crossover design study. Seventy men and women with moderate to severe erythema of rosacea were included. Subjects were randomized 1:1 to either BG once daily or AG twice daily for 15 days. After a washout period, subjects were given the other treatment for 15 days. The primary efficacy endpoint was composite success defined as a 2-grade improvement in both the CEA and PSA 6 hours after application on day 15. Secondary endpoints included 2-grade improvement in CEA and PSA and changes in chromameter readings 6 hours after application on day 15. All outcomes were in comparison to baseline (Day 0). **RESULTS:** Per the protocol, the results of the second period were discarded as there was significant treatment carryover from the first period. The percentage of subjects with composite success in period 1 was 14.3% and 5.7% for BG and AG, respectively. The percentage of subjects with a 2-grade improvement for CEA was 37.1% and 11.4% for BG and AG, respectively and those with a 2-grade improvement in PSA was 28.6% and 20.0% for BG and AG, respectively. Chromameter readings decreased by 9.64% and 2.38% for BG and AG, respectively. **CONCLUSIONS:** Improvements were larger and more pronounced with the CEA and chromameter than with the PSA suggesting that subjects may view their rosacea severity and improvements with treatment differently than either a clinician or objective instrumentation.

PRM4

A SCOPING LITERATURE REVIEW ON THE EXTERNAL VALIDITY OF RANDOMIZED CONTROLLED TRIAL POPULATIONS

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OBJECTIVES: The aim of this scoping literature review was to report the findings of studies that have attempted to quantify external validity by comparing the patient population included in randomized controlled trials (RCTs) with patients from everyday clinical practice. **METHODS:** We conducted a literature review of English language journal articles published since 2003 that compared a RCT patient population with a 'real-life' patient population. Studies were limited to pharmaceutical interventions undertaken in adults. A protocol was developed that outlined the search approach. A range of databases were interrogated (MEDLINE; EMBASE; Science Citation Index; Cochrane Methodology Register). Double abstract review and data extraction were performed in line with protocol specifications. **RESULTS:** Out of 5456 de-duplicated abstracts, there were 73 studies that met the inclusion criteria. Studies covered a range of therapy areas, with the majority undertaken in mental health (n=18), cardiology (n=16), and oncology (n=13). Studies either assessed the proportion of people from a clinical setting that would be eligible for an RCT or undertook a post-hoc analysis of RCT patient characteristics compared with the real-world population. A range of comparisons were made, including demographic, socioeconomic, and clinical parameters. The vast majority of studies (n=59) concluded that study selection criteria excluded many patients from clinical practice; most commented on how this limited the RCT's external validity. A number of recommendations were made to improve the generalizability of RCTs or facilitate better understanding of their limitations. **CONCLUSIONS:** RCTs designed to maximize internal validity frequently result in a loss of external validity. Designers of RCTs should carefully weigh inclusion/exclusion criteria to ensure study objectives are met without unnecessarily sacrificing external validity, and the extent to which generalizability is compromised should be reported. Ultimately, a combination of explanatory and pragmatic studies is necessary to meet the diverse needs of regulators, prescribers, payers, and patients.

PRM6

ESTIMATION OF LONG-TERM CARE NEEDS FOR 9 MAJOR CANCER IN TAIWAN

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OBJECTIVES: The lifetime functional disabilities associated with cancer have received little attention in the literature. This study determines the dynamic changes of different physical functional disabilities over time and their total duration after cancer diagnosis to understand their potential long-term care needs. **METHODS:** 395,330 patients with pathologically verified cancer registered in the National Cancer Registry in Taiwan between 1998 and 2007were used to estimate the survival functions and extrapolate to lifetime through a semi-parametric method. A convenience sample of 6,189 measurements of patient's functional disability with EQ-5D was collected for measuring impairment levels and care needs. Lifetime functional disabilities were obtained by extrapolating the gender and age-stratified survival functions to lifetime, and multiplying them with the proportions of different kinds of functional disability over time. **RESULTS:** The common care needs for cancer patients were mobility and usual activity; the older the patient, the higher the prevalence of functional disabilities and care needs; the shorter the life expectancies (LE), the higher the proportion of expected years of living with disability (EYLD). Male patients with nasopharyngeal and oral cancer represented the longest for EYLD, or were 2.66 and 2.07 years, respectively, which would be about 20 and 17 percent of their LE's. The EYLD of cervical cancer was over 3.6 years, or about 9 to 40 percent of their LE. **CONCLUSIONS:** Cancer patients suffer from functional disabilities approximately 1.4 to 31.2 percent of their remaining lifetime, and may in need of long-term care. More detailed studies are warranted to comprehensively care these patients.

