Introduction. The National Institute for Health and Care Excellence (NICE) has increasingly agreed to reimburse innovative products with high levels of uncertainty as part of managed access agreements (MAAs) while additional data are collected, through the new Cancer Drugs Fund (CDF) or highly specialized technology (HST) pathways. This research aimed to review the data collection stipulations of current MAAs.

Methods. We reviewed all current MAAs entered into between NHS England and manufacturers as of 29 October 2018 and key data were extracted.

Results. Twenty-two MAAs were identified (19 through the CDF; three through HST). All MAAs involved an observational data collection component. The source of observational data collection was existing NHS databases (19/22 MAAs: 86.5 percent), existing independent registries (one MAA: 4.5 percent [ataluren]); bespoke MAA registry maintained by manufacturer (1/22 MAA: 4.5 percent [asfotase alfa]), and registries developed as a part of regulatory approval and maintained by the manufacturer (1/22 MAA: 4.5 percent [elosulfase alfa]). Only eight MAAs (asfotase alfa, ataluren, elosulfase alfa, brentuximab vedotin, venetoclax, ibrutinib, daratumumab, and pembrolizumab) had observational data collection as the primary method of data collection. Additionally, 17/22 MAAs (77 percent; all from the CDF) also required ongoing data collection from clinical trials as a key component of the data collection arrangement.

Conclusions. This research identified observational data collection as a requirement in all MAAs, which is primarily through existing registries (except ataluren, which required development of a bespoke registry), while ongoing trial data collection was limited to the CDF. The relatively low cost of using existing registries to fulfil data requirements, with the ability to achieve reimbursement whilst still collecting data from ongoing RCTs, make MAAs an attractive proposition for manufacturers. NICE reportedly plan to increase use of MAAs, with ongoing NICE consultation for changes in the appraisal process potentially allowing expansion to include all indications, which would mean increased opportunities to explore innovative MAAs to support access in the future.

OP129 Healthcare Utilization After Bariatric Surgery

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Introduction. Bariatric surgery has become one of the fastest growing operative procedures due to its sustained results and the increasing prevalence of obesity worldwide. Despite this fact, bariatric surgery carries the usual risks and threats of surgical interventions and therefore its benefits might be undermined by its mid and long-term complications.

Methods. This retrospective study included obese patients requiring bariatric surgery from January 2004 to December 2017 provided by a private healthcare organization in Belo Horizonte, Brazil. Data regarding healthcare utilization were extracted from an administrative database (software Oracle Business Intelligence). Continuous variables were expressed as mean and standard deviation. Log-Rank test was used to adjust the survival curve (software STATA 13.1, Stata Corp, USA). This historical cohort resulted in no interventions, neither during the instituted treatment nor after the observed outcome. Privacy of subjects and the confidentiality of their personal information were handled in accordance with the ethical principles of the Declaration of Helsinki.

Results. In total, 16,786 patients were included in the study (mean age 37.2 ± 10.2 years; female 79.2 percent; mean body mass index 42.4 ± 5.5 kg/m^2). Patients were followed for up to seven years before and after surgery (total of 78,113 patients/year). For this group, the hospitalization rate was 0.099 / patients-year before versus 0.151 / patients-year after the bariatric surgery ($p < 0.001$). There were 224 deaths (1.33 percent) identified during the follow-up period, 0.4 percent in the first 30 postoperative days. The average costs for hospitalization were USD 3,339.36 and USD 4,305.04 for open and laparoscopic surgery, respectively.

Conclusions. Bariatric surgery has been an increasingly popular choice in the management of obesity. In our sample, it did not reduce the overall mid-term healthcare utilization rate.

OP130 Evidence-Informed Policy For Biologic Medicines In Brazil

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Introduction. The Department of Sciences and Technology (Decit) of the Brazilian Government has played a vital role in drafting of the National Policy for Biologic Medicines. Decit has provided methodological support to the working group, conducting a rapid review and a rapid evidence synthesis to subsidize decisions and recommendations.

Methods. We used the Methodological Guidelines for the Elaboration of Evidence Synthesis for Health Policies, which is a product of our own team, based on the SUPporting POlicy relevant Reviews and Trials (SUPPORT) Tools for evidence-informed health Policymaking.

