morning stiffness), BASFI, ASQoL and the SF-36. Literature review, and clinician and patient interviews, provided information on instrument content validity. Statistical analysis of measurement properties evaluated the reliability (test-retest and internal consistency), responsiveness and construct validity. Measurement properties were assessed using data from the RAPID-axSpA trial investigating certolizumab pegol (CZP) efficacy in axSpA. **RESULTS:** Reviewed AS literature revealed relevant concepts: physical function, pain, disease activity, morning stiffness, fatigue, disturbed sleep, depression, mobility problems, problems performing recreational activities/household tasks/self-care/work, and problems socializing. The same concepts were evident for the overall axSpA population in expert interviews. Concepts identified in patient interviews were consonant with both literature and expert opinion. All PRO instruments were satisfactorily reliable in the RAPID-axSpA population, with all test-retest intra-class correlation coefficients and internal consistency Cronbach's alphas >0.8. Validity was supported by agreement between PRO and clinician-rated measures. All the PRO measures showed good sensitivity to change, with large response sizes (effect size >0.8) on almost all measures from week 12 in RAPID-axSpA. No significant variations in psychometric properties were noted between axSpA sub-populations. **CONCLUSIONS:** This study indicates that both the content validity and the measurement properties of PRO instruments used in AS are preserved in the broad axSpA population. Questions remain about relying on classical test theory for validation and the value of using generic outcome measures when well-developed disease-specific measures are available.

PRM159

THE EFFECT OF LEAD TIME IN TIME TRADE-OFF VALUATION OF HEALTH STATES

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OBJECTIVES: Lead-time time trade-off (TTO) is a promising alternative to conventional TTO. The purpose of this study was to compare the values of EQ-5D-5L health states as measured by two TTO variants using different ratios of lead time to unhealthy time. **METHODS:** Data were collected as part of a wider multi-country pilot study. We elicited the values of 10 selected EQ-5D-5L health states from a convenience general population sample (N=406) using two lead-time TTO variants: 10 years of lead time in full health preceding 5 years of unhealthy time (standard method), and 5 years of lead time preceding 5 years of unhealthy time (experimental method). Participants self-completed the tasks using personal computers, with an interviewer supervising groups of participants. Participants were randomized to receive one of the two TTO variants to value a block of 5 EQ-5D-5L states. The TTO values were compared between the two study arms using random-effects linear models, with adjustment of age, gender, education, and health states. **RESULTS:** Health-state values generated from TTO valuation exercises using the longer lead time were slightly lower than those generated from exercises using the shorter lead time. The proportion of non-negative values in the standard and experimental arms was 81.2% and 86.7%, respectively (p=0.046); the grand mean TTO value was 0.35 and 0.43 for the standard and experimental arms, respectively (p=0.049). Exhaustion of tradable time occurred only in the experimental arm (0.46%) where the lead time was shorter. **CONCLUSIONS:** This study confirms earlier findings that the ratio of lead time to time in poor health exerts an effect on TTO values of health states. The more lead time is offered, the more time is traded. Different lead-time TTO variants should be carefully studied in order to achieve the best measurement of health-state values using this new method.