PRM7

ROLE OF TELEREHABILITATION IN PATIENTS FOLLOWING TOTAL KNEE ARTHROPLASTY: EVIDENCE FROM SYSTEMATIC LITERATURE REVIEW

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OBJECTIVES: Increased physical activity and functional ability are the goals of total knee replacement surgery. Therefore, adequate rehabilitation is required for the recovery of patients after discharge from hospital following total knee arthroplasty (TKA). This systematic literature review aims to evaluate the effectiveness of home telerehabilitation in patients who underwent TKA. **METHODS:** Studies published in the English language between 2000 and 2014 were retrieved from Embase, PubMed and Cochrane databases using relevant search strategies. Two researchers independently reviewed studies as per the Cochrane methodology for systematic reviews. We considered telerehabilitation sessions as those that were conducted using videoconferencing by experienced physiotherapists to patients' home via an internet connection. The outcomes assessed include knee movement (knee extension and flexion); quadriceps muscle strength; functional assessment (the timed up-and-go test); assessment of pain, stiffness and functional capacity with Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and visual analog scale (VAS) for pain. **RESULTS:** In total, 160 potentially relevant studies were screened. Following screening of studies as abstracts and full-text publications, seven primary publications (four randomized controlled trials [RCT], one non-RCT, and two single arm trials) were included in the review. Patients experienced high levels of satisfaction with the use of telerehabilitation alone. The patients in the home telerehabilitation group showed improvement in physical activity and functional status similar to patients in conventional therapy group (comparative studies). The detailed analyses of the findings from studies are still ongoing and will be presented on completion. **CONCLUSIONS:** A preliminary analysis shows that home telerehabilitation method is an acceptable rehabilitation method to patients who underwent TKA. The evidence from this systematic literature review will hopefully demonstrate telerehabilitation to be a practical alternative to conventional face-to-face rehabilitation therapy in patients who underwent TKA.

PRM8

DIFFICULTY IN ESTABLISHING THE IMPACT OF DRUGS ON QUALITY OF LIFE IN COGNITIVELY IMPAIRED PATIENTS: EXAMPLE OF ATTEMPTING TO DERIVE UTILITY IN PATIENTS TREATED WITH RIFAXIMIN-A FOR THE REDUCTION OF RECURRENCE OF EPISODES OF HEPATIC ENCEPHALOPATHY

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OBJECTIVES: Hepatic encephalopathy (HE) is a serious complication of liver disease. HE presents as a spectrum of neurocognitive impairments, from mild HE to coma. Direct measurement, or derivation of utility values related to treatment using a generic QoL mapping procedure may not provide the most valid measures, given the nature of the condition. Rifaximin-α is a treatment for HE that has been shown to reduce the recurrence of HE and HE-related hospitalisation. Following an exercise using a disease specific instrument that yielded a utility difference of 0.155 units, here we attempted to indirectly estimate the utility impact of Rifaximin-α in patients with HE. **METHODS:** Data from a six month, phase-3 RCT of rifaximin-α in HE patients was used. In this study, monthly PROs including SF-36 were recorded until an HE event had occurred or until the end of study. We estimated the EQ-5D index (estEQ-5Dindex) using a recognised SF-12 mapping procedure. Due to missing observations and differences in baseline utility, linear interpolation of utility values was applied, and the individual changes from baseline in the estEQ-5Dindex were characterised. **RESULTS:** At baseline, the estEQ-5Dindex was 0.563 units (SD 0.263) units in the rifaximin-α arm, and 0.587 (0.211) in the placebo arm (p=0.368). There was no discernible difference using mean values throughout (overall mean estEQ-5Dindex at end of study 0.643 (0.23) for rifaximin-α vs. 0.647 (0.24; p=0.922)). The overall percentage of *missing data* was 20% of subjects and 14% of potential observations. The mean difference from end of study to baseline in utility was 0.018 units (SEM 0.02 for rifaximin-α vs. -0.013 for placebo (0.031; p=0.171). **CONCLUSIONS:** Even with an insensitive methodology using generic quality of life we demonstrated that rifaximin-α was associated with a discernible, clinically meaningful change in utility in cognitively impaired patients. In these patients, direct measurement of utility using a PRO was inappropriate.

