

EAA Fall Convention

EU HTA – Procedural Insights & First Learnings

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Impulse Presentation

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Abstract

Comparison is the conceptual backbone of the EU HTA procedure for new drugs. Their value is assessed in comparison to the current standard. The relevant clinical elements are well summarized in the PICO scheme. The first experiences on the clinical side were dominated by two questions:

- What is the current treatment standard?
- Who knows it?

What is the current treatment standard?

In principle, treatment standards are defined by guidelines. Guidelines are evidence-based recommendations for action. They bridge the gap between the rapidly growing body of external evidence in many areas and the individual situation of patients. Unlike regulations or directives, guidelines serve as decision-making aids. Many activities in the past two decades have focused on the implementation of guidelines into the healthcare system and the individual physician-patient interaction.

However, in modern oncology the implementation of guidelines is increasingly determined by national / regional access to the recommended diagnostic and therapeutic tools. A recent analysis in hematooncology has revealed an enormous heterogeneity with the EU member states. The gaps are even widening. Differences relate to almost all aspects of the

PICO elements: population of treated patients, comparator availability and outcome parameters.

Who knows it?

Many EU HTA discussions in the past months have dealt with the identification of clinical experts. Based on legal aspects, selection has centered on the criteria of conflict of interests. Although important, this HTA discussion is not congruent with the discussion within national and international medical societies in the creation of guidelines. The selection criteria focus on the quality of experts for the respective indication covering all areas of healthcare ranging from epidemiologists to oncological practitioners. The selection procedure aims at exclusion of as few key opinion leaders as possible. Medical societies increasingly foster the concept of collective intelligence and try to balance ever-existing conflicts of interests by detailed discussion and consensual decisions.

The current experiences in the EU HTA process challenge the selection process of medical experts. Insufficient medical expertise may affect the quality of the JCA and jeopardize the final evaluation.