PRM160

DEAD TODAY OR DIE TOMORROW? A LITERATURE REVIEW OF THE EMPIRICAL EVIDENCE FOR INTER-TEMPORAL PREFERENCES OF HEALTH

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OBJECTIVES: Time preferences and discounting has become indoctrinated in the evaluation of health care technologies that generate future benefits and costs. Moreover, it remains a fundamental economic concept that is relied upon for the understanding of individuals' decision making with respect to health. The aim of this paper is to provide a systematic review of the empirical studies that have attempted to measure either individual or societal inter-temporal preferences regarding health. **METHODS:** A systematic search of peer-reviewed articles published in English during 1980 to 2012. The Preferred Reporting System for Systematic Reviews and Meta-Analysis (PRISMA) strategy was followed to ensure systematic selection of the papers. Articles were excluded if they did not report a discount rate or factor(s); and if health (and or life years) was not the domain for which discount estimates were provided. Two reviewers assessed the results of the search against a predefined exclusion and inclusion strategy to ensure appropriate inclusion of papers. **RESULTS:** A total 64 studies were identified within 54 published articles. A variety of methodological approaches have been implemented to measure preferences as well as testing over a variety of functional forms including hyperbolic and quasi-hyperbolic models. Estimates for a constant discount rate vary significantly from below zero to over 1000%. However, a weight of evidence in support of hyperbolic or at least non-constant discounting is emerging. Evidence is equivocal at best with regards to the relationship between time preferences measured and health behaviors. **CONCLUSIONS:** It has become common practice, and is often advised, that economic models of future costs and consequences should conduct sensitivity analyses regarding the discount rate chosen. From the empirical evidence it appears as important that such models also consider the sensitivity of models to other debatable concepts regarding discounting including the use of hyperbolic functions.

PRM161

IDENTIFYING PATIENT SUBPOPULATIONS IN EARLY DEVELOPMENT TO SUBSTANTIATE VALUE

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OBJECTIVES: Optimizing the clinical trial design and establishing the appropriate populations early in development are essential to substantiating a compelling value proposition. This project sought to provide an example of how a subpopulation investigation can inform early development strategy. **METHODS:** US 2012 National Health and Wellness Survey data were used. Respondents with pain in the past month were included. The distribution of work productivity (using the WPAI questionnaire) was examined and subpopulations of pain patients with particularly high or low impairment were described and compared to uncover groups with the highest likelihood of showing incremental benefit substantial enough to demonstrate value and compel funding. **RESULTS:** A total of 24,215 respondents (34.0%) reported pain in the past month (mean age=49.96; 51.92% were female). Mean level of pain severity in the last week was 4.71 (SD=2.72) and mean overall work productivity loss was 22.04% (SD=27.84%). Although these variables were significantly related (r=0.45, p<0.05), a substantial percentage of people with pain reported no work impairment (44.23%) creating a floor effect whereby regardless of the improvement in pain, no effect would be observed with respect to the ability to work. Conversely, 3.6% of people with pain reported 90% or more of their work week being impaired. Few demographic differences (age, sex) were observed between these two extremes, though those with 90%+ impairment were more likely to be obese (43.40%) versus those without any impairment (32.80%). **CONCLUSIONS:** Pain severity and work productivity loss were significantly related but many of those with pain reported so little impairment that no intervention could provide a compelling proposition. However, key subgroups (e.g. those obese) reported significant impairments with a much greater likelihood of demonstrating treatment benefit. Subgroup analysis early in development can identify the most relevant patient populations and help inform clinical trial design, optimize incremental value, and drive cost effectiveness.

PRM162

CROSS-CULTURAL ADAPTATION OF A RESEARCH VERSION OF THE REY AUDITORY VERBAL LEARNING TEST (RAVLT) INTO JAPANESE

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OBJECTIVES: The Rey Auditory Verbal Learning Test (RAVLT) is a cognitive test assessing verbal learning and memory. Fifteen words (List A) are presented across five learning trials and queried during two delayed-recall trials. A second 15-word list (List B) designed to interfere with recollection of the primary list is used. A recognition trial is administered during which subjects are asked to detect List A words from amidst distractor words from List B plus 20 others that have a semantic and/or a phonetic link with words from the lists. The objective of this abstract is to present the translation process of the RAVLT into Japanese. **METHODS:** For the 30 words from the two lists a direct translation was recommended based on collaborative efforts involving a speech therapist and a neuropsychologist. The goal was to maintain similar frequency of use and syllables (±1 syllable or ±2 syllables and ±2 characters) to the source English terms. For the 20 additional words used in the recognition trial, the translations had to respect the semantic and/or phonetic links to the words from the two lists. **RESULTS:** Discussions ensued around six of the 30 words from the lists due to difficulties in finding direct translations with the appropriate number of syllables. For the recognition words, the most problematic issue was finding equivalents maintaining the phonetic link to the Japanese translation. Ten recognition words had to be changed to uphold this linguistic property. For instance, the recognition word "Tree" required a phonetic link to the recall word "Turkey" so it was translated as "Box" (Ha Ko) to preserve the phonetic link with the word chosen to replace "Turkey" (i.e., "Pigeon" (Ha To)). **CONCLUSIONS:** This methodology enabled the production of a Japanese version of the RAVLT that preserved the intent and integrity of the source US English test.