PRM9

THE IMPLEMENTATION OF THE EXTRACT OF CENTARIA ISLANDICA IN PATIENTS SUFFERING FROM EGZACERBATION OF CHRONIC PHARYNGITIS

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OBJECTIVES: The objective of this paper is to establish if the implementation of Isla lozenges influences the intensity of sore throat sensation in patients suffering from egzacerbation of chronic pharyngitis and whether their use influences the need of antibiotic therapy administration. **METHODS:** The number of 60 patients with egzacerbation of chronic pharyngitis has been observed. 30 of them used Isla lozenges during 10 days/ 6 times a day, while the remaining 30 did not take any. According to the VAS scale (0-10 cm) the intensity of sore throat sensation was determined at the beginning of the disease and after 10 days. Also, it was determined in how many patients it was necessary to introduce antibiotic therapy. **RESULTS:** The average value of sore throat sensation in the initial stage in the group in which Isla lozenges were administered was 6.80, while in the group that did not take them was 6.60; p> 0,05. After ten days of trial, the average value in the group that took Isla lozenges was 1.60; p< 0,05. In the group that did not take the lozenges, the average sore troat sensation was 5.90 after ten days; p> 0,05. The average values of sore troat sensation after 10 days of Isla lozenges implementation were statistically significantly lower in comparison to the second group; p< 0,05. The group in which Isla lozenges were given for 10 days, 5 patients needed additional antibiotic therapy, whereas it was 14 patients in the second group; p< 0,05. **CONCLUSIONS:** Implementation of Isla lozenges in patients with egzacerbation of chronic pharyngitis statistically significantly lowers the intensity of sore throat sensation as well as the need for later antibiotic therapy administration. This research was supported by Provincial Secretariat for Science and Technological Development, Autonomous Province of Vojvodina project No 114-451-3551/2013-01

PRM90

COMPARISON OF THE 4-ITEM AND 8-ITEM MORISKY MEDICATION ADHERENCE SCALE IN PATIENTS WITH TYPE 2 DIABETES

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OBJECTIVES: The 4-item Morisky Medication Adherence Scale (MMAS-4) and more recent 8-item version (MMAS-8) have both been validated and demonstrate concurrent validity among patients with hypertension, but the extent to which the scales can be compared has received little attention. This study assessed the comparability of adherence scores obtained with these scales in patients with type 2 diabetes (T2D) as well as the feasibility of integrating results across the scales using 4 items of the MMAS-8. **METHODS:** Data were taken from the 2011 and 2012 US National Health and Wellness Survey (NHWS). The NHWS is a large cross-sectional survey representative of the total adult population in several major markets; N~75,000/year in the US. A total of 13,007 respondents self-reported physician diagnosis of T2D and were administered MMAS-4 in 2011 or MMAS-8 in 2012. The two adherence scales were evaluated by comparing the frequency distributions of the MMAS scores for the two scales, Cronbach's alpha and inter-item correlations, and the creation of a new 4-item scale including the questions in MMAS-8 that best matched the questions in MMAS-4. **RESULTS:** In T2D patients, both MMAS-4 and -8 scores are Poisson-like distributed, with median at zero (high adherence) for MMAS-4 and at 1 (medium adherence) for MMAS-8. Chronbach's alpha was 0.55 for MMAS-4 and 0.71 for MMAS-8, while average item-test correlations were 0.65 and 0.57, respectively. The reduced 4-item scale created out of MMAS-8 is also Poisson-like distributed, Cronbach's alpha was 0.62 and the average item-test correlation was 0.68. **CONCLUSIONS:** Scores of the two MMAS show similar qualitative and quantitative characteristics, suggesting that it may be appropriate to integrate data sources using the two different versions, particularly when the responses to the subset of 4 MMAS-8 items are available. Future research should confirm that the scales can be integrated in different therapeutic areas.

