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.

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