PRM163

TOOLS USED TO IMPROVE MEDICATION ADHERENCE: A SYSTEMATIC REVIEW

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OBJECTIVES: According to PhRMA, 75% of Americans are non-adherent on one or more of their medications. Low adherence leads to worsening of the disease and unnecessary health care spending. Various tools have been used by health care professionals to improve medication adherence. The objective of this study is to conduct a systematic review to identify tools used to improve medication adherence and their impact on medication adherence. **METHODS:** PRISMA guidelines were followed for conducting a systematic review. A comprehensive electronic search of research databases (PubMed, MEDLINE, EBSCO, and PsycINFO), was performed. Combinations of search terms were generated by reviewing existing literature and consulting an expert librarian. Search terms included the names of each tool, adherence, compliance, persistence, and medication adherence. Studies were included if they were conducted after January 2000; involved the use of an adherence tool recommended by a certified health care professional; and measured the rate of medication adherence as an outcome. Studies on measuring adherence to vaccines and lifestyle modifications were excluded. **RESULTS:** Preliminary search yielded 637 articles. Articles were excluded following a title review (552) and an abstract review (43). Forty-two studies met the criteria for full review. Six different adherence tools

were used. Of these, 27 studies used telephone and text reminders. Four used educational materials and books while another four used blister packing. Three studies used interactive voice response system, two studies used letters and faxes, and another two studies used pill boxes. Improvement in medication adherence was found in all studies. The largest change in medication adherence was observed through the use of telephone and text reminders. **CONCLUSIONS:** Medication adherence is a problem that pharmacists are addressing through health care reform legislation. It's important for pharmacists/researchers to educate about effective adherence tools in order to improve quality of care to patients and society.

PRM164

THE CORRELATION BETWEEN PATIENT REPORT OUTCOMES AND CLINICIAN REPORTED OUTCOMES

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OBJECTIVES: To explore evidence of the degree of correlation between patient reported outcomes (PROs) and clinician reported outcomes (ClinROs), and how this varies by therapeutic area, measure and language. **METHODS:** A review of the literature and analysis of existing patient registry data was conducted to qualitatively assess degree of correlation between PROs and ClinROs – at points in time, change over time, and how the relationship between these assessments varies by disease area and measure. A review of translation and linguistic validation projects involving PRO and ClinROs was also conducted to examine language-related differences and correlations between the scales. Specific examples of PRO-ClinRO pairs are given for multiple sclerosis, rheumatoid arthritis, and atopic eczema, among others. **RESULTS:** For multiple sclerosis and rheumatoid arthritis, moderate correlation (0.5-0.7) was found between patient assessments of disease severity and physician assessment, with patient assessments influenced by concomitant feelings (e.g., depression, anxiety). The correlation between patient and clinician assessment of change/responsiveness depends on whether an improvement or deterioration is experienced, where deterioration has a perceived stronger impact, patient-wise, than an improvement. Differences in language complexity and terminology between PROs and ClinROs were essential for the appropriate comprehension by the target population. Clinically appropriate and current terminology used for ClinROs was key to clinicians accepting the scale as relevant. Simple, clear phrasing and wording with language with lower education level was important for PROs. **CONCLUSIONS:** For reviewing PROs and ClinROs, specific differences in language and terminology must be taken into account, both in the development of instruments and linguistic validation into various target languages. In some disease areas, a significant and strong correlation of patient's assessment with objective clinical measures may support its use as a valid proxy measure of clinical status, thus opening up multiple research design opportunities where the perspective of the patient is paramount.

