

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<sub>2</sub>) therapy, there is relatively little available information on routine O<sub>2</sub> administration and monitoring; this is an issue particularly when considering the potential risks associated with inappropriate O<sub>2</sub> 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<sub>2</sub> 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<sub>2</sub> 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<sub>2</sub> 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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