incorporating headroom analysis, return on investment, one-way sensitivity analysis and scenario analyses using data from secondary sources.

Results. The review of the literature, focus groups with CKD patients, and qualitative interviews with technology developers helped to understand relevant characteristics of WDHT and user preferences helped inform the next R&D iteration. Compared to the standard care, WDHT that support stage ≥3 CKD patients self-management at home by measuring blood pressure and monitor mobility has the potential to be cost-effective at conventional cost-effectiveness threshold levels. From the headroom analysis, novel WDHT can be priced up to GBP280 (EUR315, USD360) and still be cost-effective compared to standard home blood pressure monitoring.

Conclusions. Our study provides valuable information for the further development of the WDHT, such as defining a go/no-go decision, as well as providing a template for performing early HTA of Digital Health Interventions.

OP437 Use Of Real-World Evidence In Survival Analysis Adjusting For Treatment Crossover In Cutaneous T-Cell Lymphoma

Neil Hawkins, Rachel Evans (rachel.evans@visibleanalytics.co.uk), Noemi Muszbek, Trefor Jones and Linda McNamara

Real-World Evidence is useful for validating crossover adjustment approaches, particularly when the adjustment is required because a trial does not accurately reflect a health technology assessment (HTA)-relevant population. We use the MAVORIC trial advanced stage mycosis fungoides and Sézary syndrome cutaneous T-cell lymphoma population and data from the Hospital Episodes Statistics to explore and validate crossover adjustment methods.

Introduction. The MAVORIC trial compared mogamulizumab to vorinostat in patients with mycosis fungoides (MF) or Sézary syndrome (SS), subtypes of cutaneous T-cell lymphoma. However, the treatment comparison within MAVORIC may not represent an HTA relevant population from a UK perspective: (i) 72.6 percent of patients randomized to vorinostat switched to mogamulizumab and (ii) vorinostat is not used in current clinical practice in the UK. This study explores methods to adjust treatment effect estimates using different crossover adjustment methods and Real-World Evidence.

This medicine is subject to additional monitoring. This will allow quick identification of new safety information. See www.mhra.gov.uk/yellowcard for how to report side effects.

Methods. An advanced stage (stage ≥IIB MF and all SS) population was included. Three methods were considered for treatment crossover adjustment. A synthetic control arm was created using the Hospital Episodes Statistics (HES) dataset. Predicted survival for the MAVORIC control arm, post-crossover adjustment, was compared to the HES to inform the selection of the appropriate methods for adjustment. A direct comparison between mogamulizumab (reweighted to represent the distribution of MF/SS patients in the HES) and the synthetic control was also conducted.

Results. Following crossover adjustment of the vorinostat arm, using the inverse probability of censoring weighting method, the overall survival (OS) hazard ratio (HR) estimate for mogamulizumab vs. vorinostat was 0.45 (95% confidence interval (CI): 0.19, 1.07). This adjustment method was considered the most appropriate based on an assessment of assumptions and a comparison of OS between the adjusted vorinostat data and the HES data. The OS HR estimate for reweighted mogamulizumab vs. synthetic control from HES was 0.33 (CI: 0.21, 0.50).

Conclusions. Real World Evidence from the HES database can be used to validate crossover adjustment methods and to better reflect current clinical practice in the UK. Results using both methods support each other.

OP440 Comparison Of Evidence Supporting Cancer Drug Approvals And Prices In The US And Brazil

Adriana Ivama Brummell (adriana.ivama@anvisa.gov.br) and Huseyin Naci

Introduction. Cancer drug prices are high on the policy agenda worldwide. Previous research found no association between cancer drug benefits and prices at the time of regulatory approval. Drugs approved in the US with uncertain benefits may have spillover effects in other settings. Our objective was to compare the evidence supporting cancer drug approvals in the US and Brazil, and to examine the association between cancer drug prices and availability of added therapeutic benefit.

Methods. We matched all novel cancer drugs approved in the US from 2010–2019 to approvals in Brazil. We extracted data on pivotal study design characteristics and outcomes in the US and Brazil, and evidence supporting price approval in Brazil, including availability of added therapeutic benefit.

Results. From 2010–2019, fifty-six cancer drugs with matching indications were approved in US and Brazil and had their prices authorized in Brazil by December 2020. Drug were available in Brazil following a median 522 days after US approval (IQR: 351–932). In the US, thirty-four (60.7 percent) of the drugs had pivotal randomized controlled trials (RCTs) and Twelve (21.4 percent) had overall survival benefit. By the time of Brazilian approval, forty-one (73.2 percent) drugs had pivotal RCTs and twenty-two (39.3 percent) had overall survival benefit. A total of twenty-eight (50 percent) drugs did not demonstrate added therapeutic benefit over other authorized drugs for the same indication and had a median reduction from requested to approved price of 6.1 percent (IQR: 0–27.8 percent) in Brazil. The twenty-seven (48.2 percent) drugs with added therapeutic benefit had a median price reduction of 2.0 percent (IQR: 0–9.2 percent).

