

ISPOR 16th HTA Roundtable [Europe]
Wednesday, November 7, 2012 (15:00-19:00)
& Thursday, November 8, 2012 (9:00 – 12:00)
ISPOR 15th Annual European Meeting
ICC Berlin, Berlin, Germany

MEETING DISCUSSION SUMMARY:

INTRODUCTION

The mission of ISPOR is to advance the science of pharmacoeconomics/health economics and health outcomes research (clinical, economic, and patient reported), and to foster and develop the use of this science in health care decisions. ISPOR holds annual roundtables to provide a forum for health care stakeholders to discuss, debate, and share information on health technology issues, as well as bridge the gap between health care decision makers and outcomes researchers to optimize health care decisions. The focus of the 16th HTA Roundtable was to discuss addressing patients' needs and exploring ISPOR partnerships with patient advocate organizations.

PARTICIPANTS

The list of participants for the HTA Roundtable that took place in Berlin is given in Appendix A (below).

DISCUSSION SUMMARY

- General Discussion:

Patient involvement in HTA is essential. Patients can help identify value aspects of e.g. quality of life and harms and contribute to outcomes research and HTA.

The following are key issues identified by the HTA Roundtable [Europe] for discussion and recommended action:

I. Patient level of involvement

Patient involvement and contribution to HTA are needed at three levels:

Policy level:

Identify extent of patient involvement at different policy levels: such as EU, national, regional, HTA organization, committee level

International alliance

Methodology level:

Developing a methodology to capture patient preferences (also outside health economic analysis), before the decision to include in reimbursement. There is a need for an actual understanding of what the patient values more.

Scoping level:

Identifying the criteria on which to select new technology for further evidence creation

Patient input on the key questions for the assessment, end points by patient involvement and by increasing their awareness of the need of resources as well as education.

II. Education/training

Training in how to use (outcomes) research information in HTA (with view to the societal perspective) should be developed for the following three groups together which would constitute a unique contribution to unmet needs

- Patients (- experts in living with disease)
- Researchers
- Decision-makers

Patient education on HTA

- Need for education/training of patient to improve their skills in communications with different health care organizations – i.e. knowing the research jargon terms commonly used within the HTA, [HTA and regulatory systems are not well understood by patients. They are seen as a hurdle until patients understand better what is going on in regulation and HTA].

III. Patient Involvement Issues:

Need to identify/ agree on the **definition of patient experts** as it varies from patient advocates or patient representatives: does it include the regular patient, the patient advocate, the patient himself with extensive knowledge of the disease? Etc.

Society needs to be involved beyond the patient. What is meant by “**Society**” **needs to be defined**. This will help in the prioritization of the questions to be addressed. What the society is willing to pay for, is seldom about patient comfort alone.

Build trust between HTA and patients. There is an issue with conflict of interest since most of the patient organizations are co-funded by industry.

Patient representation

- Broadening the platform of “patient” involvement beyond just the patient organizations to civil society organizations
- Standardize the selection process for patients and patient advocates to participate in the decisions. Same representatives are being invited over and over again based on personal communications, networking or well-known organizations
- There is a real need to hear patients’ voice from patients across all conditions to avoid unbiased opinions; those who have the disease in question, and the ones who are suffering from a different condition and do not have a particular interest in the condition in question. Can physicians represent patients?
- Patient should acknowledge that when decisions are made, it is not all about their condition, there are other diseases and conditions out there that need treatment too and the importance of balancing all those needs within limited resources should be kept in mind

HTA issues

Need for standards/guidelines at the regulatory and HTA level that are aligned but necessarily similar
Need for HTA that is responsive to therapeutic trends and the possibility of redoing HTA after more data is present

Need for clear identification of the rights and responsibility of all stakeholders

Need for more collaboration across stakeholders and early dialogue which will result in better data that address relevant questions and concerns early in the process. For e.g. information relevant to reimbursement need to be collected prior to market access.

Need for transparency so that all stakeholders can be involved. Lack of communication from early stage is an obstacle.

IV. Recommendations of the HTAR:

Capacity building for using/ understanding outcomes research information in HTA (with view to the societal perspective) Patient experts, researchers, Decision Makers through courses, workshops, media communications, education programs.

Topics to consider include:

- Critical appraisal of research literature
- How patients can be involved in the HTA process and appraisals
- Interpreting the numbers
 - Difference between the statistical and practical significance
 - PRO and QoL
- Looking at uncertainties
- Balancing benefits and harms
- Expressing the questions
- Life cycle of technologies (role of research)
- Context, societal perspective
- Basic health economics (opportunity cost, marginal cost)
- Potential bias
- Define and provide explanation for terms used, such as HTA, ICER (Patients that have expertise with dealing with a condition, but methodological naïve, they need to know health economic and HTA terms)

Translating research to the patient level.

Communicate research result.

Define patient expert.

V. Action:

- The HTA Roundtable decided to produce a 2-3 page document reflecting discussion and reaching conclusions on stakeholder (patients) involvement and support to capacity building, and joint training for patients, researchers, and decision-makers

**The following participants volunteered to lead the group: Finn Kristensen, Alric Ruther, Elizabeth George, Gottfried Endel, Antonio Sarria Santamera, Mirjana Huić, Iris Pastenak.*

***Patient Representatives (TBD)*