Drug Regulation in the Context of the Economic Crisis: the Role of NICE in the UK

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Summary

- Economic context
- Health policy context
- Expanding role of NICE
- Changes in Technology Appraisal Programme
- Developments in appraisal of drugs
- Future developments

Economic Context

- Main economic policy of the new government is to reduce the public sector deficit
- Health spending will receive some protection with real terms increases in NHS funding promised each year of this Parliament
- Within the health sector £15-20 billion of efficiency savings are expected over the next 5 years to maintain spending on frontline services
- Other budgets related to health care will be cut (e.g. in local government) putting more pressure on health services

Efficiency Savings

- Annual productivity improvements are built into the budget calculation
- **QIPP** programme to achieve savings- **Q**uality **I**nnovation **P**roductivity and **P**revention
- Use of “best practice” tariffs

Health Policy Context

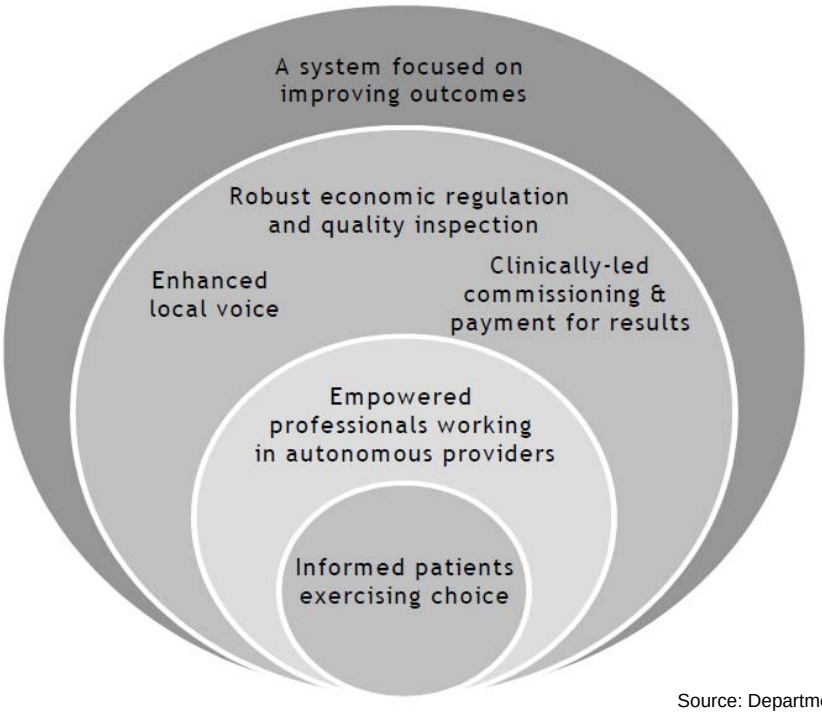
New White Paper Proposals

- Commissioning budgets to be managed by GP Consortia
- All providers to become FTs or equivalent, regulated by CQC and Monitor, but independent of local NHS control
- Dept of Health to focus more on public health
- Independent NHS Commissioning Board, to oversee the GP Consortia
- SHAs and PCTs to disappear

Guiding Principles

- The values and principles of the NHS will be upheld: comprehensive, available to all, free at the point of use, based on clinical need not ability to pay.
- Much greater role for patients in decision-making about their care
- Give control of resources to those delivering the service
- Focus on “outcomes” of care not processes
- Distance NHS management from political interference
- Reduce bureaucracy