PRM11

VALIDATION OF THE TELEPHONE-ADMINISTERED OF THE AGE AND STAGE QUESTIONNAIRE AND THE REVISED-PRESCREENING DENVER QUESTIONNAIRE: RESULTS FROM THE OTIS ANTIDEPRESSANTS IN PREGNANCY STUDY

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OBJECTIVES: We aimed to validate the telephone administration of the Revised Prescreening Denver Questionnaire (R-PDQ) and the Ages and Stages Questionnaire (ASQ), 2 tools used to pre-screen and screen children development, respectively. **METHODS:** The OTIS Antidepressants in Pregnancy Study cohort was used. Women were recruited through nine North American Teratogen Information Services and at the CHU Ste-Justine outpatient obstetrical clinic (Montreal). To be included, women had to be >18 years old, <15 weeks pregnant, and not using known teratogens. Both questionnaires were self and telephone- administered to mothers at 12-months postpartum. The ASQ includes five domains (communication, gross motor, fine motor, problem-solving and personal-social). The R-PDQ tests gross and fine motor, personal-social and language skills. Socio-demographic variables were collected through telephone interviews. Concordance between the telephone and self-administration of both questionnaires were assessed with Intraclass Correlation Coefficients (ICC) with 95% Confidence Intervals (CI). **RESULTS:** Overall, 61 and 56 women filled the ASQ and R-PDQ, respectively. Concordance between the self and telephone-administered ASQ was substantial for the communication scale (ICC=0.76;95% CI (0.63;0.84)), almost perfect for the gross motor scale (ICC = 0.83; 95% CI (0.73; 0.90), and moderate for the fine motor, problem-solving and personal-social scales (ICC = 0.44; 95% CI (0.21; 0.62); ICC = 0.43; 95% CI (0.19; 0.61); ICC = 0.52; 95% CI (0.31; 0.68); respectively). Regarding the R-PDQ, the following concordance estimates were found: gross motor scale (ICC = 0.90; 95% CI (0.83; 0.94)), language (ICC = 0.58; 95% CI (0.38; 0.72), personal-social scales (ICC = 0.27; 95% CI (0.07; 0.49). The agreement was perfect for the fine motor scale. **CONCLUSIONS:** The telephone administration of the ASQ is a valid method of child development screening. However, only the R-PDQ gross and fine motor and language scales should be administered through telephone when pre-screening infant development.

PRM13

VALIDATION OF CLAIMS DATA TO IDENTIFY SURGICAL SITE INFECTIONS WITH ANTIBIOTIC UTILIZATION DATA***

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OBJECTIVES: *International Classification of Diseases* (ICD-9-CM) diagnosis codes are increasingly being used to identify hospital-acquired infections, often with insufficient evidence demonstrating validity of the codes used. Absent medical record verification, we sought to confirm a claims algorithm to identify surgical site infections (SSI) by determining the presence of clinically expected SSI treatment. **METHODS:** We performed a retrospective cohort study using private insurer claims data from persons < 65 years with ICD-9-CM procedure or CPT-4 codes for anterior cruciate ligament (ACL) reconstruction from 1/2004–12/2010. SSIs occurring within 90 days after ACL reconstruction were identified by ICD-9-CM diagnosis codes. Antibiotic utilization, surgical treatment, and microbiology culture claims within 14 days of SSI codes were used for validation. **RESULTS:** Of 40,702 ACL reconstruction procedures, 409 (1.0%) were complicated by SSIs, 172 (0.4%) of which were specifically identified as septic arthritis. Most SSIs were associated with an inpatient admission (n=232, 57%), and/or surgical procedure(s) for treatment (n=258, 63%). Among SSIs included in the validation, temporally-associated antibiotics, surgical treatment procedures, and cultures were present for 84% (338/401), 61% (246/401), and 59% (238/401) respectively. Only 5.7% (23/401) of procedures coded for SSI post-procedure had no antibiotics, surgical treatment, or culture within 14 days of the SSI claim. **CONCLUSIONS:** Over 94% percent of patients identified by our claims algorithm as having an SSI received clinically expected treatment for infection, including surgery, cultures, and antibiotics, suggesting this algorithm has very good positive predictive value. This method may facilitate retrospective SSI surveillance and comparison of SSI rates across facilities and providers.

