with chronic conditions more control over their health, safety and wellbeing. Involving patients early on in the design of these technologies facilitates the development of person-centered products. It may increase the potential uptake of (and adherence to) any intervention they are designed to deliver. This research aims to elicit chronic kidney disease (CKD) patients' preferences for WDHTs that may help patients manage their conditions.

Methods. We used discrete choice experiments (DCE) to elicit preferences for WDHTs characterized by their generalizable characteristics. The study design was informed by a multi-stage mixed-method approach (MSMMA). This included a review of the published literature, focus group interviews and one-to-one interactions with CKD patients to identify relevant characteristics (that is, attributes and levels) associated with wearable DHTs. We collected the data from 113 patients (age ≥18 years) with stage 3 or above CKD. The analysis started with a conventional multinomial logit model and was extended by investigating heterogeneity in preferences via latent class models.

Results. Our MSMMA yielded ten potential attributes for consideration in a choice task. The final list included five attributes, cross-checked and validated by the research team, and patient representatives. The most preferred attributes of WDHTs were device appearance, format and type of information provided, and mode of engagement with patients. Respondents preferred a discreet device, which offered options that individuals could choose from and provided medical information.

Conclusions. We show how to use MSMMA to elicit user preferences in (and to inform the) early stages of the development of WDHTs. Individuals with CKD preferred specific characteristics that would make them more likely to engage with the self-management support WDHT. Our results provide valuable insights that can be used to inform the development of different WDHTs for different segments of the CKD patients population, moving away from a one-size-fits-all provision and resulting in population health gains.

OP345 Evaluation Of An Artificial Intelligence-assisted Service For Cardiac Monitoring As Part Of A National Institute For Health And Care Excellence (NICE) Digital Health Technology Pilot

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Introduction. Zio XT Service was one of five Digital Health Technologies (DHTs) to be assessed by the National Institute for Health and Care Excellence (NICE) as part of their evaluation pilot. The King's Technology Evaluation Centre (KiTEC) act as an External Assessment Centre for NICE and worked on this pilot evaluation. The service comprises a I-Lead ECG patch, an inbuilt software that makes use of artificial intelligence (AI) algorithms to record, store and analyze ECG traces, and a team of cardiac physiologists.

Methods. Although the methods were based on NICE's existing Medical Technologies Guidance Process, they were modified to suit the assessment of DHTs. The process was split into two sections, with the option to discontinue the assessment if it was considered that insufficient evidence was available for the technology. Clinical experts and patients were consulted through the process and clinical, economic and technical evidence was considered. Costs for three care pathways were modelled.

Results. A total of thirty relevant clinical studies were identified, with a further study being reviewed as part of a separate technical assessment, focusing on the AI component of the technology. Four of the studies were considered to be pivotal to the decision problem, one of which was a Randomized Controlled Trial. The technology was found to have a greater diagnostic yield than a standard ambulatory monitor, however diagnostic accuracy measures were absent in the literature. Three economic models were developed to represent three care pathways: patients with syncope, patients who have had a stroke or transient ischaemic attack and a third model assessing downstream costs associated with stroke treatment.

Conclusions. Digital Health Technologies and Artificial Intelligence Technologies pose novel and unique challenges to health technology assessment (HTA) bodies. Zio XT Service is a diagnostic tool, with both human and AI input, making it a particularly complex technology to assess. This work serves as a case-study in the evaluation of DHTs and AI and the lessons learned may contribute to the development of guidelines for such technologies.

OP348 Assessing The Potential Value Of Wearable Digital Health Technologies In Chronic Kidney Disease Using Early Health Technology Assessment Methods

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Introduction. Wearable digital health technologies (WDHTs) offer several solutions in terms of disease monitoring, management and delivery of specific interventions. In chronic conditions, WDHTs can be used to support individuals' self-management efforts, potentially improving adherence to (and outcomes resulting from) interventions. Early health technology assessment (HTA) methods can inform considerations about the potential clinical and economic benefits of technology in the initial phases of the product's lifecycle, facilitating identification of those Research & Development (R&D) investments with the greatest potential stakeholders' payoff. We report our experience of using early HTA methods to support R&D decisions relating to novel WDHT being designed to support self-management of chronic kidney disease (CKD).

Methods. We performed a literature review, focus-group interviews with patients, and qualitative interviews with the prototype development team to understand the relevant characteristics of WDHTs, quantify relevant clinical indications and existing technological constraints. An early economic evaluation was used to identify the key drivers of value for money, and a discrete choice experiment shed light onto patient preferences towards what key features the WDHT should have for the users to adopt it. Then a model-based cost-effectiveness analysis was undertaken

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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

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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

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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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