Conclusions. Half of new cancer drugs approved in Brazil failed to demonstrate added therapeutic benefit. The Brazilian pricing system secured considerable price reductions, ensuring that prices for

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medicines with no added therapeutic benefit were not higher than existing treatments for the same approved indication. Although evidence was more mature by the time of Brazilian review, pivotal studies often lacked randomization and overall survival endpoints.

OP443 Evaluating The Value Of Endovascular Innovations For Aortic Valve Replacement Through Clinical Benefits, Patient-reported Outcomes And Resource Consumption.

Eduardo Pinar, Juan García de Lara, José Hurtado, Miguel Robles, Gunnar Leithold, Belén Martí-Sánchez, Mónica Cerezales (mcerezales@axentiva.com) and Jesús Cuervo

Introduction. The use of most recent Transcatheter aortic valve implants (TAVI) in the treatment of symptomatic severe aortic stenosis (SAS) is evolving with expanded indications from inoperable/high-risk to intermediate and low risk patients. Consequently, TAVI outcomes must be monitored to highlight its value under real-world conditions. Our aim was to prospectively evaluate TAVI (SAPIEN 3) outcomes in terms of patient's health-related quality of life (HRQoL), clinical outcomes, and healthcare resource utilization (HRU).

Methods. An observational prospective study including all consecutive patients with SAS undergoing a transcatheter valve implantation with Edwards SAPIEN 3 valve (transfemoral access) was conducted in full accordance with clinical guidelines from the European Society of Cardiology. Patients were evaluated before the intervention (baseline), at discharge, and after one, six and twelve months from the implant. A thoughtful and systematic evaluation of patients' HRQoL (EQ-5D 5L, the Short Form-36 Health Survey -SF-36- and the Kansas City Cardiomyopathy Questionnaire -KCCQ-), clinical endpoints (that is, cardiovascular mortality, and rates of stroke, major bleeding, myocardial infarction, and re-hospitalization), echocardiographic measurements, and HRU (that is, Length of stay-LOS- in ward/intensive care unit -ICU-) was implemented. Multivariate regression models were applied to test outcomes while controlling key risk factors (that is, patient' severity at baseline).

Results. A total of seventy-six patients (fifty percent female, fifty-five percent of intermediate-high risk) with a mean age of 82.1 ± 4.78 years were included. Implant success was 97.34% and cardiovascular death was 2.6% at one year. Significant reductions in mean and maximum gradients were achieved and maintained during follow-up. Mean LOS in ward (5.2 ± 4.0days) and ICU (0.22 ± 0.64 days) were low. Statistically significant improvements were detected in the KCCQ overall summary scores, EQ-5D, and SF-36 (Physical component summary) - all adjusted - $p < 0.05$ - after the intervention.

Conclusions. TAVI represents a safe and effective innovation for SAS with clinical benefits translated into significant improvements in terms of HRQoL. Besides, the low HRU provides new insights for health-economic modelling and the optimization of limited resources of special importance under current pandemic situation.

OP456 Encouraging Shared Decision-Making Of Goals Of Care Discussions In Lung Cancer Patients Using A Smartphone Application

Amanda Lovato and Nisha Almeida (nisha.almeida@mail.mcgill.ca)

Introduction. An important reason for receiving non-beneficial treatment at end-of life is the lack of timely discussions on goals of care and end-of-life preferences. A recent randomized clinical trial demonstrated that patients primed with a questionnaire on their end-of-life preferences were more likely to initiate such conversations with their doctors. Our objective is to integrate the questionnaire into a smartphone application to facilitate early goals of care discussions. To achieve this goal, we first plan to undertake a feasibility study to understand stakeholder preferences.

Methods. As part of a quality improvement initiative at our Canadian quaternary-care hospital, we conducted focus groups with oncology and palliative care physicians and patients to understand barriers to early conversations on end-of-life preferences, and to assess feasibility of using smartphone technology in facilitating these conversations. The app would integrate a questionnaire to patients and send prompts to physicians on patient readiness and timing of conversations.

Results. We conducted separate focus groups with lung cancer patients (n = 6) and clinicians in oncology (n = 6) and palliative care (n = 6). Clinical teams expressed enthusiasm about early conversations but raised several barriers including system (lack of electronic documentation and access to data; multiple physicians), clinician (lack of time) and patient (stigma associated with end-of-life) barriers. Clinicians agreed that an app could overcome some of these barriers such as access to patient and electronic data by making patients the repository of all their data and empowering them to initiate discussions. However, they raised concerns about universal accessibility of such technology, especially among the elderly. Patient focus groups will take place in March 2021 and inform us on feasibility in this population.

Conclusions. There is a consensus among physicians at our hospital that early end-of-life conversations have the potential to mitigate adverse events and that use of a smart phone app could facilitate such conversations.

Poster Presentations

PP89 The Investigation And Development Of A National Formulary Monitoring System Across Wales

Richard Boldero (richard.boldero@wales.nhs.uk), Thomas Curran, Kath Haines, Miranda Morton and Phil A. Routledge

Introduction. The New Treatment Fund (NTF), launched in January 2017, aims to support the faster introduction of new

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