Vision

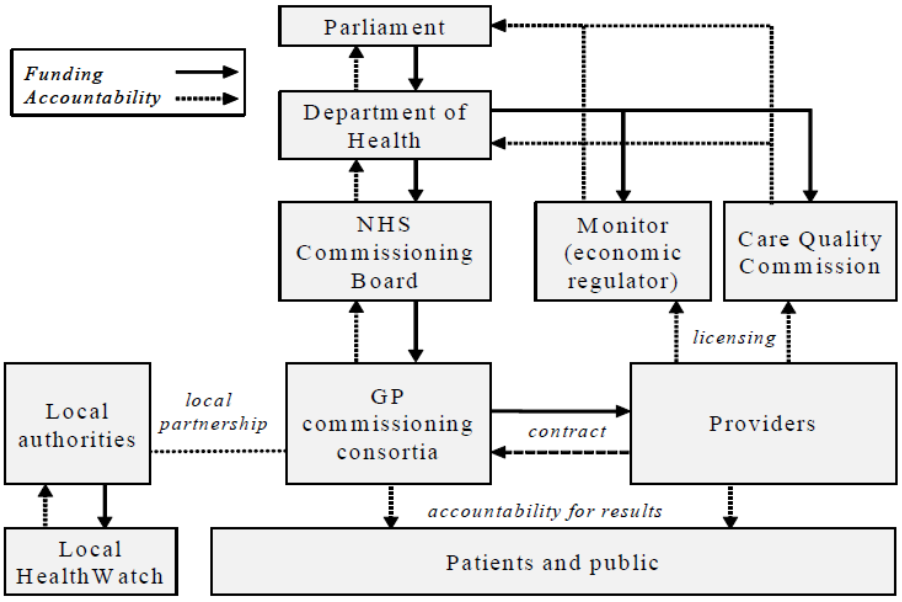


Source: Department of Health, July 2010

Key Features

- Almost complete separation of commissioning and provision – GPs will continue in a provision and commissioning role
- Separation of NHS and DH
- Enhanced economic regulatory role for Monitor to include ensuring fair competition
- CQC to monitor quality standards
- Increased role for Local Authorities in public health

New Structure



Source: Department of Health, July 2010

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Timetable

- Health Bill in Autumn 2010
- 2010-11 Create GP Commissioning Consortia
- April 2012 NHS Commissioning Board operational
- Autumn 2012 Commissioning budgets to GP Consortia
- April 2013 new system in place – SHAs and PCTs abolished

Implementation of GP Commissioning

- Autumn 2012- budget allocations for 2013-14 to GP Consortia
- 2012-13 SHAs abolished
- April 2013 GP Consortia hold contracts with providers
- April 2013 onwards PCTs are abolished
- All providers subject to Monitor regulation

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Expanding Role for NICE

New Tasks for NICE in White Paper

- Main provider of evidence base for decisions
- Use clinical guidelines to develop 150 quality standards against which provider performance will be monitored
- Extended remit to social care

Main NICE Activities

- Evidence-based clinical guidance
- Technology appraisals
- Public health guidance
- Performance indicators:
  - Quality standards for secondary care
  - Quality indicators for primary care

Changes in Technology Appraisal Programme

Thanks to Dr Elizabeth George of NICE for statistics

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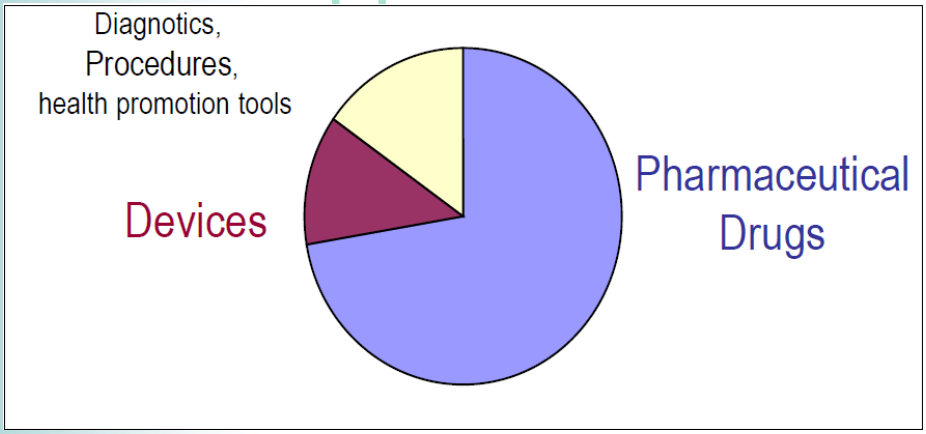
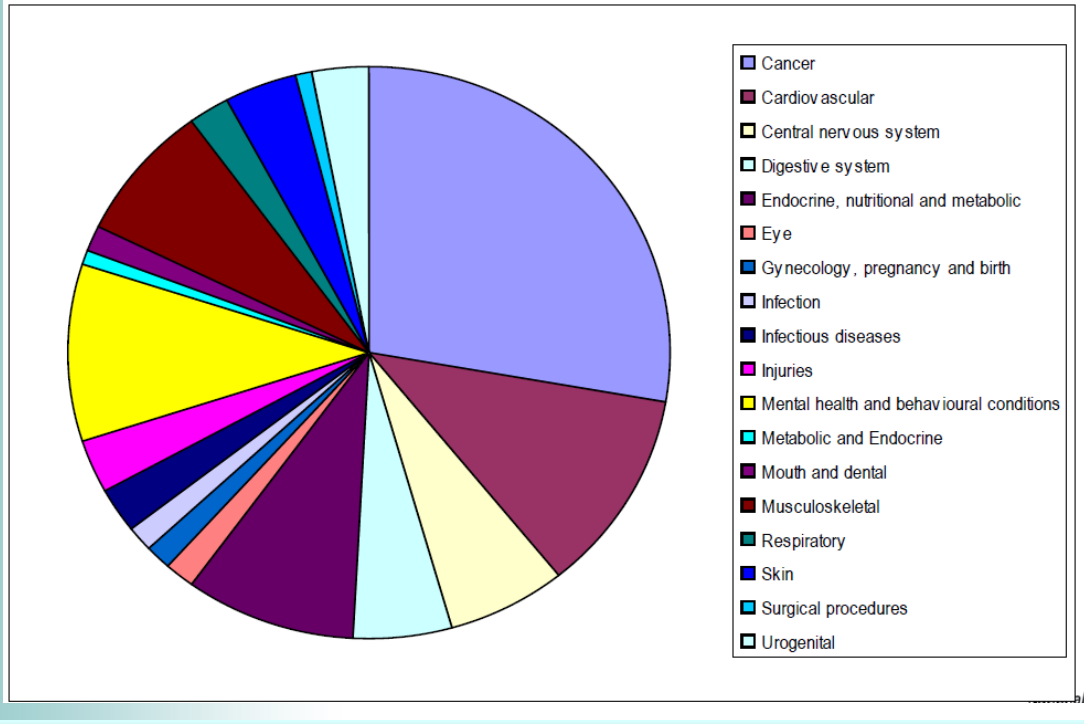
What technologies does NICE appraise?



