-up suggests a significant clinical impact of using PROMIS scores for pre-surgical decisions as well as provides a road map for recovery for patients and surgeons.

30. Performance of PROMIS Short Forms and PROFILE-29 in Golimumab- or Infliximab- Treated Rheumatoid Arthritis Patients

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Objective: PROMIS questionnaires have been used in clinical practice and observational studies in rheumatoid arthritis (RA) patients (Pts) (Bartlett 2015). AWARE is an ongoing multi-center United States-based, real-world evidence study of golimumab IV (GLM) vs. infliximab (IFX) in RA and utilizes PROMIS instruments and the Clinical Disease Activity Index (CDAI) to assess response to therapy. The aim of this analysis was to examine PROMIS measures in a RA treatment setting.

Methods: We report on 421 GLM and 326 IFX Pts' baseline PROMIS Pain Interference Short Form-6b (PISF), PROMIS Fatigue Short Form-7a (FSF), PROMIS-29 Profile v2.0 (P29v2) and CDAI. PROMIS T-scores for GLM and IFX Pts were compared between and across CDAI levels of disease activity using ANOVA. Data are mean \pm standard deviation.

Results: GLM Pts were 61.0 ± 13.0 years and IFX Pts were 57.2 ± 13.0 years with disease duration for GLM 9.0 ± 9.3 and IFX 7.0 ± 10.0 years (both $p<0.0001$). Baseline CDAI scores were similar for GLM (31.1 ± 14.6) and IFX (34.3 ± 16.2). PROMIS T-scores (PISF, FSF, P29v2 domains) were compared across CDAI disease activity categories. GLM PROMIS T-scores correlated with CDAI disease category, with HDA Pt T-scores significantly ($*$, $p<0.05$) different from those of MDA, LDA and remission (except between HDA and remission for Anxiety, Depression and Sleep Disturbance domains). Similar results for IFX were observed for MDA and LDA (not remission as $n=2$ for IFX). For both GLM and IFX Pts, all PISF, FSF and P29v2 domain T-scores were significantly worse in Pts with $CDAI>22$ vs. $CDAI\leq 22$ ($p<0.05$).

Conclusions: These interim findings confirm the known groups' validity of PROMIS measures according to CDAI

disease category. Follow up assessments after GLM and IFX treatment will provide important information concerning responsiveness of these measures.

31. Reading the future: Predicting who will benefit from Bunion surgery

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Objective: A previous study suggested pre-operative PROMIS physical function (PF), pain interference (PI) and depression scores could predict post-operative outcomes in foot and ankle surgery. However, specific conditions were not considered separately. The purpose of this study was to evaluate the validity of applying a published comprehensive pre-surgical PROMIS profile to patients undergoing bunionectomy surgery.

Methods: PROMIS scores were prospectively collected in a specialty foot and ankle clinic. 42 patients with minimum two-month follow-up following bunionectomy surgery were included. Using pre-operative scores and scores at the last follow-up visit, minimally clinically important differences (MCID), receiver operating characteristic (ROC) curves, and area under the curve (AUC) were obtained to determine if pre-operative PROMIS scores predicted achieving MCID with 95% specificity or failing to achieve a MCID with 95% sensitivity. New cut-off values were compared to the previous study.

Results: The AUC for PF ($p=0.01$) and depression ($p=0.03$) were significant. However, PI AUC was not significant ($p=0.14$). The PF cut-off for exceeding MCID was 39.6 and 50.2 for failing to achieve MCID. The depression cut-off for exceeding MCID was 39.4 and 58.1 for failing to achieve MCID. Patients below the 50.2 threshold had greater improvements on PF (2.3 95% CI 0.5 to 4.3) and PI (-3.8 95% CI -6.9 to -0.7) but not depression. Patients above the 50.2 cut off were significantly worse on PF (-7.3 95% CI -12.0 to -2.7) and were statistically unchanged on PI and depression.

Conclusions: Bunionectomy-specific cut-off scores were one standard deviation higher for PF (>50.2 versus previous study >42) and similar for Depression (<39.4 versus previous study <41.5) compared to all foot and ankle surgeries. Patients meeting the new cut-off experienced better outcomes; patients not meeting the cut-off were significantly worse. This study suggests a significant clinical impact of using PROMIS scores for pre-surgical decisions.

32. Update from the Australian PROMIS Users' Group

Rebecca Mercieca-Bebber^{1,2}, Melissa Tinsley³, Brendan Mulhern⁴, Karl Bagraith⁵, Madeleine King^{1,2}, Philip Batterham⁶ on behalf of the Australian PROMIS Users Group

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Objective: The Australian PROMIS Users' Group was formed in 2012 as a local forum for researchers and clinician using PROMIS measures to network, collaborate and share findings. The Group currently has 20 active members. Group activities have included training workshops, colloquia, and e-newsletters. This presentation aims to provide an update on current activities.

Methods: Australian PROMIS User's Group members were invited to provide updates.

Results: NSW Health is responding to challenges associated with the growing number of Australians with chronic/complex health conditions in a \$180 million investment to transform the NSW healthcare system. New, value-based, innovative models of integrated care aim to streamline healthcare delivery, reduce costs and improve patient outcomes. Following pilot work that demonstrated the feasibility and acceptability of using patient-reported measures of experiences and outcomes, the NSW Agency for Clinical Innovation will use PROMIS-29 to assess patient outcomes in the integrated care strategy. Fifty services across NSW (>1000 patients) are currently involved. To our knowledge, this project represents the most significant application of PROMIS measures in Australia. Dr. Mulhern and colleagues are using the PROMIS-29 in an online Australian general population ($n=400$) and patient sample ($n=397$) to compare the psychometric performance PROMIS with other widely-used HRQOL measures including the EQ-5D and SF-36, initially using Rasch techniques, and possibly using other IRT-based methods in the future. Dr Bagraith is routinely using the PROMIS Global Health measure in chronic pain clinics in QLD and is working on analyses to provide further evidence of the convergent, divergent and discriminant validity of the measure in chronic pain. Dr Batterham and colleagues recently published a study demonstrating the psychometric validity of the PROMIS depression, anxiety, and anger item banks in a

large Australian population-based sample (n=3175).

Conclusions: Australian researchers, particularly along the east-coast, are using PROMIS measures in research and clinical settings.

33. Variation in Interpretation of Fatigue Across Neuro-QoL - Fatigue - Version 1.0 Translations

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Objectives: To explore the interpretation of *fatigue* across translations of the Neuro- QoL - Fatigue - V1.0, adapted from PROMIS item bank questions. Historically, translation projects have indicated that while the term is well-understood, some variation in interpretation exists. Because *fatigue* assessment can measure impact on physical, mental, and social domains, the variations of interpretation across languages and disease sufferers should be considered.

Methods: Back translations of the Neuro-QoL - Fatigue - V 1.0 in 9 languages were analyzed to assess the synonyms provided for *fatigue*. Translated questionnaires underwent cognitive debriefing (CD) with 5 subjects per language. Subjects paraphrased *fatigue* and were asked to differentiate it from *tired* and *exhausted*. Linguists were sent a follow-up questionnaire asking them to define *fatigue* in a variety of contexts.

Results: CD data showed variation in *fatigue* interpretation, though no one misunderstood the term. Out of 45 subjects, 7 classified *fatigue* as “chronic tiredness,” while 16 considered *fatigue* to be “extreme tiredness.” Five found *fatigue* to be indistinguishable from *tired*, and another 4 felt it was unclear whether *fatigue* was physical or mental. Thirteen linguists responded to the follow-up questionnaire, and reported no issues translating *fatigue*, but challenges finding distinct terminology when *tired* and *exhausted* appear within the same questionnaire.

Conclusions: While translation of *fatigue* for the Neuro-QoL and the PROMIS item banks does not present significant difficulty, its interpretation may vary within and across languages. Results show that some respondents questioned whether it refers to mental or physical *fatigue*, and a number of respondents reported that *fatigue* and *tired* are not clearly distinguished. Due to these findings, it is recommended that linguists receive additional guidance on the conceptual domains that underpin fatigue questions within the item definitions.

34. Impact of Fibromyalgia (FMS) on PROMIS t-scores in patients with rheumatoid arthritis (RA).

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Objective: Compare pain, physical function and depression scores as assessed by PROMIS in patients with RA and FMS and assess the effect of coexisting fibromyalgia on these scores in RA patients.

Methods: This was a single center retrospective assessment of prospectively collected PROMIS data obtained as a standard of care on all RA and FMS patients between January 1st and April 30th, 2016 at an academic health center RA clinic. The mean PROMIS scores were compared between patients with RA, FMS and RA with overlapping FMS.

Results: A total 169 RA patients, 17 patients with FMS and 30 patients with both RA and FMS with complete PROMIS scores were identified. The mean patient ages (years) for RA (56.7+/- 14.9), FMS (52.2 +/- 6.2) and both conditions (55.7 +/- 9.4) were similar. A larger proportion of females were in the FMS (16/17; 94.1%) and those with both RA and FMS (28/30; 93.3%) compared with the RA only cohort (126 /169; 74.6%). The scores for pain (63.6+/- 6.5) and depression (55.4 +/- 7.9) were notably higher in patients with FMS compared with RA patients (54.9+/- 8.3) and 46.7 +/- 10) respectively. The mean score for physical function on the other hand was notably lower in FMS patients (38.5+/- 7.6) compared to RA patients (44.6+/- 8.9). Interestingly patients with RA with coexisting FMS had scores similar to those with FMS only: pain (63.5 +/- 5.9), depression (55.1+/- 9.8) and physical function (37.5 +/- 5.5).

Conclusions: Coexistence of FMS in patients with RA can negatively impact PROMIS t-scores for pain, depression and physical function. These results suggest that although patients with RA have a worse quality of life as assessed by PROMIS than the average US population (t-score =50) patients with FMS or FMS and RA have worse PROMIS scores than RA patients.

35. Accuracy of the PROMIS-57 depression and anxiety scales in kidney transplant recipients

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Objective: Depression and anxiety are frequent among kidney transplant recipients (KTRs). Patient reported outcome measures are used to assess distress but concerns remain about measurement precision and questionnaire burden. We evaluate the accuracy of the Patient Reported Outcomes Measurement System (PROMIS-57 and -29 item) depression and anxiety domains among KTRs.

Methods: Participants of this cross-sectional, convenience sample of stable KTRs completed the PROMIS-57 (includes PROMIS-29), GAD-7 and PHQ-9 questionnaires. Raw scores of legacy tools were converted to PROMIS T-scores using PROsetta Stone© crosswalk files. Pearson correlations were conducted between legacy scores, calculated PROMIS (from legacy scores), and reported PROMIS-57 scores. The cut off score of ³10 on GAD-7 or PHQ-9 legacy scales were used to indicate clinically significant depression or anxiety, respectively. The corresponding cut off scores on the reported PROMIS-57 and -29 scales were used to identify depression and anxiety. We calculated Cohens Kappa values to assess the degree of agreement between legacy instruments and respective PROMIS-57 and -29 domains to assign patients to “depression” and “anxiety” categories.

Results: Our sample included 101 KTRs (mean (±SD) age was 49 (±16) years, 50% male, 59% white). Based on legacy instruments, 7% had anxiety and 11% had depression. Calculated PROMIS anxiety scores showed strong correlations with reported PROMIS-57 ($r=0.77$, $p<0.001$), and PROMIS-29 ($r=0.76$, $p<0.001$) anxiety scores. Calculated PROMIS depression scores showed strong correlations with reported PROMIS-57 ($r=0.72$, $p<0.001$), and PROMIS-29 ($r=0.68$, $p<0.001$) depression scores. The Kappa values indicated moderate agreement between GAD-7 categorization of anxiety versus PROMIS-57 ($K=0.55$) and PROMIS -29 ($K=0.56$). Similarly, there was moderate agreement between PHQ-9 classification of depression versus PROMIS-57 ($K=0.45$) and PROMIS -29

($K=0.52$).

Conclusions: The PROMIS-57 and -29 depression and anxiety domains are valid self-report tools to assess depressive and anxiety symptoms. Furthermore, the shorter questionnaire seems to be a good alternative to reduce questionnaire burden.

36. Validation of the PROMIS-57 profile questionnaire in kidney transplant recipients

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Objective: The Patient Reported Outcomes Measurement Information System (PROMIS) aims to address the lack of generalizable and universal measure of patient reported outcomes to assess many health-related quality of life domains. It has undergone extensive psychometric testing for validity and reliability but it has not been tested among patients with chronic kidney disease. Here, we validate the PROMIS-57, questionnaire among kidney transplant recipients.

Methods: A cross-sectional, convenience sample of stable kidney transplant recipients was recruited. Each participant completed the PROMIS-57, a 57-question instrument that measures 7 domains – physical function, anxiety, depression, fatigue, pain, sleep disturbance, and social functioning – alongside validated legacy questionnaires (Patient Health Questionnaire (PHQ9), General Anxiety Disorder (GAD7), and Kidney Disease Quality of Life (KDQoL-36)). Structural validity of PROMIS-57 was assessed using a principal-components factor analysis. Construct validity was assessed with known group comparisons. Internal consistency was assessed with Cronbach's α and convergent validity was assessed through Spearman's Rho.

Results: Mean (±SD) age of the 102 participants was 52 (±15), 50% were male, and 58% Caucasian. Principal component analysis confirmed the proposed seven factors. Internal consistency of each domain was high (Cronbach's $\alpha>0.90$ for each). PROMIS anxiety demonstrated strong correlation with GAD7 ($\rho=0.754$, 95%CI: 0.647-0.754). PROMIS depression demonstrated strong correlation with PHQ9 ($\rho=0.639$, 95%CI: 0.495-0.749). PROMIS physical function and pain demonstrated strong correlation with the KDQoL-36 physical composite score ($\rho=0.840$, 95%CI: 0.771-0.889; $\rho=-0.683$, 95%CI: -0.775- -0.586). Known

group comparisons also supported validity.

Conclusions: Our results confirmed that the PROMIS-57 profile is a highly reliable and valid instrument among kidney transplant recipients. We propose it is a valuable tool to assess domains of the disease experience that are relevant and important for patients. Further studies are needed to examine the validity and reliability of computer adaptive testing and shorter versions of the PROMIS-57 profile to reduce questionnaire burden.

37. **An Overview of The Pediatric Patient Reported Outcomes in Chronic Diseases (PEPR) Consortium**

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Objective: To describe the structure, purpose and progress of The Pediatric Patient Reported Outcomes in Chronic Diseases (PEPR) Consortium.

Methods: The Consortium was established in 2015 and is comprised of four Centers of Excellence (CoE). Each CoE is responsible for managing individual research projects across 11 chronic disease cohorts. Both qualitative and quantitative methods are being used to develop new pediatric patient-reported outcome (PRO) measures, create chronic condition specific short forms and clinically validate existing PROMIS® pediatric PRO measures using longitudinal data. The PEPR Consortium's Infrastructure and Opportunities Fund (IOF) is designed to provide support for additional projects undertaken by PEPR investigators to advance the overall goals of PEPR.

