lowed in the majority of manufacturer submissions where supplementary searches were included. However, the results from this study are limited due to the low number of appendices published online. Supplementary search methods used in manufacturer submissions should be reported in full and ERGs should be consistent with critique of supplementary search methodology to ensure no evidence is omitted in decision making.

PRM23

INCREASING PRECISION OF REAL-WORLD DATA ESTIMATES: THE IMPORTANCE OF A STEPWISE PROCESS TO LIMIT DATA COLLECTION ERRORS AND DATA INCOMPLETENESS

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OBJECTIVES: Create a step-wise process to mitigate data collection errors and missing data by utilizing all available prospective and retrospective observational study methods. METHODS: Based on three multinational retrospective chart review studies and two multinational time and motion (T&M) studies completed in 2015, key factors were identified during all study phases (design, implementation, conduct, and analysis) and diverse clinical implications. It presents a step-wise process to help identify risk factors and provide effective solutions to improve data quality. RESULTS: During study design, study variables should unequivocally be defined with terminology/semantics matching the source document (e.g., medical chart) or what is observed in the real-world. Differences between countries need to be considered. Training using real-time demonstration of electronic data collection (EDC) tool using examples of de-identified patient data is critical for chart reviews. For T&M studies, observers must be trained on accurate data measurement and recording. For a chart review using an EDC tool, logic and edit checks should be built into the EDC tool to limit data errors and incomplete data at entry. For a T&M design, speed of data transmission and fast quality control is essential to allow recall by the data observer. Queries for missing data or outliers should be phrased objectively and clearly. Effectiveness of quality control measures need to be assessed particularly at the start of data collection, and retraining performed, if needed. CONCLUSIONS: Limiting data collection errors and data incompleteness at study design. Essential components of a step-wise process include appropriate variable selection and description (terminology/semantics), (re)training/understanding quality control in place, and step by step, how such steps are followed, data collected would result in more accurate dataset, therefore improving the overall quality of study data and precision of study results.

PRM24

A COMPREHENSIVE DISEASE MODEL OF POLYCYSTIC OVARY SYNDROME (PCOS)

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OBJECTIVES: Polycystic ovary syndrome (PCOS) is one of the most common female endocrine disorders. It presents with a broad range of symptoms and has significant and diverse clinical implications. In order to develop a comprehensive understanding of PCOS, a (conceptual) disease model was developed. METHODS: The disease model was generated based on three lines of concept evaluation: (1) a targeted literature review (2) interviews with clinical experts; (3) concept elicitation interviews with patients, for which data was recorded, transcribed and coded. Collectively, this provided a comprehensive list of the sign, symptom and impact concepts important and relevant to women with PCOS. Peer-reviewed articles were included in the literature review. Five clinical experts (USA, Turkey, Netherlands) and 20 PCOS patients (mean SD age 29 2.9 (5.9) years) were included in 1.3 hours interviews. Concept satisfaction was observed in patient interviews, relevant significant overlap was seen in the sign, symptom and impact concepts of PCOS across the three lines of evidence. Signs/symptoms were categorized into pain, infertility, hirsutism, alopecia, acne, menstruation (e.g. irregular menstruation, heavy bleeding), bloating, weight-related (e.g. weight gain, fluctuations), and metabolic abnormality (i.e., obesity, diabetes with weight loss, etc) symptoms. Some symptoms, such as pain at non-menstrual times, were uniquely reported by patients. Impacts of PCOS included sleep disturbance, emotional functioning, social role functioning and physical functioning. Compensatory behaviours (e.g. hair removal, diet changes, use of medication) were common. The relationship between these concepts is presented in a disease model. CONCLUSIONS: This is the first known comprehensive disease model for PCOS. It shows many of the defining features of the condition can only be accurately and reliably captured by asking patients how they feel and function. This work underscores the need for measurement of PCOS from the patient perspective using a patient reported outcome (PRO).

PRM25

EVALUATION OF QUALITY ASSESSMENT TOOLS FOR NON-RANDOMISED CONTROLLED TRIALS ASSESSING SURGICAL INTERVENTIONS: A SYSTEMATIC REVIEW OF SYSTEMATIC REVIEWS

