

LIVERPOOL REVIEWS AND IMPLEMENTATION GROUP (LRiG)

NICE – Process of decision making

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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)



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LRiG team



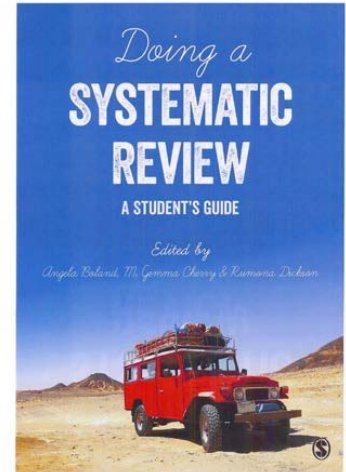
LRiG

- 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)



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Group expertise

- Systematic review methodology
- Information searching
- Medical statistics
- Health economics
- Economic modelling



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Clinical expertise

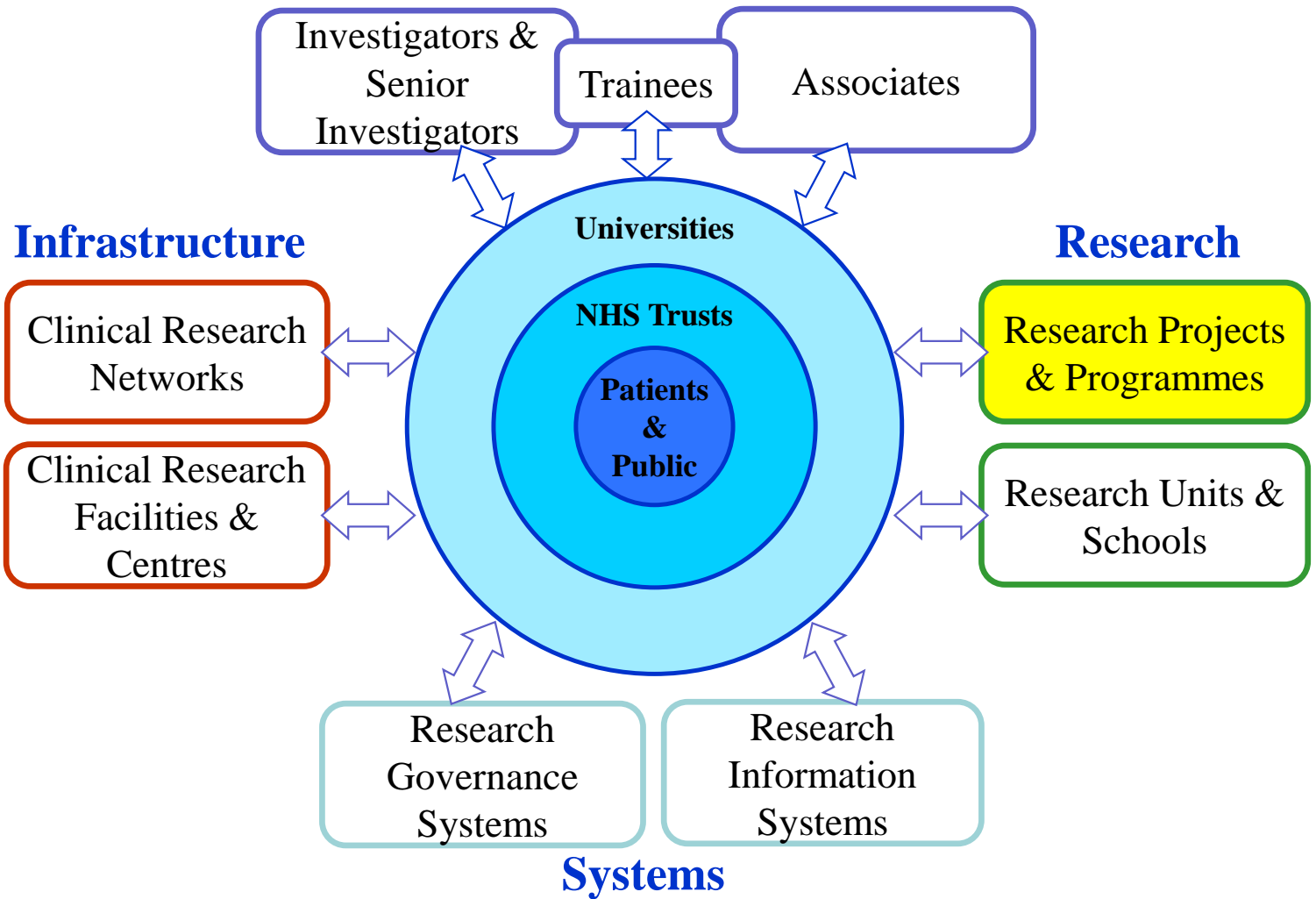
- Establish review panel for each assessment
- Panel made up of review team +
- Clinical experts recruited to provide
 - Critique review protocols
 - Critique manufacturers' submissions
 - Comment on draft reports
 - Co-authorship of papers (review specific)