Results: The Consortium is evaluating 24 new or existing pediatric PRO measures in 11 chronic condition cohorts including atopic dermatitis, asthma, cancer (active and survivors), chronic kidney disease, Crohn's disease, type 1 diabetes, juvenile idiopathic arthritis, lupus, sickle cell disease and ulcerative colitis. As of March 2017, the consortium has enrolled approximately 1,700 of 4,800 targeted children and parents and has approved two IOF-funded projects: 1) Utilizing Geographic Information System (GIS) analysis to assess area-level effects on the lived experience of chronic disease among children and 2) Evaluate Association between Activity and PROMIS Pediatric Measures in Children with Chronic Conditions.

Conclusions: The four CoEs are collaborating through a variety of individual research projects and shared efforts to achieve the three overall goals of the PEPR Funding

Opportunity Announcement: 1) To advance pediatric PRO adoption in clinical practice and research, 2) To develop reliable and valid clinical tools for pediatric PROs to improve the assessment of outcomes in clinical trials and personalize ongoing care of children with chronic disease, and 3) To examine the impact of environmental stressors on children's health including their symptoms and quality of life.

38. **A comparative analysis of measurement properties of fatigue measures in systematic lupus erythematosus (SLE) using an item-response-theory (IRT)-based common metric.**

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Objective: Fatigue is one of the most commonly reported symptoms of systemic lupus erythematosus (SLE) with debilitating effects on patients' daily life. The primary objective of this study is to compare the psychometric properties of four measures of fatigue in SLE – the LUPUSQOL fatigue domain, the SF-36 vitality domain, the FACIT-F and PROMIS-fatigue. A secondary objective is to develop a common metric based on item response theory, to facilitate score conversion of instruments to PROMIS scores.

Methods: This is a post-hoc analysis of pooled baseline data from the 24-week ADDRESS Phase IIb study of Atacicept in patients with SLE. Included patients had active disease (SLEDAI-2K score ≥ 6), autoantibody-positive SLE and were being treated using standard-of-care.

Psychometric testing will include assessment of item descriptive statistics, internal consistency, known-groups validity and convergence validity. Further, confirmatory factor analysis will be performed to assess whether the items from all measures can be combined into a single scale (i.e. assumption of unidimensionality). Finally, single-sample linking design will be employed for development of common metric scale based on item response theory (IRT). The PROMIS fatigue items will be used as anchors. Standard IRT analyses (e.g. testing of individual item fit and scale-to-sample targeting) will be performed to compare measures.

Results: In total 306, patients (female = 91.5%) were randomized in ADDRESS II. The mean age of the patients was 39 +/- 11.9 years. Fifty-two percent (n = 158) of the patients had SLEDAI-2K of ≥ 10 .

Conclusions: This study will elucidate on marginal differences in the measurement attributes across fatigue measures, support PRO endpoint design in clinical trials. Findings from this study may potentially identify current measurement gaps/needs not addressed by current

measures.

39. PROMIS depression measures versus legacy PROMs and structured diagnostic interview for depression in cancer patients

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Objective: Depression is an important aspect of emotional distress in cancer, because it is common, treatable and has serious negative effects if left untreated. Screening in clinic is therefore recommended. Our objective was to assess the concurrent validity of the Patient Reported Outcomes Measurement Information System (PROMIS) depression measures relative to legacy measures and criterion validity against a structured diagnostic interview for depression in an oncology sample.

Methods: 132 oncology/haematology outpatients completed the PROMIS Depression Computer Adaptive Test (PROMIS-D-CAT) and PROMIS Depression Short Form (PROMIS-D-SF) along with seven legacy measures: Beck Depression Inventory (BDI); Centre for Epidemiological Studies-Depression (CES-D); Depression, Anxiety and Stress Scale; Hospital Anxiety and Depression Scale; Patient Health Questionnaire; Distress Thermometer and PSYCH-6. Correlations, area under the curve (AUC) and diagnostic accuracy statistics were calculated with Structured Clinical Interview as the gold standard.

Results: Both PROMIS measures correlated with all legacy measures at $p < .001$ ($\rho = .589-.810$) and all AUCs ($> .800$) were comparable. At the cut-off point for "mild" depression, PROMIS measures had sensitivity $> .80$ (same as 4/7 legacy measures) and negative predictive value in excess of $> 90\%$ (as did all other measures). At a "moderate" level the PROMIS measures had specificity $> .90$ (as did 3/7 legacy measures) and positive

predictive value $\geq .50$ (similar to 3/7 legacy measures).

Conclusions: The concurrent and criterion validity of the PROMIS depression measures in cancer populations was confirmed, although further research is needed to confirm the optimal cut-off points. The PROMIS measures had advantages over the BDI-II and CES-D in terms of brevity but did not offer any advance in terms of diagnostic accuracy, reduced response burden or cost over other legacy measures of depression in oncology patients.

40. Measuring Patient-Reported Outcomes (PROs) in a High Volume Trauma Clinic in Pelvis and Acetabular Fracture Patients Using PROMIS® CAT: A Preliminary Study

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Objective: To demonstrate the feasibility and patient experience and satisfaction when compared to current standard of care with measuring PROs in pelvis and acetabular fracture patients utilizing PROMIS CATs Mobility (PM) and Pain Interference (PI) in a high volume trauma clinic.

Methods: Patients with pelvis and acetabular fractures returning to clinic are administered the PROMIS PM and PI and the current standard PRO, Short Musculoskeletal Function Assessment (SMFA) at 2-week, 6-week, 3-month, 6-month and 1 year follow-up visits. Patients were provided the SMFA when roomed and were asked to complete while waiting for the surgeon. The PROMIS PROs were administered by the surgeon on a handheld computer device and the surgeon reviewed the scores with the patient immediately after. Subjective level of usefulness, ease of use, and preference between the SMFA and PROMIS are measured.

Results: Eleven participants (4 females and 7 males) with an average age of 50.08 (SD=18.5) filled out the PROMIS PROs. The mean PROMIS t-score for mobility in this population was 38.99 (SD=11.30) and for pain interference was 56.75 (SD=6.85). The completion date was on average 78 days post-operatively (median 48, SD=62). 6 of 9 participants said the PROMIS measures were either somewhat or very useful to complete compared to 3 of 9 who stated that the SMFA was somewhat useful to complete. The majority of participants (8/9) stated that the PROMIS was easier and would prefer to complete it as opposed to the SMFA at their next visit.

Conclusions: We present preliminary data suggesting PROMIS CAT PROs can be successfully administered in a

busy trauma clinic. Patients find them easier to complete and preferable compared to SMFA. On average pelvic and acetabular patients show significant deviance from the general population in terms of mobility and less so for pain interference in the early post-operative period.

41. Utilization of PROMIS in Board Certification: American Board of Orthopaedic Surgery (ABOS) Patient Reported Outcomes Program

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Objective: In 2017, the ABOS began utilizing Patient Reported Outcomes (PRO) as an additional tool to evaluate patient outcomes in the case collection period leading to the ABOS Board Certification Oral Examination. PROMIS data will assist in the ABOS Board Certification process and contribute to a surgeon's continuous practice improvement.

Methods: Candidates for the 2018 ABOS Part II Oral Examination enter a 6 month surgical case list into the ABOS Scribe Case List System – that Case List forms the basis for the examination. During that process, candidates are required to enter patient email addresses for surgeries performed during the months of May and June 2017. Patients are given the opportunity to opt out of the program. The ABOS contacts the patient via email, preoperatively and at 6 and 12 months post- operatively. That email provides the patient an electronic link with the PROMIS Physical Function assessment. PROMIS physical function scores will be reviewed as part of the certification process to determine a candidate's eligibility to sit for the Part II Oral Examination. The candidate will also receive the results obtained from his/her patients to assist with practice improvement efforts.

Results: For the month of May 2017, 699 of 732 candidates enrolled at least one patient. Of 8864 emails to patients, 4352 completed the pre-operative PROMIS physical function survey (49.1%). During that same time period, 8 of 732 candidates had all patients opt out of providing an email.

Conclusions: The potential for hearing the "voice of the patient" in the certification process with use of CAT enabled PROMIS scales has been recognized by the ABOS. We will report our early findings related to response rates and discuss our vision for incorporating PROMIS measures in board certification process.

42. PRO Provider Adoption Survey Development

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Objective: To describe the development process of the *PRO Provider Adoption Survey*

Methods: Using standardized methodology of construction for survey research, the *PRO Provider Adoption Survey* was developed to obtain feedback to provide direction for further improvements to the collection, dissemination and analysis of PRO data. The process involved accessing open ended provider forums, constructing questions, reviewing content with content experts and implementing the survey. Initial questions were chosen by a team experienced with clinical collection of PROs. A draft was then shared with 12 providers of various specialties who are interested in clinical use of PROs and with experts on PROMIS for input. Modifications were made based on this feedback. The survey addresses four areas of interest based on the Unified Theory of Acceptance and Use of Technology (UTAUT) model: PROs and the patient clinic visit, the use of PRO data for research and analysis, the motivating factors for PRO use in clinical settings and provider burnout.

Results: After construction, the PRO Provider Adoption Survey was sent as a link to providers in the Departments of Orthopaedics (N=80) and Cardiology (N=64) via email and returned anonymously using REDCap. 107 surveys were returned (74%). Analysis of the Orthopaedic responses shows the two most common uses of PROs are for research (46%) and to review data for clinical decisions (37%). Only 24% of providers review data with patients.

Conclusions: Understanding clinician acceptance of PROs into the patient care arena provides critical information to assess and alter perceptions and needs for PROs to alter care for patients. This survey used standardized methodology to obtain that information. Knowing how providers want to use, view and analyze PRO data will allow for modifications to the system that will expand provider adoption and increase the utility of PRO use in a clinical setting.

43. PROMIS-29 Profile in the Longitudinal Research on Aging Drivers (LongROAD)

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Objective: To describe baseline health-related quality of life in a new prospective cohort study of older adult drivers with the aim of understanding the factors involved in keeping older adults driving safely.

Methods: Five study sites (California, Colorado, Maryland, Michigan and New York) recruited 2,990 older drivers (ages 65-79) and collected health measures both via self-report and performance-based, medications, vehicle inspection and driving data. Follow-up by phone at 1 and 3 years and another in-person at 2 years. This study will focus on the eight domains that the PROMIS-29v2 covers and will be summarized descriptively along with baseline characteristics of the LongROAD cohort, including: Emotional distress (anxiety and depression), fatigue, pain (interference and intensity), physical function, sleep disturbance and ability to participate in social roles and activities.

Results: Baseline dataset will be available before by October, 2107. Pain intensity will be added along with the full final cohort. The first domain in the table, Ability to Participate in Social Roles and Activities, is interpreted as a T-score of 60 is one SD better thus this preliminary cohort has almost one SD better more ability to participate.

Conclusions: This study will report the final baseline PROMIS-29 Profile v2.0 for this new older driver cohort. Future studies will look at the trajectories of PROMIS-29v2 when older adults stop driving by urban and rural status.

44. Outcomes Between the Depuy Sigma and Attune for Total Knee Arthroplasty; Does the Implant Matter?

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Objective: Newer implants for total knee arthroplasty (TKA) often gain market share at an increased cost with little clinical data supporting their benefit. We compared

outcomes after TKA using two different TKA implants: Depuy PFC Sigma and Attune.

Methods: Using a prospective data repository from an American academic tertiary medical center, we analyzed 2,116 TKAs (1,603 Sigma and 513 Attune) from 4/2011 – 7/2016. Outcomes included length of surgery, length of stay, discharge disposition, early reoperations (<90days), and patient-reported physical function (PCS, derived from PROMIS-10 or cross-walked Veterans RAND-12).

Preoperative adjusters included surgeon, bilateral, second unilateral, year, sex, age, tobacco use, Charlson Comorbidity Index, body mass index, PCS, and patient-reported mental function.

Results: No significant association was identified between the implant and length of surgery (Attune -2.87 minutes, 95% CI -6.70 to 0.96, P = 0.143). The implant was not associated with prolonged LOS (>3 days) (OR 0.80, 95% CI 0.45 to 1.42, P=0.864). There was no difference in discharge to rehabilitation facility between Attune vs. Sigma (OR 0.65, 95% CI 0.39 to 1.09). Reoperations within 90 days were 1.0% vs. 0.4% for Attune vs. Sigma cohorts, respectively (5/513 Attune, 7/1,603 Sigma, P=0.158); counts were too low for further analysis. There was no clinically significant difference after adjustment in absolute PCS improvement (Attune 0.12, 95% CI -1.23 to 1.47, P = 0.864).

Conclusions: The newer Attune implant showed no statistically significant difference in length of surgery, length of stay, discharge disposition, 90-day reoperation rates, or PCS improvement compared to the established PFC Sigma implant. Adoption of new technology and the cost of innovation compared to its value is a constant struggle in healthcare. Elevated prices of implants and the expenditure of marketing a new product should lead hospitals and systems to consider prospective outcomes and cost containment when adopting new technology.

45. Translation of the Concept of “Bothered” in PROMIS[®] Measures

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Objective: The concept of “bothered” is used often in English PRO’s to assess the extent to which patients feel physically and emotionally troubled, disturbed or distressed by symptoms, treatment or treatment side effects. Given the multidimensional nature of “bothered,” finding an equivalent term for translation is difficult, as in other languages there is a variety of words to choose from depending on the item’s intention. The objective of this study is to report on challenges and solutions when translating “bothered” in

PROMIS domains.

Methods: Items containing the concept of “bothered” were translated using an iterative process of forward, back-translation, expert review, harmonization across languages and cognitive interviewing. Interviews assessed the understandability, interpretation and appropriateness of the translations.

Qualitative analyses of participant comments determined the linguistic equivalence of each translation and provided insight into the relevance of the concept in each language.

Results: One of the examples of the varied interpretation of the term “bothered” across languages is presented from the linguistic validation of Fatigue item “How much were you bothered by your fatigue on average?”. Latvian participant comments indicated they interpreted “bothered” as how fatigue interfered with, inconvenienced, or caused difficulties in their everyday life. In Lithuanian “bothered” was perceived as “suffering.” Estonian participants reported that the item measures the “impact” of fatigue; and that fatigue is such an extreme tiredness, that of course people who experience it are bothered by it. Final translation solutions were discussed with PROMIS item bank developers to ensure that the interpretation of “bothered” was within acceptable parameters.

Conclusions: While the overlap between experience and impact is apparent, determining an acceptable range of variance in interpretation is necessary to best ensure conceptual equivalence across languages. When translating items containing the concept of “bothered,” it is essential to establish a precise definition which can be used to promote harmonization across all languages.

46. PROMIS: An Organizing Principle for a Registry?

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Objective: To investigate the value and feasibility of a registry organized around PROMIS reporting across multiple specialties.

Methods: The OBERD data collection and storage system is a worked example, on a much smaller scale, of how such a system could operate. A first approximation was obtained by extrapolating from this existing system.

Results: Over the last six years OBERD has collected comprehensive outcome data from over 2,000,000 patients. Approximately 5,000,000 separate forms have been stored, with response rates of 85% achieved. Scenarios studied include the following. (A) Maximum centralization: Prerequisites would involve a universal health identifier (it works in Europe and it works for computers); the provider obligation to submit a one-time registration of each patient, including list of PROMIS

forms; and a collection schedule. There would also be an ongoing obligation to provide ICD and CPT data. The central registry sets up sessions for patients to fill out the forms, stores the results, pushes results to provider (if desired); or provider may pull results when needed or use online analytical tools. If a patient has multiple providers, collection schedules can be merged, duplicate pollings eliminated, and appropriate results shared with all providers. Sharing just the PROMs could alert a patient’s orthopedist to a cardiac event that would otherwise confound the efforts of the orthopedist to understand patient improvement. (B):The physician maintains his own data to dump a portion to the central registry to assist both within-specialty and cross-specialty research and treatment, as in (A).(C): Public health entities can participate by using the same concept of collecting data from individuals in addressing some of the current enemies of healthy cities, such as gun violence, unhealthy environments, and limited healthcare facilities.