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OBJECTIVES: To evaluate the effectiveness and safety of surgical techniques, operations, and involved medical devices is relatively difficult, sometimes unethical, with randomized controlled trials (RCTs). Non-randomized designs are commonly applied and used to inform decision making. Quality assessment (QA) methods for these studies have previously been reviewed, but not specifically for their applicability to non-RCTs in surgical interventions. The objectiveness of this systematic review is to evaluate how QA tools have been used in this research field and critically appraise these tools. METHODS: We systematically searched three electronic databases (MEDLINE, Embase and Cochrane Library) and Health Technology Assessments. Systematic reviews applying the quality of non-RCTs on surgical interventions were included. RESULTS: In total, 1,741 potentially relevant citations were identified. After removing duplicates, 1,525 citations were screened. Of these, 159 full text reviews were reviewed and 85 systematic reviews met predefined inclusion criteria. Five QA methods were most commonly employed: Newcastle-Ottawa Quality Assessment Scale (NO) or modified NO, (28%) developed by authors; the Cochrane checklist or modified version (11%), modified checklists (13%) and two other authors. The reliability and applicability of the most commonly employed tool in this research field, NO, were questioned in included reviews, corresponding with concerns on the validity of the NO tool. Further research methodology is needed. CONCLUSION: The available evidence demonstrates a lack of consensus on the use of QA tools for non-RCTs assessing surgical interventions. Various methods have been adapted or newly developed by researchers, and the most commonly applied are often based on NO. Overall, there is an urgent need for a validated QA tool to appraise the quality of evidence to help inform evidence-based decision making on the use of surgical devices and types of surgical approaches.

PRM26

INCIDENCE AND PREVALENCE ESTIMATIONS BASED ON CLAIMS DATA – NEW PHARMACOLOGICAL CONSIDERATIONS

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OBJECTIVES: Scientific analyses with claims data such as burden of disease analyses are often based on incidence and prevalence estimates. Latest methodological considerations indicate that the diagnosis-free observation period should be extended as much as possible to include periods of true risk. The aim of this study was to evaluate the impact of expanding the diagnosis timeframe for the incidence as well as the prevalence estimates. METHODS: This methodological algorithm covered several chronic diseases diabetes mellitus (DM) and multiple different diagnosis-free intervals before a diagnosis in 2013 (1 to 5 years) were assessed. Correspondingly, the prevalence estimation for 2013 was varied by expanding the timeframe for diagnosis from 1 year up to 5 years, as it was assumed that chronic diseases were selected from the health care database and retraining performed, if needed.

RESULTS: DM incidence was 24% higher when a 1-year diagnosis-free observation period was applied compared to years (26% in 5 years). When expanding the prevalence timeframe up to 5 years, the prevalence estimation increased by 14% in DM and 21% in MS, respectively. The relative proportion of incidence to prevalence also changed by varying the utilized timeframe. Out of the prevalent diabetes patients in 2013 10% were considered to be diagnosed only when 5 years were applied (11.7% and 7.9% in MS, respectively). CONCLUSIONS: The methodological concepts should coincide when estimating both the incidence and the prevalence of chronic diseases in claims data. Estimates may be biased especially when only short timeframes are utilized.

PRM27

STATISTICAL ASSESSMENT OF A CASE-FINDING ALGORITHM FOR IDENTIFYING NON-SMALL CELL LUNG CANCER (NSCLC) PATIENTS IN ADMINISTRATIVE CLAIMS DATABASES

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OBJECTIVES: The ICD-9-CM coding system does not differentiate between small cell lung cancers (SCLC) and NSCLC, which poses a challenge for database research on forms of lung cancer. We examined the accuracy of an algorithm designed to identify likely NSCLC cases among lung cancer patients in a claims database. METHODS: Lung cancer patients were selected from the HealthCore Integrated Research Environment (IRE)-Oncology database which combines US administrative claims database, and the clinical oncology data (type, stage, etc.) on lung cancer patients. Index event was defined as the patient’s first lung cancer diagnosis during 6/1/14 to 12/31/15 in the claims database. Eligibility criteria were: ≥ 1 lung cancer diagnosis & > 12 months continuous pre-enrolment in the claims database; and presence in the oncology database. A treatment regimen algorithm was used to identify NSCLC patients from claims data. This was assessed against the cancer type information from the oncology database. Diagnostic accuracy of the algorithm was assessed using statistical measures; Sensitivity, Specificity, False Positive Fraction (FPF), Positive Predictive Value (PPV), Negative Predictive Value (NPV), Positive Likelihood Ratio (LR+), Negative Likelihood Ratio (LR-), Diagnostic Odds Ratio (DOR), and Agreement (kappa). RESULTS: 585 lung cancer patients (median age = 62, 53% male) met all eligibility criteria for analysis. The algorithm classified 464 (79%) patients as NSCLC and 121 (21%) as SCLC, whereas, the clinical data classified 513 (88%) patients as NSCLC and 72 (12%) as SCLC. Algorithm sensitivity was 86% and specificity was 71%. The FPF = 0.29%, PPV = 96%, and NPV= 42%. LR+ = 2.96, LR- = 0.19, and DOR = 6.7. Chance corrected κ agreement was 0.516 (p < 0.5). CONCLUSIONS: The algorithm showed good statistical properties for identifying NSCLC patients in claims data except for a high false positive fraction. Future research should focus on improving the algorithm’s specificity.

PRM28

SYSTEMATIC LITERATURE REVIEW OF ADJUVANT ANTI-EPILPTIC DRUG TREATMENT IN PATIENTS WITH PRIMARY GENERALISED TONIC-CLONIC SEIZURES ILLUSTRATES CHANGES IN STANDARD OF CARE OVER 20-20 YEARS

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