the user’s behavior upon navigating the site. RESULTS: Since the site began to get more visits on the July 1, 2012 up until June 25, 2013, with a monthly average of 1,661 hits. More than 65 countries accessed the site, the majority coming from the USA, UK and Portugal. Brazil leads with 93%. The rate of return of people who frequently accessed the site was 24%. Upon navigating the site, more than 3,000 actions of the website were performed. This monitoring began in 2012 and therefore no previous years exist to serve as a basis for comparison. The results show that a considerable number of users have access to the website. In the last 12 months, the number of hits is still low, however, considering that the HTA field is a recent one in Brazil, its growth has been gradual. On an international level, new dissemination strategies are necessary in order to create greater visibility and promotion of the network.

PRM46

DESCRIPTION OF TREATMENT PATHWAYS IN CHRONIC DISEASES USING LARGE GENERAL PRACTITIONER LONGITUDINAL DATA: THE EXAMPLE OF PHARMACOTHERAPY IN PARKINSON’S DISEASE IN THE UNITED KINGDOM

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OBJECTIVES: Identifying treatment pathways based on administrative data or electronic medical records is generally a complex task, as many incidental events may hide the key trends. The purpose of this study was to propose a transparent methodology for defining treatment pathways using a large longitudinal real life database. The application of two alternative algorithms with different variants in Parkinson’s disease was described. METHODS: A new treatment pathway identification model was assumed to start when a pre-specified number of consecutive prescriptions of drugs from the same PD drug class or combination of classes (rasagiline, selegiline, dopa, levodopa, COMT inhibitors, levodopa and derivatives) occurred. In the second method, start and end dates of continuous treatment periods (i.e. without gaps higher than six months between prescriptions) were determined for each drug class independently. Combinations that were not hitherto used were identified, and treatment periods overlapped. Algorithms were tested using medical records of patients with Parkinson’s disease (PD) extracted from the UK Clinical Practice Research Datalink (CPRD). The output of the different algorithms were described in detail using ten patients, randomly selected. The sensitivity of the algorithms to changes in assumptions was tested. RESULTS: The first algorithm did not systematically capture the addition of a new drug to the current treatment as combined drugs were not necessarily prescribed or renewed during the same consultations. However, the second method well captured the treatment lines observed but sometimes created undue treatment lines from isolated prescriptions. This issue was overcome by deleting short lines lasting less than three months. CONCLUSIONS: The second algorithm was subjected to further evaluation based on publicly reported information, questionnaires and/or interviews with data source owners, and informed consent of the treatment strategies developed by promoters in Parkinson’s disease in the UK using a limited number of assumptions and may be useful for other chronic diseases.

PRM47

IDEENTIFICATION AND QUALITATIVE ASSESSMENT OF REAL WORLD DATA SOURCES: EXAMPLE OF LYMPHOMA AND MULTIPLE MYELOMA IN EUROPE


OBJECTIVES: To identify and assess real world data sources for observational research on lymphoma and multiple myeloma (MM) in Europe. METHODS: Using a combination of keyword searches, a systematic search of online databases (e.g., clinicaltrials.gov, medline, Embase) and a manual search of the literature, 55 candidate data sources were identified. A quality assessment was conducted and performance factors were associated with the risk of bias. RESULTS: The majority of the data sources had a monthly average of 1.661 hits. More than 65 countries accessed the site, the majorities of users accessed the site from the following countries: France, Germany, Spain, Sweden, The Netherlands, and The UK. NR data sources were primarily non-registry data sources (67%). More than 65 countries accessed the site; the majorities of users accessed the site from the following countries: France, Germany, Spain, Sweden, The Netherlands, and The UK. NR data sources were primarily non-registry data sources (67%). Over 2700 publications were screened; 12 registries, and 21 databases were identified as key data sources spanning multiple geographic regions when conducting RWE research. CONCLUSIONS: These studies may provide the most flexibility and simplicity of protocol template language. All template language was created as adjustable to meet the typical study designs encountered in PASS studies. This additional information was to support the protocol development team in creating the final protocol in a timely manner and in reviewing client-provided templates.