Conclusions: It is estimated that a basic registry designed along these lines might operate for about \$5.00/patient/year.

47. PROMIS: A Case-Study in Diffusion of Innovation

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Objective: To elucidate the rate of acceptance of PROMIS by a broad cross- section of users of Patient Reported Outcome instruments. In view of its several novel elements, PROMIS adoption may be regarded as a *diffusion of innovation*.

Methods: Control of three confounding issues—attitude of physicians toward PROMs in general, resources of the practice environment, and equal access to alternatives—was achieved by using outcome statistics from the OBERD data collection system. This online system has included a full implementation of PROMIS since 2014, along with about a hundred traditional instruments that had been previously available. Data is collected for 1200 surgeons and 500 other providers, although a possible limitation of the study is that almost all are orthopedic specialists.

Results: The first six months of PROMIS availability were a textbook case of the “knowledge gathering” phase in the Rogers diffusion model. The subsequent 36 months begin the adoption phase: PROMIS sessions numbered 166,000; distinct patients using PROMIS numbered 124,072. CAT sessions were 17% of PROMIS

use in the first half-year, 32% in the second half-year, and stable at 38% in the two years since. The Global-10 accounted for most of the non-CAT use. As a percentage of total forms administered by OBERD, PROMIS use was <1% in the first half-year, 2% in the second half-year, 8% in the third half-year, and 9% thereafter. In terms of patients receiving one or more PROMIS forms the corresponding percentages were <1%, 3% 12%, and currently 14%.

Conclusions: These figures place PROMIS among the five most popular of the 50 or so instruments which have significant use in OBERD. Despite strong interest in PROMIS CAT the short forms have gained even more traction. The collected data have permitted analysis in terms of Rogers- Bass models for diffusion of innovation.

48. The Validity of PROMIS Instruments Among Individuals with Adult Spinal Deformity

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Objective: To determine if baseline PROMIS Computer Adaptive Testing (CAT) measures of Pain Interference (PI), Physical Function (PF) and Depression (D) scores correlate with legacy measures in adult spinal deformity.

Methods: 3 baseline PROMIS scores (PI, PF, D), were compared to 3 legacy PRO measures: SRS-22, ODI, and VAS, and to 2 common radiographic parameters of deformity: max coronal cobb and SVA. All patients were >18 yo and identified from a single-institution dataset. Only those with a diagnosis of ASD (adult degenerative scoliosis, adult idiopathic scoliosis, kyphosis, post-traumatic, iatrogenic deformities, and isthmic spondylolisthesis) were included. The association between PROMIS scores and legacy measures were estimated using Spearman's rank correlation coefficients.

Floor/ceiling effects of these measures were evaluated.

Results: 74 patients were analyzed. Mean age was 54.1 years, and 74.7% were women. Mean ODI scores were 45.1, SRS Pain=2.49, Function=2.71, and Subscore=2.83. PROMIS means included, PI=55.6, PF=33.9, D=53.03. PROMIS PI and PF domains had the strongest association with ODI, 0.716 and 0.783 respectively. With regard to PROMIS PI, SRS-22 Function and Subscore correlated well (0.689 and 0.681). PROMIS PF scores also had strong correlations with SRS Function and Subscore (0.696 and 0.610). PROMIS D scores correlated strongest with SRS Mental health (0.790) and secondarily with SRS subscore (0.689). Radiographic parameters including maximum coronal cobb angle and Sagittal Vertical Axis (SVA) did not

correlate with PROMIS domains (all<0.4).

Conclusions: In patients with ASD the PROMIS domains performed well with appropriately matched legacy PROs. The SRS22 subscore correlated well with all 3 PROMIS domains. Given the performance of the PROMIS measures and their benefits over traditional PRO collection, surgeons should consider adoption.

49. Cross-Linking Legacy Questionnaires with PROMIS® Measures in Parkinson Disease Patients

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Objective: To identify common anchor items between legacy questionnaires and PROMIS scales to enable cross-linkage and longitudinal use of data in a large clinical database.

Methods: The University of Maryland Parkinson Disease (PD) and Movement Disorders Center maintains a research database with data on Activities of Daily Living (ADLs), anxiety, depression, and fatigue. These constructs were previously measured with the Older Americans Resource and Services (OARS) ADL scale, Brief Symptom Inventory-18 (BSI-18), and the Fatigue Severity Scale (FSS). Over the last two years, the Center discontinued these legacy questionnaires (OARS, BSI-18, FSS) and adopted PROMIS scales for these constructs. To continue use of all available data from the past 15 years for longitudinal analysis, legacy measures needed to be cross-linked to PROMIS scales. During legacy measure phase-out, PD patients were administered both the legacy questionnaires and PROMIS scales. Expert raters selected anchors—items from the legacy measures and PROMIS scales that were similar to one another. Factor analysis and Item Response Theory 2-parameter logistic models were estimated using fixed model-estimated factor loadings and thresholds on four latent constructs (disability, anxiety, depression, fatigue). Factor loadings were externally scaled to the PROMIS normative sample using publicly available information, and differential item functioning was tested.

Results: Data were available from 539 visits on 426 patients. Patients were predominantly male (61%) and white (90 %) with an average age of 68.5±10.5, MoCA score of 24.4±5.1, and Hoehn & Yahr stage of 2.8±1.1. Factor loadings on the four latent constructs were high, confirming the measurement model between PROMIS and the legacy

questionnaires. Additionally, there was no differential item functioning by legacy versus PROMIS.

Conclusion: In PD, anchor items between the legacy questionnaires and PROMIS scales were successfully identified and cross-linked. This methodology can be replicated in different settings when changing from legacy scales to PROMIS.

50. Validation of the PROMIS-29 in Elective Hip and Knee Arthroplasty Patients

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Objective: To evaluate the validity of PROMIS-29 v2.0 in osteoarthritis patients undergoing elective total hip (THA) and knee (TKA) arthroplasty by comparing the PROMIS-29 with legacy instruments.

Methods: Patients ≥65yo scheduled for primary THA/TKA completed the following pre-operatively: PROMIS-29, Short Form-36-derived Short Form-12 (SF-12), Depression Screening (CES-D 10), Lubben Social Network Scale (LSNS-18), Katz Scale of Independence in Daily Living (ADL), and Hip/Knee Injury and Osteoarthritis Outcome Score (HOOS/KOOS respectively). Telephone follow-up was used to complete missed questions. PROMIS-29 domain t-scores and Pain Intensity score were compared with legacy instruments using Spearman correlations.

Results: 464 patients (187 THA, 277 TKA) were enrolled (8/2015 to 4/2017). Mean PROMIS-29 t-scores: Physical Function 38.9, Pain Interference 59.7, Anxiety 48.9, Depression 45.8, Fatigue 47.9, Sleep Disturbance 49.2, Social Roles 49.7. Among all patients, PROMIS-29 Depression, Anxiety, and Fatigue showed strong correlations with CES-D ($r=0.61$ to 0.71 ; p -values <0.001) and SF-12 Mental Component Score ($r=-0.56$ to -0.68 ; p -values <0.001). PROMIS-29 Physical Function, Pain Interference, Pain Intensity, and Social Roles correlated strongly with SF-12 Physical Component Score ($r=-0.53$ to -0.69 ; p -values <0.001). PROMIS-29 Pain Intensity correlated strongly with HOOS/KOOS Pain and Daily Living ($r=-0.62$ to -0.73 ; p -values <0.001). For THA, PROMIS-29 Physical Function correlated with all 5 HOOS domains ($r=0.57$ to 0.69 ; p -values <0.001). However, for TKA, PROMIS-29 Physical Function only correlated with KOOS Daily Living ($r=0.56$; p -value <0.001). Unlike in THA, in TKA no PROMIS-29 domain correlated with KOOS Symptoms. No PROMIS-29 domain correlated with Katz ADL or LSNS-18.

Conclusions: Arthroplasty patients had worse than average PROMIS-29 Pain Interference and Physical Function t-

scores, providing face validity. PROMIS-29 domains demonstrated excellent convergent validity with generic mental and physical health measures. However, PROMIS-29 correlations with disease-specific instruments differed between THA and TKA patients; TKA patients' pre-operative knee-specific symptoms appear to be poorly captured by PROMIS-29. Further research is needed to elucidate these differences.

51. Using PROMIS-29 to Identify Frailty and Predict Adverse Events in Total Joint Arthroplasty (TJA) Patients

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Objective: Whether PROMIS-29 domains are worse among frail TJA subjects, and if PROMIS-29 identifies TJA at risk of adverse events or being dissatisfied with surgery, is unknown.

Methods: Community-dwelling patients ≥65yo scheduled for elective total knee (TKA) or hip (THA) arthroplasty were recruited from a musculoskeletal specialty hospital. Patients received a pre-operative medical consult and were approved for surgery. Pre-operative frailty was defined as having at least 3/7 characteristics derived from two validated frailty criteria. PROMIS-29 was administered pre-operatively. Adverse events were obtained from medical records and by phone. Patients self-reported satisfaction at 1 year.

Results: 464 subjects: 73.0 years (range 65-94), 94.6% Caucasian, 61.4% female, 59.7% TKA, 40.3% THA. 8.3% were frail. Frail subjects had significantly worse median PROMIS-29 t-scores for Physical Function, Anxiety, Depression, Fatigue, Social Roles, Pain Interference, and Pain Intensity, (p -values <0.017). All differences were clinically meaningful, (> 5 points). Of 373 patients with 30-day follow-up, 180 (48.3%) had 263 adverse events and 35 (9.4%) had 51 serious adverse events. Among TKA and THA combined, worse PROMIS-29 Anxiety was an independent predictor of ≥ 1 adverse events (OR=1.05; 95% CI 1.02-1.08) after controlling for gender, age, pre-operative anemia, and which joint was replaced. Similar results were found for TKA (OR=1.04; 95% CI 1.003-1.08). No PROMIS-29 domain predicted adverse events in THA or severe adverse events in any group. Worse pre-operative PROMIS-29 Anxiety correlated with a lower likelihood of 1-year self-reported satisfaction (OR 0.86; 95% CI 0.74-0.98).

Conclusions: Multiple PROMIS-29 domains were worse in

frail patients scheduled for TJA. PROMIS-29 may be a simple method of identifying frailty in this patient population. Worse PROMIS-29 Anxiety may also help identify patients at risk of 30-day adverse events and worse 1-year satisfaction. Further work needs to be done to investigate the impact of frailty on outcomes in TJA.

52. PROMIS in Hematopoietic cell transplantation (HCT)

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Objectives: Hematopoietic cell transplantation (HCT) is a curative therapy for patients with malignancies and other blood disorders, however there is a burden of late-effects which can impact long-term quality of life (QOL). Although patient-reported outcomes (PRO) in this population are well-characterized using established measures; there is little experience administering PROMIS measures. Our aim was to investigate the correlation between the PROMIS Profile-29 and Short Form 36 (SF36) measures in HCT survivors.

Methods: 4,446 adult HCT survivors from Fred Hutchinson Cancer Research Center were mailed QOL measures including the PROMIS Profile-29 and SF36 as part of an annual survey of HCT survivors.

Results: Both the SF36 and PROMIS measures were available for 1,634 (503 autologous, 1,131 allogeneic) HCT recipients, and an additional 382 (119 autologous, 263 allogeneic) had one set of measures; overall response rate 46%. The median time post-transplant for allogeneic and autologous recipients was 12.0 (range, 0.4-44.1) and 6.1 (range 0.4-30.1) years, respectively. Compared to the general population norms, HCT recipients had somewhat lower physical scores but somewhat higher mental scores. Five domains appear to measure similar constructs within the SF36 and Profile-29: physical function, pain, vitality/fatigue and mental health/anxiety and depression.

Mean differences between measures in these domain scores were not clinically meaningful. Strong correlations were seen between similar constructs (Pearson correlation coefficient in allogeneic (0.87, 0.82, 0.82, 0.74 and 0.78, respectively) and autologous (0.83, 0.82, 0.81, 0.71 and 0.73 respectively) HCT recipients. Using the functionality provided in PROsetta stone, we found statistically significant correlations (0.71-0.86) between these domain scores mapped from the SF36 measures and scores from the PROMIS measures, as well as the SF36 Mental Health and PROMIS Anxiety and Depression

Conclusions: PROMIS measures appear valid and generalizable to HCT survivors, and may provide benefits compared to SF36 in terms of delivery, logistics and cost.

53. Does PROMIS® Reflect Hearing Status Enough to Supplant a Hearing-Specific Quality of Life Instrument?

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Objective: characterize both disease-specific (Inner EAR) and general (PROMIS) health status in patients who report hearing loss and to determine whether there are strong enough correlations between Inner EAR and PROMIS, such that the general instrument could supplant a disease-specific assessment.

Methods: Consecutive adult patients with a chief complaint of hearing loss completed the Inner EAR scale and the PROMIS instrument. Summary statistics, including means, percentiles, and measures of variance were calculated. The Spearman rho statistic was used to test the null hypothesis that there were no correlations between the Inner EAR composite score or global score and the various PROMIS scores.

Results: The mean Inner EAR composite score was 35.6 (SD 23.1), while the global item had a mean score of 4.8 (SD 2.4). Mean PROMIS-10 scores were 16.0 (SD 2.8) for physical health and 15.3 (SD 2.9) for mental health. The global item and social item had mean scores of 3.6 (SD 1.0) and 3.8 (SD 0.9) respectively. Inner EAR composite scores were significantly correlated with the PROMIS mental health summary scores and the PROMIS social item score. Mental health scores were moderately correlated with a Spearman rho of 0.3 (p=0.0066). The social item score was more strongly correlated with a Spearman rho of 0.4 (p=0.0005). The Inner EAR global item was moderately correlated with the PROMIS social item score (Spearman rho 0.3,

p=0.0118), while there was no significant correlation between the Inner EAR global item and the PROMIS physical health summary scores, mental health scores, or global item score.

Conclusions: The Inner EAR scale and PROMIS-10 have significant but weak to moderate correlations. A subset of PROMIS scores track with hearing health status, and may be representative.

54. Early PROMIS scores 6 weeks following total hip arthroplasty (THA) can identify patients who are unlikely to demonstrate improvement at greater than one year follow-up.

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Objective: The purpose of this study was to evaluate the use of PROMIS scores at 6 weeks following THA to identify patients who are unlikely to have improved at greater than one-year follow-up.

Methods: Prospective PROMIS physical function (PF), pain interference (PI), and depression (D) scores were collected for all orthopaedic patient clinic visits at a multi-surgeon tertiary total joints clinic from February 2015 to May 2017. Patients were identified by CPT code. Patients were selected with complete data as well as follow-up at both 31-50 days and >365 days. The change in PROMIS scores at 31-50 days were compared to baseline scores and assigned as delta scores. The MCID for each PROMIS domain at >365 days was calculated using the distribution method. Receiver operating characteristic (ROC) curves were created using the change in PROMIS scores (delta) from baseline to 31-50 days to predict the likelihood of achieving MCID at >365 days. A 70-80% specificity cut-off for failing to achieve MCID was selected for each domain.

