Methods for developing new Clinical Outcome Assessments (COAs) are well-established and documented. While the COA development literature emphasizes the importance of linguistic and cultural equivalence, exact methods to achieve this are often not clearly presented. For multinational or multicultural studies, Simultaneous Item Development (SID) of a COA in all languages and cultural groups required for the research program is the most efficient approach to ensure valid COA data and interpretable results. This is because SID increases the likelihood the COA data collected in multiple languages or cultures will be conceptually equivalent and culturally relevant. Reliable and valid measurement explaining how to implement SID is limited, this presentation provides an overview of a purposeful and pragmatic (recognizing the practical challenges associated with COA development) SID approach that incorporate both qualitative and quantitative methodologies. In our experience, SID is valuable at four stages of COA development: concept elicitation, item generation, cognitive testing, and content harmonization. Generally, SID is most efficient when a single reference or ‘core’ version is used throughout the four stages (typically the English language version for the UK or the United States). This stage is managed by researchers fluent in the language for the core version. Their primary objective is to ensure that the core COA version has a clear conceptual framework that evolves in a consistent manner across language/culture versions at each stage to find those areas which can be generated processes use and development of an entire scientific field, such as health economics, and not exhaust the use of a few tools on whoms or vices of health systems.

PRM150  SCIENTIFIC PRODUCTION ANALYSIS ON HEALTH ECONOMICS IN LATIN AMERICA BASED ON THE CLASSIFICATION METHODOLOGY OF WAGSTAFF AND CULVER

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OBJECTIVES: Determine growth and focal points for the development of health economics in Latin America, through the classification methodology proposed by Wagstaff and Culver. METHODS: From the results of the development of a literature review of health economics for Latin America in Scopus Database were classified the articles according to the different groups of different general items, which were proposed by Wagstaff and Culver in 2012, based on the Williams defining nodes 1989. It was analyzed the changes of production trends, as well as countries and institutions which developed the matter. RESULTS: Production trend changes were found from 1997, where an annual growth of over 50% of production for each year is evident, until 2003. With regard to issues of production about 50% focus on public health, as an item of the twelve general items, followed by the production of 20% in economic evaluation. Clusters in Positive and Negative studies were identified, the field, under the creation of courses, masters and specialization, and the creation of research groups. CONCLUSIONS: Taking as a reference these studies it is possible to see a vision of the different types of research that involves in the scientific field, such as health economics, and not exhaust the use of a few tools on whoms or vices of health systems.

PRM161  RESOURCE MODELLING: THE MISSING PIECE OF THE HTA JIGSAW?

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OBJECTIVES: Resource modelling has been largely ignored in health technology assessment (HTA) and this paper argues the need for it to be considered as a separate set of analyses to deal with the issue of implementation and feasibility. METHODS: Economic evaluations and budget impact models, which are the two economic analyses that currently feed into HTA, are briefly described before highlighting their limitations in identifying issues of feasibility and implementation. Resource modelling is defined as the quantitative assessment of technology diffusion curves, their related resource requirements and their capacity constraints. The resource modelling examples from the literature include studies performed alongside traditional economic evaluation methods such as CEA or CBA and studies that were performed in the field of health care operational research. RESULTS: Resource modelling can be performed using a number of different approaches. However, there are a number of general issues that need to be considered when choosing the appropriate resource modelling methodology and these include a) understand the different types of resources, b) the characteristics of different resource modelling techniques and, c) challenges for the generalising the estimation and validity of resource modelling results. CONCLUSIONS: Guidelines are provided as to when resource modelling is necessary and the go forward conditions and the choices of methodology. Finally, the choice of data is also linked to the type of methodology chosen for resource modelling.

DISEASE-SPECIFIC STUDIES

MENTAL HEALTH – Clinical Outcomes Studies

PMH1  Mirtazapine Antidepressant Therapy is Associated with Rhodomyolysis Risk

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OBJECTIVES: Among other factors, the breakdown of skeletal muscle fibers (rhodomyolysis) is a leading cause of acute kidney failure. While rhodomyolysis is multifactorial in etiology, there has been a concern about the link between therapy with mirtazapine and the condition. This study characterizes rhodomyolysis signals for mirtazapine and other antidepressants. METHODS: Adverse event reports submitted for antidepressants between 1997 and 2012 were retrieved from the FDA Adverse Event Reporting System (FAERS). Reporting Odds Ratios (ORs) of RHODOX (Rhodomyolysis) were measured as proportional reporting of rhodomyolysis for individual antidepressants, including mirtazapine. The MedDRA preferred term and drug generic names were used for searching. RESULTS: Use of antidepressants in drug-event combinations with RHODOX≥2.0 are deemed as signals that warrant further review. RESULTS: There were 1,178 rhabdomyolysis reports submitted for all antidepressants, 85 reports were for mirtazapine. Signals of rhodomyolysis (ROD and 95% CI) were detected for mirtazapine (2.62, 1.2-5.7), fluoxetine (2.52, 1.41-4.43), sertraline (2.01, 1.01-3.99), and trazodone (4.6, 2.6-8.0). There was disproportional reporting of rhodomyolysis for the following agents either despite signal threshold was not reached (<1×ROD<2): amoxapine, maprotiline, amitriptyline, mianserin, and trazodone, respectively. As a class, antidepressants were not associated with rhabdomyolysis risk (1.28, 0.91-2.0). Disproportionality measures were found for heterocycles (2.10, 1.53-3.0), tricyclics (1.52, 1.13-2.94), nonselective monoamine oxidase inhibitors (MAOIs) (0.78, 0.42-1.5), and MAOIs (1.52, 1.3-2.34), nonselective monoamine oxidase inhibitors (MAOIs) (0.78, 0.42-1.5), and MAOIs (1.52, 1.3-2.34).Serotonin-norepinephrine reuptake inhibitors (SNRIs) (1.08, 0.85-1.2), and other antidepressants (0.82, 0.63-1.1). CONCLUSIONS: Rhabdomyolysis is a potential risk associated with mirtazapine. In light of inherent limitations of spontaneous reporting systems, such as FAERS, signal evaluation activities in real-world data are required to further characterize rhabdomyolysis risk in relation to mirtazapine and other antidepressant agents.

