the baseline utility coefficients for disease control and progression were assumed as .67 and .52, respectively.

Only direct costs estimated from the Italian Health Service perspective were included (tariffs and Diagnosis Related Group - DRG - reimbursements).

The model was evaluated according to a cut-off of sensitivity at 85 percent and specificity at 70 percent. A 3 years horizon was chosen. Life expectancy, quality-adjusted life years (QALYs) and costs were discounted at 3.5 percent annually.

RESULTS:

Applying the World Health Organization (WHO) cost-effectiveness threshold of 3 times the gross domestic product for Italy (EUR66,402), PF+C POS resulted a cost-effective choice in comparison to PF+C ALL for a MT cost lower than EUR5,750.

CONCLUSIONS:

Adding cetuximab to PF only to patients positive to a predictive test may be cost-effective. Efforts should be spent to build such a test upon existing evidences in order to save resources for the health systems and spare unnecessary toxicities to patients.

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OP119 Advanced Therapy Medicinal Products: Are Current Health Technology Assessment Methods Suitable?

AUTHORS:

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INTRODUCTION:

There is considerable excitement around the development of regenerative medicines (or advanced therapy medicinal products, ATMPs), with the expectation that they may bring substantial clinical gains and offer cures for previous debilitating and fatal diseases. However, high costs mean that Health Technology Assessment (HTA) and reimbursement decisions are challenging for payers and manufacturers, even when the therapies are expected to offer good value for money.

In Europe, seven ATMPs have market authorization, yet only one has achieved national level reimbursement. Statistics such as these put HTA bodies under pressure to review their methods and consider how these can apply to regenerative medicines.

METHODS:

We present a review of one example, from the United Kingdom's National Institute for Health and Care Excellence (NICE), who commissioned an external organization to undertake a mock appraisal of a hypothetical ATMP using standard methods. The therapeutic area chosen for the mock appraisal was chimeric antigen receptor (CAR) T-cell therapy for treating relapsed or refractory B-cell acute lymphoblastic leukaemia.

RESULTS:

The role of uncertainty was a key consideration within the report, yet we found that the presentation of uncertainty within the mock appraisal was misleading for decision makers.

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We found that the exercise represents a thorough mock HTA of CAR T-cell therapy. However, it focused on testing whether ATMPs could fit into the existing HTA pathway for conventional medicines, rather than seeking to identify the most suitable approach for assessing regenerative medicines. We suggest the latter would have been a more relevant question for the mock appraisal.

CONCLUSIONS:

Any significant departures from the usual HTA process must be based on solid economic rationale if we are to ensure efficient allocation of resources. Thus, in order for regenerative medicines to be given 'special treatment,' it must be demonstrated that societal preferences, or the full extent of health (or non-health) benefits, are not being realised for this group of treatments through existing HTA methods.

OP120 Recommendations From The Newly Developed French National Authority For Health (HAS) Guide On Budget Impact

AUTHORS:

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INTRODUCTION:

Budget impact analysis (BIA) provides short and medium-term estimated effect of new health interventions on budgets and resources. Since January 2016, BIA is required as part of economic dossiers submitted to the French National Authority for Health (HAS) by manufacturers for innovative drugs with an expected 2-year sales revenue above EUR50 million. To this end and in order to promote good practices for conducting BIA, HAS developed a guide for BIA.

Our objectives are:

- to present the guide development method and the resulting recommendations;
- to compare the HAS BIA guide with existing BIA guides.

METHODS:

The HAS guide development process rests on findings derived from a systematic literature review on BIA methodology, an HAS retrospective investigation of BIA, public consultation, international expert advice, and approval from the HAS Board and Committee of Health Economic and Public Evaluation (CEESP). Relevant publications were identified through Pubmed and EMBASE and the grey literature (search dates: January 2000 to June 2016).

RESULTS:

The search strategy captured 144 publications of which 31 were retained (14 methodological papers, 12 national guides and 5 learned society recommendations). On the basis of this result, an extraction template was designed to synthesize the methodological aspects of BIA. Based on its research findings, HAS developed its first BIA guide which includes recommendations on the following main topics: BIA definition, perspective, populations, time horizon, compared scenarios, BIA models, costing, discounting, choice of clinical data, reporting of BIA and uncertainty exploration.

Compared to existing BIA guides from other Health Technology Assessment (HTA) agencies, the HAS guide specifically described issues relating to off-label use of drugs, disease-related costs and scenario analysis.

CONCLUSIONS:

It is expected that the HAS BIA guide will improve the quality, transparency and standardization of BIA in France. It should also enhance the usefulness of BIA as an essential part of a comprehensive economic assessment of health care interventions.

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