analyses reduce the probability of finding significant results due to chance while large numbers of our patient events reduce the overestimation of treatment effects. Our analysis finds that a statistically significant gain in OS is an important decision driver for even the most critical HTA agencies, although the treatment effect may still be questioned when the trial is unblinded early. HTA agencies appreciate to receive a large amount of informative data and may reject the use of oncology drugs when there is too much uncertainty around OS estimates to justify the proposed price. It is generally useful to continue data collection as long as the descriptive statistics should highlight that HTA agencies still request more reliable OS estimates for modeling purposes (UK and Australia) or long-term risk-benefit evaluation (France). CONCLUSIONS: Payers are aware of the overestimation of effect size due to early trial termination and may reject drugs for high uncertainty around OS estimates. Therefore, it is important to propose to patients more reliable data, it is advised to continue data collection and follow-up patients. PRM22
THE MANAGEMENT OF IRITRIBLE BOWEL SYNDROME (IBS) IN ENGLAND: A REAL WORLD STUDY IN PRIMARY CARE CLINICAL PRACTICE
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OBJECTIVES: IBS is often a diagnosis of exclusion, with poor diagnosis coding in primary care and identification of eligible research participants challenging. We present the methodology of an on-going multi-centre, observational, retrospective research study, designed to overcome the challenges of IBS patient identification. METHODS: FARSITE, a software tool for identification of research participants developed and coordinated by Manchester Local Research Ethics Committee (MREC). North West eHealth, was used to screen anonymised primary care records for potentially eligible patients. Ethical approval reference 13/L0/0692. Search criteria: patients aged 18-60; combination READ code symptoms indicative of IBS and pre-defined exclusion criteria: medical diagnosis of IBS or meeting ROME III criteria, provision of consent. Exclusion Criteria: diagnosis excluding IBS, IBS symptoms secondary to other condition, IBS medications only for non-GI symptoms. RESULTS: FARSITE identified 1089 patients with a total of 297 (27.3%) were eligible, 97 patients consented to participation (79.7%). Main reasons for non-eligibility were not meeting ROME III criteria or IBS excluded by medical opinion. Patients were most commonly coded as irritable colon (37%), difficulty defeating (31%), abdominal pain (18%), diarrhea symptoms (14%). Four (4%) patients had a READ code specific for IBS. The median (IQR) time from 1st presentation with abdominal symptoms to study eligibility was 3.98 (0.00-9.04) years. CONCLUSIONS: Identification of patients with IBS using READ codes is under-utilised and can improve study selection. A combination of READ codes with symptom and prescription data via FARSITE has enabled potential participants to be identified with a reasonable screening failure rate. FARSITE is a valuable research tool aiding study feasibility by reducing the need for manual patient identification.
PRM22
THE IMPACT OF A LIKELY OVEREMPHASIS ON FICIOENCY-RELATED TEST ATTRIBUTES ON ACGM RECOMMENDATIONS AND ACCESS TO NEWBORN SCREENING (NBS)
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OBJECTIVES: Patient access to NBS has been greatly influenced by the 2006 American College of Medical Genetics (ACMG) recommended expansion of NBS. ACGM relied largely on a stakeholder survey on 19 attributes of 84 rare conditions. Our methodological framework is compatible with the EUnetHTA core model and demonstrates how to consider other health care technologies. CER of medical devices (MD) faces some challenges that raise questions about how adequate current CER methods account for the specific features of MD and how well MD fit in the paradigm of drug HTA. Our aim is to identify methodological gaps in the current CER methods. Methods: We performed a targeted literature review for CER methods and specific features of MD. An electronic database search was combined with systematic screening of tables of content of selected journals in the fields of epidemiology, HTA, statistics, and evidence-based medicine to identify studies with a strong focus on MD. Additionally, we screened the reference lists of the most relevant papers. RESULTS: More than 200 publications about the general evaluation of MD and about specific CER methods were included. The MD’s physical mechanism of action, the dynamic development and regulatory evidence requirements are the driving factors that suggest the increased use of certain methods for the evidence generation, finding of information for HTA, data analysis and synthesis, and interpretation of results. Rather than following the paradigms of drug evaluation, MD resemble more the notion of complex interventions. The most important cause of poor generalization of the findings is that the EUnetHTA core model and integrates existing recommendations for other complex interventions. CONCLUSIONS: The assessment of the clinical effectiveness of MD does require specific, although not necessarily new methods.
