NICE National Institute for Health and Care Excellence

NICE's approach to the development of guidance for medical devices and diagnostics

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About NICE

The National Institute for Health and Care Excellence

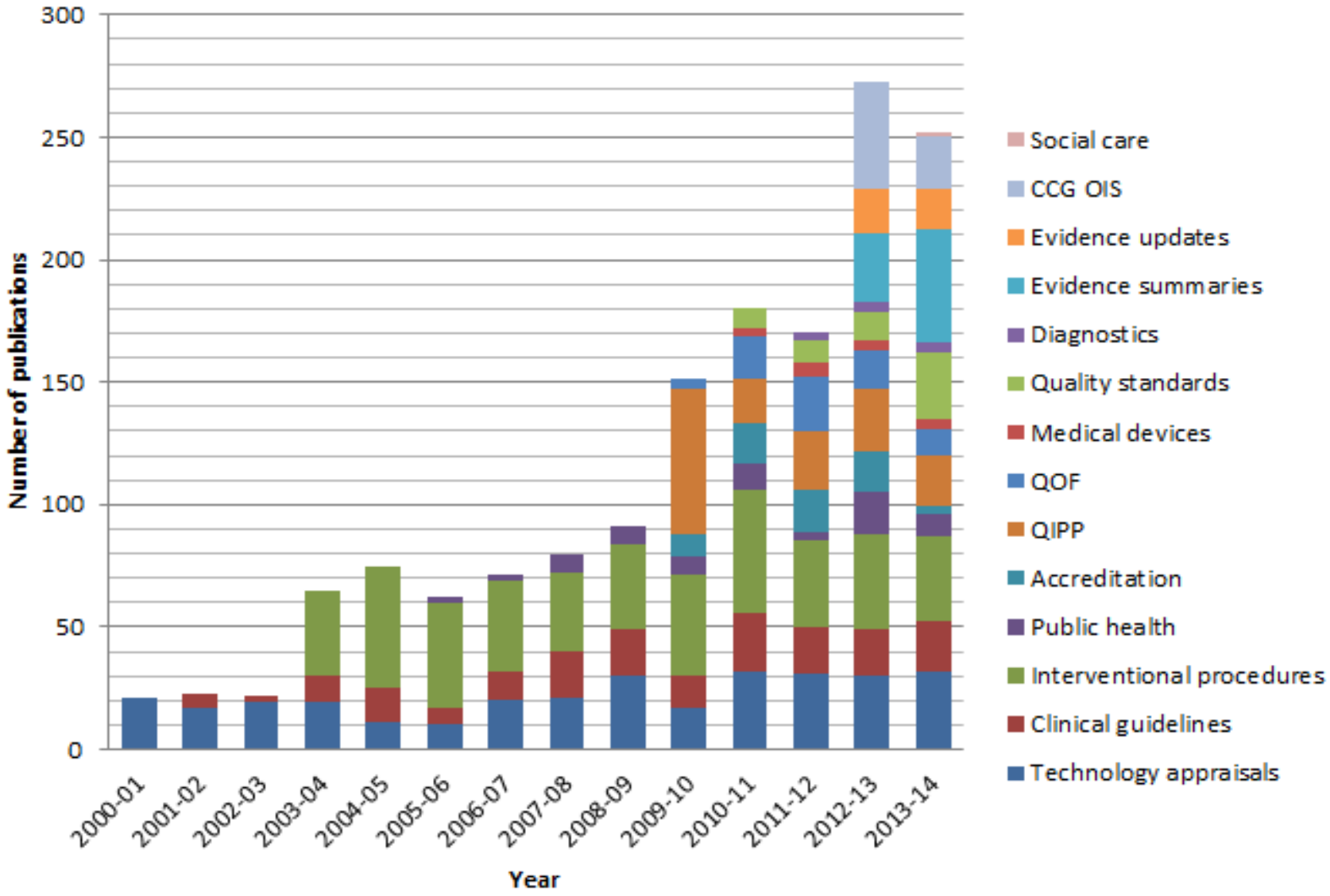
- Established in 1999 to reduce variation in the availability and quality of NHS treatments and care
- Enacted in legislation in 2012
- Run by an independent board appointed by public advertisement
- Decisions and outputs independent of government
- Offices in London (~200 staff) and Manchester (~400 staff)

NICE National Institute for Health and Care Excellence

NICE

Improving outcomes for people

NICE over time



NICE medical technology evaluation programme

Background, methods & process

Background to MTEP

- Medical Technologies Evaluation Programme (MTEP) established in 2009
- Selects and evaluates new or innovative medical technologies (including devices and diagnostics).
- Aim to help the NHS adopt efficient and cost effective medical devices and diagnostics more rapidly and consistently.
- Use of appropriate methodology