- Similar method of appraisal
- Clinical and cost effectiveness of intervention
- Compared with standard care

…for which conditions?



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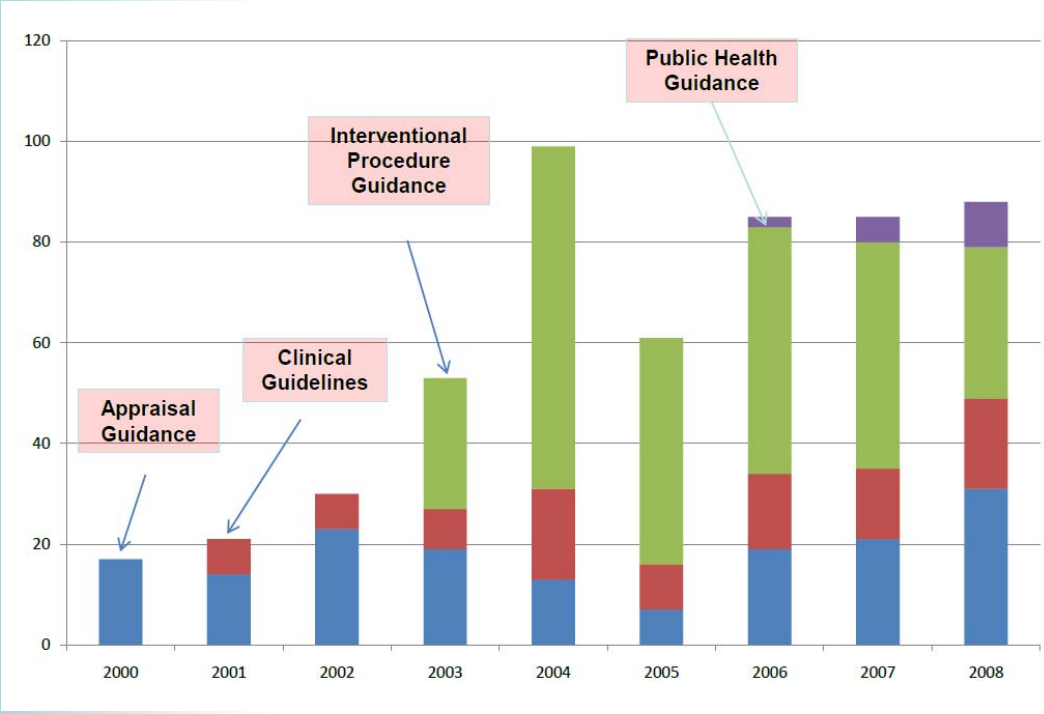
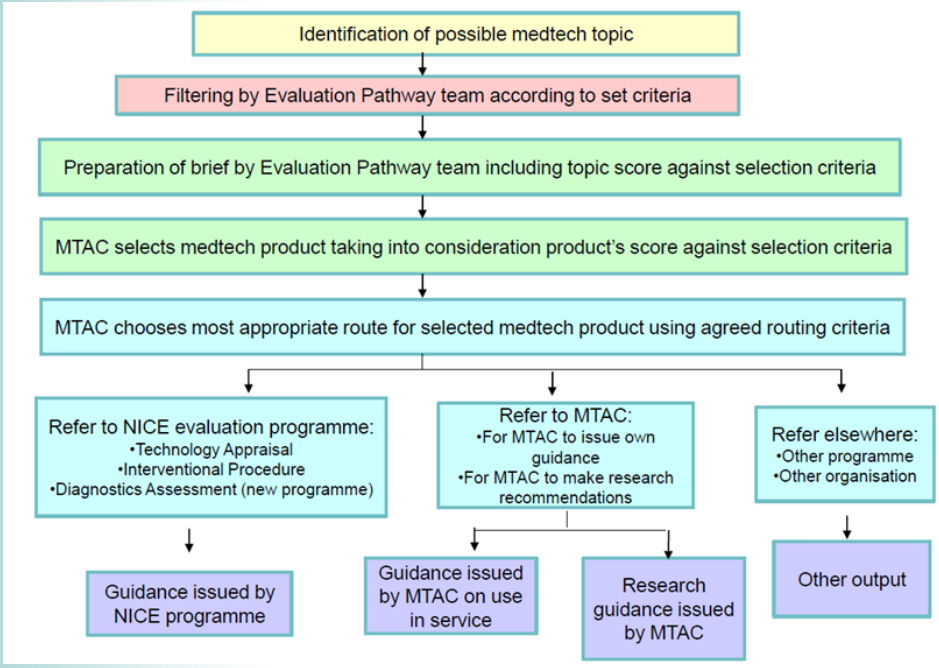
NICE Guidance



