

outcomes. **METHODS:** Nine clinicians and 43 patients with linear surgical scars participated in a photograph sorting exercise. Patients sorted approximately 50 scar photographs consistent with their own skin type (light, medium or dark skin), while clinicians sorted all three sets of photographs (n=151 photographs). All participants arranged the photographs into 5 categories of perceived scar severity (least to most severe) and 5 photographs were considered for inclusion in the photonic guide based on analysis of inter-rater reliability, response consistency, redundancy, and variability. When photographs yielded similar results, clinical judgment was used to select the best photo. Instruction and response anchors were developed for the 5 scar photographs and the final guide was cognitively debriefed for relevance, comprehensibility, and acceptability in 24 additional scar patients. **RESULTS:** Based on the pre-specified criteria for inclusion and exclusion, 5 light skin and 5 dark skin photographs were included in the final photonic guide. A "medium" guide was not developed because of significant overlap between it and the light skin guide rendering it superfluous. Inter-rater reliability of the 52 subject cohort was strong (0.95-0.96) across all skin types. The 5 photographs included in the photonic guide demonstrated goodness-of-fit (infit mean-square < 1.4 and > 0.6), low variance in severity ratings (SD < one category change), and strong agreement between patients and clinicians. **CONCLUSIONS:** The Patient and Clinician Reported Scar Severity Scales were systematically developed to easily assess scar severity outcomes in clinical trials. Continued psychometric evaluation of the guide is planned to ensure the scales meet regulatory standards for labeling purposes.

#### PRM107

##### MAPPING RELATIONSHIPS AMONG PAIN DESCRIPTORS USED BY PATIENTS: EVIDENCE FROM QUALITATIVE INTERVIEWS IN FOUR CHRONIC PAIN CONDITIONS

Scanlon M<sup>1</sup>, Martin ML<sup>1</sup>, McCarrier KP<sup>1</sup>, Wolfe M<sup>2</sup>, Quintanar-Solares M<sup>1</sup>

<sup>1</sup>Health Research Associates, Inc., Seattle, WA, USA, <sup>2</sup>Health Research Associates, Inc., Mountlake Terrace, WA, USA

**OBJECTIVES:** To describe how pain descriptors are used to represent patients' pain experiences by mapping word clusters identified by patients as synonyms for the same pain sensation. **METHODS:** Subjects were recruited by web posting and telephone screening. Those self-reporting current pharmacological treatment for Migraine, Low Back Pain (LBP), Osteoarthritis (OA), or Rheumatoid Arthritis (RA) were enrolled and completed in-person interviews using card sort exercises with 93 different pain descriptors. Subjects were asked to identify the descriptors they commonly used to describe the pain associated with their condition, and to isolate any pairs of words that describe the same pain sensation ('linked' descriptors). Network maps that diagrammed subject-identified links between descriptors were created for each condition using Netdraw (Borgatti 2002) and compared. **RESULTS:** The 72 subjects ranged in age between 19 and 84 years (mean=45). Sixty-eight percent were female, 63% were working full- or part-time, and 61% were Caucasian. OA and Migraine subjects used more synonyms to describe similar pain experiences (14% and 10% of all identified synonym pairs, respectively) than the LBP and RA groups (at 7% and 6%). For Migraine, most linked descriptors formed a single group of connections, or single integrated relationship. For the OA group, several smaller unassociated subgroups of synonyms were identified. For the LBP group, two main clusters emerged, differentiating low-intensity and high-intensity pain. For the RA group, several descriptors were weakly linked to only one other descriptor. Some synonyms were common to all four groups (e.g., STIFFNESS-TIGHTNESS), but others were condition-specific (e.g., SPREADING-RADIATING for OA, but SPREADING-GNAWING for Migraine). **CONCLUSIONS:** While some descriptors were used to convey a more consistent meaning across groups, other descriptors' synonyms varied by condition, demonstrating condition-specific meaning. These findings emphasize the importance of tailoring item language to the specific population of interest when assessing pain with PRO instruments.

