NICE – Process of decision making
Overview

Information regarding LRiG
- Who are we/what we do

Brief overview of HTA in the UK

Overview of the NICE appraisal process
- Multiple Technology Appraisal (MTA)
- Single Technology Appraisal (STA)
LRiG team
LRiG

Research group established in 2001
- DOH - contract to deliver 5 TAR units/annum
- Support to NHS staff
- Support to trials
- Other

Current a team of 16 (10 FTE)
Annual budget ~£900 K
One of nine groups in the UK (7 academic/2 private)
Group expertise

Systematic review methodology
Information searching
Medical statistics
Health economics
Economic modelling
Clinical expertise

Establish review panel for each assessment
Panel made up of review team +
Clinical experts recruited to provide
- Critique review protocols
- Critique manufacturers’ submissions
- Comment on draft reports
- Co-authorship of papers (review specific)
NIHR Clinical Evaluation, Trials and Studies

- HSR
- Public Health
- SDO

MRC led Experimental Medicine workstream

MRC led Methodology programme

The Efficacy and Mechanism Evaluations Programme

The Health Technology Assessment Programme

£15m

£5m

£10m

£12m

£86m+
Identification / Prioritisation
Input to vignettes

Commissioning
Peer review: full proposals

HTA Programme

Research Community
Peer review: project changes/ extensions

NHS

Assessment/ Communication
Peer review: draft reports

Monitoring
Health Technology Appraisal Process
  – Guidance
  – Diagnostics programme

Public Health
  – Guidance

Clinical practice
  – Guidelines

Other
  – International work
  – Scientific advice

http://www.nice.org.uk/
NICE appraisals

Multiple technology appraisals

- Review group conducts a systematic review of clinical and cost effectiveness
- Review group examines manufacturers’ submissions (clinical and economic)
- Review group provides a report to NICE that is used in the appraisal process
- Time period 8-10 months
Figure 2: Summary of the appraisal process to develop of the Appraisal Consultative Document (ACD)

1. The Secretary of State for Health and the Welsh Assembly Government consult a group of relevant people to agree the remit.
2. Institute an informal process of appraisal within each speciality.
3. Institute a formal process of consultation and a consultation group to participate in the appraisal.
4. Institute a formal process of consultation.
5. Institute a formal process of consultation for clinical specialists or patient groups.
6. Appraisal Committee Chair and project team consult general practitioners and patient groups.
7. Clinical specialist and patient groups submit comments.
8. Appraisal Committee Chair and project team submit comments to the Secretary of State for Health.
Single technology appraisal (STA)

The STA process
- single product, device or other technology
- single indication
- most of the relevant evidence lies with one manufacturer

Clinical review and economic model provided by the manufacture

Evidence review group (ERG) provides critique
- Examine clinical evidence and model parameters

Timeframe – 8 weeks
Single technology appraisal
NICE Appraisal Committee

Interprets evidence on the clinical and cost effectiveness of health technologies and formulates recommendations on their use

Members expected to apply the experience and judgment from their individual backgrounds to the topics

Members help the Institute make some of the most difficult decisions in public life
Appraisal Committee

Each committee is made up of between 25 and 30 members. Members are drawn from the NHS, patients and carers, and the academic world. Each committee has its own designated chairperson. For each appraisal, two clinical experts sit with the committee to give their clinical opinion and answer any clinical questions that arise. A patient representative is also invited to provide the patient perspective. The manufacturer.
Appraisal committee meeting

Part 1 - the clinical and cost-effectiveness sections of the ERG report are summarised and presented by a member of the committee. The evidence presented is considered and the clinical experts and patient representatives consulted. The ERG may be asked for clarification of any aspect of the report.

Part 2 - the committee hears any ‘in-confidence’ information and comes to a decision – the Advisory Committee Decision (ACD)

The clinical experts, patient representatives, manufacturer and the general public are not in attendance for Part 2.
But what does it look like?

Price of Life – Alan Wishart

http://vimeo.com/4796083

http://www.adamwishart.info/
Next steps…

The ACD is issued to all the consultees involved in the appraisal (pharmaceutical companies, clinicians, patient groups etc). The consultees are invited to comment.

The ERG may be requested to carry out additional work in the light of these comments.

A second committee meeting is held to consider the comments on the ACD. The ERG may be asked to attend. A Final Appraisal Determination (FAD) will subsequently be issued.
And finally

The FAD may be appealed on three specific grounds:

- The Institute has failed to act fairly and in accordance with the Appraisal Procedure set out in the Institute’s Interim Guidance to Manufacturers and Sponsors
- The Institute has prepared Guidance which is perverse in the light of the evidence submitted
- The Institute has exceeded its powers.

An independent appeal panel consisting of 3 non executive Directors of the Institute (who have not previously been involved in the appraisal) and two members nominated by patient organisations and the healthcare industries considers the evidence.
Other considerations

Equity issues always considered

Cost per QALY – 20-30,000 (GBP)

End of life criteria (up to 50,000 GBP)
- Less than 2 years of life
- Small patient population
- At least 2 months life gain
At the end of the day

Working with NICE is a bit like herding cats

http://www.youtube.com/watch?v=Pk7yqlTMvp8