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and prioritize the ICBs, a survey was conducted with the international group of experts from the educational sector. The outcomes of the expert survey were used to create the condensed list containing the most important ICBs.

**Results.** The literature search allowed identifying additional ICBs and creating a comprehensive list of items. In order to improve its usability, a multi-dimensional list was constructed distinguishing between tangible (i.e. special education) and intangible items (i.e. cognitive deficits). Based on the expert survey, the international applicability of the list was validated and the most important ICBs from the economic perspective were determined.

Conclusions. Mental health interventions can affect a large number of educational facilities. The list of ICBs developed in this study could be used to select relevant educational facilities for economic evaluations of specific mental health disorders. Further research is needed to define, measure, and valuate the identified ICBs in order to facilitate the practical application of the list in economic evaluations.

### OP151 Cost-Utility Of Gender-Neutral HPV Vaccination In Ireland

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**Introduction.** A number of economic evaluations of genderneutral human papillomavirus (HPV) vaccination have been published, generally finding that the cost-effectiveness is sensitive to the uptake rate in girls. In Ireland there is a girls-only program in place, but the initial high uptake rate (>85 percent) was substantially impacted by high profile negative publicity concerning perceived vaccine safety issues. Efforts to address perceived safety concerns have recently yielded a partial recovery in uptake rates. The aim of this study was to estimate the cost-utility of extending the program to include boys and explore the impact of fluctuating uptake rates.

**Methods.** A previously published cost-utility model used in the United States of America and Norway was adapted to the Irish setting and populated with Irish epidemiological and cost data. Comparators included no vaccination, and girls-only and genderneutral vaccination, both with either a 4-valent or 9-valent vaccine. Vaccination is at age 12 years and oropharyngeal and penile cancers were excluded in the base case analysis. Additional analyses were used to incorporate fluctuating uptake rates into the model.

**Results.** A 9-valent girls-only program dominated the existing girls-only 4-valent program. The incremental cost-effectiveness ratio (ICER) for a gender-neutral 9-valent program was EUR 50,823/quality-adjusted life year (QALY). Gender-neutral vaccination would be cost-effective at a willingness-to-pay threshold of EUR 45,000/QALY when the uptake rate is below 78 percent. The ICER decreased to between EUR 41,000 and EUR 42,000/QALY when the uptake rate was allowed to fluctuate across six to 12 yearly cycles.

**Conclusions.** The cost-effectiveness of gender-neutral HPV vaccination is highly sensitive to the assumed uptake rate in girls. Large fluctuations in HPV vaccine uptake rates have been observed in a

number of countries in the last decade. Incorporating fluctuating uptake rates in the model shows that a gender-neutral program may be more cost-effective than when a stable uptake is assumed.

## OP152 Pharmacoeconomic Assessment And Drug Expenditure Reduction In Ireland

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**Introduction.** All new products to be reimbursed from the Irish health budget are subject to a rigorous assessment by the National Centre for Pharmacoeconomics (NCPE). Following assessment, a recommendation is made regarding its cost-effectiveness at the submitted price. This may lead a reduction in the drug price. This study aimed to determine the reduction in expenditure due to the pharmacoeconomic assessment process in Ireland.

Methods. Product details, submitted price and gross budget impact were recorded for each NCPE submission from 2012 to 2015. The latter was chosen as reimbursement data are currently available until 2016. A product was included if its assessment suggested price reduction was required and the product was reimbursed under the High-Tech Drug Scheme (HTDS), a scheme for high cost drugs in a primary care setting. The utilization and actual expenditure of each product was extracted from national reimbursement data for the year after approval. The expected expenditure, calculated using the submitted price, was then compared to the actual expenditure.

**Results.** A total of 162 products were assessed during the study period. There was a potential price reduction for 65 products based on the assessment outcome. Of these, 15 were reimbursed under the HTDS. A reduction in expenditure was evident for eight of the 15 products (53 percent). The average reduction was eight percent of the expected expenditure. All products showed an actual expenditure greater the predicted budget impact submitted by the applicant.

Conclusions. To the authors' knowledge, this is the first report of expenditure reduction due to a pharmaco-economic assessment process. With the ever-increasing utilization of high cost drugs, the study demonstrates the importance of a process to assess and negotiate cost-effective drug prices. However, the study underestimates reductions, as it is yet to include commercial rebates returned to a central budget. Future research will aim to capture these reductions.

# OP157 Carbon Ion Radiotherapy: A Systematic Review

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**Introduction.** Due to the promising physical dose distribution of carbon ion radiation therapy (CIRT), CIRT can be regarded as a novel tumor irradiation technique and is sometimes considered as a breakthrough therapy for various tumor types. However, it is unclear whether superiority or inferiority can be claimed when

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compared to standard irradiation. This study aimed to assess the scientific evidence regarding the effectiveness and safety of CIRT.