Results: A total of 128 patients were identified. The mean age of the cohort was 64.19 years with 62.5% female. The mean follow up periods were 43 days (32-50) and 483 days (365-756) The MCIDs were: 4.10 PF, -4.62 PI, -4.06 D. The Area Under the Curve (AUC) for the ROC curves were: 0.691 PF, 0.773 PI, 0.803 D. A delta PF of less than -2.66 corresponded to a 71% risk of failing to meet MCID and represented 14.8-15.6% of the cohort. A delta PI of greater than +0.05 corresponded to a 78% risk of failing to meet MCID and represented 9.4-10.2% of the cohort. A delta D of greater than +1.74 corresponded to 79% risk of failing to meet MCID and represented 10.2-10.9% of the cohort.

Conclusions: PROMIS PF, PI, and D scores at 6 weeks following THA can identify patients who are at risk for failing

to achieve MCID at greater than 1 year. Identification of patients at this time point may allow for earlier or additional intervention that could potentially improve their final outcome.

55. Early PROMIS scores 6 weeks following total knee arthroplasty (TKA) can identify patients who are unlikely to demonstrate improvement at greater than one year follow-up.

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Objective: The purpose of this study was to evaluate the use of PROMIS scores at 6 weeks following TKA to identify patients who are unlikely to have improved at greater than one-year follow-up.

Methods: Prospective PROMIS physical function (PF), pain interference (PI), and depression (D) scores were collected for all orthopaedic patient clinic visits at a multi-surgeon tertiary total joints clinic from February 2015 to May 2017. Patients were identified by CPT code. Patients were selected with complete data as well as follow-up at both 31-50 days and >365 days. The change in PROMIS scores at 31-50 days were compared to baseline scores and assigned as delta scores. The MCID for each PROMIS domain at >365 days was calculated using the distribution method. Receiver operating characteristic (ROC) curves were created using the change in PROMIS scores (delta) from baseline to 31-50 days to predict the likelihood of achieving MCID at >365 days. A 70-80% specificity cut-off for failing to achieve MCID was selected for each domain.

Results: A total of 138 patients were identified. The mean age of the cohort was 66.3 years with 65.9% female. The mean follow up periods were 43 days (32-50) and 482 days (365-804) The MCIDs were: 3.31 PF, -4.12 PI, -4.00 D. The Area Under the Curve (AUC) for the ROC curves were: 0.603 PF, 0.663 PI, 0.754 D. A delta PF of less than -3.75 corresponded to a 75% risk of failing to meet MCID and represented 33.3-34.1% of the cohort. A delta PI of greater than +1.82 corresponded to a 75% risk of failing to meet MCID and represented 32.9-33.3% of the cohort. A delta D of greater than +0.12 corresponded to 82% risk of failing to meet MCID and represented 32.6-33.3% of the cohort.

Conclusions: PROMIS PF, PI, and D scores at 6 weeks following TKA can identify patients who are at risk for failing to achieve MCID at greater than 1 year. Identification of patients at this time point may allow for earlier or additional intervention that could potentially improve their final outcome.

56. PROMIS scores following total hip arthroplasty demonstrate continued improvement at greater than one year.

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Objective: The purpose of this analysis was to use PROMIS data to describe patient outcomes and recovery following total hip arthroplasty (THA) past 1-year follow-up.
Methods: Prospective PROMIS physical function (PF), pain interference (PI), and depression (D) scores were collected for all orthopaedic patient clinic visits at a multi- surgeon tertiary total joints clinic from February 2015 to May 2017. Patients who underwent primary THA were identified by CPT code. PROMIS scores of the cohort were analyzed preoperatively and at follow up of 10-30 days, 31-50 days, 160-200 days, and greater than 365 days. For each follow up the change in PROMIS scores from the preoperative baselines were determined. The minimal clinical important difference (MCID) was calculated for each PROMIS domain using the distributive method. The change in PROMIS scores and the percentage of patients who met MCID were compared between each sequential follow up to determine the point of maximal improvement.
Results: A total of 1149 patients with complete data were identified. The cohort was 57% female with a mean age of 63.18 years. The mean time of follow up for the >365 day group was 479 days (365-756). The calculated MCIDs were: 3.68 to 4.10 (PF), -4.06 to -4.99 (PI), and -4.06 to -4.61 (D). The mean change in PROMIS scores are shown as Table 1 and Figure 1. The percentage of patients who achieved MCID are shown as Table 2 and Figure 2. Table 1. Change in mean PROMIS scores for PF, PI, and D at various times of follow-up
Conclusions: PROMIS scores can be utilized to track outcomes following THA. This study establishes PROMIS MCID values and provides a benchmark for measuring outcomes with PROMIS following THA. It also demonstrates patients continue to make significant improvements up to at least one year following THA.

57. Psychometric Evaluation of the PROMIS Physical Function CAT, PROMIS Pain Interference CAT, PROMIS Depression CAT, and ASES for a Variety of Shoulder Diagnoses

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Objective: The purpose of this study is to evaluate the psychometric properties of the PROMIS PF CAT, PROMIS PI CAT, PROMIS D CAT, and ASES across a variety of orthopaedic shoulder conditions.
Method: PROMIS Physical Function (PF), Pain Interference (PI), and Depression (D) Computer Adaptive Tests (CATs) as well as the American Shoulder and Elbow Surgeons Shoulder Score (ASES- pain subscore, function subscore, and total score) were collected on all clinic visits for two high volume shoulder surgeons between 1/25/16 and 8/10/16. Data was included for all new patient visits with complete records and age over 18 years old. Diagnoses included were: Impingement Syndrome/ Rotator Cuff Tear (n=193), Pain (n=119), Arthropathy (n=33), Instability/labral pathology (n=18), Adhesive Capsulitis (n=8), and Fracture (n=8). The respondent burden was determined by the mean number of questions answered and was considered a measure of efficiency. Person-Item maps were created to calculate ceiling and floor effects in addition to person reliability, where $r > 0.8$ was considered good and $r > 0.9$ was considered excellent. Convergent validity was analyzed by comparison to the ASES with Pearson's Correlations. Correlations of $r > 0.7$ were considered strong, $r > 0.5$ moderate, and < 0.5 poor.
Results: For PROMIS PF CAT the mean number of items answered was 4.49 (range 4-12). The Ceiling effect was 2.90% and floor effect was 1.85%. The person reliability was 0.94. Pearson correlation coefficient compared to ASES were: 0.649 (ASES Func), 0.383 (ASES Pain), and 0.594 (ASES Total). For PROMIS PI CAT the mean number of items answered was 4.17 (range 3-11). The Ceiling effect was 3.17% and floor effect was 7.92%. The person reliability was 0.91. Pearson correlation coefficient compared to ASES were: 0.680 (ASES Func), 0.554 (ASES Pain), and 0.718 (ASES Total). For PROMIS D CAT the mean number of items answered was 7.10 (range 4-12). The Ceiling effect was 2.64% and floor effect was 19.26%. The person reliability was 0.92. Pearson's correlations compared to ASES were: -0.410 (ASES Func), -0.301 (ASES Pain), and -0.418 (ASES Total). For ASES Function the mean number

of items answered was 9.42 (range 4-10). The ceiling effect was 24.54% and the floor effect was 5.01%. The person reliability was 0.87.

Conclusions: The PROMIS PF and PI CATs demonstrated high efficiency, minimal ceiling and floor effects, and excellent person reliability. PROMIS PF CAT had moderate correlation to ASES Function and ASES Total. PROMIS PI CAT had moderate association to ASES Function and Pain subscores, but strong correlation to ASES Total. PROMIS D CAT also demonstrated good efficiency, minimal ceiling effect, and excellent person reliability. However, PROMIS D CAT had greater floor effect than all other measures and had poor correlation to all ASES components. ASES Function had the greatest respondent burden and the greatest ceiling effect of the tested measures. It also demonstrated low floor effect and good person reliability. The psychometric properties of PROMIS PF and PI CATs were favorable across a variety of shoulder diagnoses and may be utilized as validated general outcome measures. PROMIS D also demonstrated favorable properties; additionally, its poor correlation to ASES component scores suggests that it measures a further entity not captured by the ASES.

58. PROMIS scores following total knee arthroplasty demonstrate no further improvement between 6 months post-operatively to greater than 1 year post-operative.

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Objective: The purpose of this analysis was to use PROMIS data to describe patient outcomes and recovery following total knee arthroplasty (TKA) past 1-year follow-up.

Methods: Prospective PROMIS physical function (PF), pain interference (PI), and depression (D) scores were collected for all orthopaedic patient clinic visits at a multi-surgeon tertiary total joints clinic from February 2015 to May 2017. Patients who underwent primary TKA were identified by CPT code. PROMIS scores of the cohort were analyzed preoperatively and at follow up of 10-30 days, 31-50 days, 160-200 days, and greater than 365 days. For each follow up the change in PROMIS scores from the preoperative baselines were determined. The minimal clinical important difference (MCID) was calculated for each PROMIS domain using the distributive method. The change in PROMIS scores and the percentage of patients who met MCID were compared between each sequential follow up to determine the point of maximal improvement.

Results: A total of 876 patients with complete data were identified. The cohort was 60.0% female with a mean age of 66.04 years. The mean time of follow up for the >365 day group was 475 days (365-804). The calculated MCIDs were: 3.31 to 3.78 (PF), -3.64 to -4.18 (PI), and -3.96 to -4.23 (D). The mean change in PROMIS scores are shown as Table 1 and Figure 1. The percentage of patients who achieved MCID are shown as Table 2 and Figure 2.

Conclusions: PROMIS scores can be utilized to track outcomes following TKA. This study establishes PROMIS MCID values and provides a benchmark for measuring outcomes with PROMIS following TKA. It also demonstrates that following total knee replacement there was no additional measured improvement between 6 months and greater than 1 year post-operatively.

59. Chinese-American Rheumatology Patients who use Traditional Chinese Medicine Have Worse PROMIS® scores

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Objective: Chinese-Americans are a fast growing immigrant group, and many use Traditional Chinese Medicine (TCM). They also have worse outcomes in rheumatic diseases. Self-management decisions are influenced by patient-perceived disease severity, but whether patient-reported outcomes differ between TCM users and nonusers is unclear. We examined PROMIS® status of TCM users and nonusers among Chinese-American rheumatology patients.

Methods: Subjects were recruited from two rheumatology clinics that serve a predominantly Chinese-American immigrant population. Inclusion criteria were English or Mandarin speaking and treated for systemic rheumatic diseases. A bilingual researcher administered PROMIS® short forms, including sleep disturbance, applied cognition, anxiety, depression, pain interference, physical function, fatigue, social health, and instrumental support. Patients reported TCM use details in the past year.

Results: 230 enrolled, median age 55 (range 20-97), 65% female, 71% ≤high school education, 70% Medicaid, and 22% spoke English. 50% reported using TCM, most frequently *tuina* massage (47%), acupuncture (45%), and herbs (37%). TCM users had worse T-scores in anxiety (median 52.9 vs. 42.9, p=0.0001), depression (median 51.3 vs. 43.1, p=0.0002), pain interference (median 59.7 vs. 56.1, p=0.002), fatigue (mean 53.9 vs. 49.3, p=0.0001), function (median 42.2 vs. 45.9, p=0.002), and social health (median 56.4 vs. 60.7, p=0.003). All domains except pain interference and function remained statistically significant

after adjusting for other factors associated with TCM use. T-scores did not differ between herb and non-herb TCM users. Those using TCM to treat an underlying rheumatic disease had worse pain (median 61.2 vs. 58.4, $p=0.03$) and function (median 41 vs. 54.2, $p=0.01$). Also, more frequent TCM users had worse pain (median 61.2 vs. 56.9, $p=0.03$) and function (median 41 vs. 44.4, $p=0.045$).

Conclusions: TCM users had worse scores in several PROMIS® domains. TCM use may be a proxy for unmet therapeutic need in this population, especially in mental health.

60. Chinese-American Rheumatology Patients with High Adherence Have Better PROMIS® Scores

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Objective: Nonadherence to prescription medicine is more common among immigrants and minorities, and may lead to outcome disparities. Adherence in Chinese-American rheumatology patients has not been studied, and whether PROMIS® scores differ by adherence level is unknown.

Methods: Subjects were recruited from two rheumatology clinics that serve a predominantly Chinese-American immigrant population. Inclusion criteria were Chinese ethnicity, speaking Mandarin or English, and actively followed and prescribed ≥ 1 non-PRN, non-intravenous medication for a systemic rheumatic disease by rheumatologist. PROMIS® short forms available in English and Simplified Chinese were administered by a bilingual researcher. Domains included sleep disturbance, applied cognition general concerns, anxiety, depression, pain interference, physical function, fatigue, social health, and instrumental support. Medication adherence was measured using the 8-item Morisky's Medication Adherence Scale. Scores range from 0-8, where <6 points is low adherence, 6-7 medium, and 8 high adherence.

Results: 230 enrolled, median age 54.5 (range 20-97), 65% female, 71% \leq high school education, 70% Medicaid, and 22% spoke English. The three most common rheumatologic diagnoses were rheumatoid arthritis (41%), lupus (17%), and spondyloarthritis (15%), with median time since diagnosis of 4.1 years (range 0.2- 52.4). High adherence was found in 28.3%, while 37.4% and 34.4% had medium and low adherence, respectively. Compared to the group with medium / low adherence, those with high adherence had better PROMIS® T-scores in sleep disturbance (median 49 vs. 52.7, $p=0.02$), applied cognition general concerns (median 33.3 vs. 36.5, $p=0.04$), anxiety (42.8 vs. 51.6, $p=0.02$), and instrumental support (51.2 vs. 47.1, $p=0.007$).

Conclusions: Overall adherence to medication was low among Chinese-American rheumatology patients, and those with high adherence had less sleep disturbance, cognitive concerns, anxiety, and more instrumental support compared to those with medium or low adherence. PROMIS scores may provide insight into nonadherence, and should be included in future studies of adherence barriers.

61. Construct Validation of PROMIS Short Form and Profile-29 T-Scores with SF-36 in Rheumatoid Arthritis Patients

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Objective: There is considerable interest in universal PROs to assess health-related quality of life for clinical practice, research studies, and clinical trials in Rheumatoid Arthritis (RA). SF36 is commonly used in RA trials, but is not easily adaptable for practice settings to guide care. PROMIS measures may address this gap but have not been widely field-tested in RA patients with highly active disease starting therapy or compared with SF36. We evaluated these measures in a real-world study of RA patients starting Golimumab (GLM) and Infliximab (IFX).

Methods: We report baseline PROMIS Pain Interference (PI) Short Form (SF) 6b (PI6b) and PROMIS Fatigue (F) Short Form 7a (F7a), PROMIS-29 Profile (P29) domain T-Scores, and SF36 subdomain and component Scores (CS) in 747 RA patients. Disease activity was measured using Clinical Disease Activity Index (CDAI). Correlations between PROMIS measures and correlative SF36 scores were calculated using Pearson Correlations. Data are mean \pm standard deviation.