PRM50

BUILDING A REAL WORLD PRACTICE-BASED NETWORK DATA PLATFORM TO LINK RARE DISEASE PATIENTS: CASE STUDY OF MYELOFIBROSIS PATIENTS IN THE UNITED STATES

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OBJECTIVES: Conducting real world evidence (RWE) research on patients with rare diseases is particularly challenging when using only one type of data (e.g. insurance claims). Myelofibrosis (MF) is a rare, hematological cancer with global annual incidence rate of ~1 - 2.4 cases per 100,000 patients. MF is characterized by the reduced ability of bone marrow to synthesize blood cells which can result in anemia, thrombocytopenia, and higher risk of infection. Absent adequate, recent data on MF patients, the disease-specific data platform provided through the RWE research on MF patients. METHODS: MF patients observed in IMS Health data-bases between November 2010 to October 2012 were identified. Academic centers of excellence and large community oncology practices treating MF patients were then identified to link additional patients into the platform using a HIPAA-compliant patient de-identification algorithm. Patient demographics and attributes of dispensed prescriptions, private practitioner visits, and electronic medical record data including laboratory information were collected. RESULTS: A total of 113 MF patients were identified in the platform. Mean (SD) age was 67 (12.6) and 45% of patients were female. Mean (SD) Charlson Comorbidity Index was 4.36 (2.4). Among the subset of 529 patients with laboratory results, 63% were identified as anemic and 50% had platelet counts 50,000/mL. The U.S. MF population was represented. CONCLUSIONS: Demographic and clinical characteristics suggest that this large sample of MF patients is comparable to prior estimates of the broader MF population. This case study of U.S. MF patients suggests it is important to look beyond any study data source to build RWE platforms with key clinical domains spanning multiple geographic regions when conducting RWE research on patients with rare diseases.

PRM51

FROM CLINICAL TRIAL TO REAL-WORLD EVIDENCE: A SYSTEMATIC APPROACH TO IDENTIFYING OBSERVATIONAL DATA SOURCES FOR OBSERVATIONAL RESEARCH


OBJECTIVES: Observational studies are often planned on an ad hoc basis, with the risk that methods are inconsistent and that aims overlap rather than complement each other. Our objective was to develop a systematic approach for identifying observational data sources for an integrated global programme of real-world evidence gathering, to support an important new indication for an antiplatelet drug. METHODS: Systematic literature and Web searches, supplemented with email and telephone contact with data owners, were used to identify and characterize regions with health care data systems suitable for use in the assessment of safety and/or efficacy of myocardial infarction and acute coronary syndromes. The ability to identify patients across data sources was also assessed. Data were captured and evaluated criteria applied to develop a comprehensive classification framework, designed to capture patients in the clinical trial (patient population, treatments, outcomes, and length of follow-up). Selection criteria included accessibility, availability of inpatient, outpatient, cardiac event, and drug data, and generalizability. RESULTS: Over 2700 publications were screened; 212 were identified. The majority of data sources were registry-based (21% registries and 38% data registries) and 89% of data sources were registry-based. Of these, 12 registries, and 21 databases met the evaluation criteria and were assessed in depth. After application of the selection criteria, 5 registries and 12 databases were recommended. Recommended data sources ranged in size, each capturing data on between 4000 and 11 million
patients, and were geographically diverse, representing populations in Europe, the USA, and Australia. Each recommended data source had unique strengths and limitations for use in real-world evidence studies, and together they had the potential to provide consistent and complementary information. The study output provided a valuable tool for global and local investigators.

**CONCLUSIONS:** Observational data are needed to address some systemic under-reporting of serious adverse events, and further work is needed to understand the reasons for this. Future work is needed to understand the reasons for under-reporting of serious adverse events, and to develop strategies to improve reporting.

