

Informing health policy and practice: NICE in the UK

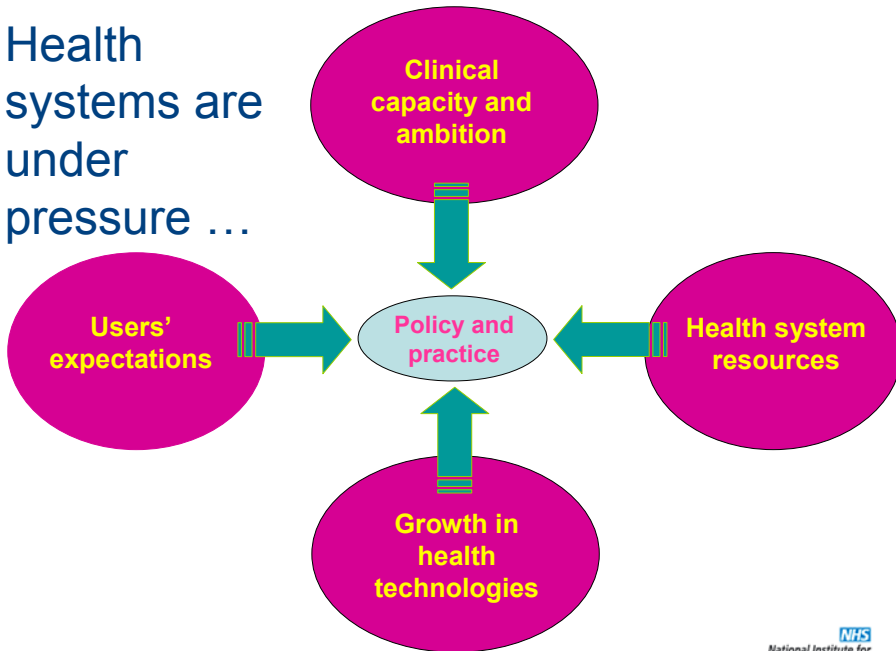
Meindert Boysen

Associate Director Centre for Health Technology Evaluation

Presentation

- Context: UK NHS
- Establishing NICE
- Developing NICE guidance
- Implementation and impact
- Transferability of the experience

Health systems are under pressure ...



Most health systems want to ...

- Improve the health status of the insured population
- Secure effective care
- Make efficient use of available funds
- Stimulate innovation in medical practice and the tools it uses

And some also need to...

- Provide universal and equitable coverage
- Make policy decisions transparently using best available evidence
- Take account of both clinical *and cost effectiveness* in approving treatment strategies

Establishing NICE

- 1990s: growing realisation of UK falling behind in uptake of new technologies
- Constant, corrosive media examination of variations in availability and quality of care
- Multiple micro-level decision points, generating uncertainty about the optimal use of new technologies
- But, concern that change, to encourage faster uptake of new treatments should be evidence-based and take account of available resources
- Broad support from professional and patient groups

The Contribution NICE makes to improving health and healthcare

- We're aiming to get us all to healthy, happy retirement!
- Through preventive and treatment guidance, we advise on optimal approaches to health and health care
- And we help the NHS make the best use of its money



