

The *NICE* Approach to the Clinical and Cost-effectiveness of Healthcare Interventions

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Outline of Presentation

- Some background on NICE
- NICE and nutritional interventions
- Issues raised by NICE's activities

Disclosure of Interests

- The Centre for Health Economics receives funding from the National Institute for Health and Clinical Excellence(NICE)
- I undertake consulting in the field of health technology assessment, both for governments and companies
- I am Chair of one of NICE's Guideline Review Panels

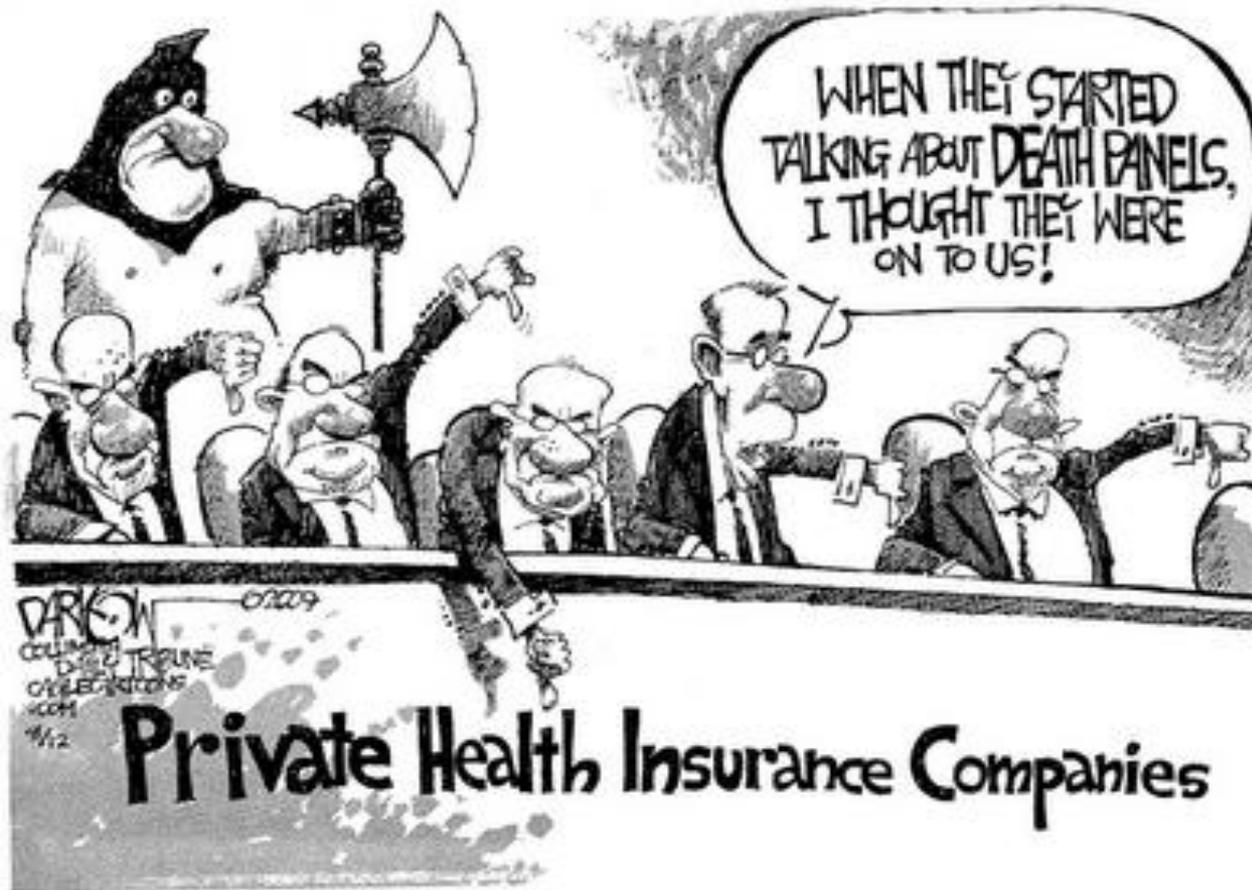
Disclosure of Interests (cont.)