PRM165

EXPLORING THE HUMANISTIC AND ECONOMIC BURDEN OF CROHN'S DISEASE: CONSIDERATIONS FOR NOVEL COMPOUNDS

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OBJECTIVES: Crohn's disease (CD) is an inflammatory bowel disease affecting approximately 1.4 million people in the United States. The aims of this study were to document current unmet needs in CD in terms of patient-reported and economic burden; and how such concepts may be assessed to capture the overall benefit of new CD therapies for patients, health care systems and society. **METHODS:** Articles were identified in MEDLINE, EMBASE, EconLit, HEED, CRD databases and PSYCINFO using pre-defined search terms/limits. 561 abstracts were identified; and 31 full articles were reviewed. Direct and indirect costs of CD were extracted as were patient-relevant concepts (symptoms and impacts) to form a patient-relevant conceptual model. Patient-reported measures were identified in PROQOLID and were assessed in context of FDA guidance. **RESULTS:** CD symptoms manifest primarily as gastrointestinal disturbances including abdominal pain/cramping and diarrhoea. Fever, fatigue and weight loss are also prominent symptoms. These symptoms impact patients' physical functioning, daily activities, emotional well-being, and ability to work. Seven patient-reported measures were reviewed in-depth; measures of HRQoL (IBDQ, SF-36, IBDQOL), occupational functioning (CPWDQ, WPAI:CD) and disease activity/symptoms (CDAI, CDAI-short, GSRS). Instruments to assess HRQoL and occupational functioning used concurrently with the CDAI may demonstrate the wider influence of treatment on other symptoms and patients' lives. CD is associated with substantial direct costs, estimated at $18-$19,000 per-patient per-year in the US, and indirect costs, estimated at $7,260 per-patient per-year. Costs are especially high in sub-groups (e.g. presence of fistulas). **CONCLUSIONS:** The disease course of CD is characterised by remissions and relapses, thus lifetime humanistic and economic burden is substantial. This review highlights the need for disease-specific patient-reported measures that provide comprehensive assessment of relevant domains of disease activity/symptoms, HRQoL and occupational functioning. Further research into drivers of direct and indirect costs of CD is necessary to meet cost-effectiveness requirements.

PRM166

PATIENT-REPORTED OUTCOMES IN FDA-APPROVED PRODUCT LABELS: RECENT TRENDS AND METHODS FOR ASSESSING SUCCESSFUL INCLUSION OF PROS

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OBJECTIVES: The FDA approved 39 new molecular entities (NMEs) in 2012, and many efficacy claims were supported by patient-reported measures or statements. In addition, many previously-approved products were approved for a new indication supported by PRO endpoints in recent years. The purpose of our research was to conduct an in-depth analysis of recently approved claims supported by PROs in order to identify notable trends, and to describe best methods for assessing the success rate of PRO inclusion. **METHODS:** Published FDA product labels, literature and Internet searches were utilized. All labels of NMEs and new indications approved by the FDA from 2010 to 2012 were reviewed. A measure or statement of efficacy was considered to be a PRO if it assessed symptoms, reduced side effects, or impacts on functioning from the patient's perspective. **RESULTS:** There were 21, 30, and 39 NMEs approved in 2010, 2011, and 2012. In these years, 12, 19, and 13 NME labels contained PRO-related claims or statements (67%, 63%, 33%), and pain-related PROs were the most common (n's=4, 11, 8). Cumulative distribution function (CDF) graphs were present in 13 NME labels during these years. Importantly, from 2010 to 2012 many products added indications with efficacy claims supported by a PRO, but such a submission was not considered an NME (e.g., pregabalin). From 2006 to 2009, PRO-related claims were included in 66% of approved NMEs. This rate decreased to 49% during 2010 – 2012; however, more PRO claims (44 versus 50; 2010-2012) are revealed when reviewing more than NMEs. **CONCLUSIONS:** Development, testing, and validation of PRO measures as clinical trial endpoints remain important for facilitating the approval of drugs and communicating value to the consumer. Reviewing NDA and BLA labels is a more accurate assessment of the success of PRO inclusions in FDA-approved labels than reviewing NMEs alone.