New Medical Technology Advisory Committee

- Result of consultation between industry and government
- Attempt to clarify evaluation process for devices
- Issuing first guidance this month

Evaluation Pathway for Medical Devices and Diagnostics



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Developments in Appraisal of Drugs

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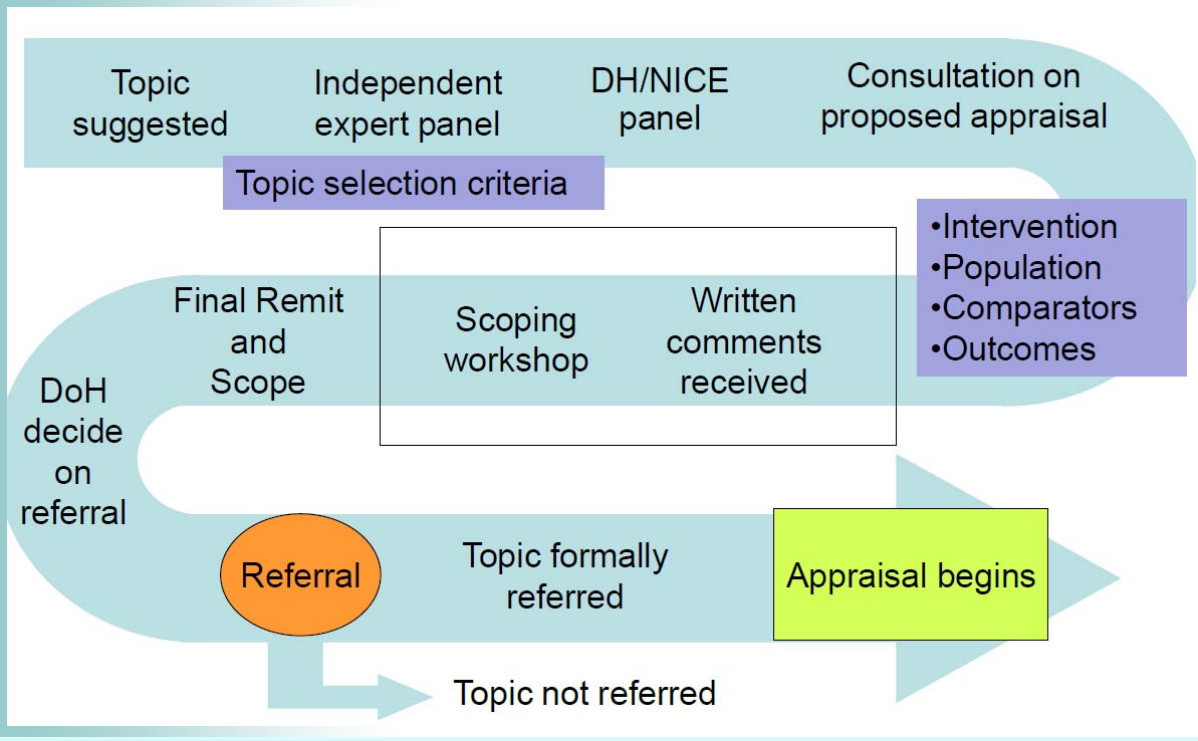
Recent Changes

