

**COST-EFFECTIVENESS ANALYSIS AND
PHARMACEUTICAL INNOVATION**

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Practice and experience in the British National Health Service

Presentation at American Enterprise Institute Conference:

**“Does the U.S. need a NICE ?-
Perspectives on the UK Model for Drug Reimbursement”**

Washington, D.C., 28th June 2006

by

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NICE

The National Institute for Health and Clinical Excellence

“responsible for providing national guidance on promoting good health and preventing and treating ill health in England and Wales”

[www.nice.org.uk].

FOCUS IN THIS PRESENTATION

ONLY on one of NICE's functions:

Technology Appraisal of medicines

especially on products that are internationally recognised as innovative.

NICE GUIDANCE

MULTIPLE SCLEROSIS MEDICINES :

“neither beta-interferon nor glatiramer acetate is recommended for the treatment of multiple sclerosis [MS] in the NHS in England and Wales”

[Technology Appraisal No. 32].

NICE APPEAL PANEL ruling:

“ international opinion on clinical and cost effectiveness was not one of the criteria that the Institute was required to take into account when appraising health technologies.”

[NICE, “Appraisal of the use of beta interferons and glatiramer acetate in the treatment of multiple sclerosis – Decision of the Appeal Panel”, January 2002]

COST-UTILITY ANALYSIS

measures

QUALITY-ADJUSTED LIFE YEARS

[QALYs]

**LENGTH OF SURVIVAL
combined with
QUALITY OF LIFE**

RELATIVE TO COST

INNOVATIVE MEDICINES FOUR CASE STUDIES

1. The 'MS CASE'

**Beta-interferons and glatiramer acetate for
MULTIPLE SCLEROSIS**

2. The 'CML CASE'

**Imatinib for
CHRONIC MYELOID LEUKAEMIA**

3. The 'PHOTODYNAMIC CASE'

**Verteporfin for
WET AGE-RELATED MACULAR DETERIORATION**

4. The 'OSTEOPOROSIS CASE'

**Bisphosphonates, raloxifene and teriparatide for
SECONDARY PREVENTION of osteoporosis**

FOUR CASE STUDIES

DURATION OF NICE PROCESS from REFERRAL to issuing of GUIDANCE

| CASE | DURATION | |
|----------------------|-----------------|---------------|
| | Years | Months |
| MS | 2 | 6 |
| CML | 1 | 5 |
| Photodynamic | 2 | 6 |
| Osteoporosis* | 2 | 10 |

**[* Secondary prevention.
Primary prevention not yet concluded]**

FOUR CASE STUDIES

RECOMMENDED NICE GUIDANCE

| CASE | GUIDANCE: MAIN POINTS |
|--|---|
| MS | Against use in NHS except optionally for patients already on treatment or in clinical trials |
| CML | Recommended first-line treatment in chronic phase CML |
| Photodynamic | Recommended only for treatment of a small segment of patients |
| <u>Osteoporosis</u> Bisphosphonates | Recommended with restrictions for age segments among patients |
| Raloxifene | Recommended as second-line treatment for patients for whom bisphosphonates are unsuitable |
| Teriparatide | Recommended as second-line treatment at age 65+ with additional restrictions |

QUESTIONS

NICE: PERFORMANCE?

Strong

NICE: CONCEPT?

MANDATORY NATIONAL GUIDANCE ON COST-EFFECTIVENESS OF INNOVATIVE MEDICINES:

**Valid or unsound?
Helpful or burdensome?
Necessary or dispensable?**

For INNOVATIVE MEDICINES

**....coming to terms with the
UNCERTAINTY PRINCIPLE
in industry and health care**

**The place of
COST-EFFECTIVENESS ANALYSIS
as a useful analytical tool is limited:**

- **Clinical limits**
- **Industrial limits**
- **Practical limits**

**U.S. HEALTH CARE –
Pluralistic, competitive**

**EUROPEAN HEALTH CARE –
Public sector
'Single Payer' dominates**

Both have advantages and weaknesses

**If pharmaceutical innovation is to remain
a major objective
in industrial and health policy:**

USE COST-EFFECTIVENESS ANALYSIS

as an optional decision-making tool

**NOT WITH MANDATORY STATUS
for centralised national guidance**

THE BRITISH HEALTH CARE SYSTEM IN OUTLINE

NATIONAL HEALTH SERVICE [NHS]

= public sector

Share of total health expenditure (2002)

| | % |
|--------------------------------|------------|
| Public sector | 83.4 |
| Private health insurance, est. | 3.2 |
| Patient out-of-pocket, est. | 10.7 |
| Other, est. | <u>2.7</u> |
| | 100 |

| Funding of pharmaceuticals | % |
|----------------------------|------|
| Public sector, est. | 74 |
| Private sector, est. | 26 * |

[*of which >20 = otc/non-prescription]

NHS Prescription charge

April 2006: £6.65 [approx. \$12] per item prescribed

Exemptions: about 84% of all NHS prescriptions

Prescription charge receipts = approx. 4% of NHS pharma expenditure

Thank you

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