

**Methods.** We carried out a thematic review of the existing evidence on the involvement of patients and the public in HTA, including: technology appraisals consultation 2017 (110 comments); technology appraisals consultation 2018 (205 comments); and PIP review consultation 2017 with a CHTE focus (162 comments). We used Thomas and Harden's (2008) thematic synthesis to code the data 'line-by-line', to develop 'descriptive themes', and then to generate 'analytical themes'. This was followed by using Patton's (1999) triangulation of qualitative data sources to further challenge and refine the emergent themes.

**Results.** We identified three themes, namely (i) earlier and full engagement, (ii) simpler and easier engagement, and (iii) patient evidence. Respondents emphasised the significance of involving patients earlier and throughout the process of developing every appraisal to enable them to gain a greater sense of participation and ownership. Respondents also expressed a strong view of making it simpler and easier for patients to engage in the process through various methods, e.g., standardising the approaches, and support and training. Finally, respondents expressed their positive attitudes toward using patient evidence in HTA, clarifying how patient evidence is captured and used, and offering a clear feedback mechanism to the impact of patient evidence on decision-making.

**Conclusions.** This review highlighted the significance of earlier and full engagement with people, making it simpler and easier for people to work with us, and being clearer about how we use patient evidence with a clearer feedback mechanism as to the impact of their input on the final decisions.

## VP04 The Influence Of Sponsorship On The Treatment Effects Of Trials

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**Introduction.** Limited public money is available for funding research and the majority of clinical research undertaken is funded by industry. Mechanisms to regulate conflicts of interest within the research process have been implemented. However, these policies by themselves do not protect against potential sponsorship bias that would affect research results to inform decision makers when using the results of these trials. Therefore, the main aim of this study was to evaluate the influence of sponsorship bias on the treatment effects of RCTs.

**Methods.** This was a meta-epidemiological study. A random sample of RCTs included in meta-analyses of physical therapy (PT) area were identified. Data extraction including assessments of appropriate influence of funders was conducted independently by two reviewers. To determine the association between biases related to sponsorship biases and effect sizes, a two-level analysis was conducted using a meta-meta-analytic approach.

**Results.** We analysed 393 trials included in forty-three meta-analyses. The most common sources of sponsorship for this sample of PT trials were government ( $n = 205$ , 52.16 percent) followed by academic ( $n = 44$ , 11.2 percent), and industry ( $n = 39$ , 10 percent). The funding was not declared in a high percentage of the trials ( $n = 85$ , 22 percent). The influence of the trial sponsor

was assessed as being appropriate in 246 trials (63 percent) and considered inappropriate/unclear in 147 (37 percent) of them. There was a significant difference in effects estimates between trials with appropriate and inappropriate influence of funders ( $ES = 0.15$ ; 95% CI -0.03, 0.33;). Trials with inappropriate/unclear influence of funders tended to have on average a larger effect size than those with appropriate influence of funding

**Conclusions.** Treatment effect size estimates were 0.15 larger in trials with lack of appropriate influence of funders. Systematic reviewers should perform sensitivity analyses based on appropriateness of influence of sponsorship in included trials.

## VP06 HTA And Health Industry: Key Aspect Of Their Relationships

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**Introduction.** Conclusions and recommendations of health technology assessment (HTA) reports have an impact on all relevant actors involved in the health system (health authorities, administrators, health professionals, patients, citizens and industry). The involvement of all those relevant stakeholders in the HTA process facilitates making valid and informed decisions and an efficient allocation of resources. Improving communication, participation and transparency among all agents will lead to more efficient evaluation and decision-making processes.

**Methods.** To review key aspects of the relations between HTA agencies and health industries, two process were carried out: a narrative review of literature searched in Medline, PubMed, Embase, CINAHL and WOS (2007-2017) and a review of websites of international HTA agencies. References and webs with information on the framework, objectives, methodologies, impact or results of the relationships were included.

**Results.** A total of 1961 references were located and forty-five were selected. From the synthesis of the selected references the following key aspects of the relationships between HTA and industry were identified: (i) the importance of early dialogues with industry to align HTA objectives with the generation of evidence; (ii) challenges of the bias in the evidence produced by industry; (iii) difficulties in industry engagement in HTA processes; and (iv) industry interest in HTA. The review of six agency websites provided information on industry involvement in strategic activities, early dialogues, provision of documentation, management of industry clarifications, review of the report/allegations and other forms of relationship.

**Conclusions.** Both the review of the literature and the contents of the web pages of international agencies with experience in relations with industry show that the interest is in the creation of collaborative frameworks between regulatory authorities that decide

on authorization and price and reimbursement and HTA agencies, while both try to maintain an early, transparent and systematic interaction with the healthcare industry.