Methods. A systematic literature review was conducted using the European Network for Health Technology Assessment (EUnetHTA) Core Model® for rapid relative effectiveness assessment. The literature search for clinical outcome studies on CIRT was performed in four databases [Cochrane (Central), Centre for Research and Dissemination (CRD), Embase and OVID MEDLINE]. The risk of bias was assessed using the Cochrane Risk of Bias Tool (for randomized controlled trials) and the Institute of Health Economics (IHE) Checklist (for observational studies). The evidence synthesis was restricted to 12 tumor regions (and 54 indications) and studies with a low or moderate risk of bias, published between 2005 and 2017.

**Results.** In total 27 studies were eligible for the qualitative synthesis of the evidence regarding the effectiveness and safety of CIRT; one randomized controlled trial that primarily focused on the feasibility of CIRT, three case-control studies, three before-after studies focusing on quality of life, and 20 further case series studies. Overall, insufficient scientific evidence was found for 13 (out of 54) indications in seven tumor regions and no scientific evidence was found for 41 (out of 54) indications.

**Conclusions.** Theoretically, CIRT is undoubtedly a promising cancer treatment. To date, however, 54 oncologic indications in 12 tumor regions under investigation lack randomized controlled trials assessing the long-term effectiveness and harms associated with its use. CIRT must be considered as an experimental treatment due to the lack of high-quality clinical research.

#### OP162 Stakeholder Involvement In EUnetHTA Relative Effectiveness Assessments

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**Introduction.** Appropriate involvement of stakeholders is one of the founding principles of the European Cooperation on Health Technology Assessment. The European Network for Health Technology Assessment (EUnetHTA) produces Rapid Relative Effectiveness Assessments (REAs) to assess pharmaceutical (PT) or other technologies (OT). Stakeholders essentially participate in the scoping, the draft assessment phase, or both.

**Methods.** All REAs published since 2013 were reviewed. Stakeholder participation in scoping (project plan) and draft assessment was evaluated. We aggregated categories of stakeholders in four groups (Health Care Providers and Academia, Patients and Consumers, Manufacturers, and Regulators and Payers). Means of collaboration (meetings, comments to project plan and draft assessment, questionnaires, focus groups) are also analyzed. Data is continuously updated with new REAs.

**Results.** More than 20 REAs have been published at the moment, with a higher number of OT. Health Care Providers and Academia acted as experts in both phases, participating in all REA of OT, and less of PT. Manufacturers participated in all REA in the scoping phase. Regulators and Payers, less involved, participated mainly

in the scoping phase. The main methods are providing comments in a standardized form and meetings. Patients' contribution, similar in OT and PT, has increased over the years. Questionnaires or interviews were the main method of involvement, followed by participation in meetings and focus groups. Visibility and transparency have also improved, with a clearer reporting of the stakeholder contribution in the last assessments.

**Conclusions.** The stakeholder involvement in EUnetHTA REAs is steadily growing, with the different nature of stakeholders' categories reflected in their contribution to the assessments. EUnetHTA is standardizing stakeholder involvement procedures taking into account the particularities of each group when generating guidance for stakeholder involvement.

### OP163 Health Technology Assessment Participation And Prioritization In Core Outcome Set Development

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Introduction. A core outcome set (COS) is a minimum standardized set of agreed-upon outcomes for clinical trials of a specific condition. COS development can improve research by aligning stakeholder priorities for the outcomes most important in decision-making across the life-cycle of a product. It is important to include health technology assessment (HTA) representatives in COS development to ensure that outcomes useful to HTA are consistently included in clinical trials. Here we describe the role of HTA representatives in two COS projects: coreHEM, for gene therapy for hemophilia, a genetic blood clotting disease; and coreNASH, for nonalcoholic steatohepatitis (NASH), a progressive form of fatty liver disease that can lead to cirrhosis. We will describe the voting patterns of HTA representatives and consider aspects of their role in shaping the final COS.

**Methods.** For each multi-stakeholder COS, a modified Delphi process was utilized (three online surveys plus an in-person consensus meeting). Candidate outcome lists were compiled via a literature review complemented by participant interviews. Voters condensed and prioritized the lists by rating each outcome on a scale of 1-9 (not important-essential). Votes on each outcome were stratified by stakeholder group; HTA votes were compared with those of other stakeholders.

Results. HTA representatives made up 12.2 percent and 13.5 percent of the voters in coreHEM and coreNASH, respectively. They tended to give the highest votes to mortality outcomes, outcomes measuring the severity of disease, and outcomes related to a patient's quality of life, general well-being and general health perspective. HTA votes helped certain outcomes meet the inclusion criteria in the final voting rounds; without HTA voters, the "mental health status" outcome in coreHEM and the "hepatic-related mortality" and "liver transplantation" outcomes in coreNASH would have been eliminated.

**Conclusions.** HTA participation in COS projects provides HTA representatives an opportunity to help shape COS in clinical research for better decision-making.