PRM23
WORKFLOW MAPPING FOR PEDIATRIC VACCINATION PROCESS IN THE UNITED KINGDOM (UK): A PRECURSOR OF A TIME AND MOTION (T&M) STUDY
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OBJECTIVES: Time and Motion (T&M) methodology allows quantifying time-related outcomes for a health care delivery process by disaggregating the process in its constituent parts to measure task durations. The design of a T&M study requires early process mapping to define the time outcomes to be measured. The mapping of paediatric vaccination process in the United Kingdom (UK), as a part of a larger study is described. METHODS: A total of publicly available information was conducted to gain comprehensive understanding of the paediatric vaccination process in the UK. A survey was designed eliciting the chronology of vaccination process prior to and on vaccination day, including estimated time to each intervention and professional involvement. Face-to-face interviews with a nurse were conducted at three general practitioner surgeries routinely performing vaccinations. A subsequent follow-up call with each nurse was also arranged to capture any unprompted responses and additional information made. RESULTS: Paediatric vaccination process can be broken down in 6 and 8 clearly discernible steps prior to and on vaccination day, respectively. Activities prior to vaccination day include, among others, inventory, ordering, cold-chain management, and are typically for multiple subjects. Mean time for these activities, recalculated per single vaccination visit, was 6.7 minutes, of which 61% dedicated to administrative duties. Activities on vaccination day include, among others, room preparation, consultation, vaccine administration. Estimated time for total visit was 25.4 minutes. Estimated total cost per single vaccine administration, with nurse salary cost from PSSRU, was £10.4. Costs may vary substantially depending on the level of on-costs to nurse’s gross salary. CONCLUSIONS: The detailed mapping of the vaccination process provides a clear understanding of tasks, time estimates, factors impacting variability of time outcomes, and early cost estimates. This forms the basis of a real-world T&M study aiming to generate robust time and cost outcomes.
PRM24
DETERMINANTS OF RISK FACTORS FOR TRAUMATIC BRAIN INJURY IN CHILDREN WITH EPIDERMOLYSIS BULLOSA (EB): A SYSTEMATIC REVIEW
OBJECTIVES: Determinants of risk factors for TBI in CBEB can be identified through a systematic review of the literature. METHODS: A systematic review of the literature was performed. Search criteria: (epidermolysis bullosa OR EB OR dystrophic epidermolysis bullosa) AND (child OR pediatric OR children) AND (trauma OR injury OR TBI OR head injury OR head trauma) AND (risk factor OR risk factors) AND (determinants of risk factors). RESULTS: 19 studies were included. The percentage of respondents agreeing to an attribute’s presence for a condition, along with its weight, determined attribute score. Sums of scores determined the recommendation of an attribute. CONCLUSIONS: The percentage of respondents agreeing to an attribute’s presence for a condition, along with its weight, determined attribute score. Sums of scores determined the entry point to an algorithm for final recommendations. This research examines 6 attributes that appear to be associated with the same concept and asks whether these are really one (over-weighted) concept. METHODS: The ACGM report provided attribute scores. Six questions addressed test efficiency (simplicity, high throughput, cost < $1), condition, multiple analytes/test run, other conditions identified/analyte, multiple conditions detected/test). We examined correlations between the 6 answers were high (mean = 85%, range: 72 - 96). Of those conditions (37) scoring at least 75% of the possible points on one question (“high throughput”), 79% were recommended as Core conditions to be screened and only 8% were Not Recommended. The mean total scores for the 6 similar questions was 339 (500 possible). Of those (19) scoring 25% or fewer of the possible points for that one question, only 3% were Core, 72% Not Recommended (mean score 89). CONCLUSIONS: The high correlations support the idea that the 6 similar questions were answered as if they were the same concept, weighting the common general attribute very highly. A more systematic approach, say MCDM, would likely have eliminated some of these questions with significant consequences for ACGM recommendations.