The role of NICE in the Assessment of Innovative Medical Technologies

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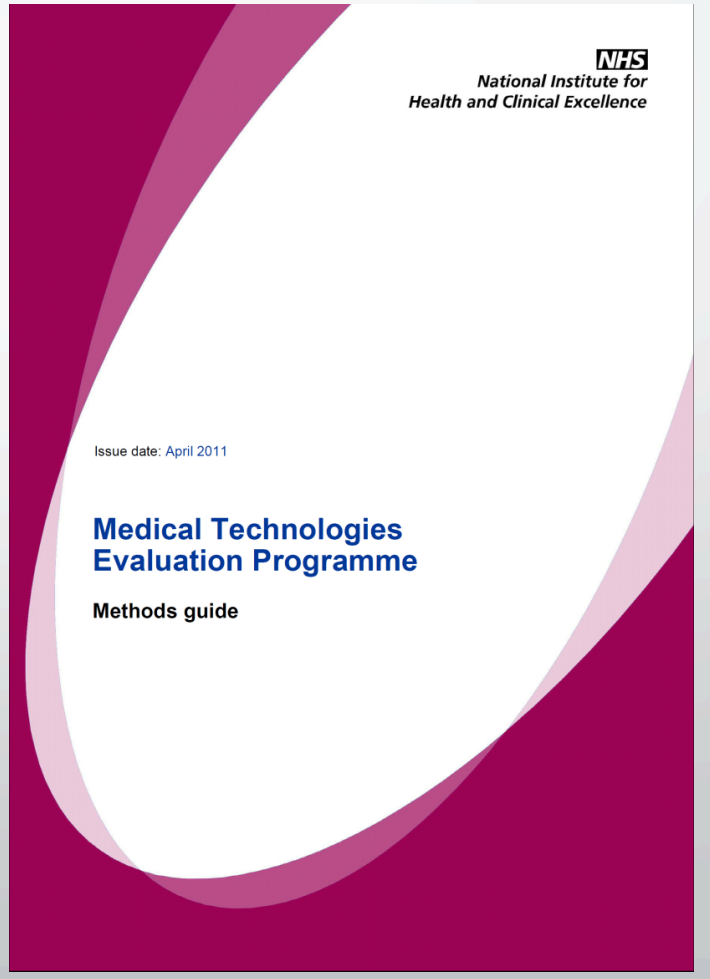
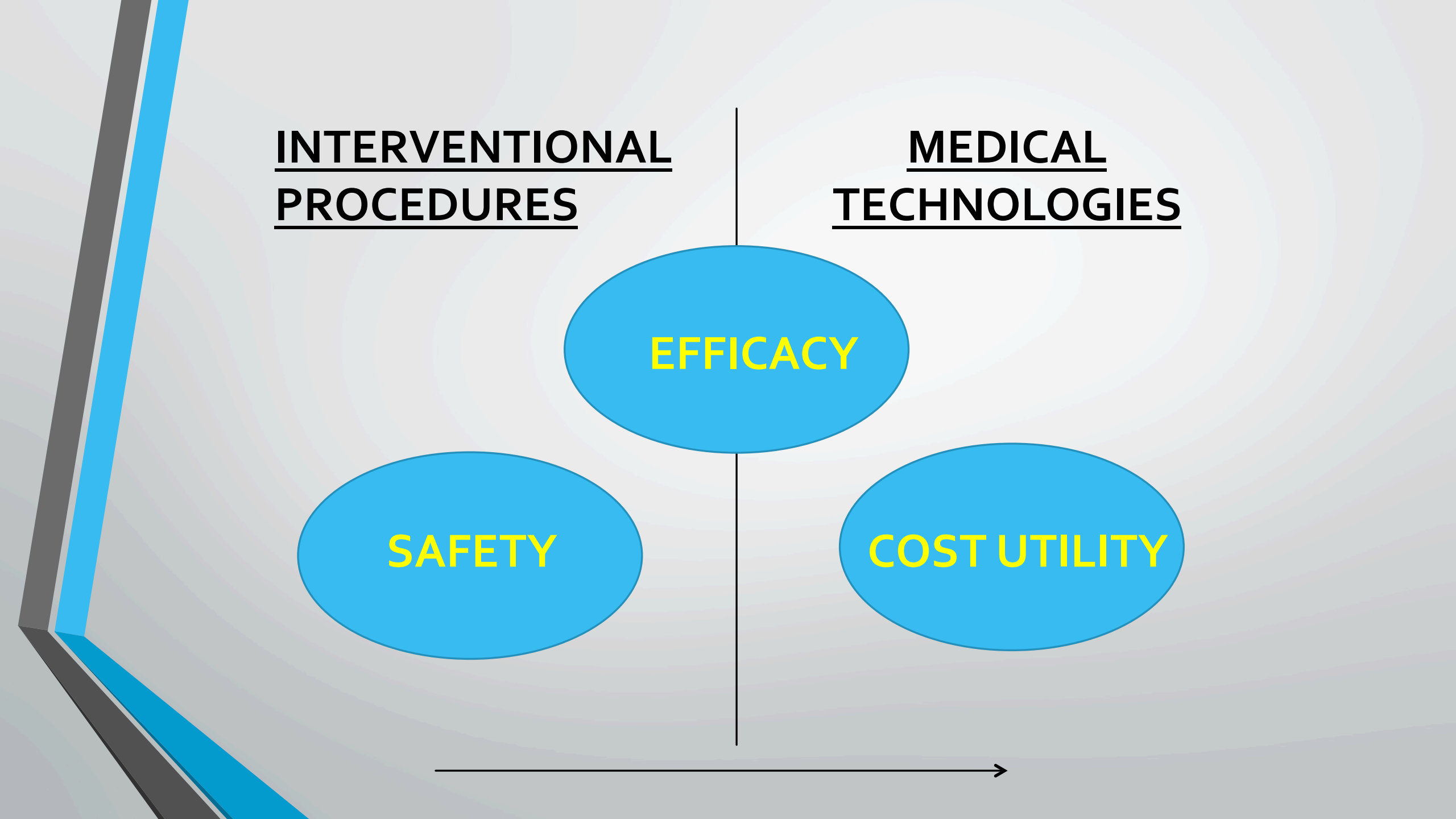
NICE

