thereby reducing their visiting frequency to a medical clinic. The aim of this work was thus to elaborate recommendations on the use of self-monitoring in the management of warfarin-treated patients in the province of Quebec.

Methods. Systematic literature reviews were conducted to retrieve the most up-to-date scientific data from primary studies and pharmacoeconomic evaluations as well as recommendations from published clinical practice guidelines. This information was then triangulated with the experiential knowledge of Quebec experts and clinicians collaborating on the project.

Results. The scientific, contextual and experiential evidence gathered during this work provided convincing support for the use of self-monitoring for long-term warfarin-treated patients, leading to a more effective treatment than standard monitoring while being safe, cost-effective and potentially improving patients' quality of life. However, physical and mental limitations can hinder the use of portable coagulometers, outlining the need for caution in the selection and support of self-monitoring patients.

Conclusions. This work led to the development of specific recommendations on the use of self-monitoring along with a clinical tool to help discussion between patients and health professionals leading to a shared decision-making. This work will be part of two optimal usage guides on oral anticoagulant therapy to be published by the Institut national d'excellence en santé et en services sociaux.

PP48 Risk Of Bias Of Systematic Reviews Connected To Journal Impact Factor?

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Introduction. Systematic reviews (SRs) are today's cornerstone of evidence-based medicine. However, their risk of bias (ROB) may critically impact their findings. Hence, an impartial assessment of their ROB is paramount to their interpretation. The objective of this study is to evaluate the potential association between the results of the ROB assessment for a series of SRs and their corresponding journal's impact factor as determined by the citation reports.

Methods. A sample of over 500 SRs and their corresponding ROB will be employed in this study. The source for these data will be the database KSR Evidence. The corresponding impact factor (IF) for the publishing journal as reported by the Science Citation Index will also be retrieved. The total of ROBIS signaling questions answered as 'yes' or 'probably yes' will be used to approximate the awarded quality (Quality) for each systematic review. An analysis of the potential correlation between Quality and the IF will be performed with a simple linear regression.

Results. Results will be presented in tables and figures. Preliminary results confirm that a statistically significant association between the suggested variables exists, though this is of low magnitude.

Conclusions. Findings confirm that the ROB of an SR and the IF of the publishing journal are correlated.

PP50 How Do Target Population Sizes In Health Technology Assessments Impact Drug Price Changes?

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Introduction. The relationship between heath technology assessment (HTA) recommendations and drug prices has received little attention in the published literature. We consider whether target population sizes estimated as part of positive HTA decisions impact future price changes. We hypothesize that larger target populations may result in larger drug price reductions, as overall budget impact is an important component of price negotiations.

Methods. HTA and pricing data were obtained from the Context Matters Market Access Platform (MAP) and IHS Markit's PharmOnline International (POLI) pricing database, respectively. We analyzed 55 HTA decisions from the Gemeinsame Bundesausschuss (G-BA; Germany) and the Haute Autorité de Santé (HAS; France) for oncology products receiving European Medicines Agency approval between 2011 and the end of 2014. Pricing and HTA histories were tracked from the beginning of 2012 until October 2018. Using multiple regression to control for HTA agency, country-specific scores (Improvement in Actual Benefit and Additional Benefit scores), pack size, and initial price, we examined the relationship between a drug's price change in the year following an HTA review and the increase in target population resulting from the HTA decision.

Results. We found that larger increases in target population were related to larger reductions in drug prices ($p = 0.014$). The magnitude of the effect size was low.

Conclusions. For the sample evaluated, we found a small but statistically significant association between target population size increases (as estimated by HTA bodies) and price reductions, supporting our hypothesis that target population plays a role in price negotiations. Confidential discounts and managed-access agreements likely account, in part, for the low magnitude of the observed association. Future work on this topic will involve larger samples covering a greater number of HTA agencies to improve the power and generalizability of the analysis.

PP52 Interim Decision-Making To Address Uncertainty At Early Assessment

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Introduction. Medicines regulation has become increasingly adaptive to support earlier patient access but the immature clinical data is often challenging for health technology assessment decision-makers due to high levels of uncertainty on long term risks and benefits. Scottish Medicines Consortium (SMC) is therefore exploring new, more adaptive approaches to help manage this challenge.

Methods. SMC consulted with key stakeholders including clinicians, the pharmaceutical industry and patient groups on a

https://doi.org/10.1017/S0266462319002071 Published online by Cambridge University Press

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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https://doi.org/10.1017/S0266462319002071 Published online by Cambridge University Press