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), construct validity, responsiveness and concurrent validity. Measurement properties were assessed using data from the Rapid-axSpA trial investigating certolizumab pegol (C2F7) efficacy in axSpA. RESULTS: Reviewed AS literature identified key concepts, physical health, mental health, pain, physical functioning, morning stiffness, fatigue, disturbed sleep, depression, mobility problems, problems performing recreational activities/household tasks/self-care/work, and problems performing daily activities. All 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 (ICC) and internal consistency coefficients (Cronbach’s α) ≥ 0.70. Construct validity was supported by agreement between PRO and clinician-rated measures. All the PRO measures showed good sensitivity to change, with large response values (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 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 were randomized to receive one of the two TTO variants that varied the ratio of lead time to time in poor health. 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 (0.4%) where the lead time was shorter. CONCLUSIONS: This study confirms earlier findings that the ratio of lead time to unhealthy time has a small 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 Meta-Analysis (PRISMA) strategy was used in the 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 searches against predefined exclusion/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, evidence in support of hyperbolic 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 economists model future costs and consequences should consider the behavior 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 market launch strategy 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 in the analysis. The productivity loss (using the WPAI questionnaire) was examined and subpopulations of pain patients with particularly high or low impairment were described and compared to understand the likelihood of sharing clinical data being 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, 51.7% male, female). Mean level of pain severity in the last week was 4.71 (SD=2.73) and mean overall work productivity loss was 0.48 (SD=0.84). 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% improvement 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 low impairment that no intervention could provide a compelling proposition. However, key subgroups (e.g. those obese) reported significant improvements with a much greater likelihood of demonstrating treatment benefit. Subgroup analysis is a powerful way to develop credibility and help inform clinical trial design, optimize incremental value, and drive cost effectiveness.

PRM162

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

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OBJECTIVES: The Key Auditory Verbal Learning Test (RAVLT) is a cognitive test used in early development to identify the most relevant patient populations and to develop product claims that will help inform clinical trial design, optimize incremental value, and drive cost effectiveness.

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 search of all available electronic search of research databases (PubMed, MEDLINE, EBSICO, and PsychINFO). 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 searches against predefined exclusion/inclusion strategy to ensure appropriate inclusion of papers. METHODS: 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, evidence in support of hyperbolic 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 economists model future costs and consequences should consider the behavior 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.
were used. Of these, 27 studies used telephone and text reminders. Four used educational materials and books while another four used blister packaging. 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 striving to improve 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 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 the 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 are provided of the differences in language and data collection/analysis processes that 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: 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 captured to measure the overall benefit of new CD therapies for patients, health care systems and society. METHODS: Articles were identified in MEDLINE, EMBASE, Econlit, HEDIS, HCUP, TransPerfect, Research Triangle Park, NC, USA 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 patient-relevant concepts (symptoms and impacts) to form a patient-relevant conceptual model. Patient-reported measures were identified in FROQOLID and were assessed in context of FDA guidance. RESULTS: CD symptoms manifest primarily as gastrointestinal disturbances including abdominal pain, cramping and diarrheoa. 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 (CPWQD, WPQ-AI) and disease activity/symptoms (CDAI, CDAD-score, GRS). Instruments to assess HRQoL and occupational functioning were 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-$31,000 per patient-year in the US, and indirect costs, estimated at $7,260 per-patient per-year. Costs are expected to increase in the future (e.g. prevalence 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 development of new 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 practices for assessing the benefit of PRO metrics. Methods of PRO inclusion and 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 or included PRO-related claims, for example, by referencing PRO data. RESULTS: Of the 39 NMEs approved in 2010, 2011 and 2012, 12 (31%) NMEs contained PRO-related claims or statements (67%, 63%, 33%), and pain-related PROs were the most common (n=4, 11, 8). Cumulative distribution function (CDF) graphs were present in 13 NME labels during these years. Importantly, from 2010 to 2012 patients predicted to be non-adherent to their medication in the next six months. CONCLUSIONS: Development, testing, and validation of PRO measures as clinical trial endpoints remain important for facilitating the approval of drugs and communicating value to patients. Reviewing FDA labels can educate about effective adherence tools in order to improve quality of care to patients and society.

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 Health1 receives a nationally representative sample of pharmacy data containing 46% of all U.S. prescription volume and comprising more than one million patient-specific IPD. 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 determine which patients are likely to 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 the drug during the six month period. For each model, the proportion of patients predicted to predict which patients will be non-adherent to their medication in the six months. CONCLUSIONS: Patients non-adherent when Proportion of Days Covered (PDC)<80%. Model covariates include patient adherence rate, 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 43.0% of the patients as likely to be non-adherent to their medication in the next six months. This varied by medication (23.7% - 64%) and patient factors (28.8% Experienced, 38.9% Moderate Experiende, 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. Non-adherence was found to be related to other symptoms and patient factors, prevention and treatment of angina. Items were determined from guidelines, and interview of patients and cardiovascular doctors. A five point Likert scale was chosen as the response format. Higher score means better management. The questionnaire was tested along with a cross-sectional angiography study for reliability and acceptability. The ASMQ contains 34 items, 19 of which assess symptoms, factors, prevention and treatment of angina. The ASMQ was found to be reliable and acceptable. The questionnaire was tested along with a cross-sectional angiography study for reliability and acceptability. The ASMQ contains 34 items, 19 of which assess symptoms, factors, prevention and treatment of angina. The ASMQ was found to be reliable and acceptable.

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 factor prevention and treatment, symptoms, preventive measures, from guidelines, and interview of patients and cardiovascular doctors. A five point Likert scale was chosen as the response format. Higher score means better management. The questionnaire was tested along with a cross-sectional angiography study and 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 groups. RESULTS: The ASMQ contained 12 items organized in two domains: risk-factor and self-management. The ASMQ was tested on 430 patients (51±12 year, 71±6, 40%); of those (25%) were out-patients, and 86 (20%) retested 24 hours later. Test-retest coefficients were 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 0.740, 0.719 of the self-management domain. The questionnaire 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±2) was higher than efficacy claims supported by a PRO, but management among in-patients (p=0.017). CONCLUSIONS: The ASMQ showed an