PRM14

DEVELOPING A COHORT OF LINKED MOTHER-BABY PAIRS TO STUDY PRETERM LABOR: HARMONIZING REAL-WORLD DATA FROM FOUR LARGE UNITED STATES INTEGRATED DELIVERY NETWORKS

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OBJECTIVES: Integrated delivery networks (IDNs) capture patient data across the continuum of care and are valuable tools for real-world research, with potential to study large, diverse cohorts with rich information on patient characteristics, treatments, physician decisions and outcomes. However, using multiple IDNs requires combination of dissimilar data to create a uniform *post hoc* analysis dataset. We used this approach to create a novel cohort to examine maternal and neonatal characteristics with the goal of better understanding preterm labor, a critical step in developing effective tocolytic treatments. **METHODS:** Retrospective data on births from 2001-2012 were collected from 4 U.S. IDNs (from Illinois, Ohio, New Mexico and central states [Missouri/Arkansas/Kansas/Oklahoma] participating in Quintiles' COMparative effectiveness PAtient Safety and Surveillance (COMPASS) Research Network. The IDNs were geographically/racially distinct with varying types of electronic medical records, catchment areas and institution types. Detailed data specifications were defined, mothers and babies were linked using medical record numbers and files were pooled to produce an overall cohort. **RESULTS:** A cohort of 109,583 mother-baby pairs among women with uncomplicated, singleton pregnancies was built each associated with their clinical records. Data were collected on maternal medication use and specific pregnancy complications (e.g., eclampsia/HELLP, placental conditions and infections) and neonatal characteristics including demographics, weekly gestational age, procedures, treatments and hospital-based clinical outcomes. **CONCLUSIONS:** IDNs offer an in-depth source of real-world data to evaluate characteristics of otherwise difficult-to-study populations. However, employing routine care information from diverse settings for research presents challenges and varying definitions, coding processes and facility characteristics should be considered before analyses. Processes must be developed to translate clinical records into standardized analytic research datasets. Development of detailed specification and harmonization processes allowed creation of a cohesive and unique mother-baby linked data resource that could be extended to a broad range of perinatal epidemiology and health outcomes research questions.

PRM15

SOME STATISTICAL CONSIDERATIONS IN ESTIMATING A DISEASE PROGRESSION MODEL FOR CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)

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OBJECTIVES: To estimate associations between attributes of COPD and to develop a model that predicts economic and health outcomes associated with COPD progression. **METHODS:** We utilized data from ECLIPSE (clinicaltrials.gov identifier: NCT00292552), a three year cohort study of COPD patients to estimate the associations between central COPD attributes (exacerbations, lung function, exercise capacity, and signs/symptoms) while adjusting for co-morbidities, body composition (BMI), biomarkers, smoking history, age, and gender. As disease progression endpoints we used the total score of the St. George's Respiratory Questionnaire (SGRQ) and mortality. We applied random coefficient models to assess the relationships between the central COPD attributes longitudinally and thereby describe patient trajectories over time. As appropriate, non-linear functional forms were explored to characterize the nature of the data. Endogeneity among the central attributes of COPD was addressed by time-lagging in the regression models. **RESULTS:** Severe exacerbations in the preceding 12-months were associated with an average decline in lung function (FEV_1) of up to 10 ml ($P<0.05$) and with a reduced exercise capacity (6 minute walk test) of 13 meters ($P<0.0001$). A 1% increase in FEV_1 % predicted was also associated with a 5% reduction in the probability of experiencing dyspnoea on most days/week ($P<0.0001$). All central attributes were found to significantly impact disease progression, measured by the SGRQ, with the largest estimated effect for dyspnoea on most days/week (18 point increase in the SGRQ score; $P<0.0001$). Lung function and exercise capacity, however, were the only central attributes that were significant predictors of mortality ($P<0.05$). **CONCLUSIONS:** The use of appropriate analytical techniques to account for the longitudinal nature and endogeneity of COPD attributes enables the estimation of their impact on important health outcomes. Our results confirm the expected associations between the central attributes of COPD and their effect on patient health status (SGRQ) and mortality.

PRM16

CAUSAL INFERENCE: COGNITIVE FUNCTIONING AND DEPRESSIVE SYMPTOMS BY LONGITUDINAL MARGINAL STRUCTURE MODEL

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OBJECTIVES: the association between depressive symptoms (Center for Epidemiologic Studies Depression Scale [CES-D]) and subsequent cognitive function