evidence in brief. Reviews were included if there was a next step advising the collection of RWE to reduce uncertainty in the drug under review.

RESULTS:

Out of eighty-four reviews, forty-one (forty-eight percent) included a next step to collect RWE to address a gap in the available evidence. Reasons for RWE data collection, in descending order of frequency, were to inform: sequencing of available therapies; magnitude of clinical benefit and cost-effectiveness or the true cost-effectiveness; duration of treatment and cost-effectiveness; defining the population or disease progression; quality of life; and dosage.

CONCLUSIONS:

In almost half of pERC's recommendation there is an indication that there is a gap in the existing evidence that could potentially be addressed through the collection of RWE. This reflects the rising number of new cancer drugs, limited evidence supporting submissions (for example non-comparative studies), and newer drugs such as immunotherapies which may not have a fixed treatment duration. Further research includes development of mechanisms for RWE data collection to help inform pERC recommendations and assist stakeholders with adoption feasibility of reviewed drugs.

VP06 The Effectiveness And Ethics Of Prenatal Testing For Cystic Fibrosis

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INTRODUCTION:

Cystic fibrosis (CF) is the most common autosomal recessive disorder in Caucasians, occurring in one out of every 2,500–2,800 births worldwide, and is associated with a high burden of disease. In Australia, prenatal testing for CF is indicated for pregnant couples identified as carriers or when a fetus is found to have an 'echogenic bowel' (FEB). We aimed to determine the effectiveness of prenatal CF testing and to assess ethical dimensions. A key challenge in assessing a prenatal test is selecting appropriate endpoints to indicate clinical effectiveness.

METHODS:

A systematic review was conducted and a linked evidence approach was used to answer the effectiveness question. The literature on ethical considerations relating to prenatal testing was also reviewed.

RESULTS:

No studies were identified on the direct effectiveness of prenatal CF testing or downstream consequences. Linked evidence showed good diagnostic performance with a test failure rate of 4.5 percent. Termination of pregnancy occurred in the majority of cases where two mutations were identified in a fetus of carrier parents (155/163; 95 percent), indicating testing impacts clinical management. In FEB cases with CF, termination occurred in around sixty-five percent of pregnancies. Both terminating a pregnancy and having a child with CF were associated with poor short term parental psychological outcomes. Evidence indicates prenatal testing leads to a decreased number of CF-affected births. However, ethical analyses indicated that 'informed decisions' should have been the primary outcome of interest.

CONCLUSIONS:

Proper counselling prior to testing ensures that the aim of prenatal testing is informing reproductive choices in a non-directive way, rather than decreasing the number of CF-affected births (which is ethically problematic). These results suggest that for health technology assessments undertaken on contentious topics, ethical analysis should be undertaken first so appropriate endpoints are selected for the subsequent systematic review of clinical evidence and for the economic model.

VP08 Description Of A Strategy To Face Judicialization Of The Right To Heal

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https://doi.org/10.1017/S0266462318003380 Published online by Cambridge University Press

INTRODUCTION:

The Ministry of Health in Uruguay has a health technology assessment division that provides decision makers with evidence-based information on the efficacy, safety, and costs of health technologies to be included in the Comprehensive Plan of Health Care. Since 2010, patients have begun to demand access to unfunded, high-cost technologies through writs of protection. Judicialization of the right to health increased rapidly from 2010 to 2014. In this context, a Technical Advisory Commission was created in 2015 to assess patient requests on a case-by-case basis. The purpose of this study was to evaluate the results obtained with a new strategy developed to face the judicialization of access to high-cost technologies.

METHODS:

The methodology used to evaluate the implementation of the strategy consisted of reviewing a database of access requests from October 2016 to October 2017. The demographic characteristics, technologies requested, prescriptions, and results of the process were analyzed.

RESULTS:

In the study period 654 technologies were requested for funding through the process. The included population had a mean age of 60 years; sixty-two percent were men. Of the technologies requested, eighty-five percent were drugs and fifteen percent were devices. The requested technologies included cancer treatments (thirty-five percent) or drugs and devices for the treatment of rheumatologic, ophthalmologic, infectious, neurologic, and cardiovascular conditions. The six most requested technologies (forty-five percent of all requests) were: abiraterone for prostate cancer; aortic endoprosthesis for vascular aneurysm; lenalidomide, rituximab, and azacitidine for oncohematologic diseases; and cetuximab for colorectal cancer. The Ministry of Health funded thirty-six percent of the requests.

CONCLUSIONS:

The new strategy was successful in reducing the judicialization of access to unfunded, high-cost technologies in Uruguay, and it helped to prioritize the inclusion of new drugs in the national formulary.

VP09 Trastuzumab For Metastatic Breast Cancer Access Assessment In Brazil

AUTHORS:

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INTRODUCTION:

Trastuzumab is the most recent biological therapy incorporated by the Brazilian Health Ministry for HER-2 overexpressed metastatic breast cancer treatment (2012). The aim of this study was to investigate if access to this technology is appropriate.

METHODS:

We performed a web-based questionnaire, which received answers from October 2016 to April 2017. Oncologists that work in the care of patients with overexpressed HER-2 metastatic breast cancer were the focus of the survey. Forty-three professionals informed work location, sector (public, private or both) and trastuzumab access. This research was approved by Brazilian Ethics Committee (CAE 59076316300005260).

RESULTS:

Among 43 valid answers, nine informed they work in the public sector, 10 in the private sector and 24 in both sectors. In total, 33 reported to work in public and 34 in private sector. We observed that 17 (51.5 percent) participants who work in the public sector do not have access to trastuzumab, while in private sector only one participant (2.9 percent) reported the lack of access to this technology for HER-2 overexpressed metastatic breast cancer treatment. Regarding the respondents who informed the lack of access, six (33.3 percent) work in Northeast Brazilian region, six (33.3 percent) in Southeast, two (11.1 percent) in South, one (5.6 percent) in Central-West and three (16.7 percent) did not give this information. Eleven respondents reported they do not have another treatment option for these patients, while seven informed access only to chemotherapy without biological therapy.

CONCLUSIONS:

Trastuzumab is a biological therapy that can increase HER-2 overexpressed metastatic breast cancer patients overall survival by nine months on average. The questionnaire results indicate that its access in Brazil is

https://doi.org/10.1017/S0266462318003380 Published online by Cambridge University Press