lowed in the majority of manufacturer submissions where supplementary searches were not conducted. 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 PATTERNS: THE IMPORTANCE OF A STEP-WISE 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, defining all three layers of prospective and retrospective observational studies. Methods: Based on three multinational retrospective chart review studies and two multinational time and motion (T&M) studies conducted in 2015, key factors were identified during all study phases (design, implementation, conduct, and analysis) of each study. In order to define the strength of each methodology, we designed 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/semanitics 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 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 changes to be assessed particularly at the start of data collection and retraining performed, if needed. Conclusions: Limiting data collection errors and data incompleteness starts at study design. Essential components of a step-wise process include appropriate variable selection and description (terminology/semanitics), (re)training/confirming observed quality control in 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 (3 interviews with clinical experts; 3 concept validation interviews with patients, for which data was recorded, transcribed and coded. Collectively, this provided a comprehensive list of the sign, symptom and impact of PCOS, relevant and important to women. Published peer-reviewed articles were included in the literature review. Five clinical experts (USA, Turkey, Netherlands) and 20 PCOS patients (mean SD age 29.2 ± 5.9 years) were included in 1.3 semi-structured interviews. Concept saturation was observed in patient interviews. 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, acneola, acne, menstruation (e.g. irregular menstruation, heavy bleeding), bloating, weight-related (e.g. weight gain, fluctuations), and metabolic abnormality (i.e., obesity, difficulty 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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**ABSTRACT:** The aim of this study was to evaluate the role of quality assessment tools in surgical trials. Methods: Non-randomised designs are commonly applied and used to inform decision making. Quality assessment (QA) methods for these studies have been reviewed, but not specifically for their applicability to non-RCTs in surgical interventions. The objectives of this systematic review were to (1) evaluate which QA tools have been identified in this research field, (2) critically appraise these tools. Methods: We 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, 74 potentially relevant citations were identified. After removing duplicates, 1,525 citations were screened of these, 159 full text references were reviewed and 85 systematic reviews met predefined inclusion criteria. Five QA methods were most commonly employed: Newcastle-Ottawa Quality Assessment Scale (NOs) or modified NOs (28%), checklist developed by authors (15%), the Cochrane checklist or modified version (11%), modified checklists of other authors (5%) and the APQA tool (2%). The reliability and applicability of the most commonly employed tool in this research field, NOs, were questioned in included reviews, corresponding with concerns on the validity of published literature. Conclusions: The available evidence demonstrates a lack of consensus on the use of QA tools for non-RCTs assessing surgical interventions. Various methods have been adopted or newly developed by researchers, and the most commonly applied tools may not be fit for purpose in this field of research. 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 METHODOLOGICAL 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 not overestimate the incidence. 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 analysis was based on two incidence cases diabetes mellitus (DM) and multiple sclerosis (MS) in 2013 in Germany and was based on anonymized data from the Health Risk Institute Research Database. Patients continuously insured for six years (2008-2013) for MS (N=2,056,145) and four 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 such as diabetes may be incident when a 1-year timeframe was considered, whereas 7.3% were incident when 5 years were applied (11.7% and 7.9% 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 10.1% were considered as incident when a 1-year timeframe was considered, whereas 5.7% were incident 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 (HIRE)-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 1/31/15 in the claims database. Eligibility criteria were: ≥ 1 lung cancer diagnosis & > 12 months continuous pre-index 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 (FFP), Positive Predictive Validity (PPV), Negative Predictive Validity (NPV), Positive Likelihood Ratio (LR+), Negative Likelihood Ratio (LR-), Diagnostic Odds Ratio (DOR), and Agreement (kappa k). Results: 585 lung cancer patients (mean 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 database classified 513 (88%) patients as NSCLC and 72 (12%) as SCLC. Algorithm sensitivity was 86% and specificity was 71%. The FFP = 0.99, PPV = 0.96, and NPV> 42%. LR+ = 2.96, LR-< 0.19, and DOR> 60. Chance agreement = 0.67. 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.