Results. The Decit team participated in the key steps to develop an evidence-informed policy. Our product, "Barriers to Access to Biologic Products: a Rapid Review" was used for the prioritization of health problems and the description of the problem. We then proceeded to the evidence synthesis planning and definition of the research question from an acronym. Together with the coordination of the working group, we decided to tackle the problem of interchangeability of biologic products motivated solely by economic factors in a synthesis of policy evidence. Our evidence synthesis went so far as to describe policy options. The working group used this product to inform a Policy Dialog.

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Conclusions. This was the first time that the Decit team provided hands-on methodological assistance the development of a health policy. Not all steps recommended in the SUPPORT Tools were feasible due to time restraints. We observed that rapid evidence synthesis products were helpful to inform decision-making.

OP131 Rapid Review For Policy: Interchangeability Of Biological Medicines

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Introduction. Due to the high judicialization rates which pressure the financing of biologic medicines by the Brazilian Unified Health System (Sistema Único de Saúde - SUS), it has been decided to formulate the National Policy for Biologic Medicines. After identification of problems and prioritization, interchangeability based only on economic criteria was the main problem to be confronted. The primary objective of this study was to identify political options to approach the problem of interchangeability in systematic reviews.

Methods. We conducted a rapid evidence synthesis for policy based on an adaptation of the SUPPORT tools, and searched in six literature databases. The selection of studies was performed in a systematic, transparent and independent manner. The International Network of Agencies in Health Technology Assessment (INAHTA) members were consulted to learn how this practice occurs worldwide.

Results. We included seven systematic reviews and one policy brief, whose options to approach the problem were: production of robust scientific evidence on interchangeability; implementation of a pharmacovigilance system; appreciation of the clinical efficacy in the practice of interchangeability; and educational strategies for healthcare professionals in Brazil. Nine countries responded to our query.

Conclusions. Evidence-informed policy has a central role for the Brazilian Ministry of Health. The present rapid evidence synthesis for policy will subsidize decision making regarding the interchangeability of biologic medicines within the Brazilian Unified Health System.

OP132 What Future For Drugs After An Early Dialogue Procedure?

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Introduction. The French health technology assessment (HTA) body, Haute Autorité de la Santé (HAS), started to provide early advice on evidence generation plans to pharmaceutical manufacturers in 2010. It became an official mission in 2016. Requests are eligible when the product has a new mechanism of action, if there is an unmet or partially met medical need in the claimed indication and when the pivotal study has not yet started. This analysis aims to provide a first overview of clinical developments for which pharmaceutical companies sought an early dialogue with HAS.

Methods. For each product that went through an early dialogue procedure with HAS, information regarding the clinical development was collected on pharmaceuticals companies' pipelines, clinicaltrials.gov, the website of the European Medicine Agency (EMA) and HAS's internal database.

Results. By the end of 2018, HAS has performed 84 early dialogues of which 53 were conducted in collaboration with the EMA and/or others European HTA bodies. They were mainly focused on phase III trials. Following early dialogue, the clinical study for which the company sought advice was not yet implemented in 25 cases. When the clinical trial was effectively launched, results were negative in 10 cases, positive in 11 cases and the study was still ongoing for 29 products. In nine cases, the clinical development was officially withdrawn or suspended before the initiation of the trial. Overall, only eight medicinal products were appraised by HAS, they all obtained a clinical added value score.

Conclusions. The success rate of clinical development for products that underwent an early dialogue procedure tends to be higher than data from literature, although it is likely to decrease in follow-up analysis. This could be partially explained by HAS's eligibility criteria that restrict early dialogues to promising products and by the scientific recommendations provided to pharmaceuticals companies.

OP135 CAR T-cell Therapy HTA Informs Australian Policy

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Introduction. Chimeric antigen receptor (CAR) T-cell therapy is offered as a once-only treatment for patients with certain cancers that are not responsive to standard treatment. While clinicians, patients and their families increasingly seek access to CAR T-cell therapy, there is no revenue stream to support access through public or private health systems.

Methods. The New South Wales (NSW) Ministry of Health and Victorian Department of Health and Human Services oversighted a health technology assessment (HTA) to explore the status and geography of regulatory frameworks supporting delivery of CAR T-cell therapy, evidence for the safety, efficacy and cost, clinical trials conducted or underway and manufacturing aspects.

Results. CAR T-cell therapies are approved in the European Union and United States of America, and being considered in Australia, Canada, China and Japan. Efficacy, safety and cost-effectiveness is limited by the size and single-arm design of early stage trials and variation between them. While overall response ranges from 36–93 percent, early results for some cancers are less favorable. Durability of treatment effect is unknown,

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