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Introduction. Severe aortic stenosis with symptoms or left ventricular dysfunction has commonly a poor prognosis and therefore, aortic valve replacement is usually performed for patients aiming at improving their functional class and survival rate.

Methods. This retrospective study evaluated a convenience sample of patients at high risk for open surgery for the correction of aortic valve dysfunction treated with TAVI from 2013 to 2018. Data from a private healthcare organization in Belo Horizonte, Brazil were used to assess all-cause mortality. Continuous variables were expressed as mean and standard deviation. Cox proportional regression model and Log-Rank test were used to adjust the survival curve.

Results. Fifty-two patients were included in the study (mean 83 ± 5.7 years of age, range 67 to 93 years; female 55.8 percent). Patients were characterized by: left ventricular ejection fraction (n = 30; mean 52.9 percent, range 26 to 81 percent); aortic valve area (n = 36; mean 0.68 cm^2, range 0.4 to 1.2 cm^2); left atrium size (n = 14; range 30 to 61 ml/m^2); pulmonary artery pressure (n = 20; mean 53 mmHg, range 31 to 70 mmHg). Death occurred in 19 patients during the follow-up period (mean 8.4 months, range 0 to 60 months). Nine deaths occurred within the first 30 days of follow-up (17.3 percent) and 14 (26.9 percent) in the first year. Stroke occurred in three patients (5.8 percent) in the post-implant period. A pacemaker device was required for nine patients (17.3 percent).

Conclusions. Transcatheter aortic valve implantation (TAVI) has become an alternative to surgical aortic valve replacement for patients at high risk for surgery. Real-world studies might result in a better understanding of the local team expertise on TAVI utilization.

PP58 The Alliance Between Health Technology Assessment And Public Health In National Screening Policies

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Introduction. Decision making regarding national population-based prenatal and newborn screening policies is recognized to be highly challenging. This paper aims to describe the formalized collaboration that has been established between the Spanish National Public Health Screening Advisory Committee (PHSAC) and the Spanish Network of Health Technology Assessment (HTA) agencies to support the development of evidence- and consensus-based recommendations to support this process.

Methods. In-depth description and analysis of the strategic and methodological processes that have been implemented within the Spanish National Health System prenatal and newborn screening frameworks, with special emphasis on the role, actions, and responsibilities of HTA agencies.

Results. The role of HTA agencies is threefold: (i) support the PHSAC by providing evidence on safety, effectiveness and cost/effectiveness of the screening tests/strategies, as well as contextualized information regarding costs, organizational, social, legal and ethical issues; (ii) collaborate with the PHSAC in the development of formal evidence- and consensus-based recommendations for defining population screening programs, when required; (iii) analyze real-world data that is generated by piloted programs. This paper will provide real-life examples of how these processes were implemented in practice, with a special focus on the development of the non-invasive prenatal testing (NIPT) policy. Recommendations for NIPT were developed by a multidisciplinary group based on the European network for Health Technology Assessment (EUnetHTA) rapid assessment report and the predictive models that were built using national statistics and other contextualized data.

Conclusions. The current work represents an innovative approach for prenatal and newborn screening policymaking, which are commonly difficult to evaluate due to the low quality of evidence and the confounding public health issues. The paper raises awareness regarding the importance of joint collaborations in areas where evidence is commonly insufficient for decision making.

PP61 Advanced Therapy Medicinal Products Germany: Drugs Or Methods Review?

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Introduction. Advanced Therapy Medicinal Products (ATMPs) comprise medicines for human use based on gene therapy, somatic cell therapy or bioprocessed tissue products. ATMPs are pharmaceutically manufactured drugs and mostly subject to central authorization requirements. In terms of social law, it is an ambiguous situation and more heterogeneously dealt with. ATMPs are assigned to method evaluation as well as to the Arzneimittelmarkt-Neuordnungsgesetz (AMNOG) procedure designated for drugs.

Methods. Guidelines from Gemeinsame Bundesausschuss (G-BA), Institute for Quality and Efficiency in Health Care (IQWiG) and respective legislation, consultation results and methods/medical devices (MDs) evaluations according to §137h and for drugs according to AMNOG were reviewed and analyzed. Decision criteria and reasoning, assessment outcomes and potential impact on price negotiations were the main aspects for comparison.

Results. ATMPs are subject to benefit assessment, with a decision at first on whether to be evaluated as a drug (e.g., Alofisel) or a method/device (e.g., Holoclar). By definition, an ATMP is classified as a treatment method, if the correct administration has at least the same significance for a successful therapy outcome as its mode of action. Depending on the respective decision, an evaluation as method follows or it must undergo the AMNOG

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process. According to G-BA's and IQWiG's point of view, randomized controlled trials (RCTs) are the "gold standard" for a benefit assessment of new therapies, including ATMPs. However, conduction of RCTs is not always possible for ATMPs which creates a disadvantage in the assessment right from the beginning. Otherwise no distinction is made between drugs and ATMPs in terms of reimbursement modalities. Outcomes based agreements could help overcoming inequalities and lead to quality-oriented reimbursement.

