

European Statistical Meeting Health Technology Assessment

On June 4th 2013, the EFSPI and BBS organized a one day meeting on Health Technology Assessment. Over 115 attendees with various backgrounds attended this meeting.

Fred Sorenson from Xcenda introduced the meeting with a presentation on “Health Technology Assessment – Why is it so important?”: Formal HTA bodies are already or are currently being established in most EU countries but HTA decision making is not harmonized, but largely decentralized at the regional level. The major HTA systems are also going through significant reforms. Price pressure is increasing, and obtaining a premium price is strongly linked with premium evidence .The demand for evidence is increasing and evidence generation needs to be carefully planned. The conclusive message is “Remain aware of the changes in your major markets and be prepared to generate the appropriate evidence to satisfy them”

The second lecture was by Matthias Egger (Univ. of Bern) and Mike Chambers (GSK) on the topic "Moving HTA forward: The Challenges of Incorporating Real World Evidence into Health Technology Assessment" presenting a summary of the scientific questions and approaches to answer the challenges of using real world evidence in HTA, with a focus on the IMI “Get Real” initiative Work Package 4 , and contributions that industry working together with academia and regulatory can make.

Claudia Nicolay from Lilly presented her view on Health Technology Assessment - What’s in for Stats?: HTA has become increasingly important during the last years and will continue to do so in the future. HTA comprises a wide variety of disciplines, data sources, methods and analytical challenges. The presentation provided an overview of the current state in HTA, highlighting the opportunities for statisticians for providing substantial contributions and guidance.



Mike Chambers, Fred Sorenson, Matthias Egger



Claudia Nicolay

Jens Grüger from Roche started the second session presenting the topic “HTA and personalized healthcare”. The scientific rationale for personalized health care (PHC) is a better understanding of underlying targets and disease mechanisms especially in cancer; allowing to identify the right combination of medicines to optimize patient outcomes. As a consequence, there is an increased need for evidence of added therapeutic value for patients across different disease segments; different characteristics of diagnostics; different combinations of medicines. Not all these data is available at the time of launch, creating the need for an integrated evidence program that extends beyond launch (eg coverage with evidence development).

PHC promotes a differentiated assessment of the incremental patient benefit. Consequently, personalized reimbursement models to align value and price are implied by PHC.

Skip Olson (Novartis) discussed the use of observational, retrospective or prospective studies in HTA. Evidence generation for HTA should start early and be built over time through the lifespan of a product, integrating data from randomised clinical trials, observational studies and other sources of data from existing databases (e.g. national registries, social insurance data, electronic medical records, etc.). Examples of database research generated evidence were presented, with their strengths and weaknesses. Caution must be taken in the analysis and interpretation of the results.



Jens Grüger



Skip Olson

Bruno Falissard (Uni. Of S.Paris & INSERM) started the afternoon session with a discussion of the place of subjectivity in the French system (HAS). Experts have often a valuable insight of the clinical aspects of effectiveness that should not be ignored. He explained by addressing four questions that one can deal with subjectivity in a transparent way if one is using statistical methods.

Ralf Bender from IQWiG provided an overview of Biometrical topics of HTA in the German system. He started by presenting the current requirements of IQWiG and illustrated examples of benefits in the same directions (isd). Thereafter he presented extensions and proposed new methods for specific situations like populations and indirect comparisons that have not been shared before.

Friedhelm Leverkus (Pfizer) discussed the AMNOG procedure by showing various examples to illustrate how additional benefit vs GBA Comperator can be proven, how additional benefit can exist in a special subgroup, the extent of the additional benefit and the certainty of the

conclusions. In addition he provided an overview of recent assessment results.



Bruno Falissard



Ralf Bender



Friedhelm Leverkus

Lou Garrison from the University of Washington presented a framework and examples of HTA in Emerging Markets. The relationship between HTA and Health Care System was discussed and the question what would be "efficient" from different perspectives (country vs global, short-term vs long-term) has been addressed as well.

Richard Nixon (Novartis) illustrated how health economic decision models early in the drug development process could support decision making during drug development. These decisions are different from those for reimbursement. In particular he stressed the importance to work hard to keep your model simple.

Chrissie Fletcher (Amgen) provided a complete overview on the use of indirect treatment comparisons to support an HTA by discussing statistical approaches to use, key steps to be taken and the integration of indirect comparisons in drug development. Chrissie also discussed a nice example of a case study for osteoporosis treatment.



Lou Garrison



Richard Nixon, Egbert Biesheuvel



Chrissie Fletcher

The successful day ended with a lively panel discussion. The panel: Tommy Bramley (Xcenda), John Doyle (Quintiles), Lou Garrison, Ansgar Hebborn (Roche) and Skip Olson, discussed the

implications of healthcare reform on HTA in the United States.

