Within large translational research consortia, a practical and valuable tool to support decisions on the allocation of research funds is the systematic review of randomised controlled clinical trials. Components of the checklist fall to the design and analysis of real-world patient-level data on patient characteristics and outcomes. The objective was to determine the status quo of current studies concerning the design of randomised controlled clinical trials in the context of real-world data. Additionally, key operational considerations include balancing science and practicality in site selection, ambiguous multinationa l ethical/ regulatory requirements, country variations informed consent, data management designed to site design, and efficient site management for quality data. CONCLUSIONS: International chart reviews are proving to be an effective methodology for capturing tailored, patient-level data. These studies can be used to address a myriad of research objectives. Through conduct and assessment of recent chart reviews, the design and operational considerations involved can be understood with opportunities for improvement learned. These lessons will help for better planning and overcoming these challenges.

PRM207
NO USE OF MULTIVARIATE JOINT MODELLING TO IDENTIFY PATIENT LEVEL FACTORS ASSOCIATED WITH TREATMENT FAILURE – EXAMPLE OF BOTOK
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OBJECTIVES: To determine the relative importance and the interaction between symptom measures for varying medical conditions, the novel use of a joint modelling approach to time-to-event data to a randomised clinical trial of patients receiving botulinum toxin for DO. We investigate the association of incontinence, urgency and voiding episodes collected at baseline, 6 weeks, 3 months, and 6 months, on patients’ perceived time of treatment failure.

PRM208
USING MULTI-CRITERIA DECISION ANALYSIS TO SUPPORT ALLOCATION DECISIONS IN LARGE TRANSLATIONAL RESEARCH PROJECTS
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University of Groningen, University Medical Center Groningen, Groningen, The Netherlands
OBJECTIVES: Large translational research projects often have abstract objectives, such as reducing the burden of disease and health care costs from type-2 diabetes (T2DM). Such an abstract objective entails: i) a very large number of possible strategies to reach the objective and ii) a lack of detailed data and high levels in uncertainty. Currently, no methods to support project selection and resource allocation decisions exist. Methods: We have developed a novel resource allocation decision tool. As a case study, we support the remaining funds in a large Dutch translational research consortium with the aforementioned objective, and compared the results to the decision made at the start of the project. We used the problem structuring model building methods from multi-criteria decision analysis to identify four different alternative research strategies, and a set of evaluation criteria. Consequently, we used a combination of judgment from experts involved in the project and previously trained case managers to select the best alternative.

PRM209
CONFRONTING HETEROGENEITY: USING SYSTEMATIC REVIEW EFFECTIVELY FOR META-ANALYSIS
Quigley MJ, Woods B, Thompson J, Bryden PA, Scott DA
Oxford Outcomes Ltd., Oxford, UK
OBJECTIVES: The pooling of treatment effects estimated from several trials via meta-analysis or network meta-analysis can be confounded by differences across studies; however, advanced methodologies are available to address many of these issues. Systematic reviews of interventions typically generate a large volume of data and lead to assimilation of a large amount of knowledge by the reviewers. Identifying key variants across trials can be difficult and important nuances can be missed by a meta-analyst. We have designed a novel checklist that highlights key areas of heterogeneity to be considered when designing and undertaking meta-analysis. It is important to identify differences early, hence we have developed a checklist that can be applied to the results of a systematic review of randomised controlled clinical trials. Components of the checklist fall into four categories of heterogeneity: methodological differences, study outcomes, and risk of bias. Sections documenting the feasibility of network meta-analysis and recommendations for analysis design are also included. The checklist has been retrospectively applied to a recent NICE technology appraisal, percutaneous vertebroplasty for osteoporotic vertebral compression fractures (TA279). RESULTS: The checklist identified the following sources of heterogeneity in the nine included studies: inclusion criteria, endpoint definitions, endpoint reporting, presence of cross-over, differences in interventions, risk of bias, and within-trial imbalances in baseline characteristics. The checklist suggests that a quality network meta-analysis of this data would exclude one study with high risk of bias, avoid applying sham procedures and optimal pain management, and control for baseline pain-score to address imbalance across arms. Meta-regression to control for differences in endpoint definitions or inclusion criteria likely would have been infeasible given the large number of studies.

PRM210
IMPLEMENTATION OF INTERNATIONAL CHART REVIEW STUDIES: AN ASSESSMENT OF KEY DESIGN AND OPERATIONAL CONSIDERATIONS FOR SUCCESSFUL CONDUCT
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OBJECTIVE: To conduct international chart review studies (chart reviews) since health care databases with required information are not consistently available. Chart reviews offer an alternative for the effective capture and analysis of real-world patient-level data on patient characteristics and outcomes. The objective was to determine the status quo of current studies concerning the design of randomised controlled clinical trials in the context of recursive source data. Additionally, key operational considerations include balancing science and practicality in site selection, ambiguous multinationa l ethical/ regulatory requirements, country variations informed consent, data management designed to site design, and efficient site management for quality data. CONCLUSIONS: International chart reviews are proving to be an effective methodology for capturing tailored, patient-level data. These studies can be used to address a myriad of research objectives. Through conduct and assessment of recent chart reviews, the design and operational considerations involved can be understood with opportunities for improvement learned. These lessons will help for better planning and overcoming these challenges.

PHASING
The focus on high-risk of bias in meta-analysis has led to the development of methods to drive physician motivation in prospective observational studies. METHODS: A web based survey was designed using input from structured literature review, investigators, and experienced observational study researchers. Through conduct and assessment of recent chart reviews, the design and operational considerations involved can be understood with opportunities for improvement learned. These lessons will help for better planning and overcoming these challenges.

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