Or, in the words of *Fox News*....

.....I serve on one of NICE's

DEATH PANELS!!!!

US Death Panel



National Institute for Health and Clinical Excellence (NICE)

- Created in 1999
- A Special Authority within the National Health Service (NHS)
- Remit is to consider 'clinical and cost-effectiveness'
- Programmes of work in:
 - health technology appraisal
 - new interventional procedures*
 - clinical guidelines
 - public health interventions

* *Efficacy and safety only*

NICE's Procedures

- Remit received from the Department of Health
- Scoping exercise undertaken
- Submissions invited from key sponsors or manufacturers of the technology
- Independent review of the evidence
- Guidance developed (by an expert group)
- Guidance issued to the National Health Service (NHS): mandatory for technology appraisals
- Monitoring of guidance and review (3 years)

NICE and Nutritional Interventions

- Most mentions in the clinical guidelines programme
- In most cases the comment is that ‘there is no evidence to support the use of...’
- Full evaluation in the case of omega-3-acid ethyl esters in the post- myocardial infarction clinical guideline

Treatment with Omega-3-acid Ethyl Esters Post-MI

NICE Clinical Guideline 48

- Guideline group reviewed the available clinical trials (eg GISSI Prevenzione Investigators, 1999) and 3 economic evaluations
- Considered the evidence to be mixed, but concluded that treatment within 3 months post-MI could be clinically and cost-effective
- Issued guidance that health professions should consider treatment in patients within 3 months post-MI who were not achieving 7g of omega-3 fatty acids per week by dietary means
- Assessment of the clinical and cost-effectiveness of treatment with omega-3-acid ethyl esters should be a research priority

Issues Raised by NICE's Activities

- Importance of a clear remit
- Need for rigorous assessments
- Methodological challenges
- Extensive stakeholder involvement
- Need for transparency in decision-making processes
- Need to manage (negative) public reaction
- Distinction between 'assessment' and 'appraisal'

Methodological Challenges

- Costing perspective (eg NHS or societal)
- QALYs as a measure of health gain
- Broader societal considerations and the 'threshold'
- Clinical comparisons in the absence of head-to-head trials
- Extrapolation beyond trials
- Characterizing uncertainty

NICE Appraisal Consultation Document.

Prevention and treatment of osteoporosis in postmenopausal women.

- Bisphosphonates are recommended as treatment options for postmenopausal women younger than 65 years of age *with a fragility fracture* if they have either of the following:
 - T-score below $-3.2SD$ established by a DEXA scan;
 - T-score below $-2.5SD$ and either a history of maternal hip fracture or long-term use of systematic corticosteroids.
- Bisphosphonates are *not* recommended for the treatment of osteoporosis in *postmenopausal women of any age who do not have a fragility fracture*.

Media View on Osteoporosis Treatments

Daily Mail, Monday, January 12, 2004

If you want NHS drugs, you must break a bone first

By **Jenny Hope**
Medical Correspondent

WOMEN with osteoporosis will have to break a bone to qualify for drug treatment under proposed Health Service rules.

Even then, some fracture victims may be refused.

Millions of women would lose the chance to take drugs to halt bone-thinning while some already being treated could have their medication stopped.

The proposals from the National Institute for Clinical Excellence are aimed at cutting spending on treatments which are not 'cost-effective'.

But critics warn that the move could lead to a massive increase in bone fractures which would actually cost more than continuing to prescribe the drugs.

Specialists say the changes will set the battle against the disease back by many years, just as new treatments are making an impact.

The NICE proposals - which could take effect as early as June - are another blow for postmenopausal women who were told two months ago that they can no longer use Hormone Replacement Therapy to prevent osteoporosis because of possible cancer risks.

The National Osteoporosis Society has launched a campaign

How this treatment transformed my life

AUDREY Capy says the new drug Forsteo 'has given me my life back'.

But 68-year-old Mrs Capy could be stopped from taking it within months - because she is deemed too young.

Although she meets one of the proposed criteria - she failed to respond to other treatments - she would have to wait until she is 70.