Senior Management Team

Centre Directors

**Health
Technology
Evaluation**
Carole Longson

**Public Health
Excellence**
Mike Kelly

Clinical Practice
Mercia Page

Chief Executive
Andrew Dillon

**Communications
Director**
Louise Fish

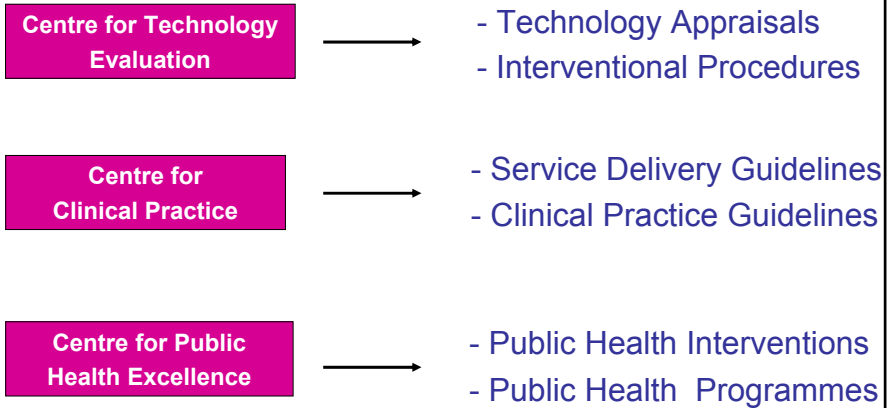
Executive Directors

**Clinical and
Public
Health Director**
Peter Littlejohns

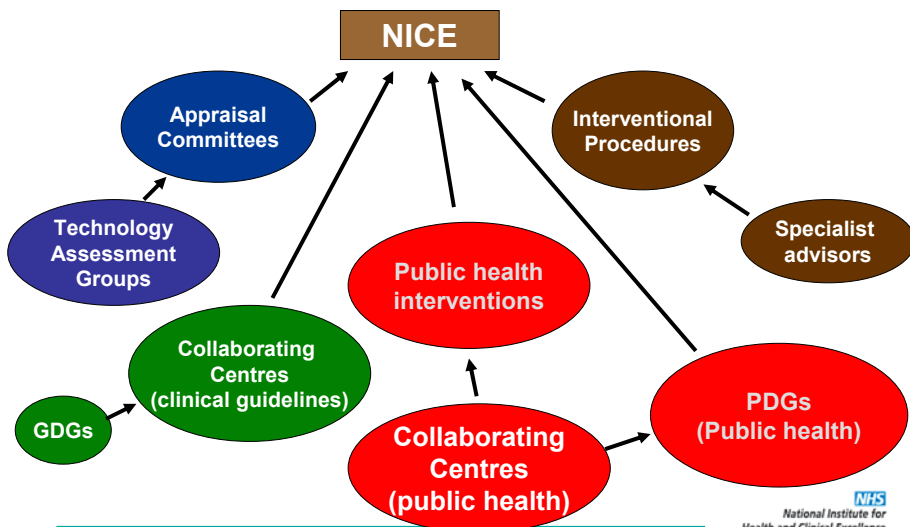
**Implementation
Systems**
Gillian Leng

**Planning and
Resources**
Ben Bennett

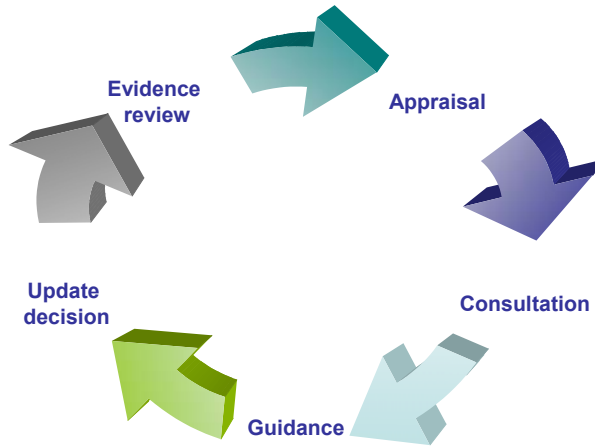
NICE Guidance Programmes



The “virtual” Institute



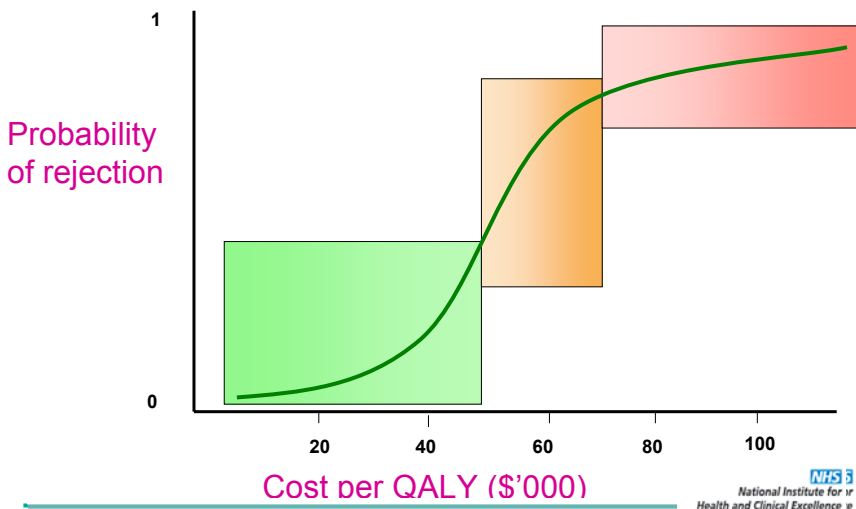
NICE decision cycle



Methods and processes



Assessing Cost Effectiveness



Breakdown of recommendations in technology appraisals *

Decision	%
Technology recommended	32
Technology recommended in subgroups only	54
Technology recommended 'only in research'	7
Technology not recommended	7