Results: At baseline, most patients had high levels of RA activity (CDAI 32.5 ± 15.4 , high >22). P29 scores were >0.5 SD worse than population means for Physical Function (PF, 37.9 ± 6.6), PI (63.5 ± 7.7), F (58.8 ± 9.9), Sleep (55.5 ± 8.7); Ability to Participate in Social Roles/Activities (PSRA, 43.2 ± 8.6). PI6b, F7a, and P29 domain T-scores were highly correlated with correlative SF36 subdomain and component scores (r 's >0.58), excepting sleep for which no correlative SF36 element was applicable. Examples include: P6b ($r=0.799$) and P29-PI ($r=0.805$) with SF-36-Bodily Pain; F7a (0.774) and P29-F with SF36- Vitality (0.786); P29-PF with SF36-PF (0.753), Role-Physical (0.684), and Physical CS (0.716); P29 Anxiety with SF36-Mental Health (0.717), Role-Emotional (0.58), Mental CS (0.712); and P29-PRSA

with SF36-Social Roles (0.662).

Conclusions: High correlations between PROMIS SFs and P29 with SF36 provide strong evidence of construct validity in a real-world population of RA patients. Comparisons of responsiveness after treatment initiation are ongoing.

62. The Relationship of PROMIS-10 Physical Function Change and Satisfaction Following Total Knee Arthroplasty

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Objective: Total knee arthroplasty (TKA) for end-stage osteoarthritis remains one of the most successful surgical interventions. Despite its success, documented patient dissatisfaction after TKA approaches 20%. The Centers for Medicare and Medicaid and private insurance companies increasingly use patient satisfaction in pay-for-performance metrics. We sought to identify associations for postoperative dissatisfaction following primary TKA.

Methods: Using our prospective orthopaedics data repository cohort at an American tertiary academic medical center, we identified 1,775 eligible patients from April 2011 through July 2016 with reported postoperative satisfaction. We used multivariate logistic regression techniques to identify associations with postoperative dissatisfaction. Satisfaction was determined based on self-reported satisfaction level with care before and after TKA. We defined "dissatisfaction" as any patient who did not report "high" postoperative satisfaction at any postoperative time period (n=503, 28%). Adjusters included preoperative satisfaction, surgeon, age, sex, race/ethnicity, year, Charlson Comorbidity Index, second primary, bilaterals, patient-reported physical (PCS) and mental function (MCS) (PROMIS-10, or Veteran RAND-12 cross-walked to PROMIS-10), body mass index, alcohol use, tobacco use, and the time period in which postoperative satisfaction was captured.

Results: Several adjusted variables were associated with patient postoperative dissatisfaction following TKA. Lower (worse) MCS was strongly associated with dissatisfaction in a dose-response relationship [Reference 60+; (50-59.99: OR 1.77, 95% CI 1.15-2.71, P=0.009); (40-49.99: OR 3.02, 95% CI 1.92-4.74, P<0.001); <40: OR 3.81, 95% CI 2.20-6.58], P<0.001]. Adjusted preoperative dissatisfaction was also associated with postoperative dissatisfaction (OR 1.95, 95% CI 1.32-2.88, P=0.001). Select surgeons were also associated with higher odds of dissatisfaction. Female gender was statistically protective against reported

dissatisfaction (OR 0.73, 95% CI 0.58- 0.92, P=0.007). The postoperative satisfaction measurement time period was not significant.

Conclusions: Patients with progressively lower MCS scores were strongly associated with reported dissatisfaction. Patients who state they are dissatisfied preoperatively have higher odds of postoperative

63. Web-based surveys using PROMIS® instruments capture important components of the Osteogenesis Imperfecta patient experience

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Objective: All current outcome measures in Osteogenesis Imperfecta (OI) have been developed by medical experts, without input from patients. Yet, patients and clinicians often disagree on level of disease burden. The Rare Diseases Clinical Research Network Brittle Bone Disorders Consortium (RDCRN BBD) is an NIH-funded project which seeks to perform collaborative clinical research in brittle bone disorders. The project has sought to identify pediatric and adult Patient-Reported Outcomes Measurement Information System (PROMIS®) instruments which capture disease characteristics important to individuals with OI. Our long term goal is to develop validated tools to assess/compare/contrast the impact of new treatments, determine future needs, and suggest topics for research.

Methods: Using a web-based platform, 300 individuals with self-reported OI, representing a wide range of self-reported disease severity, were recruited from the RDCRN BBD Contact Registry to respond to a survey utilizing PROMIS® instruments focused on a wide range of health issues including mobility, anxiety, fatigue, pain interference, and satisfaction with participation in social roles. Parent proxy surveys were provided for children.

Results: We confirmed that the RDCRN BBD contact registry can be successfully used to recruit participants for PROMIS® online surveys. All PROMIS® instruments explored except fatigue and depression in children showed a significant difference between OI patients and the general population. Some PROMIS® instruments showed a hint of floor effects which could impact the power of future studies. No important ceiling effects were detected and floor effects were under the widely accepted 15% cut-off point.

Conclusions: We demonstrated the feasibility of using the RDCRN BBD contact registry to recruit patients with OI and analyze their experience. Our next step will be to integrate PROMIS® measures into the OI Longitudinal Study. This

will allow us to better define levels of change in clinical measures that correspond to significant differences in PROMIS® assessments.

64. Do PROMIS Computer Adaptive Tests Correlate with Disease Activity in Juvenile Idiopathic Arthritis?

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Objective: The importance of patient-reported outcomes is increasingly recognized in clinical care and research. PROMIS is an NIH-supported collection of patient-reported outcome measures, covering a variety of domains, designed without disease specificity. While ‘short forms’ have been studied in juvenile idiopathic arthritis (JIA), PROMIS computer adaptive tests (CATs) have not. This study evaluates whether PROMIS CATs correlate with disease activity in patients with JIA.

Methods: Patients with JIA (N = 21) were recruited from a single center. Patients aged 10-17 years completed all available pediatric PROMIS CATs, and parents of younger children completed parent proxy PROMIS CATs (fatigue, pain interference, peer relations, anxiety, depressive symptoms, and mobility). Correlation of the CATs T-scores with disease activity, as measured by the Juvenile Disease Activity Score-71 (JADAS- 71), was evaluated using Spearman correlation coefficients.

Results: All families approached completed PROMIS CATs: 13 patients and 8 parents. Median age was 12.7 years (range 1.3 – 18.6 years), and mean JADAS-71 score was 9.58 (SD 2.07). 69% of patients completed PROMIS CATs remotely via smartphone. Anxiety ($r = 0.74$, $p = 0.006$), depressive symptoms ($r = 0.84$, $p < 0.001$), and pain interference ($r = 0.64$, $p = 0.018$) CATs correlated strongly with JIA disease activity. Among parent proxy CATs, only anxiety correlated with disease activity ($r = 0.71$); however the association was not statistically significant.

Conclusions: Our results demonstrate feasibility of administering PROMIS CATs in the outpatient setting. Anxiety, depressive symptoms, and pain interference were significantly correlated with disease activity, despite mean disease activity being relatively low. This underscores the negative effect of mild disease on quality of life. Parent proxy CATs showed poor correlations with disease activity, demonstrating the limitations of parent- reported quality of life measures. Larger prospective studies are needed to evaluate the sensitivity of PROMIS CATs to changes in disease activity over time.

65. Development of the PROMIS Pediatric Physical Activity Instruments

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Objective: Physical Activity refers to one’s experience and amount of bodily movement and activity performance that require physical actions, ranging from simple static behaviors with minimal muscle activity to more complex activities that require dynamic or sustained muscle activity and greater movement of the body. The objective of this report is to describe the psychometric evaluation and item response theory calibration of the PROMIS Pediatric Physical Activity item bank, child-report and parent-proxy editions.

Methods: An intensive mixed-method instrument development process was applied to develop child- and parent-report Physical Activity instrument for integration into the National Institutes of Health Patient Reported Outcomes Measurement Information System (PROMIS®). The initial PA item pool consisted of a range of items that estimates the amount of complex physical movements and behaviors, experiences and symptoms associated with being active, and the contexts in which PA occurs. The initial item pool comprising 79 items for Physical Activity, developed using qualitative methods, were administered to 2032 children 8-17 years old and 1034 parents of children 5- 17 years old. Analyses included descriptive statistics, reliability, factor analysis, item response theory (IRT) calibration analyses, differential item functioning, and construct validity

Results: A total of 69 items were deleted, and 4-item and 8-item short forms were constructed from the remaining 10 items. The PA instruments were administered to a national sample of 1,001 children 8-17 years old, and 1,302 parents of children 5-17 years old. The combined sample was used in a final iteration of IRT calibration. The final PA item bank was unidimensional, items were locally independent, free from differential item functioning, showed excellent internal consistency and test-retest reliability, and a high degree of precision across a wide range of the latent trait (>3 SD units). The scales showed moderate convergent and discriminant validity with existing self-report PA instruments.

Conclusions: The PROMIS Pediatric PA instruments reflect one’s experiences of, and physical responses to physical activity. They are efficient, precise, and valid measures and are ready for use in clinical practice and research.

66. Development of the PROMIS Pediatric Strength Impact Instruments

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Objective: Assessment of strength is a component of physical health and physical fitness and clinical assessment of health. While self-report instruments and wearable sensors are widely available to capture physical activity behaviors, instruments that capture strength and strengthening related functional activities are not widely available. The objective of this report is to describe the psychometric evaluation and calibration of the PROMIS Pediatric Strength Impact item bank, child-report and parent-proxy editions.

Methods: An intensive mixed-method instrument development process was applied to develop child- and parent-report Strength Impact instruments for integration into the National Institutes of Health Patient Reported Outcomes Measurement Information System (PROMIS[®]). The PROMIS Pediatric Strength Impact domain assesses a child's capacity to perform functional activities of daily living that require significant amount of muscle force generation. Each item includes the phrase "were you strong enough to..." providing attribution of the functional capacity to one's strength. The initial item pool of 25 items were developed using qualitative methods, were then administered to 1824 children 8-17 years old and 919 parents of children 5-17 years old. Analyses included descriptive statistics, reliability, factor analysis, differential item functioning, and construct validity

Results: A total of 13 items were deleted (items of specific sports and exercises which demonstrated poor factor loading), and 4-item and 8-item short forms were constructed from the remaining 12 items which primarily reflected the impact of strength in functional activities. The final item bank was unidimensional, items were locally independent, free from differential item functioning, and showed excellent internal consistency and test-retest reliability, as well as a high degree of precision across a range of the latent trait (>1 SD units).

Conclusions: The *Strength Impact* domain items reflect the capacity of individuals to perform functional activities of daily living that require significant amount of muscle force generation. Items may include a phrase (e.g. "were you strong enough to...") providing attribution of the functional capacity to one's strength. The PROMIS Pediatric Strength

Impact instruments are efficient, precise, and valid measures and are ready for use in clinical practice and research.

67. Differential item functioning of Spanish PROMIS[®] emotional distress domains between two Spanish speaking populations

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Objective: The Spanish version of PROMIS was obtained using a "universal" approach, aiming at creating one language version for multiple Spanish-speaking countries. The objectives of this work were to evaluate differential item functioning (DIF) of Spanish PROMIS emotional distress item banks (Depression, Anxiety, and Anger) between a Spanish-speaking Hispanics sample from the US and a representative sample from Spain general population.

Methods: Participants from Spain were recruited from an Internet panel vendor with age, sex, and region distributions comparable to the adult general population (n=1,807). The US Spanish speaking sample was obtained from the online panel vendor Toluna (n=642), with 20% of the sample reading and speaking only Spanish, 46% speaking Spanish better than English, 34% commanding both languages equally. Calibration was carried out with a Graded Response Model. Uniform (constant across scores) and non-uniform (varying across scores) DIF was assessed through ordinal logistic regression models, conditioning on IRT Theta estimates. Criteria for DIF was McFadden's pseudo R² change>0.015.

Results: No DIF was observed for any of the Depression items. For the Anxiety items, uniform DIF was observed for EDANX30 ("I felt worried"/ "Me sentí preocupado") and EDANX41 ("My worries overwhelmed me"/ "Mis inquietudes fueron demasiado para mí") (R² change of 0.022 and 0.024, respectively). For Anger, uniform DIF for item EDANG56 ("Just being around people irritated me"/ "El solo hecho de estar con otras personas me irritó") was found (R² change= 0.017). The impact of each of the items on the respective overall scores, as compared to the purified score, was very small (absolute value differences <0.12).

Conclusions: Results support the adequacy of the

“universal” approach applied for the adaptation of PROMIS measures into Spanish. They also provide further evidence on the validity of these measures for its use in Spain and on direct comparability of PROMIS mental health in different countries.

68. PROMIS® Pediatric Measures of Family Relationships: Development and Psychometric Evaluation

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Objective: To describe development of the PROMIS® pediatric Family Relationships measures, with versions for child self-report (8- 17 years) and parent-report on children 5-17 years old.

Methods: Semi-structured interviews with 10 experts, 24 children, and 8 parents were conducted to elicit and clarify essential elements of family relationships. A systematic literature review was conducted to identify item concepts representative of each element. The concepts were transformed into items that were iteratively revised based on cognitive interviews (n=43 children) and item translatability review. Psychometric studies involving 2,846 children and 2,262 parents were conducted to further refine and validate the instruments.

Results: Qualitative procedures supported the development of content valid Family Relationships item banks. Final child- and parent-report item banks each contain 47 items. Unidimensional item banks were calibrated using IRT-modeling to estimate item parameters representative of the US population and to enable computerized adaptive test administration. Four and eight-item short forms were constructed for standard fixed format administration. All instruments have strong internal consistency, retest-reliability, and provide precise estimates of various levels of family relationship quality. Preliminary evidence of the instruments’ validity was provided by known-group comparisons and convergence with legacy measures.

Conclusions: The PROMIS pediatric Family Relationships measures can be applied in research focused on determinants, outcomes, and the protective effects of children’s subjective family relationship experiences.

69. PROMIS® Pediatric Measures of Stress Experiences: Development and Psychometric Evaluation

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Objective: To describe development of the PROMIS® pediatric Psychological and Physical Stress measures, with versions for child self-report (8-17 years) and parent-report on children 5-17 years old. **Methods:** Semi-structured interviews with 10 experts, 17 children, and 6 parents were conducted to elicit and clarify essential elements of children’s stress experiences. A systematic literature review was conducted to identify item concepts representative of each element. The concepts were transformed into items that were iteratively revised based on cognitive interviews (n=39 children) and item translatability review. Psychometric studies involving 2,875 children and 2,212 parents were conducted to further refine and validate the instruments.

Results: Qualitative procedures supported the development of content valid Psychological Stress (*thoughts and feelings that occur in response to threatening events*) and Physical Stress (*consciously perceived manifestations of the body’s response to threat*) item banks. Final item banks were unidimensional and items were locally independent and free from impactful differential item functioning.

Four and eight-item short forms were constructed for standard fixed format administration. All instruments have strong internal consistency, retest-reliability, and provide precise estimates of various stress levels. The instruments’ construct validity was evidenced by known-group comparisons and convergence with legacy measures.

Conclusions: The PROMIS Pediatric Psychological and Physical Stress item banks and short forms provide efficient, precise, valid, and meaningful assessments of children’s stress experiences.

