

Modeling – what is accepted by the authorities?

Interview with European experts

Models are increasingly used in the field of pharmacoconomics and epidemiology. The reasons particularly are to generate a likeness (picture) of the reality concerning budget analysis as well as cost utility, cost effectiveness or cost consequences of new treatments, new drugs and medical devices. The pharmaceutical and medical device industry more and more fall back on this approach to achieve in their negotiations with Ministries and pricing committees market access, reasonable reimbursement rates or a higher price level for their products. The introduction of health economic guidelines in various European countries allows partially different interpretations how to generate a model and which data, used within the model will be accepted by payers. With this survey we wanted to investigate in different European countries, to what extent models are considered in the decision making process concerning pricing and reimbursement of new drugs or devices, which role they might possibly play in the future and what the requirements are from a payer's and from a Health Economist's point of view.

The use of models from a payer's perspective

? According to your experience, in which therapeutic areas have models been used for economic evaluation of drugs and medical devices?

Alistair McGuire (United Kingdom)

- ▶ Metabolic disorders (e.g. diabetes type II)
- ▶ Chronic diseases
- ▶ Infections
- ▶ Coronary heart disease; mental illness; oncology; preventive medicine

? According to your experience, under which circumstances should models be used?

Alistair McGuire (United Kingdom) All economic evaluations will require some modelling; if only to extrapolate beyond trial time, or to a different population.

? Under which circumstances are models less appropriate?

Alistair McGuire (United Kingdom) Models are always appropriate!

? How would you rate the overall acceptance of your authority/committee with regard to Health Economic models in the range of low to high?

Alistair McGuire (United Kingdom) Medium.

? Are the submitted models in line with the Health Economic guidelines and/or requirements in your country?

Alistair McGuire (United Kingdom) We do not have any guidelines.

? How would you rate the importance of models in Pricing & Reimbursement negotiations in your country?

Alistair McGuire (United Kingdom) It is quite low.

? Who assesses Health Economic models in your authority/committee?

Alistair McGuire (United Kingdom) External academic institutions as well as other institutions, e.g. the department of health.

? According to your experience, what are the most frequent weaknesses of submitted model?

Alistair McGuire (United Kingdom)
Bad data.

? Data used in submitted models, do they have to be nationally gathered data?

Alistair McGuire (United Kingdom) No.

? With regard to economic data, are European data accepted?

Alistair McGuire (United Kingdom)
Concerning cost data: All effectiveness data would be used regardless of country if the trial was acceptable, so I would answer no.

? Are adapted European data accepted? (i.e. taking into account the purchasing power parity)

Alistair McGuire (United Kingdom) No.

? Are American data accepted?

Alistair McGuire (United Kingdom) No.

? Are adapted American data accepted?

Alistair McGuire (United Kingdom) No.

? With regard to effectiveness data: Are European data accepted?

Alistair McGuire (United Kingdom) Yes, data of any well substantiated trial data regardless of country are accepted.

? Are American data accepted?

Alistair McGuire (United Kingdom) Yes.

? Are there any publications/information with regard to the country-specific requirements for models available for pharmaceutical companies?

Alistair McGuire (United Kingdom) No.

? Do you need Health Economic models in the Pricing & Reimbursement decision process of drugs used in prevention therapy?

Alistair McGuire (United Kingdom) No.

? Assuming a new product results in an increase of the health care budget in short terms, whereas in the long run saving are achievable because of a reduction of side-effects and adverse events. Assuming this would be shown based on a model. Would you/your agency accept an higher price compared to existing products or treatments?

Alistair McGuire (United Kingdom) Yes.

? Assuming the product would be reimbursed at a higher price based on the modelling approach. Would you request any prospective data after launch of the product to verify the model results?

Alistair McGuire (United Kingdom) Yes.

? Assuming the prospective data do not verify the modelling results, would a pay-back agreement with the pharmaceutical company be possible?

Alistair McGuire (United Kingdom) No.

Modelling from a Health Economic perspective

? In which indication have you been latest involved in a Health Economic model?

Alastair Gray (United Kingdom) In the field of cardiovascular diseases.

Robert Launois (France) Cardiovascular diseases.

Maiwenn Al (The Netherlands) Rheumatology: GI side effects of NSAIDS in RA and OA.

Hans-Helmut König (Germany)
Ophthalmology (Amblyopia screening).

