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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adverse events are common and can be life-threatening and risk of delayed onset toxicity remains unknown. Treatment requires access to approved manufacturing facilities (none in Australia) and specialist clinical staff.

Conclusions. CAR T-cell therapy is promising and demand is increasing, but the limited safety profile and evidence base should mitigate policy and investment decisions. Broader consideration should be given to developing, or identifying access to, manufacturing and clinical workforce capability and capacity to meet national demand. Australia is likely to encounter similar issues in other jurisdictions, such as limited evidence base and complex safety issues. Factors to be considered on a local and national basis for assessment and implementation include: (i) Regulatory support for industry; (ii) Strategies to manage uncertainties in long-term risks, benefits and costs; (iii) Access to accredited manufacturing facilities; (iv) Developing clinical and manufacturing workforce capability and capacity.

OP136 Provision Of A Chimeric Antigen Receptor T-Cell Program: A Rapid Review

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Introduction. The recent European Medicines Agency (EMA) approval of chimeric antigen receptor (CAR) T-cell therapies, axicabtagene ciloleucel and tisagenlecleucel, means the imminent arrival of health technology assessment (HTA) submissions to HTA agencies. HTA requires identification of all resources and organizational impacts pertaining to an intervention. Rapid review is a form of knowledge synthesis that abbreviates certain methodological aspects of systematic reviews to produce information in a timelier manner. Considering the time-sensitive nature of CAR T-cell HTAs, the aim of this research was to conduct a rapid review to identify the institutional requirements for the provision of a CAR T-cell program.

Methods. A Rapid Review protocol was developed and registered in PROSPERO. Electronic databases, EMBASE and MEDLINE, and grey literature were searched. All study designs published in English after the year 2000 were included. Studies pertained to the use of CAR T-cells in adult and pediatric patients with solid and hematological malignancies. No restrictions were placed on the comparators or study setting. Primary outcomes were organized into two categories: (i) resource use, (ii) processes relating to implementation of CAR T-cell programs. Secondary outcomes included associated costs of implementation and barriers to successful implementation. Screening, review, and extraction of relevant data was conducted by a single reviewer. Extracted data included publication details, population and setting, study characteristics, outcomes and outcome measures, and strengths and limitations of research. Data was synthesized by means of thematic analysis.

Results. Results indicate that the provision of a CAR T-cell program in Ireland will require the establishment of bespoke infrastructural support. This includes additional outpatient facilities, ICU resources, and nursing capacity. Close relationships will need to be formed between hematology, ICU and neurology.

Conclusions. The findings of this Rapid Review will inform the assessment of organizational impacts associated with the introduction of a CAR T-cell program, ensuring a robust HTA assessment.

OP137 Translating Results From Clinical Audit Studies To Local Context

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Introduction. Despite widespread use of oxygen (O_2) therapy, there is relatively little available information on routine O_2 administration and monitoring; this is an issue particularly when considering the potential risks associated with inappropriate O_2 utilization. A rapid health technology assessment (HTA) was conducted to inform the Respiratory Health Strategic Clinical Network Oxygen Summit in Alberta on aspects related to current practice in the use of O_2 therapy in acute care, including administration, safety and quality, and inappropriate practice. Clinical audit is a tool used to determine deviations in practice and to identify opportunities for improvement. The objective of this presentation is to describe the experience and lessons learned from including clinical audit studies in the rapid HTA.

Methods. A standardized rapid review approach was used to identify, select, and synthesize evidence from studies published in English from 2005 to 2016. A supplementary literature search conducted in 2018 provided additional background information on the value, applicability, and limitation of using results from clinical audit studies to inform questions of good practice.

Results. Twenty-four clinical audit studies on O_2 therapy were identified; the majority were conducted in the United Kingdom. The studies varied in design, methodology, and data and outcomes reporting. Ten studies investigated the appropriateness of O_2 therapy prescription pre- and post-implementation of local initiatives and interventions, which helped pinpoint major gaps in current practice, and identified general recommendations for improvement of practice. A list of reporting criteria is proposed for improving the reporting of clinical audit studies results.

Conclusions. Conducting clinical audit studies is resource-intensive. In the absence of other research evidence and local practice data, translating results from clinical audit studies conducted in other jurisdictions, while challenging, can help address appropriateness questions. However, inferences from these studies may be suitable only for certain topics or an operating context.

OP138 Stakeholders' Involvement When Developing A mHealth Assessment Tool

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