70. Preoperative Depression and Anxiety Predicts Self-Reported Shoulder Function in Patients with Symptomatic Rotator Cuff Tears

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Objective: There is increasing evidence that mental health has a substantial influence on self-reported physical function among patients with shoulder pathology. The purpose of this study was to investigate the relationship between preoperative PROMIS Depression and Anxiety scores with the American Shoulder and Elbow Surgeons (ASES) score and Simple Shoulder Test (SST) in patients with rotator cuff disease.

Methods: This cross-sectional study analyzed a series of 120 consecutive patients undergoing arthroscopic rotator cuff repair at a single tertiary institution. Study inclusion required preoperative completion of ASES and SST evaluations as well as PROMIS Depression and Anxiety computer adaptive tests (CATs). Pearson correlation coefficients were calculated for ASES and SST and preoperative PROMIS mental health domain scores.

Results: The PROMIS Anxiety score demonstrated a moderate negative correlation with ASES ($r = -.38, P < 0.001$) and SST ($r = -.39, P < 0.001$). There was also a moderate negative correlation between preoperative PROMIS Depression scores and SST ($r = -.40, P < 0.001$). There was a weaker but significant negative correlation between PROMIS Depression and ASES ($r = -.28, P = 0.002$). PROMIS Pain Interference also demonstrated moderate negative correlation with both ASES ($r = -.37, P < 0.001$) and SST ($r = -.42, P < 0.001$). We observed significant floor effects for the PROMIS Depression scale as 30 of the 120 patients (25%) scored as having the least depressive symptoms possible. After excluding these patients reaching the floor score, the remaining patients demonstrated a stronger correlation between PROMIS Depression and ASES ($r = -.36, P < 0.001$) and SST ($r = -.40, P < 0.001$) scores.

Conclusions: Patients undergoing rotator cuff repair who had worse PROMIS Depression, Anxiety and Pain Interference scores produced lower preoperative ASES and SST scores. We recommend that preoperative ASES and SST scores require correction to adjust for depression and anxiety symptoms. PROMIS Depression is associated with a substantial floor effect which may either be a factor associated with the instrument or this population of orthopaedic patients.

71. Validation of the Patient Reported Outcomes Measurement Information System (PROMIS) Instruments in Patients with Rotator Cuff Disease

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Objective: There are many well established patient-reported outcome measures used to quantify shoulder function for patients with rotator cuff pathology. Traditional patient reported outcome scores such as the American Shoulder and Elbow Surgeons (ASES) score and Simple Shoulder Test (SST) are associated with significant responder burden and ceiling and/or floor effects. The purpose of this study was to investigate the relationship between ASES, SST and the PROMIS Physical Function (PF) and Upper Extremity (UE) Function scales for patients with symptomatic rotator cuff tears.

Methods: This cross-sectional study analyzed 164 consecutive patients undergoing arthroscopic rotator cuff repair. Study inclusion required preoperative completion of ASES and SST evaluations as well as PROMIS PF, PROMIS UE and PROMIS Pain Interference computer adaptive tests (CATs). Pearson correlation coefficients were calculated for ASES and SST as well as preoperative PROMIS functional and pain interference scores.

Results: PROMIS PF demonstrated a moderate correlation with ASES ($r = .43, P < 0.001$) and SST ($r = .51, P < 0.001$). PROMIS UE demonstrated a stronger correlation with ASES ($r = .59, P < 0.001$) and SST ($r = .62, P < 0.001$) as compared to PROMIS PF. PROMIS Pain Interference demonstrated moderate negative correlations with both ASES ($r = -.43, P < 0.001$) and SST ($r = -.41, P < 0.001$). Patients answered fewer questions on average using the PROMIS PF and UE scores as compared to the ASES and SST.

Conclusions: For patients undergoing rotator cuff repair there is a moderate correlation between the PROMIS PF instrument and ASES and SST. PROMIS UE demonstrated a stronger correlation with the legacy shoulder scores as compared to PROMIS PF. Utilization of the PROMIS CATs allows for more efficient patient reported outcome data collection when compared to the traditional outcome scores. Our data indicates that PROMIS UE out performs PROMIS PF for patients with rotator cuff pathology, and highlights the need for more specific PROMIS instruments for patients with shoulder pathology.

72. Can PROMIS-29 Help Predict Mortality in Elderly Hip Fracture Patients?

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Objective: We sought to determine whether PROMIS-29 can be used to predict death or adverse events within 3 months in patients over 65 yrs with hip fractures.

Methods: Low-trauma hip fracture patients 65 years admitted to a tertiary care center who had surgical repair of their fracture were enrolled in our prospective cohort study, starting January 2016. We excluded patients with active cancer, or dementia. PROMIS-29 was administered 2-4 days post-op (patients were asked about the week prior to fractures as a surrogate for pre-fracture status), 3 months post-op, and 1-year post-op. Adverse events were recorded 1-month post-op. We performed descriptive statistics, and Shapiro-Wilk test to determine distribution of PROMIS-29 domains. Analysis was performed using SAS version 9.4.

Results: 109 patients were enrolled, 72.5% female, 92.7% white, 78% college educated with mean age of 80.7± 8.5 years . 63 completed 3- month follow-up, and 5 patients died within the first 3 months. When comparing initial PROMIS-29 domains between the patients who were alive at 3-months versus those who died, patients who died had worse PROMIS-29 pain (median t-score 53.0 vs. 41.6 , p=0.032) and pain visual analog scale (median 3 vs. 0, p=0.020). There was no statistically significant difference in anxiety, depression, fatigue, physical function, sleep, or ability to participate in social roles. Of the 109 patients who completed the 1-month follow-up, 19 had adverse events: pulmonary emboli, hypotension, hypoxia, urinary tract infection, periprosthetic fracture , CHF exacerbation, cholecystitis, lower extremity cellulitis, falls, wound dehiscence, and duodenal ulcers. There was no statistically significant difference in any PROMIS-29 domain between the patients who experienced adverse events versus those who did not.

Conclusions: Baseline pain domains in PROMIS-29 were statistically significantly and clinically meaningfully worse among low trauma hip fracture patients who died within 3 months of hip fracture repair compared with those who did not. As the study proceeds, longer follow up time will allow us to assess if this remains an independent risk factor for mortality.

73. Does baseline dominant hand grip strength correlate with changes in PROMIS-29 scores 3 months after surgical repair of low-trauma hip fracture?

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Objective: To ascertain if dominant hand grip strength measured 2-4 days after surgical repair of low-trauma hip fracture correlates with changes in PROMIS-29 scores and changes in Lower Extremity Activity Scale (LEAS) scores 3 months after surgery.

Methods: PROMIS-29 and the Lower Extremity Activity Scale (LEAS), which corresponds to physical function, were administered to 109 cognitively intact patients; 65yo with no active cancer, 2-4 days after surgical repair of hip fracture . Patients were specifically asked about their pre-fall status. Grip strength was measured 2-4 days after surgery using a hand-held dynamometer. Grip strength z-scores were calculated using grip strength means normalized for age and gender provided by the dynamometer manufacturer. PROMIS-29 and the LEAS were administered again 3 months after surgery and changes between scores at baseline and at 3 months were calculated. Associations were evaluated using Spearman correlations.

Results: Subjects were mostly female (72.5%), Caucasian (92.7%), college-educated (78%) with a mean age of 80.7±8 .5 years. Mean dominant hand grip strength z-score was -1.3±0.9. Mean baseline LEAS was 10.3±2.6. All correlations between baseline hand grip strength and change in PROMIS-29 domains were weak and non-significant; Physical Function (r=0.15), Ability to Participate in Social Roles (r=0.07), Fatigue (r=-0.06), Anxiety (r=0.06), Depression (r=0.024), Pain Interference (r=0.113), Sleep Disturbance (r=0.008). There was also no correlation between baseline grip strength and change in LEAS scores (r=-0.082) (all p>0.074).

Conclusions: Baseline dominant hand grip strength did not correlate with changes in PROMIS or LEAS scores 3 months following hip fracture repair in older adults. While hand grip strength is a known predictor of mortality and morbidity following hip fracture, it does not appear to correlate with self-reported short-term functional recovery. The best use of PROMIS-29 in the hip fracture setting requires further delineation. We will continue to study these patients up to 1-year post- operatively.

74. Correlation of Patient Reported Outcome Data with Discharge Disposition after Total Hip Replacement

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Introduction: The routine use of patient reported outcome data to help assess treatment options and measure outcomes has increased. In the current value driven environment, significant efforts to increase discharge to home rather than post-acute inpatient facility have been

undertaken as an effective way to reduce costs and maintain or improve the quality of care. The purpose of this study was to assess the correlation of patient reported outcomes to discharge disposition mission in the total hip arthroplasty population.

Methods: A retrospective analysis was performed on database of in-patient surgeries and patient reported outcomes measures in a single-institution in a large urban area. Preoperative PRO scores were collected for 328 patients undergoing primary total hip arthroplasty with a primary diagnosis of osteoarthritis between January 2014 and September 2015. The EuroQol 5D (EQ5D) and the Hip Osteoarthritis Outcome Score (HOOS) were collected. Univariate analysis and multivariate linear regression was used to evaluate the relationship between discharge disposition and baseline PRO scores.

Results: We found a statistically significant difference between patients baseline patient reported outcome scores and discharge disposition after total hip replacement. The average global EQ-5D score was 0.60 (SD=.20) compared with 0.45 (SD=.21) in patients able to go home ($p < 0.05$). HOOS ADL score was 46.96 (20.24) compared with 36.63 (SD=24.86) ($p < 0.05$) and HOOS pain score was 45.95 (20.04) compared with 37.96 (SD=23.54) ($p < 0.05$) for patients able to go home compared with those who went to a post-acute inpatient facility.

Conclusions: We found a significant relationship between a patient's baseline patient reported outcome scores and discharge disposition. This can assist in the planning and coordination of post-operative care after total hip arthroplasty, which is critical in the current value based environment where services must be coordinated and managed for an entire episode of care.

75. Feasibility and Implementation of PROMIS CAT as Part of Standard of Care in an Orthopaedic Spine Population

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Objective: To evaluate the feasibility and implementation of the Patient-Reported Outcomes Measurement Information System (PROMIS) computer adaptive tests (CAT) and traditional PRO measures into the electronic health record (EHR) as part of standard care in a high-volume orthopaedic spine practice.

Methods: A multidisciplinary team of clinicians and experts in information technology, user experience, medical informatics and population health developed a PRO web

application that integrates with the EHR to allow patients to complete PROMIS CAT (Physical Function, Pain Interference), PROMIS Pain Intensity Short Form, EQ-5D, Oswestry Disability Index (ODI), Neck Disability Index (NDI) and Scoliosis Research Society questionnaire (SRS-22) for patients visiting a university-based orthopaedic spine clinic. All questionnaires were collected electronically using a tablet computer in the patient waiting area prior to the physician encounter. PRO measure scores were seamlessly integrated into the patient EHR after completion. Completion rates and times the PRO measures were recorded.

Results: Over three months, 1,387 patients were administered the tablets; 85% of patients completed the PRO measures once starting the PRO web application. Median time to answer all items in PROMIS CAT, EQ-5D, plus either NDI, ODI, or SRS-22 was 9 minutes, 2 seconds. Feedback from patients completing the application was positive, with most reporting it was very user-friendly. Although a high completion rate was achieved once the application was started, only 34% of patients began the measures, and 29% of all patients completed them.

Conclusions: It is feasible to develop and implement technology that integrates PROMIS CAT into the EHR at a large academic orthopaedic clinic. The primary challenge was ensuring the application start for each patient, as once started, completion rates were high. Further exploration to streamline implementation in the clinical setting is necessary as is facilitating higher completion rates and comparing usefulness of PROMIS CAT with traditional PRO measures.

76. Efficacy of a Dedicated Research Assistant for Collection of Patient Report Outcomes Data

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OBJECTIVE: Collection of outcomes data is of growing importance in both academic and private practice. Patient reported outcome measures can be used to gain insight into the patient experience of disease, and are useful measure of quality in healthcare.

The Patient-Report Outcomes Measurement Information System Computer Adaptive Test (PROMIS CAT) is a collection of patient reported outcome metrics. Hiring a dedicated research assistant is an efficacious and cost effective way of increasing outcomes data capture rates.

Methods: A dedicated research assistant was equipped with an iPad and assigned to collect PROMIS CAT surveys from patients being seen by any of 4 orthopedic surgeons during Orthopedic Trauma Surgery Outpatient Clinic.

Residents, attendings, and clinic staff were also trained on the administration of the administration of the PROMIS CAT survey. Survey collection rates by the clinic with and without a research assistant were compared using a two-proportion z-test.

Results: Surveys were collected during outpatient clinic visits from patients seeing any of 4 orthopedic surgeons. While employing a dedicated research assistant, 1164 of 1585 patient visits resulted in one or more surveys collected (73%). 0 of 1642 patient visits resulted in survey collection when a dedicated research assistant was not employed (0%). The difference between the two groups was statistically significant ($z = 43.4$; $p < .0001$). In order to quantify the savings generated by employing a research assistant to collect surveys, a cost analysis was completed. Employing a research assistant results in a savings of \$8.50 per survey, for a total cost of \$4 per survey.

Conclusions: Comparison of the data collection rates shows that employment of a dedicated research assistant increases data capture. Further research could explore ways to integrate PROMIS CAT data and electronic medical record data to better predict patient outcomes

77. Patient Reported Outcomes Assessment helps improve Quality of Life in patients with Cirrhosis

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Objectives: Integrating Patient Reported Outcomes (PRO) assessment in routine care can allow for ascertainment of individual symptoms, physical and psychosocial issues that can supplement clinical measures. Our aim was to test the clinical value of PRO assessment as an intervention within care of cirrhotic population. Clinical value was assessed by evaluating the change in quality of life (QOL) and pain intensity over time, and assessing the prognostic value of PRO scores.

Methods: This was a prospective cohort study. All patients with diagnosed cirrhosis who were scheduled for an office visit were eligible. Consented patients were asked to complete PROMIS-29 questionnaire, immediately before the clinical visit. The PRO scores were available upon completion, and were shared with patients and providers for point of care use. Utility surveys were completed by both patients and hepatology providers following the clinical visit. QOL and pain was assessed by phone at 3 and 6 months. Prognostic value of PRO scores was assessed using multivariable analyses.

Results: 75 patients were enrolled. In 88% of clinical interactions, providers reported that PROs added information that helped structure symptom specific

education. In 26% of interactions, this helped add a new diagnosis and make changes in treatment plans. From **baseline to 3 months**, global CLDQ scores improved and pain intensity declined in 52% of patients. The Fatigue subscale improved in 76% patients. 76% of patients agreed that they understood the visual presentation of PRO scores. Greater physical impairment predicted greater severity of cirrhosis at 6 months ($p < 0.001$). Greater sleep disturbance predicted a higher probability of mortality at 6 months ($p = 0.001$).

Conclusions: PRO assessment provides direct clinical benefit through informing the structure of medical interview, improvement in pain and QOL over 3 months and immediate changes in the treatment approach. Future studies need to assess sustainability of improvements.

78. Implementing PROMIS® as standard of care in a high surgical volume, nationally leading orthopedic hospital

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Objectives: Develop a method to routinely collect the PROMIS-Global as a routine component of care delivery for all patients at one large multidisciplinary musculoskeletal health provider at specified time intervals including before and after procedures.

