INTRODUCTION:

Hemophilia gene therapy trials demonstrate a "cure" could be achievable, thereby changing disease management. CoreHEM aims to develop multi-stakeholder consensus around a clearly defined, core outcome set (COS) - a minimum set of outcomes that should be measured and reported in all clinical trials of a specific condition - that will demonstrate and allow differentiation of the effectiveness and value of gene therapy relative to the current standard of care. Health technology assessment (HTA) frequently suffers from a lack of relevant, consistently reported outcomes. When uniformly implemented, COS increase the predictability and consistency of appraisals, coverage, and reimbursement decisions by payers and HTA agencies.

METHODS:

A COS was developed using a modified Delphi process, including online surveys and an in-person consensus meeting. A literature review and key informant interviews were used to create an initial list of outcomes for voting. Participants (patients, including representatives from the National Hemophilia Foundation and the World Federation of Hemophilia, healthcare providers, payers, HTA agencies, regulators and industry representatives) condensed and prioritized the list by rating each outcome on a scale of 1 (not important to include) to 9 (essential). Participants could also suggest outcomes for voting. Outcomes were eliminated from consideration if $<$70 percent rated the outcome from 7–9, unless the patient stakeholder group average score was $\geq$7.

RESULTS:

After two Delphi rounds, there was consensus on three outcomes: frequency of bleeds, factor activity level, and duration of expression. Additional outcomes included after an in-person consensus meeting were chronic pain, mental health status, and utilization of the healthcare system (direct costs). Adverse events of interest were evaluated and separately reported.

CONCLUSIONS:

Including the coreHEM COS in clinical development programs will ensure that relevant, consistent outcomes are available for decisions by HTA agencies, clinicians, and patients. This should result in faster access to novel, high-value therapies for appropriate patients.

PP95 Engagement Of Local Policymakers In HTA With Positive Results

AUTHORS:

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INTRODUCTION:

São Paulo city in Brazil has implemented social and health care for homeless people with pulmonary tuberculosis since 2007. We conducted a health technology assessment (HTA) of the interventions provided based on a national theoretical model using 2015 data and an overview of systematic reviews. The HTA was requested by national policymakers. The results demonstrated that the interventions for pulmonary tuberculosis were satisfactory. The municipal secretariat implemented actions to improve the national treatment recommendations and adopted incentives to increase adherence to treatments. Our objective was to describe the feedback process for the Health Secretariat.

METHODS:

The feedback was categorized as: (i) an executive abstract with key messages (i.e. ninety-seven percent of notified cases underwent sputum smears, nineteen percent were hospitalized, and fifty-nine percent were cured) reported to policymakers involved in the surveillance program; and (ii) three meetings were organized jointly by the research group and local policymakers.

RESULTS:

In 2016 we conducted a meeting to present the results. Thirty-nine professionals involved in the primary care team working on the streets (thirty-five percent) and the Tuberculosis Surveillance and Control Program (five percent) were present. The main barriers presented by the professionals were issues of human resources (i.e. suboptimal professional staff and having two different social organizations responsible for health care). The main facilitators presented by professionals were: (i) using homeless-peers as healthcare workers; (ii) having a network linking the primary care and surveillance programs; and (iii) periodic training.

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CONCLUSIONS:

In addition to the positive results, the HTA presented an opportunity to discuss the sustainability of incentives for adhering to treatments adopted by the policymakers, such as meal allowances and housing support, to improve social conditions among the homeless.

PP96 Which Data For Dual Mobility Cups In Hip Arthroplasty?

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INTRODUCTION:

The dual mobility concept was invented to prevent postoperative hip dislocation. It has been used for 40 years, but demonstrative data are limited and many designs are available. In France, many implants for hip arthroplasty are reimbursed by the national health insurance system through a generic description that corresponds to a class of products having the same indications and technical features (designs, coatings, types and systems of fixation). Dual mobility cups were one of them until 2017. The ministry decided to set up the assessment of each design of dual mobility cup, marketed in France for their reimbursement.

METHODS:

Manufacturers of these devices submitted medico-technical application dossiers, with technical characteristics and clinical data, to the French National Authority for Health (HAS). HAS has assessed prospectively the actual benefit of these implants.

RESULTS:

Sixteen companies marketing 42 kinds of dual mobility cups associated with 22, 28 or 32 mm femoral heads and cementless or cemented fixations have submitted dossiers. Their demands were argued on non-specific and specific clinical data. For few implants with non-specific clinical data, arguments to demonstrate the equivalence towards other implants were not accepted for reimbursement. For other implants, the specific data available were only low quality studies. No randomized controlled trials were identified. When the risk/benefit balance was acceptable, the implants were approved for reimbursement and HAS required post-launch data to assess the real-world safety of these implants (i.e. dislocation and long-term survival).

CONCLUSIONS:

All the dual mobility cups marketed in France have been assessed by the French health technology assessment authority. Most of them have been approved for reimbursement, despite of low level of evidence. The brand name inscription enables a specific follow up and the analysis of a post-approval study results in five years.

PP97 Delineating Key Components Of Community Paramedicine Programs

AUTHORS:

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INTRODUCTION:

Population growth, epidemiological and demographic transition, and a shortage of healthcare workers are affecting health care systems in Australia, Canada, the United Kingdom (UK), and the United States (US). Community paramedicine (CP) programs provide a bridge between primary care and emergency care to address the needs of patients with low acuity but lack of access to primary care. However, how to capture the key characteristics of these programs and present them in a meaningful way is still a challenge. The objective of this presentation is to identify and describe the characteristics of currently existing CP programs in the four countries to inform policy-making on CP program development in Alberta.

METHODS:

Information was obtained from systematic reviews, health technology assessments, general reviews, and government documents identified through a comprehensive literature search. The characteristics of the CP programs are described using a framework originally developed in Australia with three categories: (i) the primary health care model, (ii) the health integration model (in Australia, called the

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