PRM52 FEASIBILITY OF USE OF MEDICAL TRANSCRIPTION DATA FOR REAL-WORLD EVIDENCE GENERATION IN THE UNITED STATES: A PILOT STUDY OF PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS INITIATED ON BELIMUMAB

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**OBJECTIVES:** To assess the feasibility of use of medical transcription data for real-world clinical evidence generation in the US. METHODS: Majority of clinical practices in the US are experimenting digitization of patient medical records for two reasons: patient-management/care-delivery and billing/administrative/financial practices in the US are experimenting digitization of patient medical records. To clarify and update e-PRO abstracts through the structured presentation of synthesized, reliable, and constantly updated data in the repository for future use. This pilot study assessed the utility of de-identified medical transcription data in evaluating patient-pharmaceutical dynamics and real-world treatment outcomes. RESULTS: Nineteen belimumab patients (total 336 medical-transcription documents) were identified as potential participants. PRM53 UPDATE OF THE PATIENT-REPORTED OUTCOME AND QUALITY OF LIFE INSTRUMENTS DATABASE (PROQOLID): INCLUSION OF E-PRO INFORMATION

Carron M, Perrier LL, Acquaro C

**OBJECTIVES:** In 2002, PROQOLID was launched to provide an overview of existing PICO instruments and a facilitated access to the instruments and their developers through the structured presentation of synthesized, reliable, and constantly updated data. With the constant growth of electronic capture of patient-reported outcomes, detailing information about modes of data collection (i.e., paper vs. electronic) in PROQOLID might become a crucial step in updating the database. The objective of this study was: (1) To review how e-PICOs are currently reported in PROQOLID; and (2) To propose (if needed) ways of clarifying and updating e-PICO information. RESULTS: PROQOLID was searched to retrieve current information about e-PICOs using an advanced search engine. RESULTS: The e-PICO information was found under the category “mode of administration.” Three options could be chosen: computer-administered, electronic-administered, and IVR (Interactive Voice Response) version. Out of the 751 instruments in the database, 37 (5%) were reported with e-PICO information. Information about existing translations of electronic versions was clearly specified for three questionnaires. To clarify and update e-PICO information in PROQOLID, several recommendations are proposed: (1) To create a new category, i.e., “mode of data collection,” in order to differentiate it from the “mode of administration” category; (2) To categorize each mode of data collection into five subcategories (i.e., Hand-Held Device, IVR, Internet web-data capture, Pen, and Tablet); and (3) To provide a list of all translations available in each mode of data collection. RESULTS’ This review has shown that PROQOLID already includes e-PICO information. Recommendations are given on how to modify the organization and content of the database to present the information on electronic capture of PICOs.

PRM54 USEFULNESS OF A COMMERCIAL HOSPITAL CLAIMS DATABASE TO IDENTIFY CURRENT ANTI-SCARRING ENDOTHELIAL GROWTH FACTOR TREATMENT PATTERNS IN PATIENTS WITH EXUDATIVE AGE-RELATED MACULAR DEGENERATION IN JAPAN

Narimatsu A, Akada K, Wang ECY

**OBJECTIVES:** To use a commercial hospital claims database to identify current anti-scarring endothelial growth factor treatment patterns in patients with exudative age-related macular degeneration in Japan. RESULTS: Currently, the claims database used was not originally designed for outcomes research, we assessed the usefulness of one of the commercial databases in identifying treatment patterns in routine clinical practice. METHODS: Treatment patterns for patients with exudative age-related macular degeneration for anti-VEGF treatment (anti-VEGF) was selected as an example to enhance our understanding of real-world clinical practice. A retrospective open-cohort study of patients diagnosed with AMD was created from January 2010 to December 2014. RESULTS: Employing Diagnostic Procedure Combination payment system was conducted by using hospital claims database provided by Medical Data Vision, Co., Ltd. Strengths and weaknesses of using the database were also identified. RESULTS: During the study period, 424 patients were diagnosed with AMD and received ranibizumab, 19 patients received pegaptanib, and two patients received aflibercept. Among the patients who received ranibizumab, the average number of ranibizumab injections per year was 2.1±2.1 (range, 1-13). The average number of the database was granularity of data including daily medical and medication procedural histories that allow us to obtain key parameters of analyzing treatment patterns. A major weakness was no unique identifier for patients; thus, a patient would be recorded as two different individuals in the database.