'It's completely ludicrous,' she said yesterday. 'It's judging by age, not clinical condition. This drug should be available to stop problems from getting worse. Women shouldn't have to wait until it is too late.'

The former teacher's agony began when she suffered two fractures in the upper part of her spine during an adventure ride in Disney World, Florida, two years ago.

At first, no one could explain the problem, which left her in constant pain and forced to spend much of her time lying down. An MRI scan of her lower spine showed nothing.

Mrs Capy, a mother of three from Wheathampstead, Hertfordshire, said: 'I had to take strong painkillers to get out of bed in the morning. Then all I could do was lie on the carpet in the living room to minimise the pain.'

'If I went anywhere by car I had to lie on the floor. My family began to wonder what was going on because nobody could find anything wrong.'



NICE Appraisal on Drugs for Alzheimer's Disease (AD)

- Drugs can be used for patients with moderate AD.
- Drugs denied to patients with mild disease on grounds of lack of value for money.
- Appraisal challenged, through judicial review, by the drug manufacturer and patient groups.

Media View of Alzheimer's Disease

Daily Mail, Saturday, November 18, 2006

Alzheimer's cover-up

Drugs watchdog refuses to reveal
why it denied thousands of patients
£2.50-a-day medication on the NHS

By **Jenny Hope**
and **Charlotte Gill**

THE drugs rationing watchdog has refused to reveal secret papers that show why it decided to stop thousands of Alzheimer's patients getting drugs on the NHS.

The National Institute for Health and Clinical Excellence is withholding vital documents that helped it reach its decision.

The medication costs just £2.50 a day for sufferers at the early stages of the disease. Drug companies have received overwhelming support from doctors and charities by seeking to challenge NICE's findings in court.

Last year, the Daily Mail launched a campaign to retain the drugs for all those who could benefit for them.

At issue are four drugs, the most popular being Aricept, which NICE have banned for use by those suffer-

How the Mail has campaigned

We spend more
on Viagra than
on drugs for
dementia. What
kind of nation
have we become

The drugs
gave dad
an extra
18 months
with me

FURY OVER
ALZHEIMER
DRUGS BAN

Why nursing homes
could be swamped

Alzheimer
victims 'may
have to buy
illicit drugs'

Assessment versus Appraisal

Assessment

- systematic review and synthesis of the available evidence

Appraisal

- decision-making process in which the available evidence is considered alongside other relevant factors

Key principles for the improved conduct of health technology assessments for resource allocation decisions

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Key Principles: How Does NICE Shape Up?

International Journal of Technology Assessment in Health Care, 26:1 (2010), 71–78.
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doi:10.1017/S0266462309990833

POLICIES

Are Key Principles for improved health technology assessment supported and used by health technology assessment organizations?

The International Working Group for HTA Advancement

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Previously, our group—the International Working Group for HTA Advancement—proposed a set of fifteen Key Principles that could be applied to health technology assessment (HTA) programs in different jurisdictions and across a range of organizations and perspectives. In this commentary, we investigate the extent to which these principles are supported and

The International Working Group for HTA Advancement was established in July 2007 with unrestricted funding from the Schering Plough Corporation. The mission of the Working Group is to provide scientifically based leadership to facilitate significant continuous improvement in the development and implementation of practical, rigorous methods into formal health technology assessment (HTA) systems and processes, by facilitating development and adoption of high quality, scientifically driven, objective, and trusted HTA to improve patient outcomes, the health of the public and overall healthcare quality and efficiency. We are grateful to Andrew Mitchell, Jill Sanders, Tony Tam, and Hong-Min Yang for providing feedback on selected HTA organizational practices. The evaluations and views expressed in this study are those of the authors and do not necessarily reflect the opinions of any of these individuals or their organizations. We are also grateful to Hannah Auerbach for excellent research assistance and to the anonymous referees for constructive comments on an earlier draft.

Conclusions Based on NICE's Experience

- It makes sense to consider the clinical and cost-effectiveness of nutritional interventions within clinical guidelines
- Often there is an absence of high-quality clinical evidence
- In the US, 'assessment' could be centralized, but 'appraisal' would probably need to take place at a local level