Conclusions. ATMPs represent a grey zone causing difficulties in classifying them either as method or drug. For individualized therapies evidence beyond RCTs and new reimbursement possibilities should be considered. Until new regulations are in place it is advisable to enter early into respective discussions with authorities.

PP62 Cost-Effectiveness Of Cervical Cancer Screening In Estonia

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Introduction. In Estonia, organized cervical cancer screening program is targeted at women aged 30–55(59) years and Pap-tests are taken every five years. Since cervical cancer is associated with human papillomavirus (HPV), a number of countries have introduced the HPV-test as the primary method of screening. The objective of this study was to evaluate the cost-effectiveness of organized cervical cancer screening program in Estonia by comparing HPV- and Pap-test based strategies.

Methods. For the cost-effectiveness analysis, a Markov cohort model was developed. The model was used to estimate costs and quality-adjusted life-years (QALYs) of eight screening strategies, varying the primary screening test and triage scenarios, upper age limit of screening, and testing interval. Incremental cost-effectiveness ratios (ICERs) were calculated in comparison to current screening practice as well as to the next best option. Sensitivity analysis was performed by varying one or more similar parameter(s) at a time, while holding others at their base case value. The analysis was performed from the healthcare payer perspective adopting a five percent annual discount rate for both costs and utilities.

Results. In the base-case scenario, ICER for HPV-test based strategies in comparison to the current screening practice was estimated at EUR 8,596–9,786 per QALY. For alternative Pap-test based strategies ICER was estimated at EUR 2,332–2,425 per QALY. In comparison to the next best option, HPV-test based strategies were dominated by Pap-test based strategies. At the cost-effectiveness threshold of EUR 10,000 per QALY Pap-testing every three years would be the cost-effective strategy for women participating in the screening program from age 30 to 63 (ICER being EUR 3,112 per QALY).

Conclusions. Decreasing Pap-test based screening interval or changing to HPV-test based screening can both improve the effectiveness of cervical cancer screening program in Estonia, but based on the current cost-effectiveness study Pap-test based screening every three years should be preferred.

PP64 Economic Evaluation For Esophageal Cancer Screening In China

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Introduction. The aim of the study was to estimate the cost-effectiveness of esophageal cancer (EC) screening compared to non-screening in China.

Methods. A Markov model was conducted that followed the history of EC. Screening strategies targeted a population aged 40-69 years, classified into six age groups. Each age group had three cohorts: screening without follow-up, screening with yearly follow-up for low-grade intraepithelial neoplasia (LGIN), and non-screening. Life years (LYs) and quality-adjusted life years (QALYs) presented the effectiveness and utility. The incremental cost-effectiveness ratio (ICER) and incremental cost-utility ratio (ICUR) were evaluating indicators. Eighteen cohorts from 100,000 hypothetical individuals were used to run the model, until aged 79 years or death. Costs were changed into USD using the purchasing power parity of 3.506 in 2017. The willingness-to-pay was set as three times the gross domestic product per capita (USD 51,340.6) in 2017. A sensitivity analysis was introduced to assess model robustness.

Results. Screening with follow-up compared to non-screening, ages 40-44, 45-49, and 50-54 years, showed cost-effectiveness, with one LY gained costing USD 6,875.0, USD 9,204.6, and USD 25,278.6, respectively. Ages 40-44 and 45-49 years explained cost-utility, with ICURs of USD 6,709.4/QALY and USD 13,991.4/QALY, respectively. Screening without follow-up compared to non-screening, ages 40-54 years, addressed cost-effectiveness, with one LY gained costing USD 6,934.8, USD 9,760.0, and USD 35,126.0 in ages 40-44, 45-49, and 50-54 years, respectively; the 40-44 years age group demonstrated cost-utility with an ICUR of USD 8,512.3/QALY. Screening with follow-up compared to screening without follow-up, all ages, explained cost-effectiveness and cost-utility. The probabilistic sensitivity analysis supported the outcome of the base cohort analysis.

Conclusions. Compared to non-screening, screening with follow-up targeting ages 40-54 years was highly recommended with the ICER as the evaluated indicator, whereas it targeting ages 40-49 years was suggested with the ICUR as indicator.

PP65 Methods Applied For Systematic Reviews Of Economic Evaluations In Health Technology Assessment

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Introduction. When making decisions in health care, it is essential to consider economic evidence about an intervention. The objective of this study was to analyze the methods applied for systematic reviews of economic evaluations in Health Technology Assessment (HTA) and to identify common challenges.

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