Methods: Patient journeys, including all physical, electronic, and telephonic touch points, across the institution were mapped and possible methods to collect the PROMIS-Global were identified. Needed resources to collect at each time point were detailed. Cost, feasibility and likelihood that patients would complete the survey were determined. A phased implementation plan was developed and put into place.

Results: Several collection options were identified: 1)Collecting during an existing call to patients prior to surgery (nurse call center). 2)Pushing out of questionnaires using the electronic health record (MyChart). 3)Collecting during the office visit. 4)Collecting during the post-surgical follow up call (patient access staff). In six months approximately 10,000 pre-procedure questionnaires were completed – 85% of all patients called by the nurse call center. At the same time less than 5% were collected using MyChart. Collection during the patient visit was not utilized during this period due concerns that it would delay the visit and over burden both patient and office staff. Data is available for clinical review in the patient chart in real time.

Conclusions: By adding the PROMIS tool into an existing workflow it is possible to successfully incorporate the collection of the PROMIS-Global into routine care.

79. A pilot study using PROMIS to assess the health and well-being of Orthopaedic Residents

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Objective: To evaluate the use of PROMIS as a measure of Resident well-being.

Methods: Higher than normal suicide rates and medical errors attributable to fatigue are real problems facing residents. The measurement of physical and mental health, which may positively or negatively affect a resident, is currently not required in most training programs. Tools that can identify the risk factors that affect resident well-being including stress, depression, anxiety, and fatigue are already available and in use for patient populations. PROMIS domains fall into three important categories of bio-, psycho- and social health making them diverse enough to assess multiple factors that influence resident well-being using one system. Six PROMIS CAT instruments and one Global Health Short Form were sent via REDCap to Orthopaedic residents at the end of seven different rotations during one year of residency. Completion rates and PROMIS scores were evaluated by year of residency and rotation.

Results: This was a voluntary, prospective, longitudinal study of a 27 orthopaedic residents facing similar occupational stresses (PGY2-PGY5). 26/27 completed the PROMIS instruments at least once and the majority completed them after multiple rotations during the year. The Hand and Foot rotations received the most responses. Global Health Score results in Table 1.

Conclusions: PROMIS is a standardized, flexible, reliable and valid measurement tool that is used to measure Patient Reported Outcomes but has the potential to evaluate the physical and mental health of other populations, including medical residents. CAT instruments can be efficiently distributed and collected via email using REDCap so residents can complete the surveys when they have time. Having a standardized metric to evaluate resident health and well-being will allow medical training programs to adapt to the needs of residents and can also be used to assess the effect those improvements have on their programs.

80. Examining predictors of resilience among adults with disability

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Objective: To examine the relationship between resilience, health, and demographic variables among aging adults with disability using PROMIS measures.

Methods: The sample (n = 1,172) consisted of individuals participating in an ongoing national longitudinal survey. Participants were required to self-report one of four disabilities including multiple sclerosis (MS), spinal cord injury (SCI), post-polio syndrome (PPS), and muscular dystrophy (MD); be 18 years of age or older; and read, write, and understand English. Self-report measures included (1) University of Washington Resilience Scale, (2) PROMIS Physical Function Short-Form for Mobility Users, (3) PROMIS Satisfaction with Social Roles and Activities SF 4a, (4) PROMIS-43 Profile v2.0 Depression, (5) PROMIS Emotional Distress Anxiety SF 4a, (6) UWCORR Self-Efficacy Scale, and (7) a demographic questionnaire. Data were analyzed using descriptive statistics and regression models.

Results: Participants with MS (31%), PPS (26%), SCI (24%) and MD (19%) were predominantly female (65%), married (58%), and white (90%), with a mean age of 62.54 (SD = 12.11). The regression model explained 53% of the variance in resilience. Self-efficacy ($\beta = .58, p < .001$) was the most strongly associated with resilience in this sample. Depression ($\beta = -.20, p < .001$) and anxiety ($\beta = -.11, p < .001$) were negatively related to resilience. Satisfaction with social roles ($\beta = .10, p < .001$), income ($\beta = .05, p < .04$), and physical function ($\beta = -.12, p < .001$) were also statistically significantly associated with resilience.

Conclusions: The results suggest that interventions aimed at improving self-efficacy and satisfaction with social roles, and reducing negative affect may have a beneficial impact on promoting resilience in adults aging with a disability.

81. Validation and Reliability of PROMIS in American Sign Language

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Objective: To evaluate the measurement properties of a new Communication Health module and validate a suite of PROMIS measures in American Sign Language (ASL).

Methods: We analyzed data from N=618 deaf adults (67%

Caucasian), 18 to 93 years old, who became deaf before 13 years of age. Hearing levels for the sample ranged from mild (1.6%), to moderate/moderate-severe (11.2%), to severe/profound (70%); 16.2% did not know or did not report their hearing level. Example items in Communication Health are: "I feel it is difficult to explain my needs to hearing people" and "In general, I feel people accept me as a person who is deaf or hard of hearing". The Communication Health Items were administered using a 5-point response scale ranging from "never" to "always" and coded so higher scores would indicate better communication health-related quality of life. Analyses were conducted to investigate reliability (e.g., internal consistency, test-retest), essential unidimensionality (e.g., single-factor CFAs), item performance (e.g., item-adjusted total score correlations, inter-item correlations, residual correlations), and measure convergent and divergent validity (i.e., inter-measure correlations).

Results: Psychometric evidence supported the development of an 8-item Communication Competence measure (internal consistency reliability: $\alpha=.78$; test-retest reliability: ICC=.84; CFA model fit: RMSEA=.08, CFI=.96; factor loadings: .50 to .74; no residual correlations >.20; item-adjusted total score correlations: .41 to .59; inter-item correlations: .21 to .49). Two additional Communication Health measures (Communication Status, Communication Challenges) are in development. A suite of PROMIS measures, including Fatigue, Anxiety, Depression, Social Support, and Global Physical and Mental Health, exhibited psychometric evidence supportive of their use in ASL (alphas ranging from .71 to .92; ICCs from .79 to .93; RMSEAs from .00 to .12; CFIs from .98 to 1.00). The Communication Competence measure correlated statistically significantly ($p<.01$) with all PROMIS measures, displaying somewhat smaller-sized correlations with Fatigue (-.23), Anxiety (-.20), and Global Physical Health (.20), and more medium-sized correlations with Depression (-.28), Social Support (.41), and Global Mental Health (.33).

Conclusions: The PROMIS-ASL demonstrates good reliability and validity for assessing generic and deaf/hh-specific quality of life in adults who use American Sign Language.

82. Responsiveness of PROMIS® Computerized Adaptive Tests (CATs) in Systemic Lupus Erythematosus (SLE)

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Objective: To evaluate the longitudinal responsiveness of PROMIS CATs in SLE outpatients using patient and physician-derived anchors.

Methods: Adult SLE patients were recruited from an SLE Center of Excellence. Subjects completed 14 selected PROMIS CATs at two visits a minimum of one month apart. SLE disease activity was measured with a patient global assessment of change, a physician global assessment and the physician-derived SELENA-SLEDAI. Responsiveness over time of PROMIS scores was evaluated using known-groups validity. Changes in PROMIS scores from baseline to follow up were compared across groups of patients who differed in their patient global assessment of change, physician global assessment, and SELENA-SLEDAI using Wilcoxon rank-sum tests.

Results: A diverse cohort of 228 SLE patients completed baseline surveys, with 190 (83%) completing a follow up survey. Using the patient-based anchor, there was a trend towards responsiveness across 11 PROMIS CATs, with statistically significant changes in T-scores with improvement and worsening of health status in Physical Function (median change in T-score +1.3, +0.1, and -1.2 [$p<0.02$] with "better", "same", and "worse" health status respectively), Pain Interference (+0.0, +0.0, +2.5 [$p<0.02$]), and Anger (-4.1, -0.9, +0.0 [$p<0.03$]) CATs. Using the physician-derived PGA and SELENA-SLEDAI as anchors, there was no notable trend or statistically significant change in scores across groups, with the exception of the Applied Cognition-Abilities CAT (+3.0, -0.1, -0.0 [$p<0.01$]) when the SELENA-SLEDAI was used as an anchor.

Conclusions: PROMIS CATs showed responsiveness over time to patient-reported, but generally not physician-derived changes in lupus health status. These data suggest that certain PROMIS CATs are precise and sensitive tools which can be used to measure and monitor important aspects of the patient experience of lupus not captured by physician-derived metrics. Further studies are needed to evaluate the role of PROMIS in optimizing longitudinal disease management in SLE.

83. Creating a PROMIS clinical registry using REDCap

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Objective: The utility of PROMIS measures in orthopaedics has been well established in recent literature. Primarily PROMIS pain interference (PI), physical function (PF), PF-upper extremity, and even depression have relevance to this

patient population. While there are several methods of administering PROMIS, one of the more common options is through the Research Electronic Data Capture (REDCap) platform. Here, we discuss the process of designing, building, and implementing a PROMIS-based clinical registry using REDCap.

Methods: REDCap is a powerful, versatile, and customizable platform that is powered and maintained by Vanderbilt University. Data is primarily collected in the clinic waiting room or exam room prior to the patient encounter through the use of a dedicated research assistant and iPads. Outcomes are also collected remotely using a link emailed to the patient, a built-in functionality of the system. The REDCap library has many of the PROMIS surveys ready for download, including both short form and computerized adaptive testing formats. Many of these forms have the feature of automatic scoring.

Experiences: There are many advantages to using the REDCap platform for administering PROMIS surveys. Administration of surveys is quick and easy, and patients rarely have issues with the electronic format. The strength of using REDCap lies in the ability to longitudinally collect PROMIS data alongside objective information such as diagnoses, procedures, intraoperative findings, imaging findings, strength, range-of-motion, etc. Data can be selectively exported in stats-ready formats for easy statistical analysis, making it a powerful tool for research applications.

Conclusions: It is relatively easy to establish and implement a PROMIS-based clinical registry through REDCap, and this system can be used to longitudinally collect PROMIS data in the context of objective clinical findings.

84. Correlating PROMIS and Traditional Patient-Reported Outcomes for Surgical Shoulder Patients

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Objective: The purpose of our study was to prospectively assess the relationship between PROMIS scores and traditional patient-reported outcome measures for early post-operative shoulder patients.

Methods: All patients undergoing non-traumatic, elective shoulder surgery by a single orthopaedic surgeon between October 2016 and May 2017 were recruited into this IRB approved study. Surgeries included rotator cuff repair, biceps tenotomy or tenodesis, subacromial decompression, labral repair, stabilization, total shoulder arthroplasty, or

reverse total shoulder arthroplasty.

Patients were instructed to complete the American Shoulder and Elbow (ASES) Assessment Form, PROMIS Physical Function-Upper Extremity (PF-UE), PROMIS Pain Interference (PI), PROMIS Depression, and a custom visual-analogue scale (VAS) questionnaire at their preoperative visit and three month postoperative visit. PROMIS PI and the custom VAS questionnaire were also given at the 1 and 6 week postoperative visits. Paired T-tests were used to assess the effects of surgery on PRO metrics. Correlations among different PRO measures were determined using Pearson correlation analysis.

Results: Seventy patients underwent elective shoulder surgery and were recruited in the study. Overall, scores significantly improved from pre-operatively to three months post-operatively for the ASES (58.4 to 73.8, $p = 0.005$) and PROMIS PI (60.3 to 55.2, $p = 0.012$). The correlation between several of the PRO metrics included in this study strengthened from preoperatively to three months postoperatively. These included ASES and PROMIS PF-UE ($r = 0.47$ to 0.90), ASES and PROMIS PI ($r = -0.61$ to -0.88), and PROMIS PF-UE and PROMIS PI ($r = -0.51$ to -0.87). In contrast, the correlations between PROMIS PI and VAS pain-related questions remained consistent throughout pre-op, 1 week, 6 week, and 3 month post-operative visits with Pearson correlations ranging from $r = 0.60 - 0.62$, $r = 0.50 - 0.76$, $r = 0.60 - 0.77$, and $r = 0.55 - 0.66$, respectively.

Conclusions: Improved correlation between traditional shoulder outcome forms and PROMIS scores at three months post-operatively compared to preoperatively suggest that surgery has an impact on the relationship between these scores; thus, the context of these scores must be taken into account when evaluating patients in the immediate postoperative period. In contrast, since PROMIS PI reliably correlates with VAS pain-related questions throughout the immediate postoperative period, PROMIS PI can be adopted as an alternative PRO for measuring pain in postoperative shoulder patients.

85. Impact of Patient Demographics on Time to Completion for Electronically Administered PROMIS and VAS Forms in Ambulatory Orthopaedic Clinics

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Objective: The purpose of this study was to evaluate patient demographic factors and their impact on time to

completion for electronically administered PROMIS forms in ambulatory orthopaedic clinics.

Methods: Ambulatory orthopedic patients were instructed to complete a series of questionnaires including a custom visual analogue scale (VAS) form, PROMIS Pain Interference (PI), and PROMIS Physical Function (PF) consisting of 6, 8, and 8 questions, respectively. Data were collected on electronic tablets using the Research Electronic Data Capture (REDCap) system. Electronic timestamps were used to calculate time to completion for each form. Demographic information such as age (stratified into quartiles), gender (male vs. female), location of pain (upper vs. lower extremity), and recent surgery (within six months) was collected for each patient. Chi-squared tests were used to detect significant differences in time to completion between each of the groups.

Results: Two hundred and fifteen patients were recruited into the study. The average time to completion for the VAS, PROMIS PI, and PROMIS PF forms was 84 seconds, 57 seconds, and 68 seconds, respectively. The time to completion for the first age quartile (18 – 45.5 years) was significantly faster than the fourth quartile (67 – 85 years) for the VAS (67 vs. 102 seconds, $p < 0.001$), PROMIS PI (47 vs. 70 seconds, $p < 0.001$), and PROMIS PF (55 vs. 78 seconds, $p < 0.001$) forms. Gender, location of pain, and recent surgery did not have a significant impact on completion time for PROMIS or VAS forms.

Conclusions: Age has a significant impact on time to completion for electronically administered PROMIS PI, PF, and VAS forms. Gender, location of pain, and recent surgery did not have an impact on completion time for PROMIS or VAS.

86. Correlating PROMIS Pain Interference and VAS Pain: which demographic factors influence VAS scores for ambulatory orthopedic patients?

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Objective: The purpose of this study was to investigate the correlation of the new PROMIS Pain Interference (PI) form with traditionally collected pain, function, and general health visual analog scores (VAS). A secondary purpose of the study was to determine the influence of patient demographics on PROMIS PI and VAS scores.

Methods: In this cross-sectional study, patient demographic information, PROMIS PI, PROMIS Physical Function (PF), and a VAS questionnaire were distributed to 215 patients in orthopaedic ambulatory clinics. The VAS questionnaire assessed current pain, pain at rest, pain during activity, pain

at night, satisfaction of function, and general health. The primary outcome was correlation between PROMIS PI and VAS questionnaires. The statistical method of seemingly unrelated regressions was used to identify significant predictors and strengths of correlation between PROMIS PI and conventional forms. **Results:** PROMIS PI was highly correlated to conventional pain and functional scores, with each standard deviation increase in PROMIS PI scores predicting a 16 point increase for pain-related VAS scores (current pain, pain at rest, pain during activity, pain at night), an 18 point decrease in satisfaction of function score, and a 6 point decrease in general health score ($p < 0.05$). Each standard deviation increase in PROMIS PF for Black/African-American patients predicted a reduction of 13 points on current pain, 12 points on pain at rest, 16 points for pain during activity, and 14 points for pain at night ($p < 0.05$).

