

THE UK NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE (NICE): NEW DEVELOPMENTS

The ERG perspective

Dr Matt Stevenson

Quick Introduction

- I am technical director of an assessment group (SchARR-TAG) who undertaken work for NICE and the NIHR:
- I am an NICE appraisal committee member
- I have undertaken economic modelling in support of interventions for Pharma via the STA process.

The STA process from an ERG perspective

- The ERG receive the manufacturer's submission (MS) and economic model.
- The ERG currently have a 2 week period in which to initially assess the MS and model and to formulate a list of clarification questions.
- Further requests for clarification or amendments may be made throughout the STA process and the policy on this differs by ERG institution

The STA process from an ERG perspective (2)

- The manufacturer has 2 weeks in which to respond to the ERG clarification letter.
- The ERG submit the report 4 weeks later, conducting exploratory analyses where appropriate, which is discussed at the appraisal committee (AC).
- New procedural rules will allow manufacturers to highlight factual errors in the ERG report before the AC. Additionally 2 representatives of the manufacturers will be able to be present at the AC to respond to clarification questions.

The smoothness of the process

- From a personal perspective, there appears to be correlation between the smoothness of this process and
- The competence of the analysts employed by the manufacturers
- The underlying cost effectiveness of the drug

Validation of an economic model undertaken by the ERG

- Internal validity – does the model do what it intended or do coding errors exist?
- External validity – does the model structure make sense?
- External validity – do the modelled results match those of the primary data?
- Are the derivation of parameter values justifiable?
- Is the comparator correct?

ERG Analyses - The general direction of travel of the MS basecase ICER.

- Understandably, when presented with a choice the manufacturers often opt to choose the option that is more favourable to their intervention.
- Individually these may have marginal effects. However cumulatively the effect may be marked. It is not unusual to see exploratory ICERs produced by the ERG to be much higher than those presented in MS sensitivity analyses.

Conclusions regarding the STA process

- Using an assessment group to undertake an in-depth scrutiny of the MS, rather than independently constructing an economic model has the potential to lead to a higher quality of evidence, with more exploration of uncertainty.
- However this is dependent on a number of factors

Conclusions regarding the STA process (2)

- The consultants have the time (and ability) to re-run the analyses and undertake structural alterations where required.
- That independent experts remain committed to being within a ERG
- That NICE has the determination to ensure that the burden of proof of cost effectiveness lies with the manufacturers.

Implications for Pharma companies re STA submissions

- Hire competent analysts
- Try not to cumulatively select the more favourable option where there is uncertainty in the correct input, or conduct extensive sensitivity analyses
- If offering a PAS or FPS scheme allow 'head room' below perceived thresholds for unforeseen biases

Ongoing Research

- Formal documentation of the STA process and the issues arising, has recently begun.
- This work, undertaken jointly by ScHARR-TAG and LRIG is expected to be published in 2010.