

myeloma (RRMM). **METHODS:** A systematic literature review was conducted to identify relevant studies. Eligible studies were assessed for transferability by two reviewers using the economic evaluation transferability tool of the EUnetHTA Adaption Toolkit. **RESULTS:** Eight studies were identified for inclusion. One study was from the UK, three were from the US, two were from Sweden, one was from Norway, and one was from Greece. All studies were deemed non-transferable to the Irish health care setting in terms of discount rate, personnel characteristics, factors which influence incidence and prevalence, demographic context, reproduction, and pre- and post-intervention care. All except for the UK study differed with regard to incentives. Six studies differed in relation to integration of the technology in the health care system. Technological context and indirect costs contrasted with the Irish health care setting in two. In four, the studies had a comparable epidemiological context and life expectancy to Ireland. All studies were in line with the Irish nationally agreed guidelines in terms of perspective, preferences, and relative costs. Ireland's nationally agreed guidelines for health economic evaluation were violated in all eight studies. **CONCLUSIONS:** Data from EEs in RRMM in the jurisdictions assessed is not easily transferable to Ireland. Many of the parameters evaluated cannot be easily adapted to the Irish health care setting and this is likely to have a significant impact on results.

## PRM273

# METHODOLOGICAL CONSIDERATIONS ON THE RECOMMENDATIONS TO CONDUCT AND REPORT SYSTEMATIC REVIEWS IN MEDICAL LITERATURE: SYSTEMATIC REVIEW

Penedones A<sup>1</sup>, Alves C<sup>1</sup>, Ribeiro J<sup>2</sup>, Batel Marques F<sup>1</sup>

<sup>1</sup>School of Pharmacy, University of Coimbra, Coimbra, Portugal, <sup>2</sup>School of Pharmacy, University of Coimbra, USA

**OBJECTIVES:** Several recommendations are available to help conducting and/or reporting a systematic review. This systematic review aims to identify and characterize the published recommendations to conduct and/or to report a systematic review of medical interventions. **METHODS:** This systematic review followed the Cochrane Collaboration and the Preferred Reporting Items for Systematic Reviews and Meta-analyses guide. A search was carried out in MEDLINE and EMBASE databases, using "systematic review" indexed term. No language restrictions or publication dates were applied. The search comprised all recommendations to conduct and/or report a systematic review assessing a medical intervention. Data on methodology of each recommendation were extracted. Descriptive analysis was performed. **RESULTS:** Fifty recommendations were identified. Almost 60% of retrieved references were published in the last 4 years. Recommendations to both conduct and report a systematic review were issued in 42% studies. A total concordance on the methods to conduct and/or report a systematic review was not observed among the recommendations. Literature search and data assessment were recommended in more than 90% of recommendations. An a priori protocol was only recommended in 54% of recommendations. Forty-two percent of recommendations endorsed their methods to any subject related with medical interventions. Half of the studies did not specify the study designs to be included on systematic reviews. **CONCLUSIONS:** Despite the recommendations to conduct and/or report systematic reviews offer guidance on the systematic search and selection and analysis of data, they can differ on other aspects. Such heterogeneity can have methodological implications on the results and their interpretation.

## PRM274

# SIDE-L: FRAMEWORK TO ASSESS INCLUSION OF NON-RCT DATA IN SUBMISSIONS

Ouwens DM<sup>1</sup>, Frise S<sup>2</sup>, Garzya V<sup>2</sup>, Griffiths J<sup>2</sup>, Hirsch I<sup>2</sup>, Berglund N<sup>2</sup>, Khosla S<sup>3</sup>

<sup>1</sup>AstraZeneca, Mölndal, Sweden, <sup>2</sup>AstraZeneca, Mölndal, Sweden, <sup>3</sup>AstraZeneca, Cambridge, UK

**OBJECTIVES:** To present the SIDE-L framework (Statistical consideration, Interpretation, Design, External generalizability and Labeling) assessing the quality and suitability of efficacy/effectiveness evidence from "non-traditional" studies (such as real-world evidence) for inclusion in pharmaceutical product labelling. **METHODS:** After reviewing the literature, considering, among others, Robins I, the ISPOR Relevance and Credibility Questionnaire for Observational studies, NICE DSU Technical Support Document 17, GRACE checklist, AHRQ and ENCePP checklists, ICH E-documents and bias lists of Sackett, we concluded based on Pharmaceutical labelling practice that a new framework needed to be developed. The framework was built and tested with two large observational studies. Pilots are ongoing for validation and optimization of the SIDE-L framework. **RESULTS:** The SIDE component pertains to the quality assessment comprising 14 items in four sections: Statistical considerations, Interpretation, Study Design and External generalizability. The Labelling (L) component contains 7 items pertaining the suitability of a study for inclusion in pharmaceutical product labelling. Each item contains detailed criteria allowing determination whether the item is 1) met, 2) not met, possible to mitigate 3) not met, not possible to mitigate for SIDE and whether the criterion is a hurdle implying that it is no longer possible to include the study for labelling for the L part. Initial testing demonstrates that the framework is

simple, adaptable and permits a robust and transparent assessment at both the end of a study and at its planning stages. **CONCLUSIONS:** The SIDE-L framework is a novel framework developed for the evaluation of study quality and suitability of efficacy/effectiveness results from "non-traditional" studies, which can be used for both labelling and Health Technology Assessment (HTA), especially given the growing interest in Real World Evidence in HTA.