PMH2  META-ANALYSIS OF DRIVERS OF COST-EFFECTIVENESS FROM SHORT-TERM LURASIDONE CLINICAL TRIALS: EFFECT OF CHANGING DAILY DOSE ON PANSY TOTAL SCORE AND WEIGHT

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OBJECTIVES: Estimates of efficacy and safety are required for economic models developed for health technology assessments and provide guidance to decision-makers regarding the benefit-risk profile of a drug. Studies synthesising clinical trial outcomes of antipsychotics in schizophrenia often focus on the drug-related heterogeneity. The objective of this analysis was to assess dose-related efficacy and weight changes after 6 weeks of treatment with lurasidone, an atypical antipsychotic indicated for treatment of patients with a diagnosis of schizophrenia at an efficacy range of dose 20 mg to 160 mg/day. METHODS: Random-effects meta-analysis was used to synthesise evidence from five, 6-week, randomised, double-blind, placebo-controlled studies of lurasidone in patients with acute schizophrenia. Outcome measures include a) change in Positive and Negative Syndrome Scale (PANSS) total score and weight (in kg). Results were pooled within and across the daily dose range (40-160 mg/day) studied in these trials. RESULTS: Pooled mean difference in PANSS total score was -8.38 (95% CI: -9.13, -5.56), and in weight was 0.51 kg (95% CI: 0.29, 0.73). Between-dose heterogeneity (I-squared = 39%, p=0.006) was 160 mg dose, which was associated with greater treatment effect (mean difference -16.20, 95% CI: -21.30, -11.30). Moderate between-study heterogeneity was observed in the mean weight change (52.8% and 56.3% for lurasidone and placebo, respectively). There was no evidence of between-dose or between-study heterogeneity in weight gain. CONCLUSIONS: Changes in PANSS total score from this meta-analysis suggest that lurasidone in the daily dose range of 40-120 mg had similar efficacy versus placebo. The 160 mg daily dose was associated with greater reduction in PANSS total score versus placebo; however, this finding was based on evidence from a single study. This analysis found no evidence of a dose-related weight gain.

PMH3  Anticholinergic Medication Use and Risk of Dementia Among Elderly Nursing Home Residents With Depression

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OBJECTIVES: Use of anticholinergic medications in the elderly can lead to adverse cognitive outcomes. This study examined the risk of dementia among elderly nursing home residents with depression using anticholinergic medications. METHODS: A nested case-control study was conducted using 2007-2010 Medicare data from all states. Patients who had continuous coverage for Medicare Parts A, B and D and no HMO coverage during the study period or until death were included. The base cohort consisted of residents aged > 65 years, diagnosed with depression, and who did not have dementia in 2007 (Baseline Period). Cases were identified as patients who developed dementia following the baseline period. For each case, 4 age and sex-matched controls were selected using incidence density sampling. The primary outcome was diagnosis of dementia, between January 1, 2008 and December 31, 2010. Anticholinergic exposure was defined using the Anticholinergic Drug Scale (ADS). Prescription of level 2/3 anticholinergic medications 30 days preceding the event date formed the primary exposure. Conditional logistic regression model stratified on matched case-control sets was used to assess the dementia risk after controlling for baseline demographic and psychiatric variables and dementia risk factors. RESULTS: The base cohort consisted of 291,504 elderly residents with depression and without dementia diagnosis. The study included 4,966 cases during 2007-2010. Anticholinergic use was associated with significant risk of dementia (Relative Risk, RR 1.21; 95% CI, 1.18-1.23) compared to non-use. The findings remained consistent across levels of anticholinergic potency (Level 2, RR 1.19, 95% CI, 1.17-1.21; Level 3, RR 1.07, 1.03-1.13). CONCLUSIONS: Use of anticholinergic medications was associated with a higher risk of dementia compared to no use among elderly residents with depression. With increasing evidence regarding cognitive effects of anticholinergic, there is a significant need to optimize anticholinergic use, especially for those who are at-risk for dementia.