#### PRM108

##### CONSTRUCT VALIDITY OF THE SF-12 IN TYPE-1 DIABETES

Jiang Y<sup>1</sup>, Huckfeldt P<sup>2</sup>, Knight T<sup>3</sup>, Goldman D<sup>3</sup>

<sup>1</sup>USC School of Pharmacy, Los Angeles, CA, USA, <sup>2</sup>RAND, Santa Monica, CA, USA, <sup>3</sup>University of Southern California, Los Angeles, CA, USA

**OBJECTIVES:** To assess the construct validity of the Short Form-12 (SF-12) in type-1 diabetes (T1D). **METHODS:** This analysis used data from a study investigating factors affecting setting and attainment of HbA1c targets. A total of 1,918 patients were recruited from the T1D exchange registry and completed a web-based survey; 1,846 of them finished the SF-12 section of the survey. The physical component score (PCS) and the mental component score (MCS) from SF-12 were compared between known groups. The known groups were defined by treatment intensity, duration with disease, complication, hospitalization, emergency room visits, glycemic control and working. Parametric or nonparametric tests were used depending on the scale of the measure. The Diabetes Quality of Life (DQoL) Brief Clinical Inventory is a disease specific quality of life (QoL) measure, lower score indicates better QoL. The correlations between SF-12 scores and DQoL score were also examined. **RESULTS:** PCS and MCS had no association with more frequent insulin injections. PCS had a positive correlation ( $r=-0.22$ ,  $p<0.05$ ) with duration of disease while MCS had a negative correlation ( $r=0.07$ ,  $p<0.05$ ). Patients with depression or anxiety had lower PCS (difference: -3.5 and -3.7,  $p<0.05$ ) and MCS (-8.4 and -6.8,  $p<0.05$ ). Patients who had hospitalization due to diabetic ketoacidosis (DKA) reported significantly lower PCS (-4.0,  $p<0.05$ ) and MCS (-2.7,  $p<0.05$ ). More, number of emergency room visits other than for hypoglycemia or DKA was associated with lower PCS (Spearman  $r=-0.05$ ,  $p<0.05$ ), but not MCS. Patients with an A1c value greater than sample median had lower PCS (-2.2,  $p<0.05$ ) and MCS (-3.6,  $p<0.05$ ). Working patients had higher PCS (4.2,  $p<0.05$ ) and MCS (1.1,  $p<0.05$ ). Finally, both

PCS ( $r=-0.38$ ,  $p<0.05$ ) and MCS ( $r=-0.53$ ,  $p<0.05$ ) had very strong negative correlations with DQoL score. **CONCLUSIONS:** This study contributed some evidence of construct validity of the SF-12 in patients with T1D.

#### PRM109

##### DEVELOPMENT OF THE READINESS FOR WORK QUESTIONNAIRE IN SCHIZOPHRENIA

Potkin S<sup>1</sup>, Bugarski-Kirola D<sup>2</sup>, Edgar C<sup>3</sup>, Le Scouiller S<sup>3</sup>, Kunovac J<sup>4</sup>, Velasco EM<sup>5</sup>, Berardo C<sup>2</sup>, Garibaldi GM<sup>2</sup>

<sup>1</sup>University of California-Irvine, Irvine, CA, USA, <sup>2</sup>F. Hoffmann-La Roche LTD, Basel, Switzerland,

<sup>3</sup>Roche Products LTD, Welwyn Garden City, UK, <sup>4</sup>Excell Research, Oceanside, CA, USA,

<sup>5</sup>Psychopharmacology Research Institute, Ciudad de Mendoza, Argentina

**OBJECTIVES:** Unemployment rates are high among patients with schizophrenia, and unemployment has a negative impact upon quality of life. There is also a significant societal and economic burden associated with unemployment. Ability to work should be considered as a target for treatment with potentially wide-ranging benefits. However, employment status is dependent on the availability of work, stigma of mental illness and cultural influences, and patients' work history and educational background. A clinician-rated scale evaluating readiness for work, independent of current work opportunities, would be a potentially valuable assessment tool. The objective was to validate a work readiness questionnaire, which would allow clinicians to assess and rate patient function with respect to ability to engage in useful activity, or work. **METHODS:** Following separate studies to establish content validity and reliability, construct validity was evaluated in a global, cross-sectional, observational, stand-alone validation study. Two hundred male and female adult outpatients with schizophrenia (DSM-IV) were included in the study. Recruitment was oversampled such that 25% of patients were working independently at the time of assessment. **RESULTS:** Readiness for work was associated with statistically significantly higher levels of functioning and lower levels of negative symptoms ( $P<0.0001$ ). For the prediction of current work status, sensitivity was 70% and specificity 63%. Positive predictive value (PPV) was 32% and negative predictive value (NPV) was 89%. The low PPV and high NPV were consistent with the interpretation that the scale correctly identifies patients unable to work and not employed, but amongst those ready to work, there may be a proportion unable to work due to demographic and socioeconomic factors. **CONCLUSIONS:** The work readiness questionnaire was strongly associated with functional outcomes and negative symptom severity in the predicted directions and showed high NPV in identifying those patients not employed.