MTEP methodology
Notification and selection

Method	Rationale
Innovators notify directly to NICE	The medtech industry is large and diverse with a high output of innovative products
Products which are novel but not new can be notified if: • they have plausible claimed benefits • they are not being routinely adopted	Innovative products may be slowly and/or unevenly adopted
The case for adoption drives the initial assessment	Medical technologies often have benefits when used in place of or addition to standard care
Short timelines: • 10 weeks from notification to selection • 38 weeks from selection to guidance development	Medical technologies evolve at a rapid pace

Process overview

Notification and selection

Notification

- Company notifies technology

Criteria met

- Notification reviewed against eligibility criteria

Selection & routing

- Independent advisory committee selects technologies for guidance
- Routes technology to appropriate programme at NICE

10 week process

Eligibility and selection criteria

Eligibility	Selection
Timing	Patient bene
New or novel	System
Suitable for evaluation	Di
	Cost rations
	Sustainability

Plausible promise

Ineligible or not-selected topics are returned to the sponsor with a summary of the Committee's considerations

MTEP methodology
Guidance development

Method	Rationale
All forms of evidence are considered • Can generate evidence	Medtech has a relatively sparse evidence base compared to pharma
Consideration given to: • System benefits • Patient benefits • Sustainability	Medical technologies are often claimed to be resource-releasing and more convenient.
Access to world-leading technical expertise	Technical considerations can significant influence clinical utility
Specific focus on products that are resource releasing • primary economic methodology is cost-consequences analysis	Improving the efficiency of health services is a top policy priority

MTEP methodology
Value proposition

Performance	Better		Non inferior
Cost	Higher		Less overall
Evaluation method	Cost effectiveness (QALY)		Cost consequences
Technologies	Devices	Diagnostics	Devices or Diagnostics
NICE programme	Technology Appraisals (TA)	Diagnostics Assessment Programme (DAP)	Medical Technologies Evaluation Programme (MTEP)

MTEP methodology
Cost consequence analysis

- Expectation technology is therapeutically near equivalent to comparator
- Costs and resource consequences of the technology as well as relevant clinical benefits
- Not required: valuation of patient health status or treatment preferences

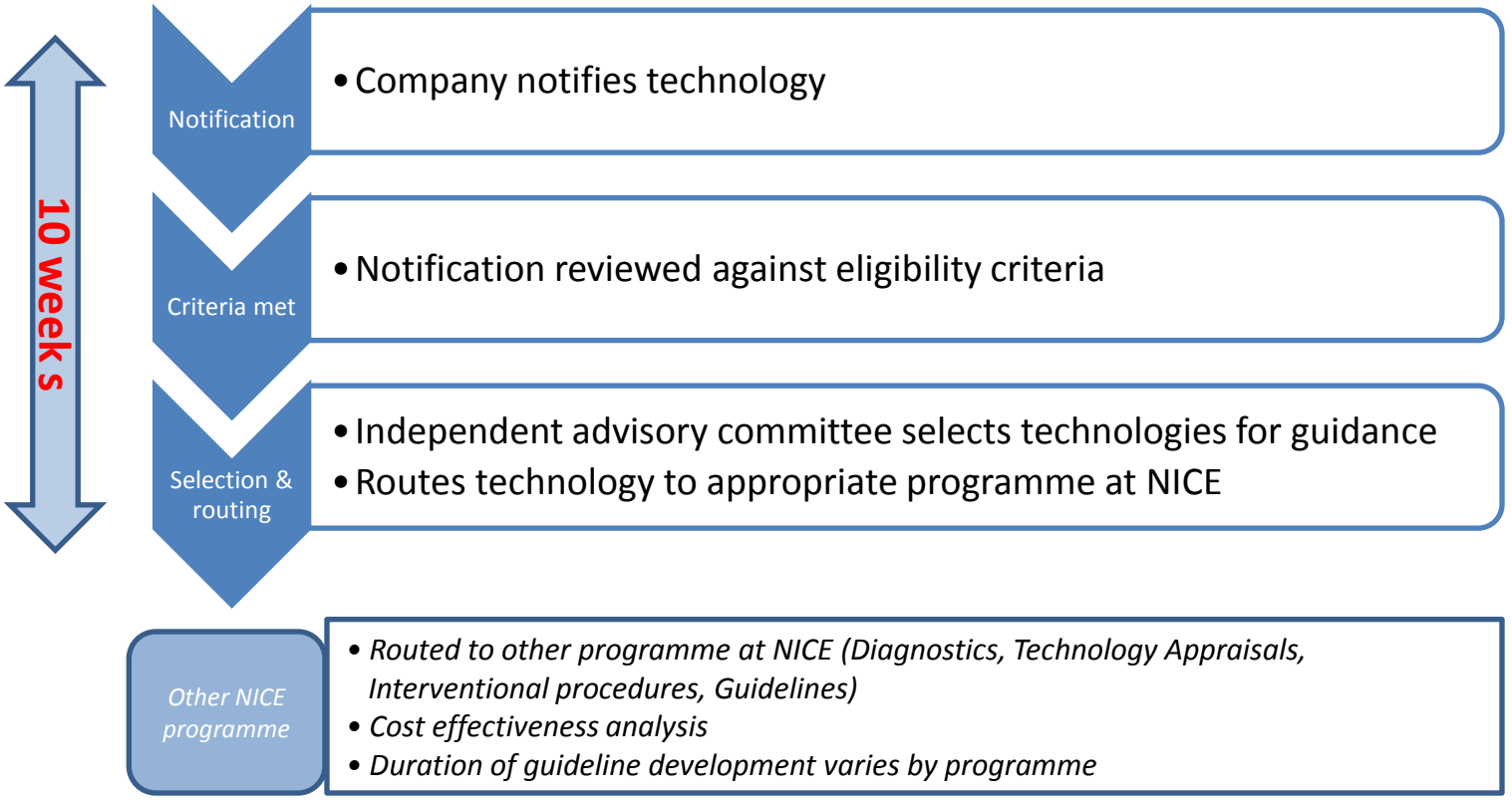
MTEP methodology
Cost consequence analysis

