METHODS:

We aimed to compare German and European HTAs for medical devices regarding processes, methods, timelines, and involvement of medical device companies. Therefore we analyzed guidelines, requirements, and output of EUnetHTA and compared those aspects with the German G-BA (Federal Joint Committee, Gemeinsamer Bundesausschuss) standard and IQWiG (Institute for Quality and Efficiency in Health Care, Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen) methods.

RESULTS:

We found differences between the European and German HTAs for medical devices regarding timelines, involvement of medical device companies, body of evidence, use of surrogate endpoints, and methodology. European HTAs for medical devices reflect the clinical reality by integrating the existing evidence (including real world data) and by using comprehensive statistical methods for medical devices. In contrast, German HTAs for medical device-based technologies are long lasting and are often restricted to a small body of evidence.

CONCLUSIONS:

As a conclusion, similar to pharmaceuticals, the European HTA framework might also become a worldwide platform for HTAs of medical device-based technologies with the potential to harmonize reimbursement decisions and patients health care across countries on the basis of clinical reality.

PP097 Challenges Of Rapid Reviews In Health Technology Assessment: Case Study From An Italian Region

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INTRODUCTION:

Rapid reviews are an attractive tool for Health Technology Assessment (HTA) as they may be a support in decision making when time and resources are limited. Rapid reviews are carried out in few weeks (from 3 weeks to 6 months) and require adjustments from standard systematic review methods. Methodology on how to carry out rapid reviews is still debated and guidance regarding the most suitable method to apply is lacking. Kaltenthaler (1) has recently proposed a checklist of items to be considered when undertaking a rapid review. We appraised our rapid assessment on the use of frequency domain (FD)-optical coherence tomography in percutaneous coronary interventions, based on a rapid review of the literature, using the items proposed (1).

METHODS:

The checklist reports four key points to consider when planning a rapid review: (i) scoping search - needed to quantify the available evidence and to inform rapid review protocol, (ii) results reporting – considering heterogeneity of intervention, comparators, and outcomes, (iii) clear communication with policy makers - ensuring that review responds to the policy question and (iv) reporting on methods - methodology used, strengths and limitations.

RESULTS:

When we applied the checklist proposed by Kaltenthaler (1) to our rapid review on the use of FD-optical coherences tomography it resulted that: the scoping search revealed no useful systematic reviews to answer policy-makers questions and a high number of relevant studies. For results presentation, we used a narrative synthesis reporting outcome data grouped in domains previously defined by an evidence profile. Domains consisted of technical performance, safety, efficacy, and change in management. No meta-analysis was performed due to paucity of randomized controlled trials (RCTs) for the efficacy domain and high heterogeneity in outcomes measures for technical performance. Analysis of some of the outcomes was

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extremely time-consuming (technical performance) and did not provide particularly useful information for the commissioning body. A clearer and more intensive dialog with policy makers to adjust extent of research question and/or outcomes to be investigated would have probably improved usability for final users. Description of methods was partial.

CONCLUSIONS:

The checklist by Kaltenthaler (1) helped us to reflect on the method we used to carry out rapid reviews and to pinpoint possible solutions to improve it.

REFERENCES:

1. Kaltenthaler E, Cooper K, Pandor A, et al. The use of rapid review methods in health technology assessments: 3 case studies. *BMC Med Res Methodol.* 2016;16(1):108.

PP100 Economic Evaluation Of A New Non-Antibiotic First-line Treatment Of Recurrent Urinary Tract Infections

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INTRODUCTION:

Urinary tract infections (UTIs) are common in female patients in general practice. These bacterial infections affect half of all women at least once in their life. Antibiotics are usually prescribed for UTIs, and continuous low antimicrobial prophylaxis is administered to patients at high risk of recurrent UTI (rUTIs) (1). However, a major concern arises due to the increased rates of severe treatment-related side effects and emergence of antimicrobial resistance, which makes rUTIs management more challenging while seeking the use of more expensive alternatives. On this basis, clinical evaluations of rUTI interventions should be accompanied by economic evaluations in order to guide healthcare policy and decision processes about healthcare resources allocation. The aim of this work was to perform a cost-effectiveness analysis of a novel effective non-antibiotic treatment option for prophylaxis of female patients with a history of rUTIs, based on intravesical administration of hyaluronic acid (HA) plus chondroitin sulfate (CS), as compared to recommended 1st-line antibiotic therapy (2).

METHODS:

A cost-utility analysis was performed in order to estimate the effectiveness of each treatment, according to the number of UTIs annual episodes, and the incremental cost-effectiveness (ICER) for patients with UTI, starting from data collected during a multicentric observational case-cross-over clinical trial involving seven European centers (2). The economic model includes the costs of HA treatment and the costs associated with each UTI, such as costs of UTI diagnostics and antibiotic treatment, additional care by the elderly-care physician, additional nursing care, and hospitalizations, as well as the expected QALY, measured through the Short Form Health Survey (SF-36) questionnaires administered to patients, for both groups (3).

RESULTS:

At this stage, preliminary findings suggest that HA plus CS is a cost-effective alternative to antibiotics for the treatment of recurrent UTIs, that could reduce UTIs events in female patients with a history of recurrent UTI at an acceptable cost.

CONCLUSIONS:

The results of this study support the use of HA plus CS against antimicrobials as 1st-line therapy in the management of rUTIs.

REFERENCES:

1. Ciani O, Arendsen E, Romancik M, et al. Intravesical administration of combined hyaluronic acid (HA) and chondroitin sulfate (CS) for the treatment of female recurrent urinary tract infections: a European

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