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BACKGROUND: Treatments associated with excellent outcomes in a research setting in randomised controlled trials (RCTs) may not be beneficial in the real-world settings which has a different spectrum of patients in different clinical situations. Therefore, healthcare providers are looking for evidence in the real-world setting in addition to RCTs. In this background, health insurance claims data are a source of invaluable real-world data. Claims data are increasingly being used for pharmacoeconomic and outcomes researchin regions like North America, Europe, Australia, and New Zealand. The major advantages of claims data over RCT data include: (a) health outcomes can be evaluated in real-world settings; (b) analysis results can be generalised to a broader population; (c) relatively inexpensivethan RCTs; (d) provide wide range of information about various conditions and procedures from a large number of patients, belonging to varied demographics; (e) data availability over extended periods of time allow retrospective cohort studies; (f) unaffected by recall bias; (g) large sample size will make the statistical methods more consistent. However, there are some limitations as well, such as incomplete diagnostic and provider identification data, and the fact that the population characteristics are largely influenced by the insurance plan, plan benefit design, and the variables of the database. Claims data in India are insufficiently used for health outcomes research. An important reason for this is that the penetration of health insurance is not up to the mark in India. It is expected that health insurance will become more popular in India, since (a) Indian health care expenditure is predominantly out-of-pocket, and (b) the healthcare costs are escalating day-by-day. RECOMMENDATIONS: With the increased penetration of health insurance in India, appropriate analysis of the resulting claims data can provide invaluable insights into demographics, disease trends, efficacy and effectiveness, and real-world information, from the Indian perspective.

PRM275

POSSIBLE APPLICATIONS OF REAL WORLD EVIDENCE IN SAFETY OPERATIONS

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Regulatory agencies are providing market authorization of pharmaceutical product solely on the basis of efficacy, compliance and side effects derived from randomised clinical trials (RCTs) which frequently fail to reflect real time use. It is important for the pharmaceutical companies and regulatory agencies to ensure that drug is performing well in the real world as it does in the closely monitored world of clinical trials. The payers like Medicare and Medicaid in the United States are also emphasizing on the drug benefits in real clinical practice. Also, the recent amendments in European Pharmacovigilance legislation emphasize continuous risk benefit assessment/risk management of pharmaceutical product following its launch in European market. Thereby, sources of good quality RWE will be essential for companies to meet regulatory authority expectations. The key activities within the area of Risk Management include compilation of Risk Management Plans (RMPs) and aggregate reports such as the Periodic Safety Update Report (PSUR), Periodic Benefit Risk Evaluation Report (PBRER), and the Development Safety Update Report (DSUR). These pharmacovigilance competencies can prove to be very useful in identifying drug's risk-benefit profile which includes potential safety concerns, risk factors, effectiveness measures, safety signals, and target population. By leveraging database and observational studies, signal detection algorithms, surveys and extensive pharmacovigilance competencies, following research objectives can be achieved with Real World Safety evidence: Define drug exposure; Assess the epidemiology of indication/target population; Identify potential safety concerns and characterize known risk factors; Determine prescribing conditions/patient characteristics for drugs; Determine the effectiveness of measures to minimize risk; Identify and evaluate safety signals in a systemized way; The above mentioned concepts can serve as a precursor for planning of RWE; prospective and retrospective studies which can lead to potential cost saving and efficient analysis of the safety apprehensions.

PRM276

HUMAN HEALTH DAMAGE MODELLING IN LIFE CYCLE ASSESSMENT: A VALUABLE ADDITION TO THE EVALUATION OF MEDICAL INTERVENTIONS?

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Current practice in Life Cycle Assessment (LCA) has, until now, focused predominantly on charting the environmental footprint of products and systems in various industries. LCA studies typically report the environmental damage on three Areas of Protection: Natural Resources, Ecosystem Quality and Human Health. The damage results from the cause-effect chain of the use of natural resources and the release of emissions during the life cycle of any product. The third Area of Protection Human health is based on e.g. particulate matter emissions causing respiratory diseases and health effects related to global warming such as a higher incidence of food and waterborne diseases or natural disasters. These effects are gathered under a common unit: the Disability Adjusted Life Year (DALY), which accounts for both the morbidity and mortality of diseases. In the pharmaceutical sector, several LCA studies have evaluated different parts of the supply chain. Drug production, patient transport and hospital heating all contribute to the global environmental damage, including Human Health, of a full medical treatment. However, medical interventions are predominantly evaluated on their treatment benefits and risks in terms of how a patient feels, functions and survives. In addition, their costs and benefits are also weighted against each other in order to define the cost-effectiveness of a medical treatment. We propose the addition of the environmental health burden to the current evaluation methodologies of a medical treatment. This would allow for a more holistic appraisal, taking into account the effects of health care indirect resource use and emissions. The existing state of the art methodology for the quantification of environmental Human Health damage is discussed.