See: König H-H, Barry JC, Leidl R, Zrenner E (in print) **Cost-effectiveness of orthoptic screening in kindergarten: a decision-analytic model.** Strabismus

? Who was the customer of this model?

Alastair Gray (United Kingdom) The pharmaceutical industry.

Robert Launois (France) Pharmaceutical industry.

Maiwenn Al (The Netherlands) Pharmaceutical industry.

Hans-Helmut König (Germany)
Scientific community (third party payers).

? What was the main purpose of this model?

Alistair Gray (United Kingdom) Health Economic publication.

Robert Launois (France)

- ▶ Faster access to third party funding/reimbursement
- ▶ Marketing instrument, e.g. arguments for sales forces
- ▶ Health Economic publication

Maiwenn Al (The Netherlands)

- ▶ Faster access to third party funding/reimbursement
- ▶ Marketing instrument
- ▶ Health Economic Publication

Interview

Hans-Helmut König (Germany)

- ▶ Health Economic publication
- ▶ Scientific interest

? How many alternatives (treatment arms) did this model take into consideration?

Alistair Gray (United Kingdom) 2

Robert Launois (France) 4

Maiwenn Al (The Netherlands) 6

Hans-Helmut König (Germany) 4

? What was the time horizon of this model?

Alistair Gray (United Kingdom) Longer than 20 years.

Robert Launois (France) ≤ 3 years.

Maiwenn Al (The Netherlands) ≤ 1 year.

Hans-Helmut König (Germany) ≤ 3 years.

? What type of analysis has been the basis of this model?

Alistair Gray (United Kingdom) Cost-consequence/cost-effectiveness analysis.

Robert Launois (France) Cost-consequence/cost-effectiveness analysis.

Maiwenn Al (The Netherlands) Cost-consequence/cost-effectiveness analysis.

Hans-Helmut König (Germany) Cost-consequence/cost-effectiveness analysis.

? Which outcome measures were applied?

Alistair Gray (United Kingdom) Life years saved.

Robert Launois (France) Disability free survival.

Maiwenn Al (The Netherlands) Lives saved.

Hans-Helmut König (Germany) Cases detected.

? Which costs were included?

Alistair Gray (United Kingdom) Outpatient visits, Outpatient procedures/investigations, Outpatient tests, Prescribed medication, Hospitalisations.

Robert Launois (France) Outpatient visits, Outpatient procedures/investigations, Outpatient tests, Prescribed medication, Hospitalisations, Patient expenses: Nursing home cost.

Maiwenn Al (The Netherlands) Outpatient visits, Outpatient procedures/investigations, Outpatient tests, Prescribed medication, Hospitalisations.

Hans-Helmut König (Germany) Outpatient visits, Outpatient procedures/investigations, Outpatient tests

? Which data sources have been used for which data?

Alistair Gray (United Kingdom) Clinical data, Publications/literature, Databases.

Robert Launois (France) Clinical Data, Databases.

Maiwenn Al (The Netherlands) Clinical data, Publications/literature, Databases, Expert interviews.

Hans-Helmut König (Germany) Publications/literature, Expert interviews.

? What was the perspective of the model?

Alistair Gray (United Kingdom) To reach the payer.

Robert Launois (France) Society.

Maiwenn Al (The Netherlands) Society.

Hans-Helmut König (Germany) Payer.

? Has an incremental analysis been performed?

Alistair Gray (United Kingdom) Yes.

Robert Launois (France) Yes.

Maiwenn Al (The Netherlands) Yes.

Hans-Helmut König (Germany) Yes.

? Has uncertainty been handled by a sensitivity analysis?

Alistair Gray (United Kingdom) Yes.

Robert Launois (France) Yes.

Maiwenn Al (The Netherlands) Yes.

Hans-Helmut König (Germany) Yes.

? Which were the main strengths of this model?

Alistair Gray (United Kingdom) Comparison of different risk equations.

Robert Launois (France) Transition probabilities were extracted from a prospective one year study.

Maiwenn Al (The Netherlands) The model provides outcomes per risk group.

? Which were the main weaknesses of this model?

Alistair Gray (United Kingdom) It was hard to do probabilistic sensitivity.

Robert Launois (France) Home care cost were not robust.

Maiwenn Al (The Netherlands) The lack of firm data on resource utilisation.

Experts

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