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

Curtis SE[1], Kennedy-Martin T[2], Faries DE[1], Robinson S[2], Johnston JA[1]
[1]*Eli Lilly and Company, Indianapolis, IN, USA,* [2]*Kennedy Martin Health Outcomes, East Sussex, UK*

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

Hung MC[1], Lai WW[2], Hwang JS[3], Wang JD[4]
[1]*Department of Public Health, National Cheng Kung University Medical College, Tainan, Taiwan,* [2]*Department of Surgery, National Cheng Kung University Hospital, College of Medicine, National Cheng Kung University, Tainan, Taiwan,* [3]*Academia Sinica, Taipei, Taiwan,* [4]*National Cheng Kung University College of Medicine, Tainan, Taiwan*

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

Shukla H, Nair SR, Shaikh JS, Thakker D, Sharma D
Capita India Pvt. Ltd., Mumbai, India

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

Berni E[1], Conway P[2], Nanuwa K[2], Currie CJ[3]
[1]*Pharmatelligence, Cardiff, UK,* [2]*Norgine Ltd, Uxbridge, UK,* [3]*Cardiff University, Cardiff, UK*

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

Raskovic A, Savovic S, Stilinovic N, Milijasevic B
Faculty of Medicine, University of Novi Sad, Novi Sad, Serbia and Montenegro

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