Conclusions: PROMIS PI consistently predicts changes in VAS pain scores and can be considered as a useful, standardized tool for measuring pain for clinical and research purposes. PROMIS PF has a significantly greater predictive value on VAS pain scores for Black/African-American patients, suggesting that their perception of pain is more strongly influenced by their physical function than in other racial groups. After accounting for all independent predictors, VAS scores pain scores strongly correlate with each other, but not with VAS general health scores.

87. Hip Arthroscopy from the PROMIS Perspective: An Analysis of Prospectively Collected Patient Reported Outcomes Data

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Objective: The purpose of this study was to analyze prospectively collected patient-reported outcome data for patients undergoing hip arthroscopy in order to describe short-term clinical progress and correlate PROMIS scores to established hip measures.

Methods: Hip arthroscopy patients from October 2016 to May 2017 were instructed to fill out PROMIS Pain Interference (PI), PROMIS Physical Function (PF), PROMIS Depression, iHOT-12, hip outcome score (HOS), and visual analogue scale (VAS) questions at their preoperative visit, 1 week, 6 week, 3 month, and 6 month postoperative visits. Paired T- tests were used to assess the effects of arthroscopy on PRO metrics. Correlations were determined using Pearson correlation analysis.

Results: Thirty-three patients underwent hip arthroscopy for conditions such as FAI and labral repair. Overall, scores significantly improved from the initial preoperative visit to the

3 month postoperative for iHOT-12 (37.3 vs. 58.8, $p < 0.05$) and PROMIS PI (62.5 vs. 54.0, $p < 0.05$). The correlation was greater at 3 months post-op than pre-op between the iHOT-12 and PROMIS PF ($r = 0.74$ vs. $r = 0.57$). Correlation analysis between PROMIS PI and iHOT-12 revealed negative Pearson values of $r = -0.51$, -0.76 , and -0.67 at preoperative, 3 month and 6 month timepoints respectively. Similarly, correlations between PROMIS PI and PF were $r = -0.88$, -0.76 , and -0.903 at preoperative, 3 month and 6 month timepoints respectively.

Conclusions: iHOT-12 and PROMIS PI scores significantly improved from pre-op to 3 months postoperatively. There is a consistent negative correlation between PROMIS PI and measures of function. As patients experience greater interference in day-to-day activities due to pain, as measured by PROMIS PI, they exhibit lower functional ability according to PROMIS PF and iHOT-12. This provides preliminary evidence supporting pain control for improved postoperative function during early recovery.

88. PROMIS and Legacy Patient-Reported Outcome Measures in the Field of Orthopaedics: A Systematic Review

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Objective: We performed a systematic review to address the following questions: (1) How do Patient-Reported Outcomes Measurement Information System (PROMIS) physical function (PF) measures correlate with legacy measures? (2) How do specific test parameters (time to completion, floor and ceiling effects, reliability) of PROMIS and legacy patient reported outcome measures (PROMs) compare?

Methods: A systematic search of PubMed database was performed according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines in order to identify published articles that referenced the various PROMIS PF measures. Three authors independently reviewed selected studies. The search returned 130 studies, 44 of which underwent review. Of these, 18 were selected for inclusion. A general linear model and paired T-tests were used to assess for differences between legacy PROMs and PROMIS.

Results: The combined sample size of all articles yielded

3047 total patients. Overall, PROMIS PF measures and legacy scores demonstrated strong correlations (range: 0.59 – 0.83) when evaluating upper extremity, lower extremity, and spine patients. PROMIS questionnaires (6.04, SE = 0.7) have significantly fewer questions than legacy forms (24.27, SE = 4.36). In lower extremity studies, the PROMIS PF (100.14 sec, SE = 28.41) forms were completed in significantly less time ($p = 0.03$) than legacy forms (243.70 sec, SE = 45.8). No statistically significant difference was found between the reliabilities of the two types of measures.

Conclusions: PROMIS PF scores correlate strongly, particularly in lower extremity patients, with some of the most commonly used legacy measures in orthopaedics. PROMIS can be administered quicker and applied to a broader patient population while remaining highly reliable.

89. Using PROMIS to Guide Patient-Centered Conversations and Care in Inflammatory Arthritis: The Patient Perspective

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Objective: Clinicians may have little insight into the day-to-day experiences of patients living with chronic disease. We hypothesized that having results from PROMIS measures available during clinic visits could offer insight into important areas and facilitate discussions to guide treatment and shared decision-making.

Methods: Participants in an observational study at an academic arthritis center completed assessments of fatigue, pain, physical function, sleep, and participation in the waiting room. PROMIS results were available during the visit for review and discussion. Within 48 hours of the clinic visit, patients completed surveys about the relevancy and impact on the clinical visit. In depth interviews were conducted with a subset.

Results: Survey data are from 68 patients who were mostly white (85%), female (81% with a mean age of 54 (13) and RA duration of 10 (9) years. Almost all (94%) reported the questions addressed important aspects of their health (“Addresses a wide range of issues, which is great”; “It shows the impact my arthritis has on me, not just the pain.”) Most (82%) reported the discussion of results improved communication and made it easier to raise issues (“Helps give a better overall picture of what’s going on”; “You can...prioritize [what to talk about];” “Doctor referred to my answers during discussion.”) A minority (3%) were unclear if results had been reviewed, or whether care was impacted (“I think my doctor [already] treats me well.”) Interviews with 15 participants provided additional support to themes

identified in the survey.

Conclusions: Patients place high value on PRO information which give greater insight into day-to-day life and unmet needs. Expanded PRO assessment provides an opportunity for more patient-centered RA care by guiding conversations and improving communication about disease-related symptoms and impacts that matter to patients.

90. Pain, Physical Function, and Worry Lead to Greater Fatigue in Rheumatoid Arthritis

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Objective: Some view fatigue as resulting from disease activity, while others see it as a natural consequence of living with the pain and burden of rheumatoid arthritis (RA). We explored how psychological and disease-related symptoms contribute to fatigue in RA.

Methods: Participants receiving care at an academic arthritis clinic and were enrolled in an observational study. All completed PROMIS fatigue, physical function, sleep disturbance, pain interference, and participation in social roles and activities, and frequency of regular exercise. Clinical RA indicators were also obtained. Pearson correlation and multiple regression were used to evaluate associations.

Results: Data are from the baseline visit of 177 RA patients who were mostly female (82%) and white (83%) with mean (SD) age of 56 (13) years; 24% had ≤ high school, and 22% were disabled. Mean CDAI was 8 (8). Most were in remission (n=56; 32%) or LDA (n=67; 38%); 39 (22%) had moderate disease activity (MDA) and 14 (8%) had high disease activity (HDA) levels. As compared to the general US population, patients with active RA had significantly higher levels of disability, fatigue, and pain; those with HDA reported significantly worse mood and sleep. Fatigue was moderately-strongly and directly associated with pain, sleep, depression, and anxiety (r 's .45-.67), inversely to PF and participation (r 's -.61 and -.64, respectively), weakly and directly with swollen joints (r =.27) and weakly and inversely with regular exercise (r 's -.24)(p 's <.001). Age and RA duration were not associated with fatigue (p 's .967 and .677). In regression, pain, physical function, and anxiety were significant independent predictors of fatigue [F (7,157) = 28.60, p <.001, r^2 =.54].

Conclusions: In active RA, fatigue is common and increases with worsening disease activity. Our data suggest that beyond pain and disability, in 28% of people with RA, anxiety may also contribute to the experience of fatigue.

91. Using PROMIS to Guide Patient-Centered Conversations and Care in Inflammatory Arthritis: The Clinician Perspective

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Objective: Clinicians are best able to provide chronic disease care that is patient-centered when they have a better understanding of their patients' lived experiences. We hypothesized that having results from PROMIS measures available during clinic visits could offer insight into important areas and facilitate discussions to guide treatment and shared decision-making in rheumatoid arthritis (RA).

Methods: Participants in an RA observational study at an academic arthritis center completed PROMIS fatigue, pain, physical function, sleep, and participation measures in the waiting room. Results were available during the visit. Semi-structured interviews were used to query clinician experiences.

Results: Data are from interviews with 4 rheumatologists and 6 fellow trainees. Among rheumatologists, access to real-time PROMIS results that could be addressed during the visit was highly valued. All stated that completing questionnaires helped patient feel "heard" and discussing results made it clear that patients' experiences mattered. Several said reports prompted them to ask about symptoms they may have overlooked. There was concern that some symptoms (depression, anxiety) may have little to do with RA; identifying these without a clear pathway to resources was potentially problematic. All noted that how they used results differed depending on the needs of specific patients and the nature of the visit. While rheumatologists felt able to control the time spent discussing results, fellows expressed less certainty about their ability to control conversations, the value of additional PROs for RA care, or its impact on decision-making. Fellows also reported greater discomfort discussing results if they had not yet built a rapport with patients.

Conclusions: Expanded PROMIS assessments of symptoms as part of routine care offers important information to make RA care more patient-centered. For trainees, the value of additional symptom information was balanced by concerns about greater time challenges and ways to integrate results into discussions and care plans.

coefficient value was equal or higher than 0.9 and good if it was equal or higher than 0.8.

Results: One hundred and eighty-four adult patients (127 females and 57 males) participated the study at the average age 62,06 years (range 28,58 - 98,29). The age of females was 61,85 years (from 30,39 to 98,29) and males 66,13 years (from 28,58 to 89,95). Seventy patients delivered repeated questionnaires for the test-retest reliability study. Excellent internal consistency was confirmed. Cronbach's alpha was high for each PROMIS PROFILE 29 domain namely: Anxiety Fear $\alpha=0.94$; Depression $\alpha=0.91$; Fatigue $\alpha=0.91$; Pain Interference $\alpha=0.95$; physical Function $\alpha=0.98$; Sleep Disturbance $\alpha=0.94$; Social Roles $\alpha=0.9$. Excellent reliability was achieved for Anxiety Fear Average (0.94); Depression (0.91); Fatigue (0.91); Pain Interference (0.95); Physical Function (0.98); Sleep Disturbance (0.94); and Social Roles (0.94) for average measures.

Conclusions: Acceptable Polish translation was obtained for all items of the PROMIS PROFILE 29. The Polish PROMIS PROFILE – 29 was found internally consistent, reliable and equivalent to the English version. The Polish version of the 29-items questionnaire fulfills the requirements for use in clinical practice.

93. Physical function and pain interference of Patients with severe bilateral Hip Osteoarthritis are comparable prior the first primary Total Hip Replacement surgery and before contralateral THR

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Objective: Assessment of the impact of severe hip osteoarthritis before primary Total Hip Arthroplasty on the daily activities utilizing PROMIS Short Forms (polish translation) (Physical Function 10a; Pain Interference - 6b and Pain Intensity – 3a) in patients awaiting the first THR compared to the group of patients who have already one artificial hip awaiting the THR of the other side osteoarthritic hip.

Methods: Study group consisted of 166 patients 126 awaiting the first THA and the 40 patients after THR of the

92. Polish version of the PROMIS Profile-29 v.2 (Translation and Validation study)

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Objective: To translate the PROMIS PROFILE – 29 v.2.0 items into Polish and to investigate test-retest reliability.

Methods: The PROMIS PROFILE - 29 is an NIH-funded patient-reported outcome measure used to assess a patient's overall QOL and has been used for selected chronic diseases. The questionnaire consists of PROMIS 29- items, including the 4-item static forms for Physical Roles, Fatigue, Pain Interference, Sleep Disturbance, Depression, and Anxiety.

Polish translation and cognitive debriefing of the PROMIS PROFILE 29 was performed by a bilingual expert group with strict implementation of to the Functional Assessment of Chronic Illness Therapy (FACIT) translation methodology, approved by the PROMIS Statistical Center. The process included forward and back translations, reviews in concern to the unified Polish language, reconciliation meetings, quality review, and cognitive debriefing interviews.

Subjects: To test understandability and clarity of the translated items, cognitive debriefing interviews were conducted with 10 adults (5 males and 5 females) at the average age 50,4 years (range 23-92). The final PROFILE – 29 was administered to adults with a broad range of medical conditions. Each subject filled out pencil-and-paper polish version of PROMIS PROFILE 29. Filled out PROMIS PROFILE 29 was scored utilizing Assessment Centre (<https://www.assessmentcenter.net/>). Cronbach's alpha was used for investigating the internal consistency of a questionnaire. Test-Retest reliability coefficients were calculated using the Intraclass Correlation Coefficient (ICC) to measure the reliability of PROFILE-29 ratings. Intraclass Correlation Coefficient was calculated for the same raters for all subjects using two-way and absolute agreement model. The reliability calculated using the Intraclass Correlation Coefficient (ICC) was excellent if the stability

one hip awaiting the same type of surgery of contralateral hip. The average age of the group was 65.5 years (average age of females - 64.8 years, and males 66.7 years). All subjects were qualified for hip replacement surgery. All subjects have been diagnosed with radiographically confirmed Kellgren-Lawrence grade 4 or higher hip osteoarthritis and suffered from moderate to severe pain. Each subject filled out pencil-and-paper versions of several questionnaires including Harris Hip Score (HHS), Western Ontario and McMaster Universities Arthritis Index (WOMAC), Hip disability and Osteoarthritis Outcome Score (HOOS), Short Form Health Survey (SF-36), VAS i Oswestry Disability Index v.2.1a (ODI), PROMIS Short Forms: Pain Intensity Short Form 3a, Physical Function - Short Form 10a and Pain Interference - Short Form 6b and PROMIS Physical Function SF10a v1.2 and PROMIS Pain Interference SF6b. All filled out PROMIS Short Forms were scored utilizing Assessment Centre (<https://www.assessmentcenter.net/>).

Results: In both study groups results were worse than average population T-scores. PROMIS Physical Function SF average T-score was 34.9, and PROMIS 6b Pain Interference average T-score was 67.3 before 1st THR (SD 5.99); and 68.3 before 2nd THR (SD 4.62). PROMIS 10a was 32.15 before 1st (SD 6.46); and 32.1 before 2nd (SD 5.35). PROMIS 3a was 53.7 before 1st (SD 6.49); and 53.7 before 2nd (SD 4.07). Overall scores of the SF 36 were low compared to the year before. However, no statistical differences were found between groups before 1st THR (25.29; SD 17.92); and before 2nd THR (21.25; SD 19.24). The hip specific instrument - Harris Hip Score (HHS) was the only one legacy instrument that revealed statistically significant differences between groups: before 1st THR (53.0; SD 15.89) as compared to the group before 2nd THR (43.5; SD 13.12).

Conclusions: The study confirmed significant deterioration of the quality of life for patients with the end stage of the hip osteoarthritis as expected. Severe hip osteoarthritis has a big impact on daily activities due to pain and limited physical function. Pain intensity, physical function and pain interference of patients with severe hip osteoarthritis are comparable prior the first primary Total Hip Replacement surgery and before contralateral THR in bilateral severe hip osteoarthritis in cases with already implanted one hip endoprosthesis.