Effects model was fitted with binomial likelihood. The performance of the methods and guidelines in the world and current debate on issues, we investigated HTA reports and methodology of economic evaluation in studies in several drugs, devices and procedures. Based on the review of these information, the research group discussed and proposed economic evaluation guidelines and baseline model. We applied all methods and combinations of them. The model for three different methods of dealing with zero cells in sparse networks in Bayesian NMA. METHODS: A review was conducted to identify methods dealing with zero cells for binary outcomes in sparse networks in a Bayesian setting. The identified methods were applied to a sparse network with six treatments and one study per comparison. The outcome was graded 5: Adverse Events and measured by Odds Ratio. A fixed effects model was fitted with binomial likelihood. The performance of the methods was assessed by the residual deviance and the Credible Intervals’ (Crl) width was compared. RESULTS: We identified three methods: apply a continuity correction (a constant factor of 0.5 or the reciprocal of the opposite treatment size), use of a binomial distribution and a set of ‘costs and benefits’ of each treatment compared to the Crl baseline model. We applied all methods and combinations of them. The model fit was adequate for all methods (residual deviance 10-12 for 12 datapoints). The use of different informative priors improved the variability estimates. CrI widths were reduced up to 15 times with respect to the original model with vague priors. CONCLUSIONS: Although the debate on the inclusion of studies with zero events in NMA is still open, our research shows that methods are available to address this issue. However, no clear recommendations can be provided. PRM219 DEALING WITH ZERO CELLS IN SPARSE NETWORKS IN BAYESIAN NETWORK META-ANALYSIS

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OBJECTIVES: Bayesian Network Meta-Analysis (NMA) models for binary data are well established and special precautions do not usually need to be taken in the context of zero cells. Furthermore, trials with zero cells in both arms are usually excluded from the analysis. However, in sparse networks with only one trial per comparison and zero cells in unique link studies, their inclusion may be meaningful. However, decisions may result in non-significant differences in treatment effects. The objective of this study was to investigate the effect of different methods of dealing with zero cells in sparse networks in Bayesian NMA. METHODS: A review was conducted to identify methods dealing with zero cells for binary outcomes in sparse networks in a Bayesian setting. The identified methods were applied to a sparse network with six treatments and one study per comparison. The outcome was graded 5: Adverse Events and measured by Odds Ratio. A fixed effects model was fitted with binomial likelihood. The performance of the methods was assessed by the residual deviance and the Credible Intervals’ (Crl) width was compared. RESULTS: We identified three methods: apply a continuity correction (a constant factor of 0.5 or the reciprocal of the opposite treatment size), use of a binomial distribution and a set of ‘costs and benefits’ of each treatment compared to the Crl baseline model. We applied all methods and combinations of them. The model fit was adequate for all methods (residual deviance 10-12 for 12 datapoints). The use of different informative priors improved the variability estimates. CrI widths were reduced up to 15 times with respect to the original model with vague priors. CONCLUSIONS: Although the debate on the inclusion of studies with zero events in NMA is still open, our research shows that methods are available to address this issue. However, no clear recommendations can be provided. PRM220 QUALITY ASSESSMENT OF OBSERVATIONAL STUDIES FOR SYSTEMATIC REVIEWS

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Observational studies are frequently included in systematic reviews, especially in those disease areas where RCTs are limited. While there are very specific tools for and guidance on assessing the quality of RCTs, the assessment of observational studies is less well established. OBJECTIVE: To develop different tools used to review the quality of observational studies and to make recommendations based on our evaluation. METHODS: First, a systematic review of literature from 2005-present was conducted in Embase and Medline to determine the frequency of use of quality assessment for observational studies and the type of tools used to conduct the assessment. Second, we reviewed documentation from NHS guidance on quality assessment of non-randomized studies. Finally, we reviewed two years of approved HTA submissions to see what methods of assessment have been used for submissions. RESULTS: A total of 4249 articles were screened. Compared to a similar study on older literature, our review found an increase in the use of quality assessment and a decrease in preparatory studies. However, we found that many studies continue to devise their own tool or adapt existing tools rather than use a tool in its entirety. Downs and Black, MOOSE, and STROBE were the most referenced tools, although STROBE was not originally intended for such use. Guidelines centered on ‘non-randomized’ studies were mixed and were not always found to be applicable to observational studies, but instead mostly to single-armed clinical trials. CONCLUSIONS: There is still a need for guidance and standardization for observational studies assessment for use in systematic literature reviews. Although quality assessment of observational studies is still not standardized, there are a few methods becoming more frequent in the literature but are difficult to compare across systematic literature reviews because they have often been adapted by each author.