## VP07 Cost-Effectiveness Of HTA Fees

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**Introduction.** Health technology assessment (HTA) bodies evaluate the clinical and/or economic impact of new therapies to inform public reimbursement decision-making. This research evaluates the value for money of current or proposed fees for HTA in countries with mandatory cost-effectiveness HTA bodies relative to their respective public drug expenditure.

**Methods.** HTA appraisal fees were identified from publicly-available websites: National Institute for Health and Care Excellence (NICE), Canadian Agency for Drugs and Technologies in Health (CADTH), Institut National d'Excellence en Santé et Services Sociaux (INESSS), and Pharmaceutical Benefits Advisory Committee (PBAC). Annual national public drug expenditure (ANPDE) were sourced from the National Health Service England, Canadian Institute for Health Information, and the Pharmaceutical Benefit Scheme.

**Results.** NICE is proposing to charge GBP 126,000 (EUR 142,582) for a single technology or highly specialized technology appraisal, CADTH charges CAD 72,480 (EUR 48,576) for a Schedule A submission, INESSS charges CAD 38,921 (EUR 26,089) for the first evaluation of a new drug or new indication, and PBAC charges AUD 136,716 (EUR 87,576) for a Major Lodgment. The ANPDE in England: GBP 16 billion (EUR 18.1 billion), Canada: CAD 14.5 billion (EUR 9.7 billion), Quebec: CAD 4 billion (EUR 2.7 billion) and Australia: AUD 8.7 billion (EUR 5.6 billion). The appraisal cost to drug expenditure ratio for these countries/regions were: 126,984, 200,055, 102,772, and 63,636, respectively.

**Conclusions.** HTA submissions in the United Kingdom, Canada and Australia require financial contributions from manufacturers. These contributions bear little relation to the market size and cumulatively exceed EUR 300,000 (assuming no resubmissions). By adopting charging/cost recovery models, HTA bodies are aiming to reinvest the proceeds to increase the efficiency and capacity of appraisals, expediting patient access. However, these fees may be burdensome, especially for SMEs with promising therapies for orphan/rare diseases, and they may thus have the potential to deter/delay their submissions.

## VP08 Can Health-Economic Evaluation Provide a Representation of 'Value For Money' For HTA?

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**Introduction.** Health technology assessment (HTA) processes typically combine both evidence and values in order to inform decisions about relative value. Health-economic evaluation and

other economic evidence are thought by many to be important for such processes, but there is typically tension between the information offered by health-economic assessment, and the context-specific interpretation of such information. This study reviews the meaning, and interpretation, of 'health-economic evaluation' aimed at informing HTA processes. One central aim is to answer the question: "Can health-economic evaluation provide a representation of 'value for money' for HTA?"

**Methods.** A seminal article was used as a starting point and then a variety of search techniques, including bi-directional citation searching, were used to obtain evidence relating to the study objective. A critical review is undertaken spanning the last fifty years of health-economic evaluation, which provides perspective on the balance between more context-independent assessments and the context-specific interpretation of those assessments.

**Results.** Although health-economic evaluation can legitimately be undertaken in a variety of ways, we find that processes of 'valuation' are fundamental to all approaches to economic evaluation in practice. Values influence how these economic value frameworks tend to be operationalized, promoted and understood. Our critical review provides those interested in prioritization with a timely reminder that health-economic evaluation should be thought of as largely context- and content -specific.

**Conclusions.** Health-economic evaluation can typically only offer a truncated representation of 'value for money' to HTA processes. In answer to the question posed above, this study finds that health-economic evaluation will typically not provide a full assessment of 'value for money'. Therefore, it should always be accompanied by an assessment of its qualities: what is covered in the analysis, how well what is covered is measured or analysed, and what is left out. Humility about what health-economic evaluation can offer would seem useful, especially given that other elements of value exist, such as the potential harms and benefits of medical-industry profits and environmental sustainability.

## VP11 Use Of Health Technology Assessment Adaptation In Latin America

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**Introduction.** The development of health technology assessment (HTA) reports is a time-consuming process that requires highly trained human resources. In many Latin American countries this type of personnel is scarce. The adaptation of HTA could be a time-saving process to get inputs for decision. The objective of this study is to determine the frequency of use of HTA adaptation process and to describe type of tools used in this process in Latin American countries.

**Methods.** The Health Technology Assessment Network of the Americas (REDE TSA) is a non-profit network formed by ministries of health, regulatory authorities and health technology assessment agencies (PAHO/WHO). During the last meeting of REDE TSA in November 2018, we performed an exploration survey to gather information related to the topic in order to promote the creation of an adaptation working group. The question was