## PRM275

# FIELD RESEARCH FOR THE DETERMINATION OF THE INDIRECT COSTS OF PERITONEAL DIALYSIS AND HEMODIALYSIS IN TURKEY

Tecirli G<sup>1</sup>, Sener O<sup>2</sup>, Agirbas I<sup>1</sup>

<sup>1</sup>Ankara University, Altındag/Ankara, Turkey, <sup>2</sup>Ministry of Health, Çankaya/Ankara, Turkey

**OBJECTIVES:** Research has been made to provide for an hta full report on peritoneal dialysis(PD) and hemodialysis (HD). In the report total social cost has been tried to be calculated. Since a national and international study representing the entire sample was not found in the literature review a new field research was designed. **METHODS:** The questionnaire consists of 6 sections and 11 pages. First section is introductory section, section A contains demographic information, section B contains patient and disease information, section C is about indirect costs are included, in this section questions consists of loss of work and productivity, transportation expenses, companion spending, out-of-pocket expenses and opportunity cost. Part D consists of questions about home care costs, child and other care costs, and other social costs of the patient's financial / in-kind benefits. Part E included some questions in order to have an idea of the quality of life of the patients. **RESULTS:** As a result, the peritoneal dialysis decreased gradually in all the patients without any difference in development, the attitudes and preferences of the doctors were the most important variable in decreasing the PD, the patients did not have adequate knowledge about all dialysis treatments and the informed patients did not prefer PD because of the fear of peritonitis. Looking at indirect costs; PD is significantly higher than HD in out-of-pocket spending (294 USD vs. 143.5 USD) and transportation costs (137.5 USD vs. 43.5 USD) on the other hand HD is significantly higher than PD (1664 USD vs. 747 USD) in labor and productivity losses. **CONCLUSIONS:** It has been seen that patients can choose PD with accurate information and that the cost of society is higher in HD, while the patients are bearing more financial burden in PD.

## PRM276

# METHODOLOGICAL ISSUES OF DRUG PRICE COMPARISON STUDIES: WHAT IMPROVEMENT IN QUALITY?

Carval G<sup>1</sup>, Degraat-Théas A<sup>2</sup>, Brizon B<sup>3</sup>, Parent de Curzon O<sup>4</sup>, Poisson N<sup>4</sup>, Paubel P<sup>2</sup>

<sup>1</sup>Paris-Sud University, Croissy sur Seine, France, <sup>2</sup>General Agency of Equipment and Health Products (AGEPS), Assistance Publique-Hôpitaux de Paris (AP-HP); Health Law Institute, INSERM UMR S 1145, Paris Descartes ; Faculté de pharmacie, Paris Descartes University, Sorbonne Paris Cité, Paris, France, <sup>3</sup>Centre de Documentation Médico-Pharmaceutique AP-HP, Paris, France, <sup>4</sup>Pharmacy department, General Agency of Equipment and Health Products (AGEPS), Assistance Publique-Hôpitaux de Paris (AP-HP), Paris, France

**OBJECTIVES:** International drug price comparisons are increasingly used to rank countries according to the drug price level, and to evaluate their pricing and policy systems. However, they often present multiple methodological biases which involve numerous uncertainties on the results. The objective of this work is to make an inventory of the latest studies that compared drug prices in OECD countries and to assess their methodological quality using a reading grid developed for this purpose. **METHODS:** The literature research focused on drug price comparisons studies performed in OECD countries, using notably the terms "international", "drug prices," and "comparative study", whose were referenced in Pubmed and published between 2008 and 2017. Literature recommendations on price comparison studies' design were updated using a grid composed by 22 criteria in 7 seven categories (including drug inclusion scope, data sources, price compared, or currency conversion). For each criterion, depending on its presence (Yes, No, No but discussed), and its level of recommendation (9 recommended items, 13 mandatory items), a methodological reserve could be rated as minor or moderate, major, or as none. **RESULTS:** Twenty-seven studies were retrieved. Eight were published in 2017. Those studies compared on average 9.7 countries, on various therapeutic areas, often on the top selling drugs. We estimated an average of 5.35 major (minimum: 2; maximum: 8) and 5.00 moderate methodological reserves by study. For instance, on the mandatory criterion: "If the results are presented globally the study uses price indexes (Laspeyres index is preferred) to weight the prices" only six studies met this requirement. **CONCLUSIONS:** Even though the ideal method to overcome biases in drug price comparisons studies does not exist because of lack of data, major methodological biases could be avoided. A standardized methodology should be used to obtain transparent drug price comparisons, therefore a better political relevance.