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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