analyses reduce the probability of finding significant results due to chance while large numbers of ongoing events reduce the overestimation of significant 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 late-stage information. However, high uncertainty around OS estimates 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 of post-marketing data and appropriate models should HTA agencies still require 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. For other indications or applications where no more reliable data is available, it is advised to continue data collection and follow-up patients.

PRM21
THE MANAGEMENT OF IRRITABLE 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 study, designed to overcome the challenges of IBS patient identification.

METHODS: FARSITE, a software tool for identification of research participants developed at the Manchester Clinical Research Network North West eHealth, was used to screen anonymised primary care records for potentially eligible patients. Ethical approval reference 13/LO/0692. Search criteria: patients with at least one READ code indicating IBS and use of IBS and/or IBS-related treatments. Symptoms (14%). Four (4%) patients had a READ code specific for IBS (1.3%) patients, of which 297 (27.3%) were eligible. 97 patients consented to participate, estimating a potential cohort totalling 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 methodology of this study will determine the (cost-) effectiveness of an MCI intervention to improve self-management. Patients aged 18-60; combination READ code symptoms indicative of IBS and pre-consent to administrative duties. Activities on vaccination day include, among others, room preparation, consultation, vaccination, follow-up patients should HTA agencies still request more reliable OS estimates for modeling purposes. MD resembles more the notion of complex interventions.

PRM22
TIME AND MOTION (T&M) METHOD TO ASSESS THE EFFICACY AND COST-EFFECTIVENESS OF A SELF-MANAGEMENT INTERVENTION FOR PATIENTS WITH MIDEPILEPSY, COMPARED TO CARE AS USUAL
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OBJECTIVES: Poor adherence to anti-epileptic drugs has been shown to be the most important cause of poorly controlled epilepsy. Furthermore, it is emphasized that an increase in quality of life among patients with epilepsy could be reached by counseling and treatments aimed at increasing their self-efficacy and thus stimulate self-management. However, there is a need for evidence on the effectiveness of such programs, especially within epilepsy care. Therefore, we have developed a multi-component intervention (MCI) which combines a self-management/education program with e-Health interventions. Hence the overall objective of this study is to assess the (cost-) effectiveness of an MCI aiming to improve self-efficacy in people with epilepsy compared to care as usual.

METHODS: A randomized controlled trial in 2 parallel groups will be conducted to compare the MCI intervention with a waiting list control condition in epilepsy patients. One group of eligible epilepsy patients will be randomized to the epilepsy center and allocated to intervention or control group. Patients in the intervention group will receive an education program of six meetings including - MCI intervention and will be followed for 12 months. The control group will be followed for 6 months after which they will be offered to participate in the MCI. The study will consist of three parts: 1) a clinical effectiveness study, 2) a cost-effectiveness study, and 3) a process evaluation. The primary outcome will be patients accessing e-Health interventions. Secondary outcomes will be used to assess self-efficacy in people with epilepsy compared to care as usual.

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 preliminary step for an upcoming T&M study, was described. Medical records were used to develop a conceptual framework. Additionally, in parallel, 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 estimates of time consumed 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. The descriptive and unstructured interviews were conducted for 60 minutes. A total of 12 interviews were made. RESULTS: Paediatric vaccination process can be broken down in 6 and 8 clearly discernable steps prior to and on vaccination day, respectively. Activities prior to vaccination day include, among others, inventory, ordering, cold-chain manipulation and storage, and typical for multiple steps. 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, vaccination, follow-up patients should HTA agencies still request more reliable OS estimates for modeling purposes. MD resembles more the notion of complex interventions.

PRM24
THE EFFECTIVENESS OF CLINICAL EFFECTIVENESS OF A MULTIPLE-COMPONENT INTERVENTION FOR ADULTS WITH EPILEPSY: STUDY PROTOCOL OF A DUTCH RANDOMIZED CONTROLLED TRIAL
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OBJECTIVES: Poor adherence to anti-epileptic drugs has been shown to be the most important cause of poorly controlled epilepsy. Furthermore, it is emphasized that an increase in quality of life among patients with epilepsy could be reached by counseling and treatments aimed at increasing their self-efficacy and thus stimulate self-management. However, there is a need for evidence on the effectiveness of such programs, especially within epilepsy care. Therefore, we have developed a multi-component intervention (MCI) which combines a self-management/education program with e-Health interventions. Hence the overall objective of this study is to assess the (cost-) effectiveness of an MCI aiming to improve self-efficacy in people with epilepsy compared to care as usual.

