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 PPROM 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 PPROM 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 PPROM and PTDs (i.e., PPROM: 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 PPROM 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

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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

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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

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assumed utility values) than usual care (not SC), presenting incremental cost-effectiveness ratios below the threshold calculated for Spain (EUR 25,000 /QALY), from both perspectives.
Conclusions. The results suggest that SC are effective for the prevention of CIA. Furthermore, assuming the utility values used in the model, SC devices are cost-effective compared to usual care (not SC).

PP68 Dexcom G6® Device For Diabetes During Pregnancy

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Introduction. Diabetes mellitus (DM) is one of the most frequent metabolic complications associated with pregnancy, affecting both the prognosis of the pregnant woman and the newborn. Pregestational DM type 1 (T1DM) and type 2 (T2DM) and gestational DM (GDM) are associated with an increased risk of pregnancy complications such as miscarriage, fetal malformations, macrosomia, preeclampsia, and neonatal hypoglycemia, among others. The aim of this review was to evaluate the efficacy and safety of using the Dexcom G6 device (Dexcom, Co., USA) to continuously self-monitor blood glucose levels during pregnancy. This report was requested by the Spanish Ministry of Health.
Methods. We systematically searched for articles published to July 2021 in the MEDLINE, Embase, and Web of Science databases. We included experimental and observational primary studies addressing the safety, efficacy, and cost effectiveness of the Dexcom G6 device for gestational and pregestational diabetes.
Results. Two non-comparative prospective studies were identified. One study of 25 pregnant women with T1DM, which evaluated glycemic control and complications during pregnancy and postpartum, reported stable hemoglobin A1c levels during gestation in women using the Dexcom G6 device. The percentage of time spent in the therapeutic glucose range (63 to 140 mg/dL) was 59 percent; 38 percent was in the hyperglycemic range and 3 percent was in the hypoglycemic range. Although some patients reported mild erythematous and edematous reactions to the sensor, no moderate or severe reactions or infections occurred at the sensor insertion site. The other study in pregnant women with T1DM (n=20), T2DM (n=3), or GDM (n=9) showed adequate accuracy of the Dexcom G6 device, compared with the reference method, especially when the sensor is placed on the arm.
Conclusions. Randomized controlled trials are required to assess the effectiveness and safety of the Dexcom G6 device in maintaining adequate glucose control during pregnancy in women with DM. Studies are also needed to compare the Dexcom G6 device with conventional capillary blood glucose self-monitoring or other monitoring methods. No cost-effectiveness studies have been conducted for the Dexcom G6 device in this patient population.

PP69 Supporting Decision Making: A Health Technology Assessment Training Proposal for Decision Makers

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Introduction. Health technology assessment (HTA) reports are complex technical documents that address multiple aspects of the incorporation of a technology into the healthcare system applying complicated methodologies coming from different disciplines. The purpose of HTA is to support decision makers, who should have an adequate level of training to fully understand these assessments. However, most HTA education programs and courses are intended for HTA doers and there is a lack of practical guidance training aimed at preparing health managers or policy makers in HTA. The objective is to describe an HTA training program developed for decision makers of the three levels (health care administration, hospital management and clinical practice).
Methods. The education program has been designed through a collaboration between the Public Health Department of the Faculty of Medicine of the University of Santiago de Compostela (USC) and the Galician Health Technology Assessment Agency that belongs to the Spanish HTA Bodies Network. The duration of the course is 200 hours and the methodology will be distance learning, through the virtual classroom of the USC. The teaching collaborators come from the academic field and the HTA area.
Results. The course will cover the legal, clinical and organizational framework in which the HTA is developed in Spain and in Europe; and will approach the methodology used in HTA. The course is structured in six modules: (i) Research, development and regulation of health technologies; (ii) Role of HTA as a decision support tool; (iii) HTA Methodology; (iv) Health information systems (including use of real world data); (v) Incorporation of HTA into society (stakeholders); (vi) Future challenges (personalized medicine and e-health).
Conclusions. A specific training about HTA from a practical approach not theoretical could be of interest for different stakeholders involved in the decision-making process across the health systems. This type of educational program will allow decision makers to have a good understanding of the wide range of information they handle.

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