various methods for adjusting confounders in estimating comparative effectiveness. A recent systematic literature review in PubMed was conducted to identify published articles with the key words such as propensity score, instrumental variable analysis, inverse probability, Propensity Instrumental, Propensity Inverse probability, machine learning, support vector machine, CART (Classification And Regression Trees), ensemble methods or random forest learning. The search was performed by comparing proportions of methods before 2008 and after 2008. RESULTS: 5021 articles were found with the key word of comparative effectiveness. 227 articles had the key word of propensity. 56 articles had the key word of instrumental. 29 articles had the key word of inverse probability. 20 articles had key words of both propensity and instrumental. 12 articles had key words of both propensity and inverse probability. 6 articles had key word of machine learning. 6 articles had key word of CART. No article was found to have the key word of support vector machine. Overall 6.2% of articles had one of the key words, indicating usage of confounder adjustment methods in comparative effectiveness research. Two articles had three key words of propensity, inverse probability and instrumental. Based on Chi-square test, significant increase of usage with P-value < 0.05 in trend has been observed. CONCLUSIONS: Based on search result, significant increase in usage of confounder adjustment methods was observed since 2008. In a few articles, results from a few instrumental variable analyses using machine learning by employing various methods for adjustment of confounders. Also application of machine learning methods is recommended to find stable estimates of models used, especially to adjust for time dependent confounders.

PRM11 EVALUATING CONTENT VALIDITY OF PERFORMANCE OUTCOMES (PerfoS): ESTABLISHING THE PATIENT-RELEVANCE OF THREE PERFOS IN ELECTIVE TOTAL HIP REPLACEMENT (eTHR) patients.

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OBJECTIVES: Performance Outcomes (PerfoS) measure tasks performed by a patient under the instruction of a health-care professional. PerfoS used to support informed consent require content validity evidence. This study explored patient experience and relevance of three elective total hip replacement (eTHR) PerfoS: the timed up and go (TUG), four step stair climb (4SC) and long stair climb (LSC). METHODS: Eight recent eTHR patients in the US were interviewed by telephone, completing three PerfoS and a Participate Device. Participants described their experience of completing the PerfoS, and how the movements, speed and level of difficulty corresponded to activities in their everyday lives. Interviews were audio-recorded, transcribed and systematically coded. Saturation was assessed by tabulated patient summaries from which new elements reported in each interview were identified. RESULTS: The sample comprised six females and two males, with mean age 67 years. All participants reported TUG movements to activities in their daily life. The 4SC and LSC were described as more difficult to complete, but on turn on the task instruction most regularly climbed a few steps at home and in a similar way to the 4SC (e.g. use of handrail). Climbing 12 or more steps (LSC) was less common. However, the majority recalled examples of this and felt the LSC accurately reflected movement and ability in their replaced hip. Two participants reported LSC completion increased their confidence and of this and felt the LSC accurately reflected movement and ability in their replaced hip. TUG was performed by all. TUG, 4SC and LSC were not identified as difficult to complete at home in a similar way to the 4SC (e.g. use of handrail). The approach was re-tested by panelists.

PRM12 CLINICAL TRIAL REGISTRIES FOR SYSTEMATIC REVIEWS – AN ALTERNATIVE SOURCE FOR UNPUBLISHED DATA

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OBJECTIVES: When conducting a systematic review it is common practice to search for peer-reviewed publications and conference proceedings to identify studies relevant to a research question. However, information about studies is increasingly available through other sources and can be of importance in systematic reviews. Clinical trials registries (CTRs) are one of the most commonly used CTRs and provides search facilities that enable the identification of trials through common search terms. In addition, there is the potential to request information from study sponsors through clinicaltrialsdataquest.com. This website is supported by several prominent study sponsors and allows reviewers to request access to unpublished data which may be of importance in a systematic review. METHODS: We searched two disease areas (melanoma and juvenile idiopathic arthritis (JIA)) for instances where there were discrepancies in reporting of endpoints between peer-reviewed publications and the clinicaltrials.gov web-page for corresponding trials. We submitted requests to clinicaltrialsdataquest.com for additional information and advanced search options. We also added additional reporting of subgroups as well as efficacy endpoints in clinicaltrials.gov that were not available in peer-reviewed publications. Results included one trial in melanoma which was reported on one of the clinicaltrials.gov and in a peer-reviewed publication; results stratified by previous therapy were available from the CTR. In addition, results from our search in JIA included additional reporting of efficacy outcomes such as change in component scores from baseline. We detail length of time for request and for receipt of data. RESULTS: 11 submissions of data were received from one of the study sponsors.

CONCLUSIONS: We conclude that sources other than peer-reviewed articles and conference abstracts should be considered when identifying study information that may be relevant to a particular review. Unpublished data may be available that can impact a systematic review and evidence synthesis.

PRM13 COMBINED MCMC WITH ADVANCED STATISTICS TO TACKLE CHALLENGES OF DATA AND JUDGMENT UNCERTAINTY: CASE STUDY OF SAFETY ASSESSMENTS

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OBJECTIVES: Comparative safety assessment can be challenging due to differences in safety profiles between comparators, scarcity of data, difficulty in establishing causality, and deficiencies in reporting. To address this, a method combining pragmatic MCMC (Markov Chain Monte Carlo) methods, epidemiologists and clinical and policy decisionmakers using a case study. METHODS: The pragmatic MCMC model categorized adverse events (AEs) generically by their frequency using hierarchical Bayesian methods; adverse events were then grouped into specific AEs (SAEs) and "Fatal AEs" (FAEs). Panelists weighted criteria using point allocation. Efalizumab for plaque psoriasis, withdrawn in 2009 due to reports of deaths associated with progressive multifocal leuкоencephalopathy (PML), was selected as case study. A pragmatic approach to identifying clinical safety endpoints was assessed using a Cochrane network meta-analysis. Incidence of PML was estimated using Poisson modelling. Panelists had one of the key words, indicating usage of confounder adjustment methods in systematic reviews. Clinicaltrials.gov is one of the most frequently used, especially to adjust for time dependent confounders.

The approach was re-tested by panelists.

RESULTS: Weights for AEs, SAEs and FAEs ranged widely between panelists with means (ranges) of 0.06 (0.01-0.1), 0.22 (0.09-