*Refers to drugs, medical devices, diagnostics and procedures; based on all appraisals published up to November 2007 (n=130 / ~210 Tech)

Implementation support

- Built a great network with our implementation consultants
- Web-based costing and commissioning tools
- Implementation support materials available for all our guidance
- Published advice on how to change professional behaviour
- A strategy for supporting health professionals to enhancing their knowledge of NICE guidance



How do we assess uptake?

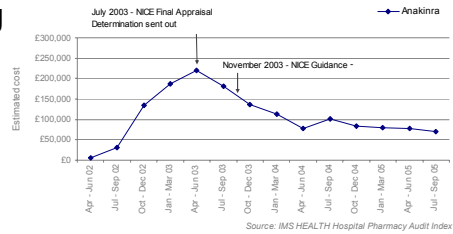
- Routinely collected national data
- Published research
- Healthcare Commission reports
- Patient surveys
- National audits
- Informal comments



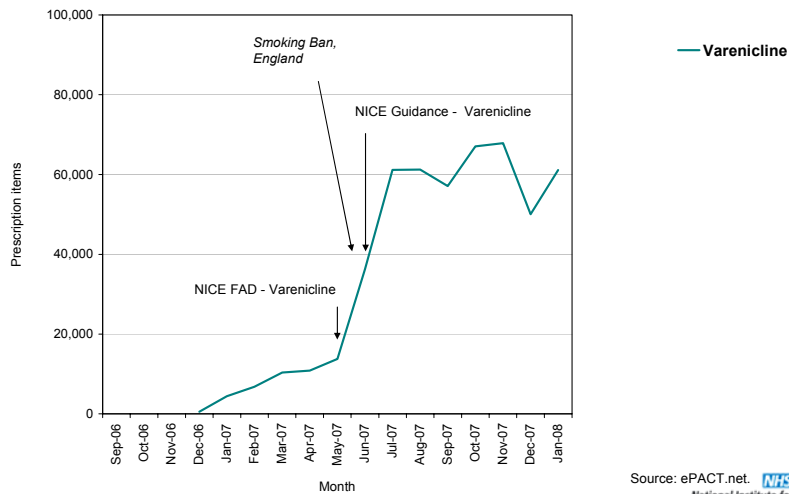
ERNIE - Evaluating uptake

- Evaluation and Review of NICE Implementation Evidence
- Searchable database providing information on the implementation and uptake of NICE guidance
- Implementation uptake reports produced in-house