- Attempt to appraise all significant new drugs
- Increase in STAs
- Patient access schemes
- End-of-life criteria
- Innovation pass
- Cancer drug fund

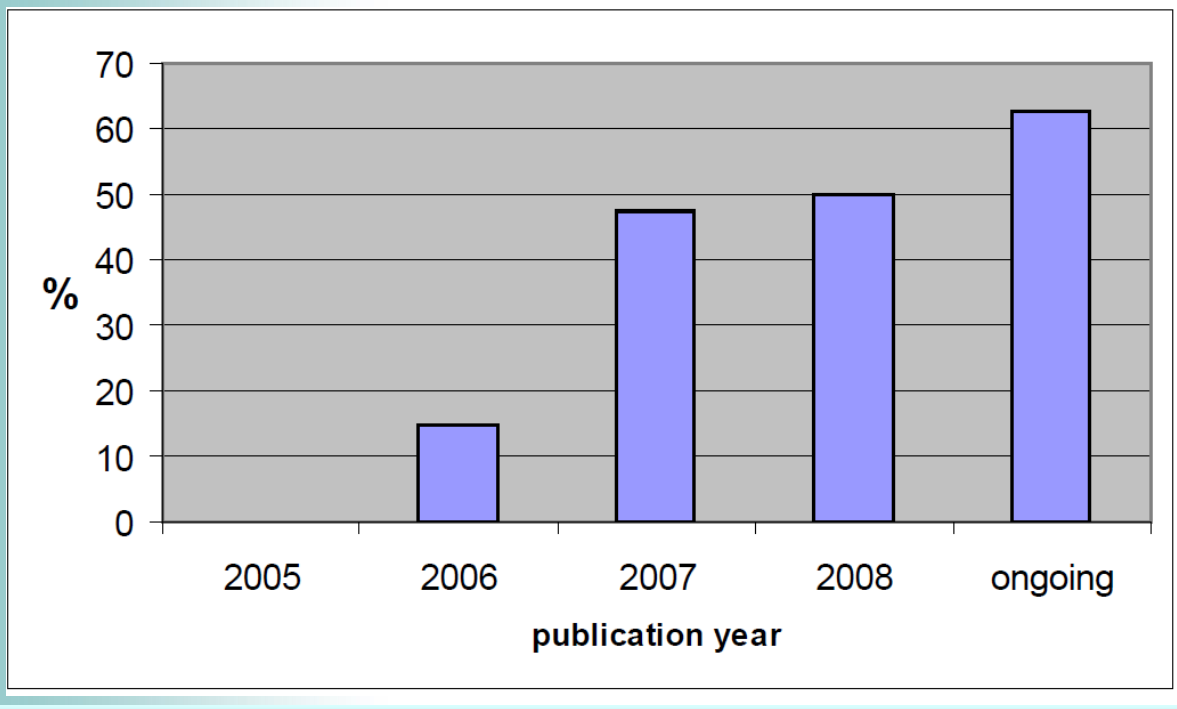
Topic Selection and Scoping



Two Types of Appraisal:

- Single Technology Appraisal (STA)
  - Single technologies, single indications, close to introduction to the NHS
  - 2006 onwards, takes ~35 weeks
  - Based on evidence provided by manufacturer, patient and clinical expert input
- Multiple Technology Appraisal (MTA)
  - Reviews, complex appraisals, classes of technologies
  - 1999 onwards, takes ~14 months
  - Based evidence provided by manufacturer and academic group, patient and clinical expert input

Proportion of STAs



Patient Access Schemes

- Way of reducing cost to NHS without challenging the cost/QALY threshold
- Financially driven e.g. cost cap per patient or discount after a given time point
- Clinically driven e.g. refund for non-response