The results show that the commercial hospital claims database was useful to understand treatment patterns of exudative AMD at non-university hospital settings. Since treatment guidelines are usually written based on published clinical research, this type of data database research provides an understanding of real life clinical practice and its associated patient outcomes, contributing to better adherence and future updates of treatment guidelines.

PRM55 COMPARISON OF THE PRICES USED IN THE MANUFACTURERS’ BUDGET IMPACT ANALYSES AND THE PRICES USED IN THE BIAS DRUGS LIST

Swiecicki T, Zawodnik S, Maiak J, Chodacka A, Szejb K

**OBJECTIVES:** To compare the pharmaceutical prices from the list of the selected drugs with the prices and limits used in the manufacturers’ Budget Impact Analyses (BIAs) submitted in the reimbursement applications and in the manufacturers’ documentations from request for remuneration, adjusting the level or method of financing, and to verify the transparency and fairness of the reimbursement applications. METHODS: Prices and limits proposed in BIAs in years 2007-2011 and official prices and limits for the same medicine were compared. Only BIAs for medicines which SLS has been reimbursed for at least one year were included in the analysis. The official prices and limits were obtained from reimbursed drugs list published in Ministry of Health’s Orders. RESULTS: In the studied period, 72 drugs were included in the analysis. Among them, 51.39% (37/72) were from reimbursed drugs for the same medicine were 95% and 91% respectively. The overestimation was found in 39% BIAs (28/72); median overestimation was 33% (IQR 29–37%); 48,61% (35/72) were from requests for removing, altering the level or method of financing of medicines, respectively. As a result, 13% (9/72) of the prices proposed in the BIAs were underestimated. RESULTS: Median and mean difference (MD) between official prices and prices used in BIAs for the same medicine were 95% and 91% respectively. The overestimation was found in 39% BIAs (28/72); median = 117%, MD = 124%. Rest of the prices were equal 95% (35/72). Limits were underestimated in 8% (6/72) of the BIAs. RESULTS: In mean difference (MD) between official limits and limits proposed in BIAs were 97% and 98% respectively. Overestimation of the limits was found in 57% (41/72) of the BIAs; median = 133%, MD = 177%. Rest of the limits were equal 95% (35/72). CONCLUSIONS: Among the contradictory prices and limits official ones were higher than the prices assumed in BIAs for the same medicines. There is a strong need for further research.

PRM56 DEVELOPING A PUBLICATION STRATEGY IN THE CONTEXT OF OUTCOME RESEARCH: A REVIEW OF THE LITERATURE

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**OBJECTIVES:** Many public health decisions are made based on information contained in medical publications. Therefore developing a publication strategy is a benefit for the pharmaceutical industry as it ensures an efficient dissemination of drug efficacy and safety evidence and an ethic development of the publications. In the context of outcome research, a publication strategy should take into consideration specific fields related to the e.g., dealing with local, regional and global levels) and is important to ensure that unbiased information is provided to medical decision makers on time for the good of public health. A literature review was conducted to investigate if published guidelines on the development of a publication strategy in the context of outcome research exist. METHODS: A literature search of English articles was conducted on MDDLINE and Scopus. Search terms included “publication strategy” OR “publication planning” OR “publication coordination” AND “health economics” OR “health outcome” OR “outcome research” OR “medical economics”. Independent extraction of articles was performed using predefined data fields. RESULTS: The search provided four citations; all were discarded after reviewing the abstracts. One article search. Lowering “publication strategy” OR “publication planning” returned 85 hits in fields as various as psychology, political science, environmental science and medicine. None of the citations were relevant to outcome research publications.

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