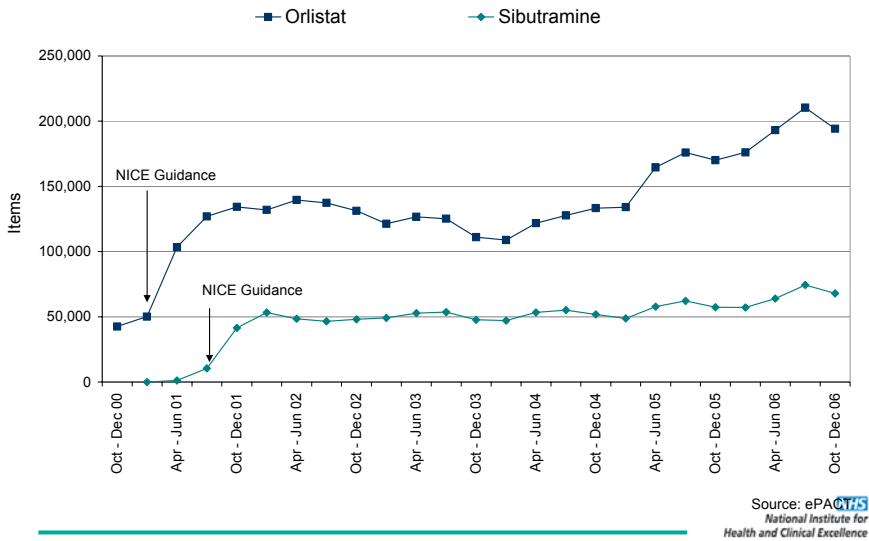
Anakinra used in hospitals in England



Uptake of Varenicline



Uptake of anti-obesity drugs



Inspection results – technology appraisals

Self assessment results – NHS Trusts

	2005/06	2006/07	2007/08
Compliant	84.6%	89.3%	95.1%
Insufficient assurance	11%	7.87%	TBC
Not met	4%	2.79%	TBC

Source: The Healthcare Commission: Annual Health Check

Perceptions of NICE: 1999

Supportive	Government, health professionals
Curious	Advocacy groups, academics, media
Sceptical/hostile	Industry
Blissfully ignorant	Public



Perceptions of NICE: 2008

Supportive	Government, health professionals, academics, advocacy groups, industry (some)
Curious	Media (most), public
Sceptical/hostile	Industry (some), media (some)
Blissfully ignorant	



Conditions for success



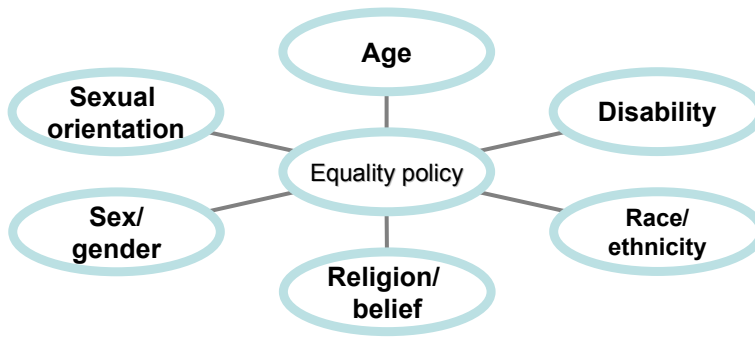
- Agreement, among stakeholders, on the value and application of technology evaluation in the health system
- Transparent, inclusive and contestable processes for developing and using outputs
- Clear statement of methods for assessing and appraising evidence
- Approach tuned to the health system, to take account of single or multiple payer structure and the expectations of users

Challenges for NICE

- Equality & diversity legislation
- Cooksey report
- Office of Fair Trading report
- Health Select Committee report
- Cancer reform strategy
- Judicial review impact
- Darzi review
- Ultra-orphan drugs

Equality policy

NICE must comply with legislation on equality and discrimination.
Areas of equality covered by legislation and best practice include:



Legal requirements vary across these areas.
Affects all stages of the appraisal process.

Guidance

- 1 Infliximab, within its licensed indications, is recommended as a treatment option for adults with plaque psoriasis only when the following criteria are met.

