ANALYSIS OF THE ANALYTICAL AND METHODOLOGICAL FRAMEWORK OF THE HEALTH ECONOMIC EVALUATION ASSESSMENTS DELIVERED IN FRANCE

Elise Cabout[1],MSc; Robert Launois[1],Ph.D.,

1: Réseau d'Évaluation en Économie de la Santé: REES France, 28 rue d'Assas 75006 Paris, France;

Background

- In France, the clinical and economic assessment for medicines and medical device is performed by a dedicated commission, called **Economic an Public Health Assessment Committee (CEESP).** This commission is a scientific committee of the French National Authority for Health (HAS) created in 2008 with the social security funding law (LFSS).
- Health economics assessment is restricted to products that show **high additional clinical benefit**, **impact health care system organization or budget**, or display a high price.
- CEESP assesses **the cost-effectiveness of products** based on data submitted by the manufacturer, according to methodological principles for economic evaluation defined by HAS. A guideline related to methodological choices for economic assessment was issued in 2011.
- The objective of the CEESP assessment has been clearly defined in the LFSS 2012 as providing **a tool to inform payers when setting prices** for pharmaceuticals and devices.
- CEESP examines the dossier for deviations from the HAS methodological guidelines, errors and methodological limitations, and judges their impact on the credibility of the health economics analysis results in a report.
- Each deviation from the guidelines leads to CEESP expressing **methodological concerns** on the credibility of the affected results (minor, important, major).
- Some publications have already analyzed the CEESP reports but focusing only on the reservations made.
- However, the methodology of health economic appraisal has evolved since 2011.

Objective

Analyze and determine the development of the new analytical framework.

Methods

Up to now, CEESP pharmaceutical assessment reports were confidential. Since December 2017, **26 reports** were published on the official HAS website.
- An Excel table was used to summarized for each report all information.
- Methodological concerns were extracted.
- The analysis focused on the methodology used, the construction of economic models in detail.

Major Evolutions

- Characterization and distinction of **populations**: target population, analysis population and simulated population
- **Systematic literature review** became essential (efficiency, AE, utilities)
- Diversification of **methods** used: generalization of survival model, network meta-analyzes, microsimulation, justification of model parameters
- Standardization of **tools**: efficiency frontier - criterion to be used to estimate the scope of a DSA

Results

Out of 26 reports, 11 received methodological concerns.
A total of 20 methodological concerns were given in particular:
- 30% concerned the lack of robust data
- 20% concerned the choice of the comparators
- 8% concerned the lack of uncertainty analysis
- 8% concerned the simulated population

Model Structure

Four types of model were identified on the 26 reports: aggregated Markov model, partitioned survival model, microsimulation and SIRS type compartment model.
- 52% are based on partitioned survival model
- 32% on Markov models

Sources of clinical data

Most of the models (68%) are based on the extrapolation of the survival curves of the studied treatment.
For the comparators,
- 24% of models are documented by a Network Meta-Analysis (NMA)
- 12% by Matching-Adjusted Indirect Comparison (MAIC)
- Only one is relied on a Bucher indirect comparison

Identification, measurement and valuation of utilities

Several techniques are used for the valuation of utilities : Standard Gamble, Time Trade Off, Expert opinion, Quality of life questionnaire,
- 48% of health states are valued with the EQ-5D
- 15% with Standard Gamble
- 15% with Time Trade Off
- 19% used the mapping procedure
- **Only 24% used French utility tariffs**

Identification, measurement and valuation of costs

All models adopt a collective perspective according to the definition of the HAS.
None of them includes **the cost of caregivers** in their analyze.

Results and sensibility analysis

- The ICERs proposed by the manufacturers can range from €6,111/QALY to €2,661,514/QALY
- The efficiency frontier of the best therapeutic strategies is presented in only 35% of cases
- Only 62% of models presenting both deterministic and probabilistic sensitivity analysis
- 73% presented acceptability curve but only 35% presented acceptability frontier
- 38% realized scenario analysis

Discussion

In France, there are **no benchmarks** for willingness to pay, but the CEESP is increasingly making a **value judgment on the amount of ICER**.
A decision support tool is beginning to emerge : **a proportionality between the price and the ICER**.
The main conclusion is that there is **no modeling without evidence**. This brings to mind the establishment of an **"adaptive pathway"** for France with restriction of the indications at the time of the discussion of the price and request confirmatory comparative studies in real life.

References

1. Haute Autorité de Santé. Guide méthodologique pour l'évaluation économique à la HAS. 2011 oct.
2. Haute Autorité de Santé. Format du rapport technique. Document support pour la rédaction des rapports techniques déposés auprès de la CEESP. 2016 mai.
3. Ghabri S, Cleemput I, Josselin J-M. Towards a New Framework for Addressing Structural Uncertainty in Health Technology Assessment Guidelines. PharmacoEconomics. févr 2018;36(2):127-30.
4. Hamers FF, Ghabri S, Le Gales C. Health-state utility estimates for health technology assessment: a review of the manufacturers' submissions to the French National Authority for Health. Expert Review of Pharmacoeconomics & Outcomes Research. 3 sept 2017;17(5):489-94.

28, rue d'Assas – 75006 Paris France; Tel: +33 1 44 39 16 90;
E-mail: launois.reesfrance@wanadoo.fr; Web: www.rees-france.com