PRM221 AN APPROACH FOR QUANTIFICATION OF PATIENT ADVOCACY GROUP INPUT IN THE HTA PROCESS

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Patient input in HTA pathways by the appropriate disease Patient Advocacy Group (PAG) uses principally humanistic and social studies as an evidence base followed by critical evaluation against traditional CEA (Cost Effective Analysis) via a scientific process. Published and PAG Involvement (PPI) in HTA is associated with a low evidence base potentially limiting its value. Research presented at ISPOR 2012 by the same authors concluded a need to improve and standardize PAG input integration in HTA decision making. To investigate the way different forms of knowledge / expertise are used by PAGs in NICE HTA for guideline development and new technology review. We will look at: 1) Influence of PAG structure, resource capability, internal process and the impact of PAG advisory board physician representatives on the review scope (based on individual treatments). We will illustrate the methodology to recreate the on-going counts of exclusions that correspond to the modified scope. The results from the component-reviews can then be combined to reflect any final review scope (based on individual treatments). We will illustrate the methodology with an example review of the comparative efficacy of licensed thiazolidinediones (TZDs) in patients with type 2 diabetes. When there are two TZDs licensed in the USA (pioglitazone and rosiglitazone) but only one in Europe (pioglitazone).

PRM222 JUGGLING JURISDICTIONS: METHODS FOR CONDUCTING MODULAR SYSTEMATIC REVIEWS?

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A critical component of a systematic review is a clear description of the disposition of studies throughout the various steps of the review process (de-duplication, abstract review, full paper review and final inclusion). This is commonly achieved using a PRISMA diagram which number of exclusions at each stage of the review. This may be supplemented with details of the reasons for exclusion. To create the PRISMA diagram it is necessary to keep an on-going count of exclusions and inclusions throughout the review process. However, this can present a challenge, especially where the scope of the review changes at the original specification. This may happen where the set of licensed treatments or HTA requirements vary between jurisdictions or over time. In these cases, it may be time consuming to recreate the on-going counts of exclusions that correspond to the modified scope. We present a methodology for conducting a modular systematic review in which PRISMA diagrams and other descriptions of study disposition can be generated corresponding to any subsequent changes of scope. This is achieved by splitting the stages of the review into sets of cycles and applying different methods and guidelines to each set. Our methodology allows for systematic review of a set of clinical guidelines. This can be done by critical evaluation against traditional CEA (Cost Effective Analysis) via a scientific process. Published and PAG Involvement (PPI) in HTA is associated with a low evidence base potentially limiting its value. Research presented at ISPOR 2012 by the same authors concluded a need to improve and standardize PAG input integration in HTA decision making. To investigate the way different forms of knowledge / expertise are used by PAGs in NICE HTA for guideline development and new technology review. We will look at: 1) Influence of PAG structure, resource capability, internal process and the impact of PAG advisory board physician representatives on the review scope (based on individual treatments). We will illustrate the methodology to recreate the on-going counts of exclusions that correspond to the modified scope. The results from the component-reviews can then be combined to reflect any final review scope (based on individual treatments). We will illustrate the methodology with an example review of the comparative efficacy of licensed thiazolidinediones (TZDs) in patients with type 2 diabetes. When there are two TZDs licensed in the USA (pioglitazone and rosiglitazone) but only one in Europe (pioglitazone).