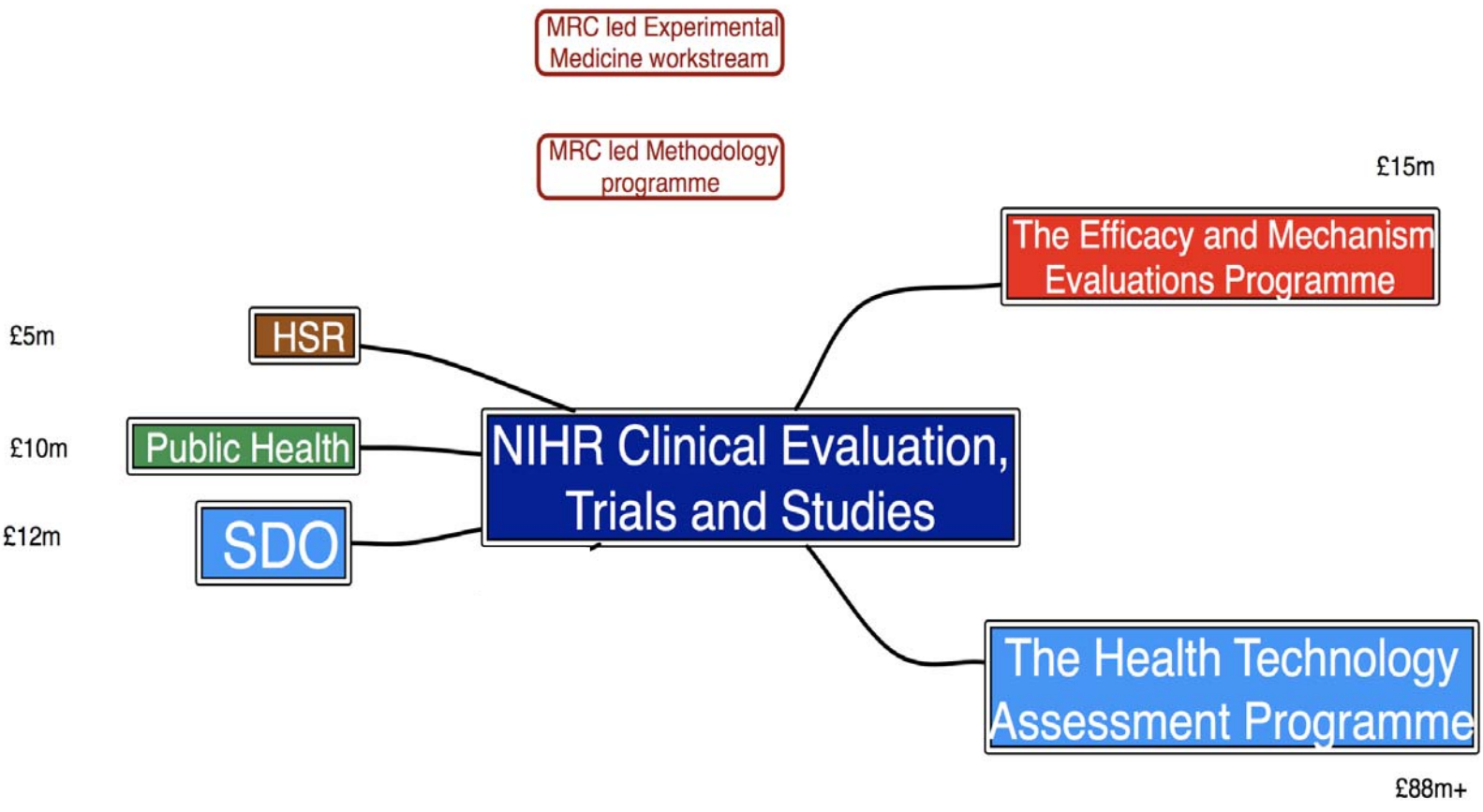


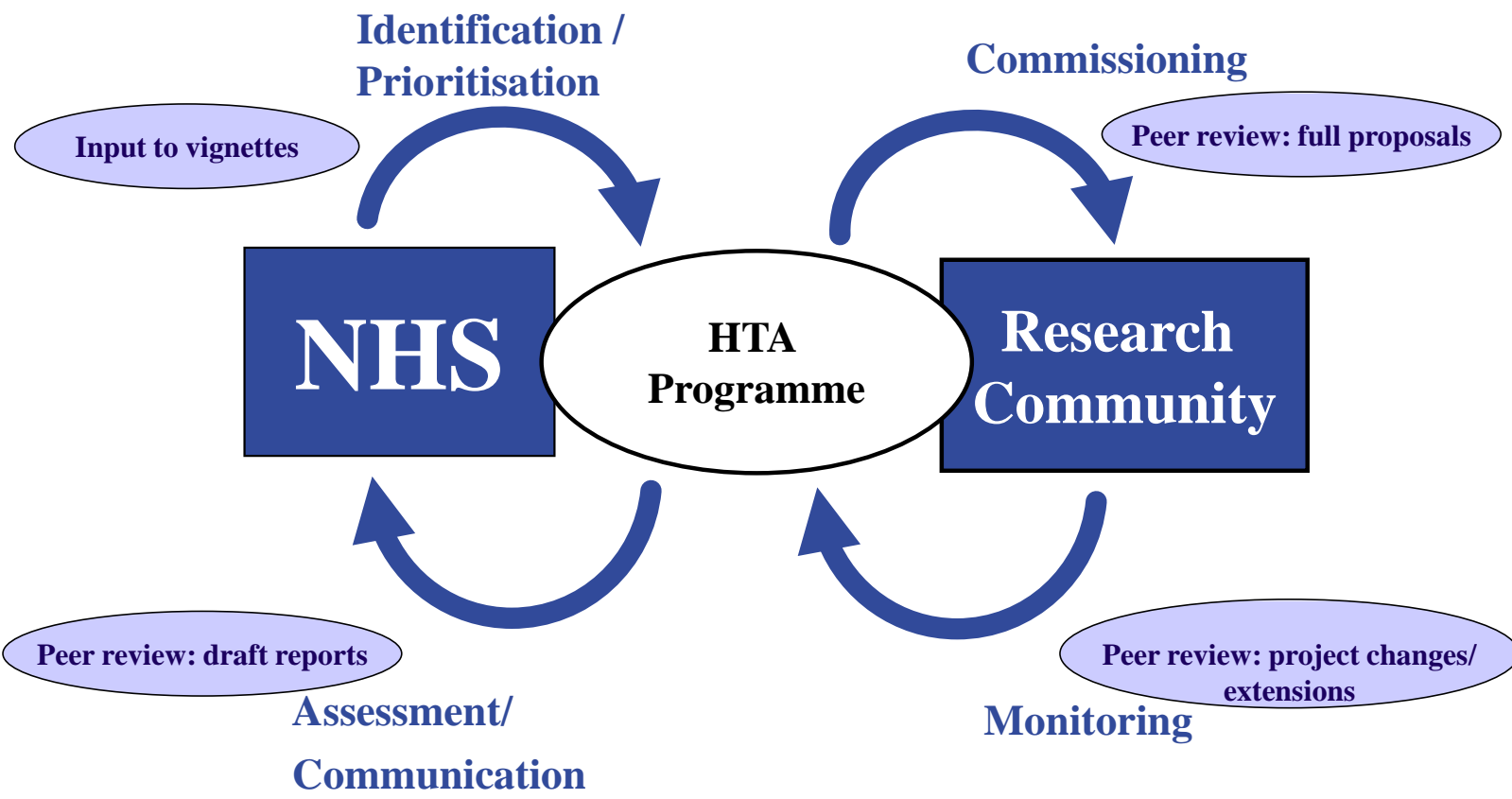
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National Institute for Health Research







NICE

- Health Technology Appraisal Process**
 - Guidance
 - Diagnostics programme
- Public Health**
 - Guidance
- Clinical practice**
 - Guidelines
- Other**
 - International work
 - Scientific advice

