NICE Guidelines: A Methodological Basis for Decision Making

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Pre Meeting Symposium - ISPOR Annual Conference
Washington May 20th 2001
NICE – What & Why?

- Issue national guidance (technology appraisal & clinical guidelines) to NHS in England & Wales
- Based on rigorous review of the available evidence
  - Clinical effectiveness
  - Cost effectiveness
  - Service impact
- Political backdrop – postcode prescribing and faster access to modern therapies
Appraisal of New & Existing Guidance for Manufacturers & Sponsors

National Institute for Clinical Excellence
December 1999
Presentation

- Process of revision of NICE’s guidance to industry
- Lessons learnt from the process
  - NICE, Industry & other stakeholders
- Future Issues
Revising M&S Guidance
Steering Group

• Membership
  – Chair: Prof Tony Culyer, Univ of York
  – Members: Relevant academics, industry (ABPI & ABHI), appraisal committee & NICE

• Define project tasks and issue RFPs (April - May 2000)

• Commissioned MEDTAP (June 2000)
Revising M&S Guidance
The Process

1. Review of current international clinical and cost effectiveness guidance
2. Consultation I
3. Preparation of draft guidelines
4. Consultation II [& workshop]
5. Review of draft guidelines
6. Publication *Planned for October 2000*
Revising M&S Guidance

1. International Guideline Review

*(June-September 2000)*

- Locate National and other authoritative guidance on submissions of clinical-effectiveness, cost-effectiveness, and health services impact data.
- Synthesis: compare statements on each methodological or practical issue
- Identify areas of consensus, disagreement or absence of clear guidance in current documentation.
1. International Guidelines Review

Guidance Compliance to Selected Criteria from ‘BMJ Checklist for Authors’

- Conclusion with Approp. Caveats
- Conclusion Follows on from Results
- Answer Study Question
- Outcomes Presented Dis. & Agg.
- Incremental Analysis Reported
- Sensitivity Analytic Approach Given
- Statistical Tests and CI Given
- Currency Data Recorded
- Resources & Costs reported sep.
- Relevance of Productivity
- Productivity Changes Separate
- Whose Values Measured
- Benefit Valuation Method
- Study Design of Effectiveness Data
- Effectiveness Source Reported
- Comparators Justified
- Viewpoint Stated
- Study Question Stated

Frequency

16 sets of guidance reviewed against Drummond & Jefferson BMJ 1996
1. International Guidelines Review

Conclusions

- Wide variation in the content/detail of existing cost-effectiveness guidance
- No trends, but formal guidance (for pricing & reimbursement) more prescriptive than informal (academic) guidance
- Very little reference to:
  - Clinical effectiveness, service impact
  - Statistical methods in general
  - Sub-group analysis
  - The question of class effects for drugs
- Limited detail on translating efficacy into effectiveness
Revising M&S Guidance
2. Consultation I *(July 2000)*

- **Aims**: To explore views on particular areas of methodological uncertainty
- **Consultation**:
  - Invited: 10 groups drawn from academics in industry & university, DoH, clinicians, health service decision managers & international HTA organisations/individuals
  - Open: via NICE web site
  - Questionnaires: clinical effectiveness, cost effectiveness, NHS impact, preparing industry submissions & reviewing industry submissions
## Consultation I - Questionnaire Distribution

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**What Are The Appropriate Measures of Health Gain For Submissions to NICE?**

**Consultation I: Variations in response by stakeholder group**
2. Consultation I (July 2000)

Conclusions

- Q’uaire responses: no more consistency than guidelines.
- Agreement across groups on general issues, such as the need to take into account equity: but little agreement on specifics.
- Need to take into account central policy
- Results did not necessarily provide a clear basis for the revised guidance.

**Principles**

- Prescriptiveness *(vs flexibility)*
- Comprehensiveness
  - Clinical/Cost effectiveness & service impact
- Scope
  - Drugs, Devices, Procedures etc.
- Transparency
  - Dutch (ZFR) guidelines format
Revising M&S Guidance
4. Consultation II (*October 2000*)

- **Aims:** Collect views (specific & general) on draft guidelines
- **Consultation:**
  - Invited: 10 groups drawn from academics in industry & university, DoH, clinicians, health service decision managers & international HTA organisations/individuals
  - Self nominated: eg. RSS, ABPI, ABHI
  - Open: via NICE web site
  - Workshop (27th October 2000)
## Consultation II
### Summary of Responses

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4. Consultation II
Conclusions

• Allowed discussion & participation
• Detailed views on a number of specific issues
  – E.g. efficiency/effectiveness
  – subgroup analysis
• Direct impact on guidance
  – Need for greater clarity in wording
  – Thinking on service impact
  – Need for context setting
Revising M&S Guidance
What have we learned?

• Importance of wide consultation and accountability
• ‘Off the peg’ solution inappropriate, due to specific NICE requirements: value of going through the process itself
• Divergence of views: aim to ‘balance’ resulting discomfort to stakeholders
• Original timelines for review were over-ambitious
• Inter-relationship between methods & process
• Widescale interest
Prediction is very difficult. Particularly the future

Neils Bohr
Revising M&S Guidance
Future Issues

• Implementation of methodological guidelines
  – Auz & Canada experience (Hill et al, 2000; Baladi et al, 1998)
  – Audit - Usefulness, adherence, ‘necessary deviations’ & impact on quality of future submissions

• Need for update
  – eg. Service impact & equity

• International harmonisation?