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.

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

AUTHORS:

Salah Ghabri (s.ghabri@has-sante.fr), Anne Isabelle Pouillé, Erwan Autin, Catherine Rumeau-Pichon, Olivier Scemama, Jean Michel Josselin

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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