

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 (O₂) therapy, there is relatively little available information on routine O₂ administration and monitoring; this is an issue particularly when considering the potential risks associated with inappropriate O₂ 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 O₂ 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 O₂ 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 O₂ 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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Introduction. Due to the specific characteristics and challenges of mobile health (mHealth) technologies there is a need to have assessment tools based on their particularities to be used by health technology assessment (HTA) agencies and evaluation experts. In the development of a comprehensive and practical evaluation tool for the evaluation of mHealth solutions we aimed to include the views and opinions of key stakeholders: health professionals, developers, hospital managers, HTA agencies, patients and general public.

Methods. Focus groups and an online modification of the Delphi technique are being used to discuss and agree on domains and criteria to be included in the mHealth assessment tool. Domains and criteria used for health apps evaluation were drawn from a literature review on the topic. The initial list includes 95 criteria grouped into the following domains: purpose of the app, privacy and security, clinical effectiveness, content of the intervention, user experience and usability, interoperability, expenses, impact on the organization, and legal and ethical aspects. Data coming from focus groups is currently being analyzed from a thematic and content analysis perspective.

Results. Focus groups with professionals have showed that the most important domains to be considered when evaluating health apps are those related with security, user experience, and clinical effectiveness. Some criteria were considered to be mandatory (mainly regarding safety issues), on which a first step assessment should indicate whether the app ‘pass or fails’ for the subsequent throughout assessment. Focus groups with patients will provide insight on critical aspects related to the choice, use and adherence to a health app.

Conclusions. Insights from main stakeholders on the design of the tool for mHealth assessment are relevant and complementary between them. Next steps include (i) the agreement of criteria by using an online modification of the Delphi Technique and (ii) piloting of the tool.

OP140 Adult Patient Access To Electronic Health Records

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Introduction. In order to facilitate patient information, patient involvement, and to support patient-centered care, healthcare organizations are increasingly offering access to patient data that are stored in the institution-specific electronic health record (EHR). Patients can access these data, read, and print them, or download and integrate them into any type of patient-held record. This EHR access is typically web-based and called “patient portal” allowing the independent access via the Internet from everywhere. A patient portal may also offer additional features such as prescription requests, appointment booking, messaging, personal health-related reminders, individual therapeutic recommendations, personal diaries, and social networking with other patients. In a Cochrane review, we assessed the effects of providing access to EHR for adult patients on patient empowerment and health-related outcomes compared to usual care.

Methods. According to the methods of evidence-based medicine, we developed a protocol for a Cochrane review, which is published in the Cochrane database.

Results. We identified ten randomized controlled trials (RCTs) including 6,668 randomized participants. Seven RCTs took place in the USA, two in Canada, and one in Japan. Additional functionalities of interventions and disease conditions were heterogeneous. Three studies (n = 601) reported on patient empowerment. The risk differences reported were neither statistically significant nor clinically relevant. Eight studies (n = 2,070) reported on nine different risk factors (blood pressure, blood glucose, poor asthma control, 10-year Framingham risk score, cholesterol, body mass index, composite score of eight variables, intraocular pressure, composite score of three variables). The results were heterogeneous. Mostly there were no statistically significant risk differences between study groups.

Conclusions. Overall, there is no evidence for a clear positive effect of patient portals on patient empowerment and health related outcomes (mainly risk factors). However, we identified only a small number of studies. The usage of portals was often low and several studies were older.

OP142 Reviewing Methods For Early Assessment

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Introduction. The project DigiHelse aims to support the municipality health in Norway by offering a digital communication platform to users of the home care service nationally. In a concept stage of innovation, an early assessment of the potential socioeconomic value of the project was carried out by means of stakeholder insight and scenario drafting. As the assessment showed favorable potential in providing decision support and reducing risk, the project received funding to move into the pilot phase. The objective of this study is to reassess the effect of stakeholder insight and scenario drafting by validating the results using empirical data from the first pilot of DigiHelse.

Methods. Through collecting empirical data on resource consumption and inquiries to the service from four intervention districts and one control district in Oslo, the socioeconomic value of DigiHelse was reassessed. In addition to survey and register data collected before and after the pilot, behavioral data was introduced as a new data source.

Results. The effect of early assessment by means of stakeholder insight and scenario drafting was successfully studied adding empirical data from the projects first pilot. The real-time data on user behavior registered in the DigiHelse server contributed to verify the assumptions from the first assessment of the project. Although the results from the analysis were less optimistic than the first assessment, the study revealed important improvement measures necessary to improve the innovation process.

Conclusions. The usefulness of early assessment is questioned, due to lack of precision of estimates caused by scarce available data. The present study presents a first step in evaluating the precision of employing stakeholder insight and scenario drafting as