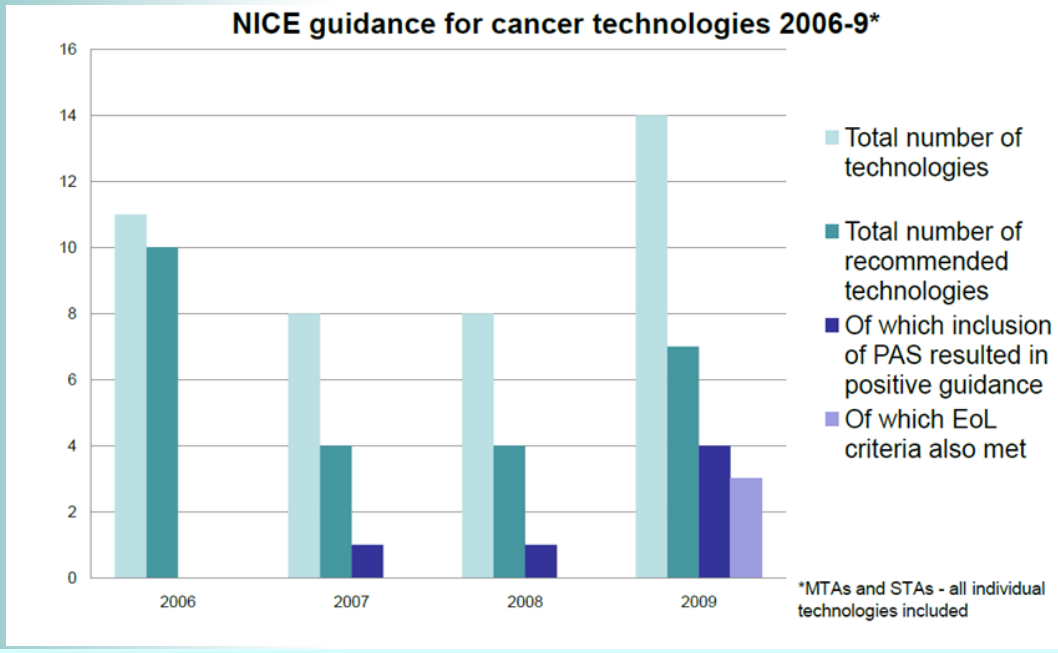
Patient Access Schemes

TA129	Multiple myeloma - bortezomib	**Response-rebate**
TA155	Macular degeneration - ranibizumab and pegaptanib	**Dose-capping**
TA162	Lung cancer (non-small-cell) - erlotinib	**Cost equalisation**
TA169	Renal cell carcinoma - sunitinib	**1st cycle free**
TA171	Multiple myeloma - lenalidomide	**Dose-capping**
TA176	Colorectal cancer (first line) - cetuximab	**rebate**
TA178	Renal cell carcinoma – temsirol/ sorafinib/ bevacizumab	**[1st cycle free; dose-cap]**
TA179	Gastrointestinal stromal tumours - sunitinib	**1st cycle free**
TA180	Psoriasis - ustekinumab	**Weight-based cost equalisation**

End of Life Treatments

- For patients with life expectancy less than 24 months
- Robust evidence of at least 3 months survival gain
- Small numbers of patients
- Higher cost/QALY threshold of between £50,000 and £60,000

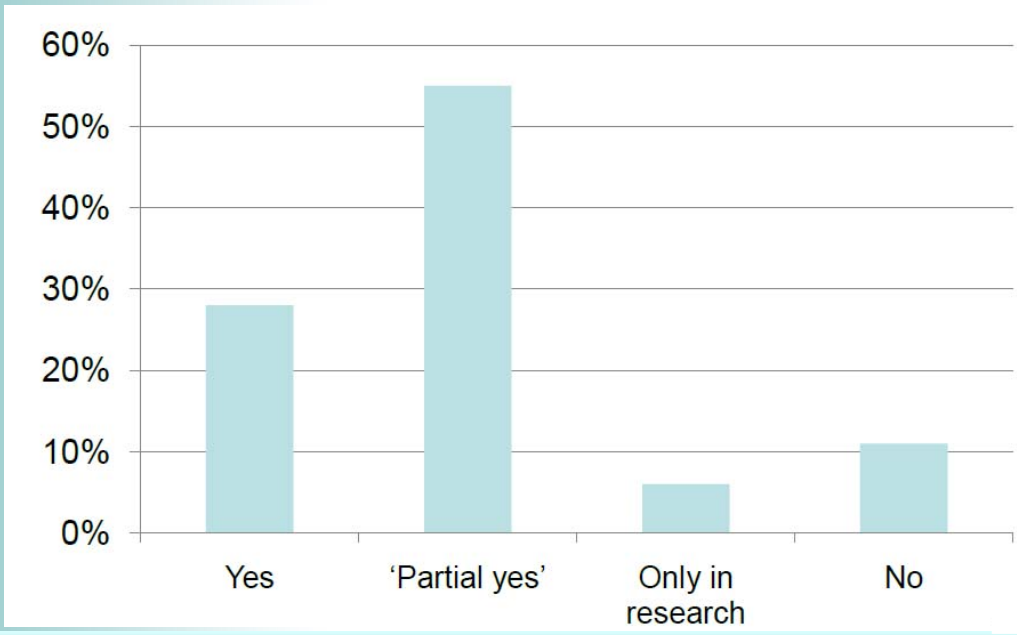
Guidance for Cancer Technologies and Use of PAs