Cost model - examples

Acquisition costs	System savings (eg change in setting)
Running costs eg disposables or concomitant treatment	Reduced costs of improved health outcomes
Staffing costs	Improved ease of use or patient acceptability

Process overview

Process overview



NICE medical technology evaluation programme

Evidence

What evidence does NICE use?

Evidence considerations

- MTEP methodology requires manufacturers to submit evidence, including an economic model
- The evidence should demonstrate:
  - Equivalent or superior clinical performance compared to current standard clinical care – the comparator
  - NHS cost savings (which may occur anywhere in the care pathway)
- The evidence may be based on:
  - Systematic review of the clinical and economic evidence with appropriate meta-analyses
  - De novo cost analysis (where needed)
  - Clinical and technical expert advice
- The submitted evidence is reviewed by an independent external assessment centre

Evidence considerations

- All relevant evidence; No design/quality thresholds
  - Published and in-press trials (academic/commercial in confidence)
  - Unpublished data
  - Regulatory data
  - Post-market register data, audits and ‘real-life’ experience
  - Forthcoming trial results
  - Planned trials in a reasonable timeframe
- Evidence is submitted by the company – Cost model
- Expert advice – clinical/patient

MTG recommendations

- Case for adoption supported (fully, partly or not)
  - Recommendation for use
  - Recommendation for use in specific circumstances +/- further research
  - Recommendation for use in research
  - Case for adoption not supported

NICE medical technology guidance addresses specific technologies notified to NICE by manufacturers. The ‘case for adoption’ is based on the claimed advantages of introducing the specific technology compared with current management of the condition. This ‘case’ is reviewed against the evidence submitted and expert advice. If the case for adopting the technology is supported, then the technology has been found to offer advantages to patients and the NHS. The specific recommendations on individual technologies are not intended to limit use of other relevant technologies which may offer similar advantages.

Development of further evidence

- MTEP has a research workstream as an integral part of programme
- Designed to facilitate research to address gaps in evidence which led to research recommendations in MTG or DG
- Work with academic partners, industry, clinical researchers to design and manage further studies
- Flexible approach to research products but must be able to be completed within ~ two years
- Subject to findings and evaluation – updated guidance
- 6 active topics + 2 completed topics

Pomfrett C.J.D, Campbell B, Pugh P.J, Campbell M, Marlow M. Medical Technologies Evaluation II: catalysing the development of primary clinical evidence for promising technologies. HTAI Bilbao 2012

