number of options that would allow the committee to make an interim decision that would be revisited based on later evidence. The ability to collect robust patient level data given data capabilities in National Health Service Scotland (NHSScotland) was an important consideration.

Results. To ensure that additional evidence would be available to inform a re-assessment, the new approach applies to medicines with a Conditional Marketing Authorisation (MA) from the European Medicines Agency (EMA). This obligates the company to provide specified clinical data to the regulator within a pre-set timeframe. For these medicines, the SMC decision-making committee can accept or not recommend the medicine as at present but can also accept the medicine on an interim basis, if the regulator's mandated Specific Obligations are likely to address the uncertainties in the clinical evidence. When the regulator converts the MA from conditional to standard, the company is required to make a further SMC submission to allow a reassessment and a final decision. The company can also provide additional supplementary post-licensing patient level evidence at reassessment.

Conclusions. This new decision option allows SMC to test an approach to managing uncertainty targeted at a small number of promising new medicines where there is unmet patient need, with the reassurance that a final decision will be supported by additional clinical data.

PP54 A Cohort Case Study On Implantable Cardioverter Defibrillators

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Introduction. Many patients presenting with arrhythmias are treated with antiarrhythmic drug therapy. However, for some patients, usually survivors of previous serious ventricular arrhythmias, treatment implies the use of implantable cardioverter defibrillators (ICDs) and/or Cardiac Resynchronization Therapy (CRT) devices.

Methods. This retrospective study evaluated a cohort of patients with arrhythmia requiring the use of ICDs, CRT or ICDs + CRT from January 2004 to March 2018. Data from a private healthcare organization in Belo Horizonte, Brazil were used to assess all-cause mortality and the need for replacement of the device. 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. Five hundred and ninety-three patients were included in the study (median age 67.6 years, range 23 to 89 years; male 62 percent). According to the type of device used to treat these patients, the distribution was 338 (57.0 percent), 169 (28.5 percent), 86 (14.5 percent), for ICDs, ICDs + CRT, CRT, respectively. After a mean follow-up time of 3.12 years (range 0 to 13.6 years), 283 devices were replaced (ICDs n = 140; ICDs + CRT n = 90; CRT n = 53) and 284 deaths occurred (median survival of 6.9 years). The median survival was 7.3, 5.8, 4.8, 5.5 years for ICDs single-chamber, ICDs dual-chamber, ICDs + CRT, CRT, respectively.

Conclusions. Randomized trials are often criticized for their enrollment of highly selected patients. Studies on real-word data can provide reliable information regarding the use of ICDs and/or CRT devices in the treatment of patients with serious ventricular arrhythmias.

PP55 The Effectiveness Of Viabahn In Peripheral Artery Aneurysms

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Introduction. Open repair was considered for several years the gold standard therapy for the treatment of peripheral artery aneurysms (PAAs). However, with advancements in endovascular technology increasing attention has been directed toward repairing PAAs using an endovascular stent graft.

Methods. This retrospective study evaluated a cohort of patients after the correction of PAAs with Viabahn. Patients treated from January 2011 to January 2018 were assessed for all-cause mortality, amputation and the need for re-intervention. Data were extracted from an administrative database from a healthcare organization in Belo Horizonte, Brazil.

Results. Fifty-two patients were included in the study (median age 69.1 years, range 15 to 90 years; male 63.5 percent), three of whom also received Viabahn for contralateral PAAs. In total, 84 devices were used (average 1.5 per PAA); distribution: popliteal and tibial arteries (n = 30; 57 percent), femoral and iliac arteries (n = 19; 37 percent), axillary artery (n = 1; 2 percent), splenic artery (n = 1; 2 percent), abdominal aorta (n = 1; 2 percent). After a mean follow up time of 1.98 ± 1.68 years, we observed death (n = 3; 5.8 percent), amputation (n = 3; 5.8 percent) and the need for re-intervention (n = 17; 32.6 percent) in 23 patients (44.2 percent). The combined overall survival for the first, second and third year of follow up was 70.2 percent (Confidence Interval [95% CI]: 58.9 - 83.6); 63 percent (95% CI: 51.0 - 78.0) and 57.3 percent (95% CI 44.6 - 73.6).

Conclusions. There are still several unanswered questions regarding the best approach for patients with PAAs. In the absence of well-designed clinical studies, the assessment of databanks on real-world patients may contribute to improve our understanding of treatment alternatives and provide guidance to improve current clinical results.

PP57 Outcomes On Transcatheter Aortic Valve Implantation

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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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