Future Developments

Experience so far

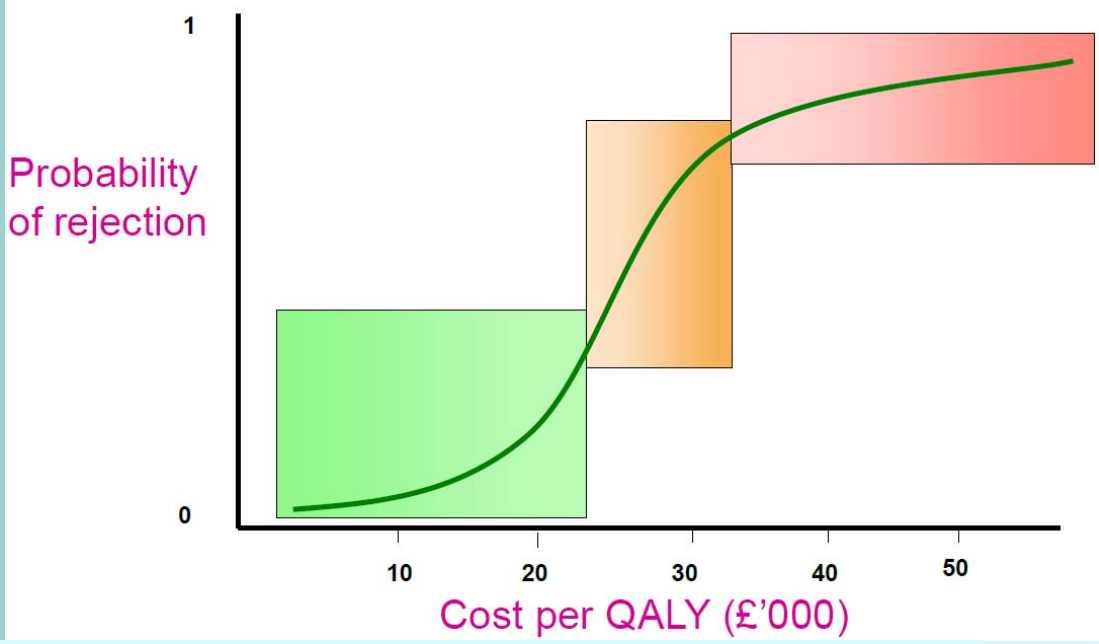
- 184 appraisals published to end Nov 09
  (45 STAs, 139 MTAs)