Guidance Generation is based on NICE's core principles

- **Independent advisory committees**
- Best evidence available
- Expert input
- Patient and carer involvement
- Open and transparent process
- Genuine consultation
- Regular review




INTERVENTIONAL PROCEDURES
MEDICAL TECHNOLOGIES
EFFICACY
SAFETY
COST UTILITY

The Aims of the Interventional Procedures Advisory Committee (IPAC)

- To protect patients and help clinicians, healthcare organizations and the NHS introduce procedures appropriately
- To provide guidance on the safety and efficacy of procedures
- To provide advice on training, data collection and analysis and other conditions of use for interventional procedures in the NHS

IPAC Guidance Recommendations

- Use with normal arrangements for clinical governance, consent and audit
- Use with special arrangements for clinical governance, consent and audit
- Use only in research
- Do not use

Medical Technologies Evaluation Programme

- Simplify access to medical technology evaluation
- Speed up the process
- Increase the evaluative capacity for devices within NICE
- Increase the uptake of beneficial new technologies
  - Support commissioners and providers
  - Assist clinicians
  - Inform patients
- To encourage collaborative research in industry and the NHS to generate evidence on the clinical utility and/or healthcare system benefits of selected technologies

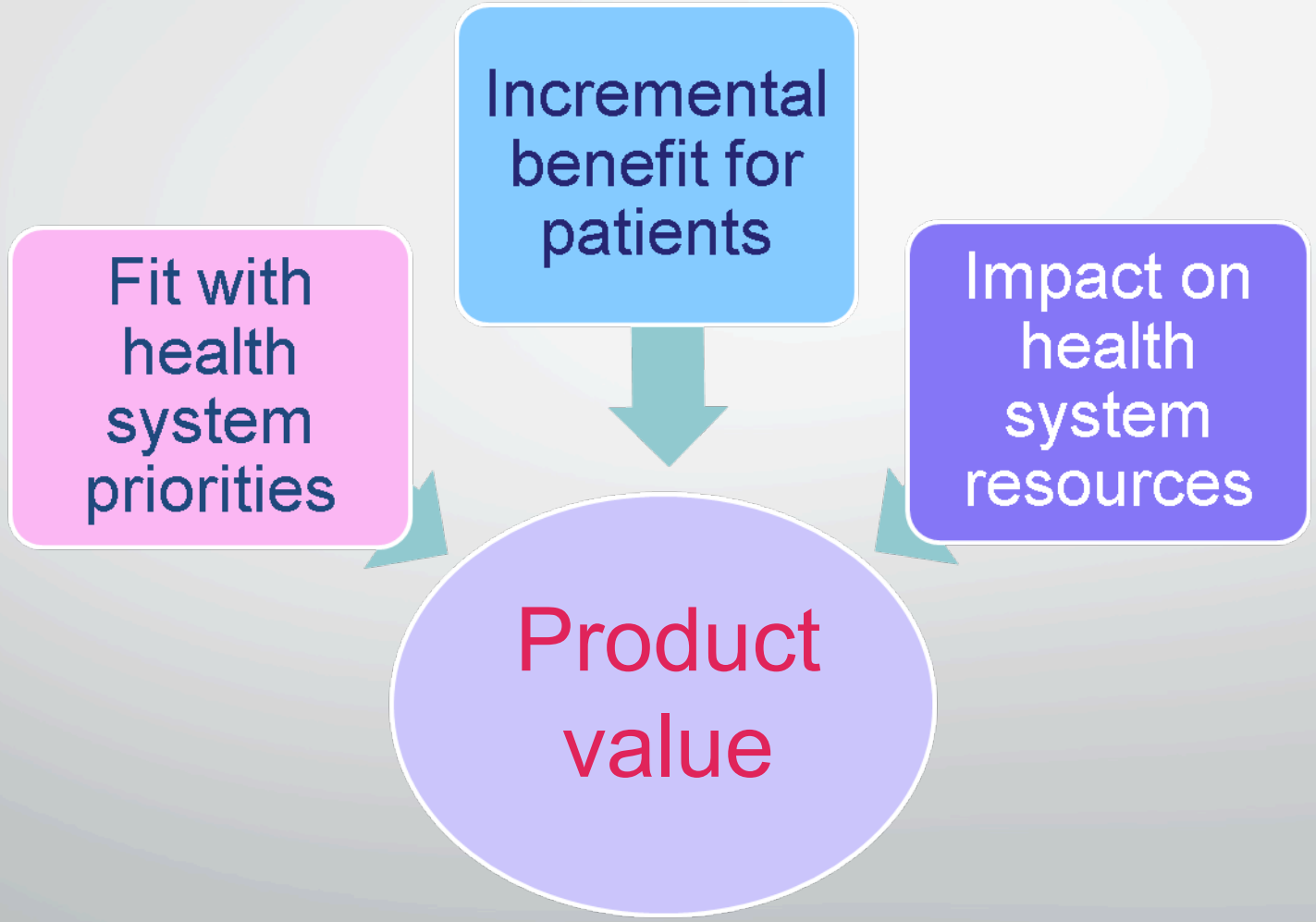
Challenges for Generating Medtech Guidance

- Limited published evidence
  - Resource constraints of industry
  - Device-specific challenges to trial design
  - Confounding factors eg. operator skills, learning curve
  - Blinding bias; recruitment; drop-out
- Short product lifecycle

NICE Medtech evaluation - levels of evidence -

- 'Permissive' approach
- No design or quality threshold
- Published research studies
- Unpublished information
  - Technical studies
  - Conference abstracts
  - Expert advice
  - Patient and carer organization views