PRM277

MOVING BEYOND THE PICOS: APPROPRIATE COMPARATIVE OBSERVATIONAL DATA SELECTION CAN FACILITATE META-ANALYSIS OF RELATIVE TREATMENT EFFECTS

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Evidence synthesis based on the quantitative analysis (indirect treatment comparisons ITC) of data from randomized controlled trials (RCTs) is the gold standard in healthcare decision making. However, when ITC of RCTs may not be practical or possible, comparative observational data may provide a valuable alternative despite potential challenges with internal validity. The present project aims to develop a conceptual framework from which valid quantitative assessment of real-world evidence (RWE) can provide necessary insights into treatment effects outside the RCT settings. Considerations of quantitative evidence synthesis in RWE were identified using published best-practice guidelines for quantitative analysis of RCT data and applied to two test cases, atrial fibrillation (AF) treated with novel oral anticoagulant (NOAC) and type II diabetes treated with antihyperglycemic agents. Data sources of RWE, sample selection, outcome definitions, and statistical method variation were assessed. Significant variations across all key factors were observed in studies for both indications. In the case of NOAC treated AF, homogeneity of the data source and geographic location did not guarantee appropriate quantitative comparison. Several factors unique to assessing observational database study comparability for meta-analyses were identified including a need for a greater focus on selection bias inherent to the type and location of the database and increased sensitivity of estimates to the index dates particularly in relation to local and international product launches, as well various outcome definition and reporting complexities. Valid ITC could be performed using RWE from comparative observational studies. Careful selection of studies is required to mitigate factors that would otherwise compromise results through uncontrolled bias. Researchers need to go beyond the obvious individual study reporting biases and fully assess the complexities of comparative data sources to be able to appropriately select studies for ITC.

PRM278

PUBLIC CONSULTATIONS: A TOOL FOR THE INCLUSION OF SOCIETY IN THE BRAZILIAN HTA PROCESS

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The participation of society in HTA is crucial and needs to be implemented. In the last years, it has been analyzing, discussing, and questioning how to actually introduce the public's participation into HTA processes within the Brazilian Public Health System (SUS) perspective. In 2011, Law 12,401 was enacted, making the participation of civil society official within the process of incorporating technologies in the health system through: the participation of a representative of the National Health Council (CNS) on the National Committee for Health Technology Incorporation (CONITEC); the execution of a Public Consultation (PC) for each theme evaluated by CONITEC; and through a Public Hearing prior to final decision-making, in case the relevance of the matter should justify such a hearing. The aim of this abstract is to describe the activities which are being developed after a study published in 2013 which identified proposals for improving the mechanisms of society's involvement in the processes of the assessment and incorporation of technologies into the SUS. Many of these proposals, among others, are being implemented by the Executive Secretariat of the CONITEC. Some of those proposals were to improve its disclosure and to attain a better use of social media. We started to disseminate information regarding PC through social network, website and mailing lists to the interested audiences, in addition to producing reports in an appropriate language for patients, which was another proposal made previously by the cited study. Furthermore, a new PC form was especially created in order to report the society's perspective (patients, caregivers and health professionals' experiences) and a Guide to HTA for Patients is also being produced. Public Consultations as a tool for the inclusion of society in HTA is legitimate and innovative; improve this will increase Patient and Public Involvement in the Brazilian HTA process.

PRM279

ASSESSING HETEROGENEITY ACROSS GROUPS OF CLINICAL TRIALS BASED ON AGGREGATE DATA

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Meta-analyses in the classical sense, comparing two treatments across clinical trials, are used for information synthesis during all phases of clinical research and development and especially in the context of reimbursement and assessment of relative effectiveness. In this meta-analytic framework we examined consistency of the relative treatment effect between groups of trials by application of a test for subgroup heterogeneity using aggregate trial data. A wide variety of software for performing meta-analyses and testing subgroup heterogeneity can be used, ranging from ready-to-use systems like the Cochrane Collaboration's RevMan software to packages requiring statistical expert knowledge. We applied this software and illustrate examination of heterogeneity in groups of trials by several examples. The first example investigates heterogeneity between groups of trials comparing different long-acting β2-agonists (LABAs) versus Placebo with regard to exacerbations in Chronic Obstructive Pulmonary Disease (COPD). Absence of heterogeneity was demonstrated and, hence, it turned out that the beneficial effect of Tiotropium in preventing COPD exacerbations, as e.g. directly demonstrated versus the LABA Salmeterol in the POET-COPD©trial, can be extended versus various LABAs. The second example examines heterogeneity in quality of life (QoL) as measured by the Saint George's Respiratory Questionnaire (SGRQ) across Placebo-controlled COPD trial groups where Tiotropium was administered either open-label or blinded. It was shown that the magnitude of response with this QoL measure is inconsistent between open-label and blinded administration of Tiotropium with a higher benefit