proposed but none is consensual, most are time-consuming while evaluating different domains of impairments, and many are not validated. Gait speed seems to be a single, reliable, valid, sensitive, cheap, quick and simple tool that identifies frailty people. However, the way to perform the test parameters vary widely, influencing interpretations of physical performance.

**Conclusions.** The evidence recommends to detect frailty in people in order to achieve an active and healthy ageing. Gait speed could be a suitable predictor to identify frailty although this systematic review found many differences between the gait speed protocols used in clinical practice. It is necessary to establish a standard protocol of gait speed agreed by experts in the area on frailty to be implemented with success in clinical practice.

## PP238 Budget Impact Of Methionine-Free Amino Acid Formula For Homocystinuria

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**Introduction.** The National Committee for Health Technology Incorporation (CONITEC) evaluates health technologies to recommend their inclusion or exclusion within the Brazilian Public Health System (SUS), and uses the budget impact assessment to estimate costs to the system. This study estimated the budget impact of the supply of methionine-free amino acid formula (MFAAf) for patients with classical homocystinuria (HCU) in the SUS.

**Methods.** The incidence of one case per 250,000 live births in Brazil and the registration of a Brazilian association of patients with HCU was assumed to calculate the population. Mortality and responsiveness to pyridoxine rates were applied. The costs of treatment were estimated according to the recommended dosage in literature and public purchasing prices. For calculating the dose of MFAAf patients, a median age of 19 years and weight of 60 kg were assumed, according to Brazilian study data.

**Results.** The annual cost of treatment was estimated at BRL 77,000 (USD 21,084) per patient. The incorporation of MFAAf for HCU would generate a budget impact in SUS of around BRL 37 million (USD 10.1 million) in 2019 and BRL 188 million (USD 51.5 million) after five years which considers the epidemiological data, and a budget impact of around BRL 6.4 million (USD 1.75 million) in 2019 and BRL 33 million (USD 9 million) after five years which considers the information of a Brazilian association of patients with HCU. The wide range of values in the incremental budgetary impact is due to the lack of information on the epidemiology of the disease in Brazil.

**Conclusions.** The incorporation of the MFAAf in the SUS represents an important budgetary impact and covers a small number of patients. CONITEC recommended the incorporation of the MFAAf in the SUS, according to clinical protocol.

# Vignette Presentations

## VP01 Methods Of Patient Involvement Now And Beyond 2020: A Case Study

Heidi Livingstone (heidi.livingstone@nice.org.uk), Gillian Leng and Victoria Thomas

**Introduction.** Involving patients and the public in the health technology assessment (HTA) has always been fundamental to NICE. To ensure the appropriate method of patient involvement remains relevant to the evolving types of HTA, NICE uses varying methods of involvement. These methods have been reviewed to ensure they remain current and relevant for HTA now and beyond 2020, and also to give guidance on the approaches that should form a standard baseline and those that could be optional.

**Methods.** We identified and mapped the different methods of patient involvement used at NICE across five types of HTAs: diagnostics; medical technologies; medicines; ultra-orphan conditions; and surgical procedures. We looked at the varying methods of early engagement identifying similarities and differences, and considered the benefits and challenges of each.

**Results.** The different methods of patient and public involvement include: lay members (generalist and topic expert) involved in decision making, individual patient input (written and oral), and patient group (organisation) input (written). The types of involvement fell into the following categories: written group submissions, written individual statements, surveys of individuals, pre-meeting events/workshops, oral testimonies at committees, and written consultation responses. The common methods across all HTA types were generalist lay members and consultations.

**Conclusions.** This review highlighted the varying methods of involvement at NICE and highlighted additional methods that could be standardised across the different types of HTAs as a baseline. These included patient organisation submissions and a method for additionally including individual patients in each type of HTA. We identified that where patient involvement started early and continued at each stage of the process including a pre-meeting event, it was particularly helpful to the stakeholders' ability to contribute.

## VP02 Involving Patients In HTA Beyond 2020: A Thematic Review

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**Introduction.** Involving patients and the public in the health technology assessment (HTA) is crucial and a key part of the NICE patient and public involvement (PPI) policy. To advance the development of our PPI policy in HTA and build capacity for 2020 and beyond, we took stock of knowledge on stakeholders' views of involving this cohort in HTA.

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**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

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