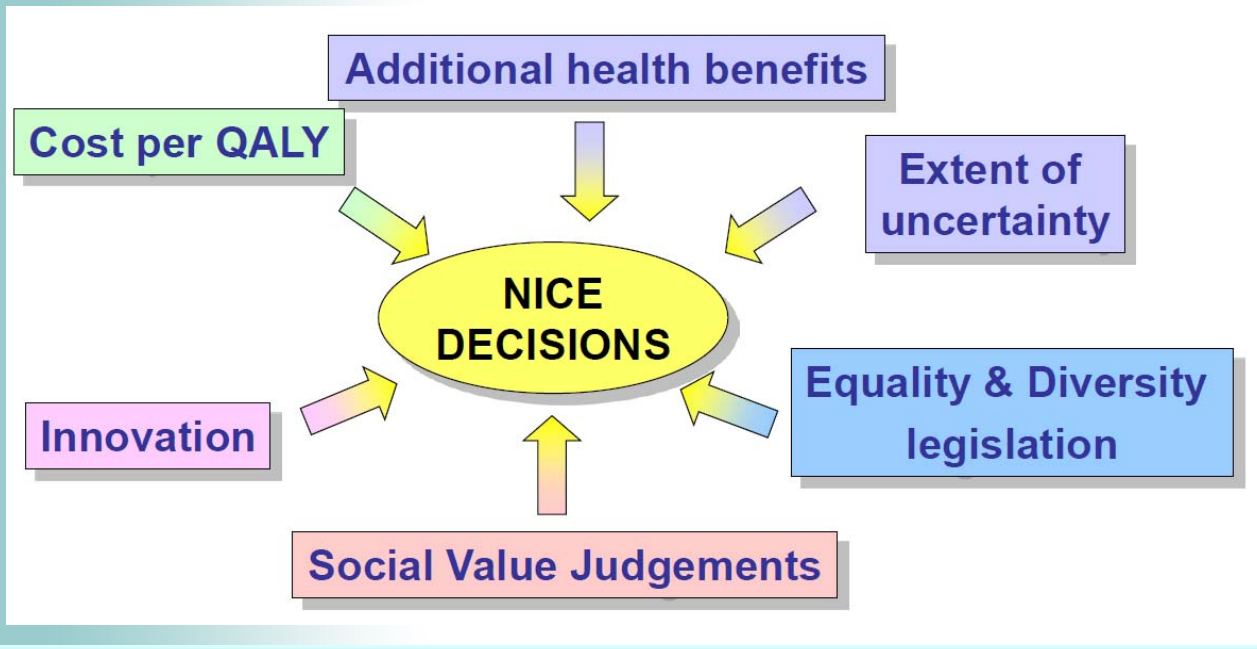
NICE and Cost Reduction

- NICE has not been used for cost-saving
- No strict application of the threshold
- Growth of NHS budgets has enabled recommendations to be funded

Being explicit about how much more can be paid for an additional QALY



Why NICE doesn't have a fixed cost effectiveness threshold?



Impact of Public Sector Cuts

- No significant growth money for NHS
- Commissioners may refuse to implement NICE guidance if it leads to increased expenditure
- Need to tighten quality and outcome performance monitoring

Value-Based Pricing

- Beginning to happen in practice
- May lead to explicit negotiations between NHS and companies on price
- Role for NICE?

Diagram from Claxton(2007)

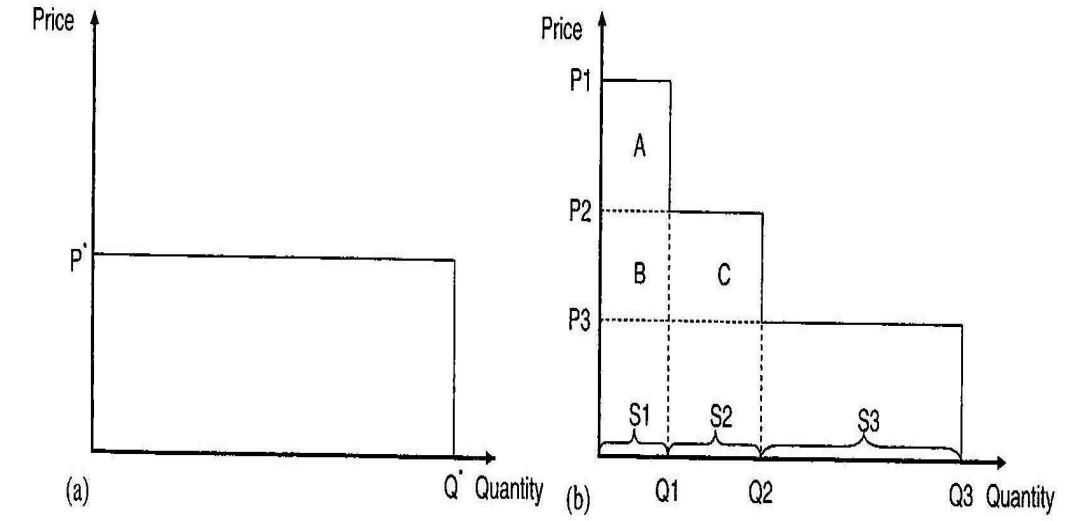


Figure 1. (a) VBP at average cost-effectiveness and (b) VBP at cost-effectiveness of the marginal subgroup

Policy Dilemma

- Conflict between health and economic policy objectives remains
- Pharmaceutical industry is important to the UK economy
- How to achieve cost-effective health care while encouraging valuable innovation?
- More use of the “Only in Research” decision?