#### PRM110

##### ACUTE BACTERIAL SKIN AND SKIN STRUCTURE INFECTIONS (ABSSSI) SIGNS/ SYMPTOMS AND PROS: A COMPREHENSIVE LITERATURE REVIEW

Cimms TA<sup>1</sup>, DeBusk K<sup>1</sup>, Howard K<sup>1</sup>, Siuciak JA<sup>2</sup>, Llorens L<sup>3</sup>, Crawley J<sup>4</sup>, Halling K<sup>5</sup>, The FNHI Biomarkers Consortium CABP ABSSSI Project Team BC<sup>6</sup>, Powers JH<sup>7</sup>

<sup>1</sup>Oxford Outcomes Ltd, an ICON plc Company, San Francisco, CA, USA, <sup>2</sup>Foundation for the National Institutes of Health, Bethesda, MD, USA, <sup>3</sup>Cerexa, Inc, Oakland, CA, USA, <sup>4</sup>AstraZeneca Pharmaceuticals LP, Wilmington, DE, USA, <sup>5</sup>AstraZeneca, Mölndal, Sweden, <sup>6</sup>The Foundation for the National Institutes of Health, Bethesda, MD, USA, <sup>7</sup>National Institute of Allergy and Infectious Diseases (NIAID) National Institutes of Health (NIH), Bethesda, MD, USA

**OBJECTIVES:** The purpose of this literature review was to investigate existing patient reported outcome (PRO) measures used in studies of acute bacterial skin and skin structure infections (ABSSSI) and to explore signs and symptoms of ABSSSI in order to inform the development of a disease model. **METHODS:** To identify relevant abstracts/articles for inclusion a search was conducted in OVID. For the purpose of this project, MEDLINE (1946 to present) and EMBASE (1988 to 2012) were searched using terms for signs and symptoms and existing PRO measures, specifically related to skin infections. **RESULTS:** The search identified 299 unique abstracts, of which 276 were excluded based on pre-specified exclusion criteria. The 23 full-text articles obtained were further reviewed for eligibility. The most frequently cited ABSSSI signs/symptoms were redness of skin/erythema (n=10), edema (n=7), elevated body temperature (n=7), induration (n=6), pain/tenderness of the area, expansion of the lesion, demarcated borders, and pus-filled drainage (n=5). No ABSSSI-specific PROs were identified in this literature review; however, four of the articles reviewed helped inform the development of a disease model. One study employed qualitative interview methodology to identify perceived sources of infection, and barriers and facilitators to the prevention of CA-MRSA. Three studies involved ABSSSI-related patient populations and included PRO measures to assess quality of life. **CONCLUSIONS:** This literature review confirmed that an ABSSSI-specific PRO measure has not been cited in the literature, and further exploration of ABSSSI signs and symptoms in the form of qualitative interviews with clinicians and patients is needed prior to the development of a relevant PRO measure for this patient population. The signs and symptoms identified in this literature review informed the development of an ABSSSI disease model, which will be used to help establish the context of use of the new PRO measure.

#### PRM111

##### ARE CANADIANS DIFFERENT FROM AMERICANS IN STATED PREFERENCES FOR HEALTH? VALUING EQ-5D-5L HEALTH STATES USING DISCRETE CHOICE EXPERIMENTS

Lin FJ<sup>1</sup>, Xie F<sup>2</sup>, Pickard AS<sup>3</sup>

<sup>1</sup>University of Illinois at Chicago, Chicago, IL, USA, <sup>2</sup>McMaster University, Hamilton, ON, Canada

**OBJECTIVES:** Probabilistic discrete choice modeling offers an alternative approach to exploring values of health states. The aims of this study were: (1) to compare whether respondents in the US and Canada differ in their preferences for EQ-5D-5L health states using discrete choice experiments (DCE); (2) to explore whether US-based respondents differed based on age, gender, race, education