<http://www.nice.org.uk/>



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NICE appraisals

□ Multiple technology appraisals

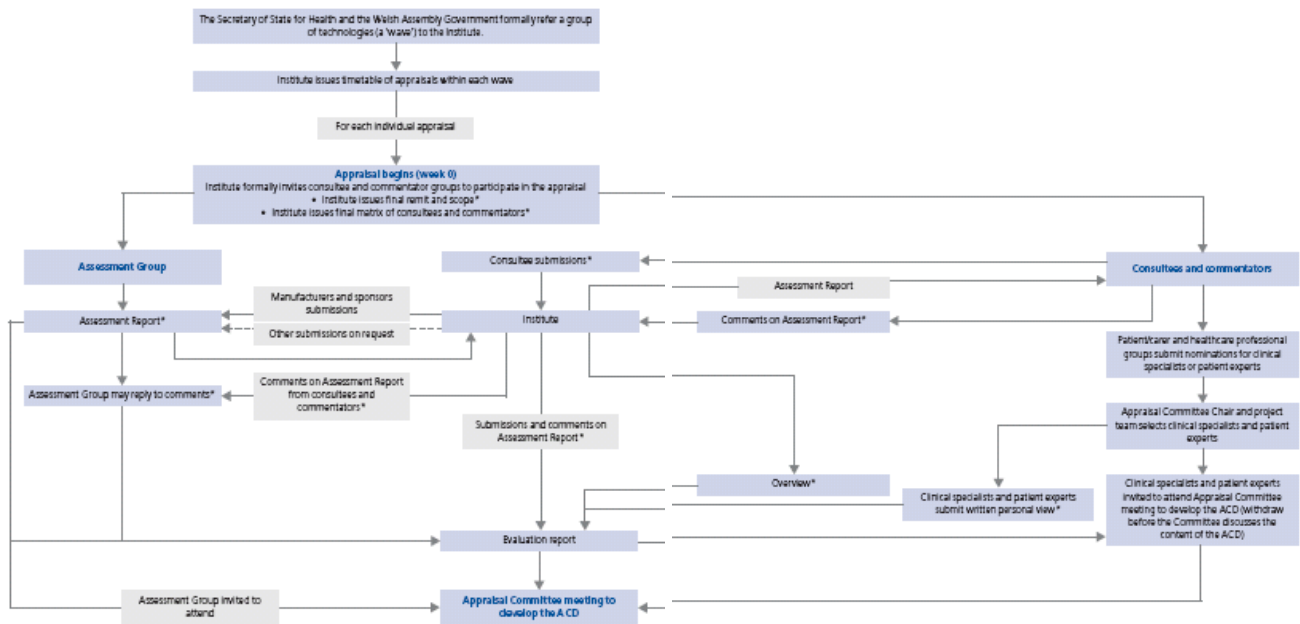
- Review group conducts a systematic review of clinical and cost effectiveness
- Review group examines manufacturers' submissions (clinical and economic)
- Review group provides a report to NICE that is used in the appraisal process
- Time period 8-10 months



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Figure 2 Summary of the appraisal process to development of the Appraisal Consultation Document (ACD).



*Component of the Evaluation Report

Single technology appraisal (STA)

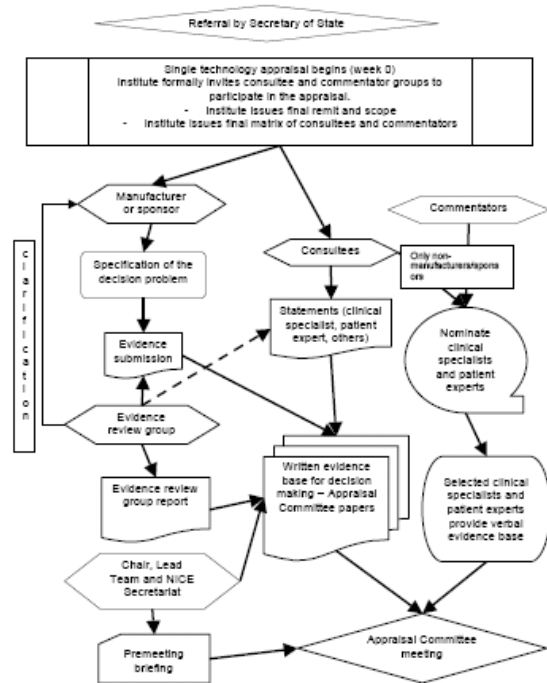
- **The STA process**
 - single product, device or other technology
 - single indication
 - most of the relevant evidence lies with one manufacturer
- **Clinical review and economic model provided by the manufacture**
- **Evidence review group(ERG) provides critique**
 - Examine clinical evidence and model parameters
- **Timeframe – 8 weeks**



Single technology appraisal

3 The STA process

Figure 1 Summary of the STA process up to the first Appraisal Committee meeting



Guide to the NICE single technology appraisal process; September 2006

8

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



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Appraisal Committee

- Each committees(4) - 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



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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



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But what does it look like?

Price of Life – Alan Wishart

<http://vimeo.com/4796083>

<http://www.adamwishart.info/>



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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.



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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=Pk7yqITMvp8>



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