UK Perspective:
MHRA ... NICE ... and IDEAL

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Past Chair NICE Interventional Procedures and Medical Technologies Advisory Committees

IDEAL Conference
5 May 2017
<table>
<thead>
<tr>
<th>REGULATION</th>
<th>EVALUATION</th>
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<td>MHRA</td>
<td>NICE</td>
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<td>Safety</td>
<td>Efficacy</td>
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<td>Performance</td>
<td>Cost effectiveness</td>
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<td>Marketing</td>
<td>Adoption</td>
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<td>Vigilance</td>
<td>More evidence</td>
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Why NICE was set up in 1999

• To reduce variations in available treatments and care - ‘postcode lottery’

• To resolve uncertainties about which treatments work best and give best value for money
NICE guidance by year 2000-2015

Number of Publications

Year

Social care
CCG OIS
Evidence Updates
Evidence Summaries
Diagnostics
Quality Standards
Medical devices
QOF
QIPP
Accreditation
Public Health
Interventional Procedures
Clinical Guidelines
Technology Appraisals
NICE guidance on health technologies

Technology Appraisals - Clinical and cost effectiveness

Interventional Procedures - Safety and efficacy
- Not cost

Medical Technologies - device/diagnostic adoption

Diagnostics – complex, costly, competing options

Clinical Guidelines - Managing specific conditions
- Link to Quality Standards
How does NICE assess technologies?

- **Wide range of “evidence”:**
  - *Published studies* (± abstracts, registers, audits)
  - Expert advice
  - Views of patients and carers
  - Manufacturers and other stakeholders

- Independent advisory committees
- Explicit and transparent processes
- Public consultation
- Opportunity for appeal/resolution
Technology Appraisal Guidance
Since 1999

• Clinical and cost effectiveness ("cost per QALY")

• Topic Selection: agreed with Department of Health

• High cost/high impact technologies
  ➢ Dominated by expensive medicines
  ➢ Some devices/procedures: hips, hernias, EVAR

The only guidance with a funding mandate
Interventional Procedures guidance

Always generic *procedure* name …. … not name of device

- Evaluates evidence on all devices
- Guidance applies to all devices
  - Different manufacturers
  - Different versions of same device
Interventional Procedures Recommendations specify circumstances for use of procedures

1. Evidence adequate: “normal arrangements”

2. Evidence limited: “special arrangements”*** for:
   – Governance – tell your hospital
   – Consent - tell your patients
   – Audit/research – review your outcomes

3. Evidence so limited research ethics oversight: “Research only”****

4. Evidence of harm or does not work: “Do not use”
Interventional Procedures guidance
578 published since 2002 (67 procedures)

• In practice the “regulator” for procedures

• Often referred to as “NICE approval”

• “Special arrangements” or “Research only”
  is not “suspect” - means need more evidence

***Potential for IDEAL***
AIM:
identify >>> evaluate >>> adoption

Specific products notified by manufacturers
1. **Topic selection by committee**

   **Advantages** over “*current management*” in:
   - Patient outcome or experience
   - System benefit (cost): facilities, staff, tests, disposables
   - Sustainability (energy saving)

2. **Evaluation** to produce NICE guidance

   “The evidence supports the case for adoption …”
What companies need to produce ……

Claims + Value proposition

List advantages (patients, service, energy)
• “Current management” as comparator

Clinical evidence
IDEAL culture would be wonderful!!!
• Relevant patients, setting, outcomes
• Clinical utility important
• Consider care pathway

Cost model with plausible assumptions
<table>
<thead>
<tr>
<th>Topic</th>
<th>Patient benefits</th>
<th>System benefits</th>
<th>Annual saving £/patient</th>
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<tbody>
<tr>
<td>MTG12 (2013) EXOGEN ultrasound system for non-union or delayed healing</td>
<td>For non-union fractures gives high rates of fracture healing</td>
<td>For non-union fractures, avoidance of further surgery</td>
<td>£1164</td>
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Evidence generation

- Plan ahead for regulators, HTA, payers, clinicians, patients

- Maximise relevance and value of evidence for these successive audiences

- IDEAL describes the framework for this …
NICE Scientific Advice

• Detailed advice packages (£££)
• Brief advice/ META Tool (£)
• Symposia (with MHRA input)
• Link with FDA initiative

***Potential to introduce IDEAL concept***