

**Methods.** We applied early-stage health economic modelling to the case of performing FETO in singleton pregnant women whose fetus is prenatally diagnosed with CDH. We simulated a cohort of women using a state-transition model over a 45-year time horizon. In our best-case scenario analysis, we compared the current care strategy to a perfect plug strategy, which reduces PPRM and PTDs by 100 percent, to determine the maximum quality-adjusted life years (QALYs) gained and costs saved. Using threshold analysis, we determined the minimum percentage of reduction in PPRM and PTDs for the plug to be considered cost-effective. Model parameters' impact on outcomes was investigated in a sensitivity analysis.

**Results.** Our model indicated that a perfect plug strategy would yield an additional 1.94 QALYs at a cost decrease of EUR 2,554 per patient per year. These values were strongly influenced by the percentage of very preterm deliveries. Threshold analysis showed that, for EUR 500 per plug, the plug strategy needs a minimum relative reduction of 1.83 percent in PPRM and PTDs (i.e., PPRM: 47.50 to 46.63 %, PTDs: 71.50 to 70.19 %) to be cost-effective.

**Conclusions.** Our model-based approach showed clear potential for the plug strategy when applied in the context of FETO for CDH fetuses, as only a small reduction in PPRM and PTDs is needed for the plug to be cost-effective. Its value is expected to be even higher when used in conditions suffering from more very preterm deliveries. Continuation of investment in the innovation's research and development seems to provide value for money.

## PP62 Recommendations On Methodologies To Obtain Comparator Efficacy In Health Economic Assessments Of Tumor-Agnostic Drugs

Reva Efe (REfe@zinl.nl) and Sylvia Vijgen

**Introduction.** Guidance on appropriate methods to obtain a comparator arm for the cost-effectiveness analysis of tumor-agnostic drugs is needed. In recent years, multiple tumor-agnostic drugs have been submitted to health technology assessment (HTA) bodies based on data from single-arm basket trials. These target a specific genetic mutation, as opposed to targeting a specific tumor type. Since HTA bodies are interested in the comparative effectiveness of a treatment, manufacturers have used several methods to obtain a synthetic control arm in their submissions. This study provides an overview of the recommendations by HTA bodies on the methodology to obtain comparator efficacy.

**Methods.** A targeted literature review will be conducted focusing on the methodology used to obtain a comparator arm in the context of tumor-agnostic drugs. The search will cover key HTA organizations; including the National Institute for Health and Care Excellence (NICE), Haute Autorité de Santé (HAS) and the Canadian Agency for Drugs & Technologies in Health (CADTH). Methodologies used in entrectinib and larotrectinib submissions will be extracted. Particular focus will be given on the impact of the applied methodology to the reimbursement decision, as well as key critiques by the HTA

bodies. Key search terms will include the following: 'tumor-agnostic', 'histology independent', 'HIT', 'entrectinib', 'larotrectinib'.

**Results.** An overview of the results will be presented. These will include the applied methodology for obtaining a comparator arm, critiques and recommendations from HTA bodies, and the impact these methodologies had on the overall reimbursement decision. This will enable comparison of HTA decision-making across regions, and key evidence gaps that need to be further explored.

**Conclusions.** The results of this study could be useful in the future assessment of tumor-agnostic drug submissions, focusing on the methodology used to obtain comparator efficacy.

## PP66 Safety, Effectiveness And Cost-effectiveness Of Scalp Cooling Devices For The Prevention Of Chemotherapy-induced Alopecia

Diego Infante-Ventura, Aythami de Armas-Castellano, Aránzazu Hernández-Yumar, Himar González-Pacheco, Tasmania del Pino-Sedeño, Yadira González-Hernández, Lidia García-Pérez, Yolanda Ramallo-Fariña, Leticia Rodríguez-Rodríguez, Antonio Rueda-Domínguez, Pedro Serrano-Aguilar and María del Mar Trujillo-Martín (mar.trujillomartin@sescs.es)

**Introduction.** Chemotherapy-induced alopecia (CIA), although reversible, is one of the most common and distressing side effects of cancer therapy, affecting approximately 65 percent of all patients and influencing treatment decisions in some of them. Scalp cooling (SC) is a method aiming to prevent CIA. Our study aims to evaluate the real value of SC devices.

**Methods.** A systematic review of the available scientific literature on the safety, effectiveness and cost-effectiveness of the use of SC compared with no intervention was performed. Overall effect size was estimated through a meta-analysis. An economic analysis in the Spanish context from the Spanish National Healthcare System (NHS) and social perspectives was performed.

**Results.** Thirteen randomized controlled trials (n = 832) were included but only nine contributed to the meta-analysis. A large effect in favor of SC reducing hair loss was found (RR=0.57; 95% CI: 0.46-0.69). No differences were observed according to the type of cancer, although there was a small positive effect for breast cancer. A higher effect was found in patients treated with a combination anthracyclines/taxanes treatment compared to those treated only with anthracyclines. The only economic evaluation found in the literature was conducted in The Netherlands and concluded that Paxman system was less costly than usual care from societal perspective and no differences in quality adjusted life years (QALYs) were observed. The de novo economic analysis showed that the strategies including SC devices generated more costs and QALYs (given some