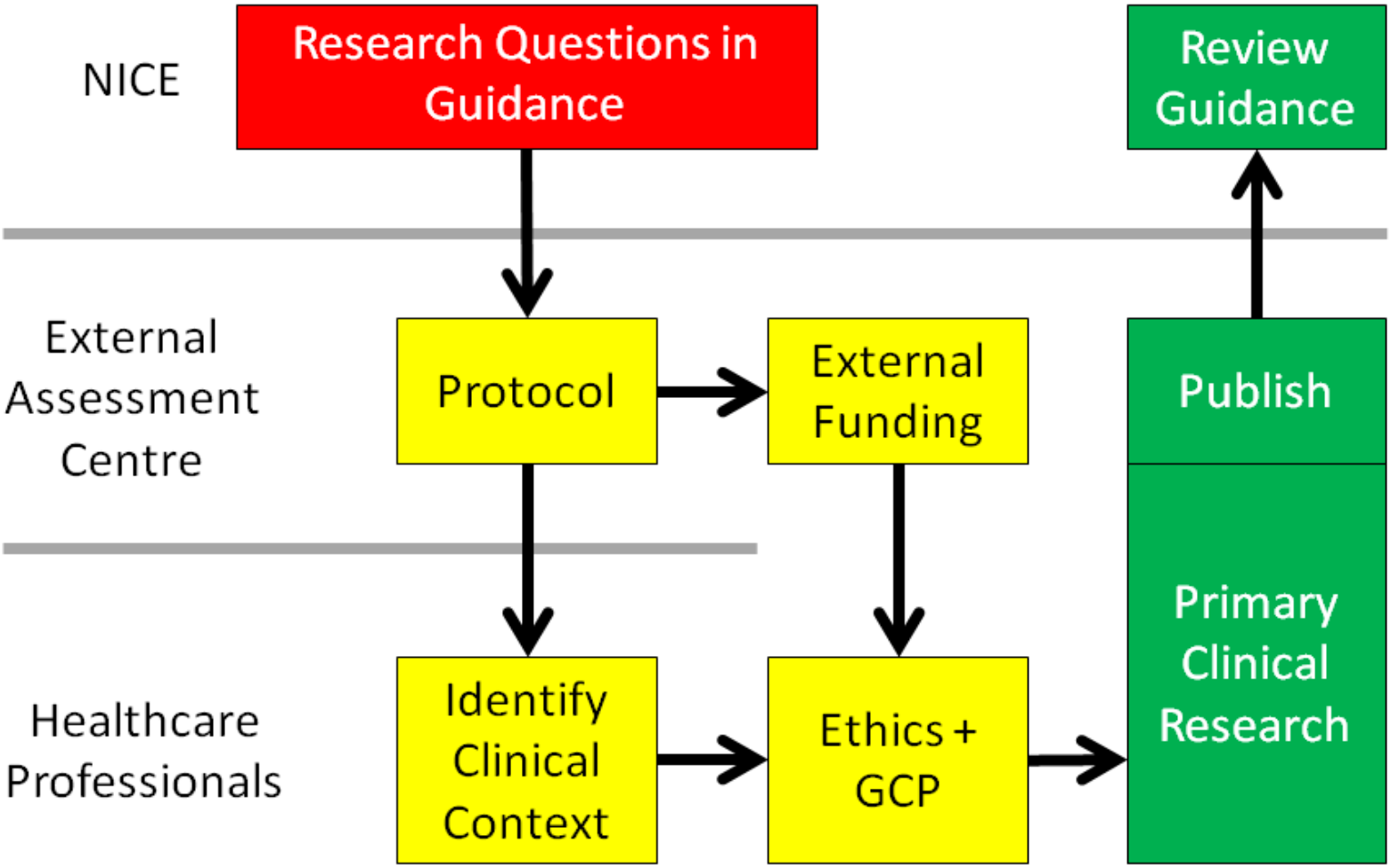


Fig 1. Indirect research facilitation. Yellow stages are facilitated by NICE.

Research facilitation examples

- Medical Technologies Guidance 5: MIST (wound healing therapy)
  - Case for adoption not supported
  - Insufficient evidence to recommend MIST, but does have potential to enhance the healing of chronic, 'hard-to-heal', complex wounds, compared with standard methods of wound management.
  - Recommendation for further research
  - Pragmatic randomised controlled trial of MIST ultrasound therapy compared to UK standard care for the treatment of non-healing venous leg ulcers.
  - Trial results do not support the technology

Research facilitation examples

- Diagnostics Guidance 5: SonoVue (contrast enhanced ultrasound) for liver imaging
  - SonoVue recommended for use in adults in whom an unenhanced ultrasound scan is inconclusive
  - Submitted evidence estimated that 43% of ultrasound scans are inconclusive, but committee lacked confidence in the evidence due to issues with the methods, technology and population used in the evidence
  - Further research also recommended, as committee were uncertain about the percentage of unenhanced inconclusive scans
  - Retrospective audit of Radiology Information System
  - Results show that unenhanced ultrasound are frequently inconclusive
  - Supports use of SonoVue

Example of outputs

March 2015

Output	Activity
Medical technologies guidance • Published • In development	 24 5
Diagnostics guidance • Published • In development	 16 9

Common problems and potential solutions

Common problem	Solution
Evidence doesn't match the claim	Be clear about best possible application of product before commissioning study
Lack of clarity about the product's position in care pathway	Talk to UK-based clinicians about how they might use the product and how it would change treatment
Unrealistic view of potential savings	Understand current treatment and availability – don't assume a more expensive comparator is widely used
Not enough evidence to support the case for adoption	Share all possible sources of data with NICE – post-market, audit, unpublished

Find out more, get in touch

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