PRM167

PREDICTING MEDICATION ADHERENCE USING RETAIL PHARMACY DATA

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OBJECTIVES: Apply data mining techniques to pharmacy data to identify patients likely to be non-adherent to their medication in the next six months. **METHODS:** Catalina Health™ receives a nationally representative sample of pharmacy data containing 40% of all U.S. retail prescription volume and 130 million unique patient ID's. The data is HIPAA compliant, longitudinal, and not projected. Select 7 prescription medications representing multiple therapeutic classes. For each medication, randomly select a 100K patient cohort filling a prescription between June and August 2010. In order to eliminate patients who switch pharmacies or migrate to mail order, exclude patients who have no history of filling any drug during the prior 18 months, or who have no fill history for any drug during the six month analysis period. Fit logistic regression models to predict which patients will be non-adherent to their medication in the next six months. Consider patients non-adherent when Proportion of Days Covered (PDC)<80%. Model covariates include prior adherence to the medication (if applicable), adherence for co-morbid conditions, days supply of the medication, ethnicity and income variables, patient age and gender, paid with cash, number of refills remaining, medication dose, and number of co-morbidities. Model accuracy is assessed using a 20% hold-out of the data. **RESULTS:** The models identified 40.3% of the patients as likely to be non-adherent to their medication in the next six months. This varied by medication (23.2% - 64.6%) and patient type (28.8% Experienced, 38.9% Moderate Experienced, and 77.5% New). The overall model accuracy rate is 70.4%. 72.3% of the patients predicted to be non-adherent were actually non-adherent (precision), while 69.1% of the patients predicted to be adherent were actually adherent. **CONCLUSIONS:** Data mining techniques applied to pharmacy data can predict patients who are likely to be non-adherent to their medication in the next six months with 72.3% precision.

PRM168

DEVELOPMENT OF THE ANGINA PATIENT SELF-MANAGEMENT QUESTIONNAIRE

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OBJECTIVES: Guidelines had present many management recommendations to physicians on angina prevention and treatment. However patients still knew less about angina management in China. They need Heart education. Thus, we want to develop an angina patient self-management questionnaire (ASMQ). **METHODS:** We hypothesized the questionnaire should carry messages of risk factors, prevention and treatment of angina. Items were determined from guidelines, and interview of patients and cardiovascular doctors. A five point Likert scale was chosed as the response format. Higher score means better management. The questionnaire was tested along with a cross-sectional angina study. Reliability was evaluated via internal consistency, and test-retest reliability. Construct validity was tested through Exploratory Factor Analysis (EFA), and discriminant validity was assessed by detecting differences between in-patients and out-patients. We assumed in-patients learn more about angina than out-patients. **RESULTS:** The ASMQ contained 12 items organized in two domains: risk-factor and self-management. The ASMQ was tested on 430 patients (age 63±12 year; 171 male, 40%); Of those, 150 (35%) were outpatients, and 86 (20%) retested 24 hours later. Test-rest correlation coefficient of the ASMQ was 0.740, and 0.719, 0.780 for risk-factor and self-management domains respectively. Cronbach's alpha coefficient was 0.616 of the overall questionnaire, and 0.692 of the self-management domain. But the risk-factor domain was 0.432, showed an unsatisfied internal consistency. Three factors were extracted through EFA, and were stratified into 2 domains as expected. The score of in-patients (43±7) was higher than out-patients (41±6), which showed a better management among in-patients (p=0.017). **CONCLUSIONS:** The ASMQ showed an