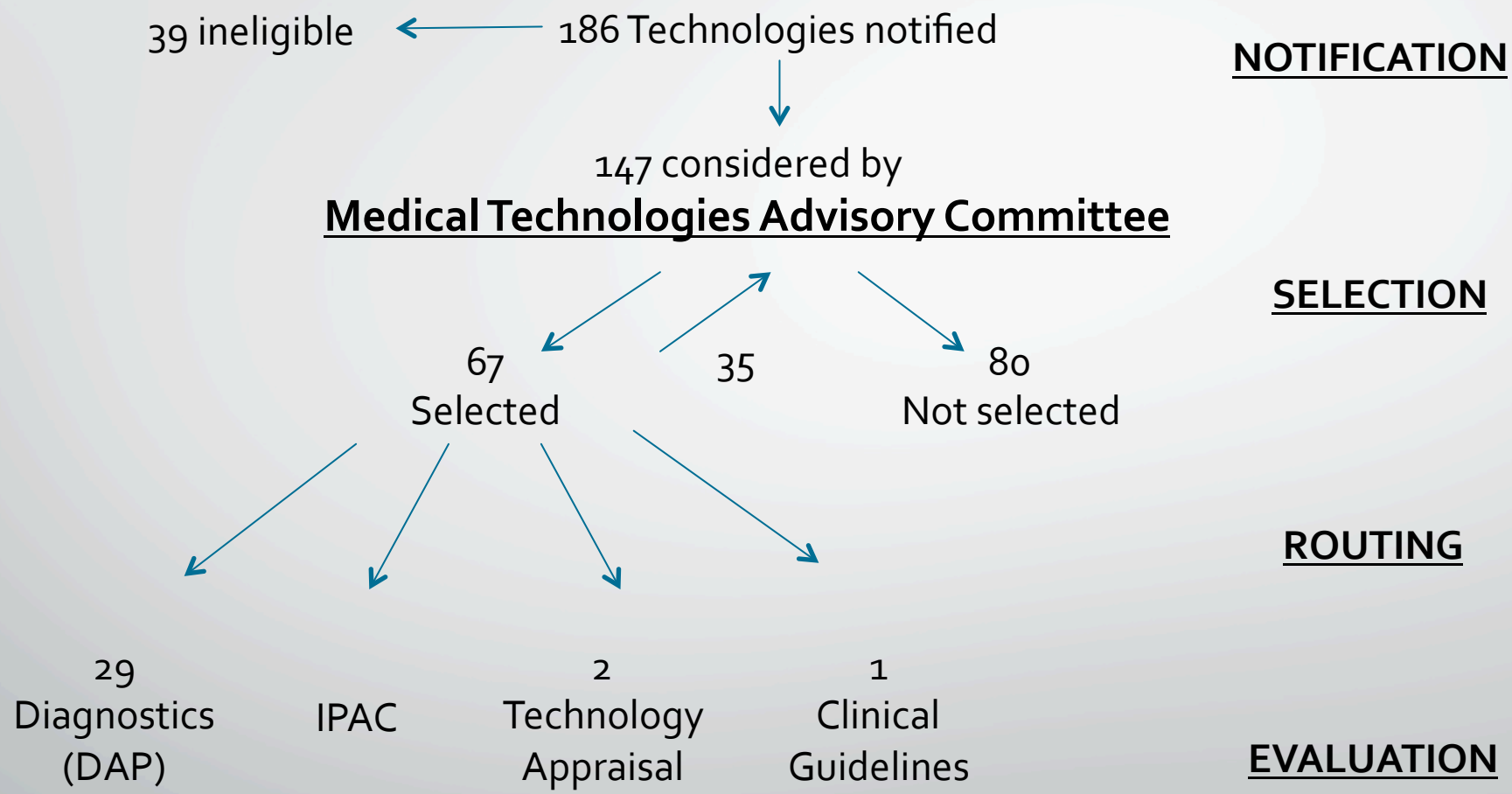
What do decision makers need to know about new technologies?



NICE medtech value proposition options

Clinical performance	Better		Non-inferior
Cost	Higher		Less overall
Evaluation method	Cost effectiveness (QALY)		Cost consequences
NICE guidance programme	Technology Appraisals Programme (TAP)	Diagnostics Assessment Programme (DAP)	Medical Technologies Evaluation Programme (MTEP)
Technologies	✓ Devices	✓ Diagnostics	✓ Devices ✓ Diagnostics

NICE Medtech Assessment of Innovative Technologies
Dec '09 – Nov '14



Campbell et al 2016 In Press

NICE Medtech Evaluation

- Scoping
- Manufacturer submission
  - Clinical evidence
  - Cost modelling
- External Assessment Centre
  - Independent expert academic group
  - Assessment report
- MTAC draft guidance
- Public consultation

MTEP AND COST ANALYSIS

- Cost and resource consequences
- Comparative analysis vs standard NHS care
- Cost of the technology (acquisition, use and maintenance)
- Cost of healthcare use and outcomes
- Appropriate time horizon
- Uncertainty analysis

NICE Medical Technology Guidance

- Can the case for adoption be supported?
  - Quality and quantity of evidence
  - Plausible promise
- What are the advantages to patients?
  - Defined benefits
  - Defined indications
- What are the advantages to the system?
  - Cost consequences
- Is further research recommended?

Research Recommendations
MTEP

- Case for adoption not fully supported but potential to provide substantial benefits to patients and/or system
- Uncertainty about whether potential benefits are realizable in normal clinical settings
- Evidence gaps and research questions explicitly stated
- Must not preclude innovation but support wider adoption
- After guidance publication, NICE works with academic partners, industry, clinical researchers to design and manage further studies
- Timely to support guidance review

Conclusions

- NICE supports the adoption of safe and effective medical procedures (IPAC) and innovative medical technologies (MTAC)
- Patient safety is paramount and is a fundamental consideration in NICE evaluations
- Please consider notification of innovative technologies to MTEP that have the potential for patient and system benefits