METHODS: A randomized controlled trial in 2 parallel groups will be conducted to compare the MCI intervention with a waiting list control condition in epilepsy patients. One group of eligible epilepsy patients will be randomized to the epilepsy center and allocated to intervention or control group. Patients in the intervention group will receive an education program of six meetings including - MCI intervention and will be followed for 12 months. The control group will be followed for 6 months after which they will be offered to participate in the MCI. The study will consist of three parts: 1) a clinical effectiveness study, 2) a cost-effectiveness study, and 3) a process evaluation. The primary outcome will be patients accessing e-Health interventions. Secondary outcomes will be used to assess self-efficacy in people with epilepsy compared to care as usual.
The majority of studies (9) were oncology focused, with two studies focused on infectious diseases and opioid-induced constipation. Sample sizes varied from 20 to 500 patients, the number of countries from 1 to 8, and the number of sites from 4 to 61. All studies included at least one European country. Across studies, key operational considerations that impacted the ethical/regulatory approval process were ambiguous/amorphous multinational regulatory requirements/ guidelines; common availability or non-availability of the sponsor product at the time of chart abstraction; data collection method(s) (i.e., retrospective vs. hybrid chart review plus prospective data collection); country variation in informed consent requirements and definitions of personal data; and multinational contractual requirements with the participating sites. Conclusions: International chart review studies are an effective methodology to resolve data gaps not solved by existing secondary health care data sources. This study helped to tailor, patient selection knowledge of the highly variable and evolving global regulatory requirements, as well as the development of a risk management plan informed by methodological and operational lessons learned at study-outset will facilitate risk mitigation and allow researchers to overcome key challenges.

PMR27
COST PER PATIENT IN NON INTERVENTIONAL STUDIES AND ADDED VALUE OF DIRECT TO PATIENT CONTACT SERVICE

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Map\, Jim, Franck
Objectives: In addition to study outcome concerns arising from patients lost to follow-up (LFU) in pharmacoepidemiology and pharmacovigilance studies, the financial impact of LFU can be significant. Our objectives were to estimate cost per patient in Non-interventional studies, to identify variables that may affect this cost per patient, to estimate cost of patient lost to follow-up LFU, and financial benefits that can be expected from LFU minimization through Direct to Patient Contact service (DPC).

Methods: Analysis of 2013 proposals and budgets submitted to study sponsors. Selection criteria: non-interventional, prospective, longitudinal patient followed-up, full CRO services. Analysis were performed according to patient sample size, study duration, disease category, and different hypothesis for LFU rates. Results: 1) 20 studies met all inclusion criteria; 2) Annual cost per patient - ranging from €1,068 to €1,470 - decreases as the study duration increases (set-up cost is more diluted in the patient annual cost). But the longer the study is the more expensive the overall cost per patient. 3) Mean annual patient cost signals the necessity to keep registry going to counter of an important criterion that greatly impacts overall and annual patient cost, especially for study lasting more than 1 year. Below 1 year, the cost per patient remains quite similar between types of diseases/populations. 4) Cost are more significant in rare diseases studies, therefore DPC can provide the best overall cost savings in these populations; and 50 The cost savings are dependent on the expected rate of patient LFU with/without DPC service and the planned patient sample size. Conclusions: Return On Investment plays an important role for Sponsors to determine if DPC is valuable in a study. The financial investment may be beneficial regardless of the cost to insure completion of the patients, thus meeting the scientific study objectives. But trade-offs are required between different objectives such as maximizing health, restricting budget impact, increasing health equity and maximizing safety. Methods such as multiple decision criteria analysis (MCDA) are therefore increasingly being used to reflect such trade-offs in a transparent and consistent manner. All potential LFU can be converted into cost-effectiveness analysis it may, however, invalidate results from Value of Information (VOI) analysis when it also includes other health-related or cost-related objectives. Methods: In two studies we first applied VOI methods directly and only to cost-effectiveness estimates, and then also applied these methods separately to all relevant decision criteria. In a simulation study on two drugs we calculated the expected value of new information (EVI), the expected value of perfect information (EVPi) and the value of perfect information (VPI) for health outcomes and/or health care services, its use in health care policy decisions, research and clinical practice.

PMR28
RETRIESTIVE CHART REVIEW STUDIES: STRATEGIES TO ENSURE ROBUST DATA QUALITY

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Objectives: Retrospective chart review studies can result in robust naturalistic data to inform evaluations of treatment patterns, resource utilization, costs of care, clinical outcomes, and drug safety. Quality concerns challenge both availability of poor quality documentation in the usual care medical chart, or as a result of data abstraction and data entry processes. Methods: Ten chart review case studies conducted in the United States, Canada and Ireland were evaluated to provide recommendations for improving chart review data quality control mechanisms. Results: All 10 studies used electronic data capture (EDC) systems. Common lessons learned across the studies were that the case report forms (CRFs) should only include necessary data elements required to fulfill the analysis. Direct chart-to-EDC data entry and remote real-time data quality control is recommended to reduce additional transcription errors that may occur if using paper CRFs. It is important to ensure the EDC system includes a cost-control plan. Moreover, selection of patient cohorts (i.e., random selection) and tracking of eligibility screening to reduce selection bias of e-interventions. Both B. F. M. Wijnen and L. A. M. Leenkn contributed equally to this work.