 - The disease is very severe as defined by a total Psoriasis Area Severity Index (PASI) of 20 or more **and** a Dermatology Life Quality Index (DLQI) of more than 18.
 - The psoriasis has failed to respond to standard systemic therapies such as ciclosporin, methotrexate **or** PUVA (psoralen and long-wave ultraviolet radiation), **or** the person is intolerant to or has a contraindication to these treatments.
- 2 Infliximab treatment should be continued beyond 10 weeks only in people whose psoriasis has shown an adequate response to treatment within 10 weeks. An adequate response is defined as either:

 - a 75% reduction in the PASI score from when treatment started (PASI 75) **or**
 - a 50% reduction in the PASI score (PASI 50) and a five-point reduction in DLQI from when treatment started.
- 3 When using the DLQI healthcare professionals should take care to ensure that they take account of a patient's disabilities (such as physical impairments) or linguistic or other communication difficulties, in reaching conclusions on the severity of plaque psoriasis. In such cases healthcare professionals should ensure that their use of the DLQI continues to be a sufficiently accurate measure. The same approach should apply in the context of a decision about whether to continue the use of the drug in accordance with section 2.

Implementation tools

NICE has developed tools to help organisations implement this guidance (listed below). These are available on our website (www.nice.org.uk/TA134).

- Costing report and costing template to estimate the savings and costs associated with implementation.
- Audit criteria to monitor local practice.

Cooksey Review

- Review proposes:
 - government, regulators and industry to create a new partnership to pilot a new drug development 'pathway' to create wins for all stakeholders
- This pathway should enable*:
 - earlier 'conditional licensing' of new drugs;
 - involving NICE earlier in the process of development to accelerate assessment of clinical and cost-effectiveness;
 - clearer processes for ensuring NICE initial assessments and recommendations for further research are followed-up more systematically;
 - the use of the NHS National Programme for IT (NPfIT) to ensure more rapid assessment of any emerging side-effects and efficacy over longer periods;

* Selected items

Pricing and reimbursement

- PPRS
 - secure safe / effective medicines - reasonable prices;
 - promote strong and profitable pharmaceutical industry - sustained R&D expenditure - lead future availability new & improved medicines;
 - encourage efficient / competitive development & supply of medicines to pharmaceutical markets
- 50 Years
- Profit caps / price cuts

Office of Fair Trading & PPRS

- Health / Industrial policy?
- Value-based pricing
 - Ex post / Ex ante
 - Brand premium
- Principles, information and institutions?
 - QALYs / Carers / Generics / Non-linearity
 - NICE / SMC / AWMSG
- 2010?
- Commission on the Value of Medicine / Medicines Pricing Commission?

OFT & PPRS (& NICE?)

- Independent
- Topic selection (<> listing)
- No absolute threshold for cost-effectiveness
- Decision making under uncertainty
- Regular review
- Budget
- Cooksey review & critical path
- Coordination of effort in UK?

Judicial Review - ruling

- Court found in NICE's favour in 5 out of 6 points. So, we:
 - didn't disadvantage carers
 - appropriately took account of long term care costs
 - provided the right economic model
 - right on no cumulative benefit after 6 months
 - Placed appropriate reliance on AD2000
- But,
 - We should have been clearer about use of the MMSE score for 'atypical groups'
- And
 - Leave to appeal refused to all parties

(Ultra-)Orphan drugs

- <> 1 in 50,000 prevalence (<> 1000 pat in EW)

Topotecan 32500/LYG	Ovarian cancer
Gemcitabine 12,550/LYG	Pancreatic cancer
Temozolomide 35,000/LYG	Malignant glioma
Etanercept 27,500/QALY	Crohn's
Imatinib 35,500/QALY	GIST

Agalsidase beta 203,009/QALY	Fabry (200)
Imiglucerase 391,244/QALY	Gaucher's disease (270)
Laronidase 334,880/QALY	Mucopolysaccharidosis (130)

Pulling the strings?



Politicians, industry, patients, clinicians, the press?

NHS
National Institute for
Health and Clinical Excellence



How it can work in other countries

- Assessment, by payers, of the value proposition of new treatments, is a global activity
- Techniques for assessment and interpretation of evidence can be shared
- Application has to be health system-specific
- NICE can help by providing advice on systems, methods and processes, sensitive to local circumstances

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