Assessment of medical devices for the National Institute for Health and Care Excellence (NICE)

Carole Cummins, Rui Duarte, George Bramley, Zulian Liu, Laurence Blake
University of Birmingham
Background

- NICE Medical Technologies Evaluation Panel requires that medical devices should be cost saving or resource releasing to be recommended for use in the NHS.
- Health technology assessment (HTA) ion of a medical device can be impeded by inappropriate evidence and faulty understanding of its place in the care pathway.
- We aim to explore issues that have arisen in NICE’s evaluations to date.
Context: the medical devices industry: the NHS and wider economy

- Government working groups have identified perceived benefits to the NHS, industry and wider economy from appropriate and early adoption medical technologies.
- The Accelerated Access Review specifies benefits as:
  - patients will have access sooner to more effective and affordable innovative treatments and achieve better health
  - businesses will benefit as a result of more joined up development pathways
  - stimulation of new investment, jobs and economic growth
Context: features of the medical devices industry impacting on HTA

- 99% Small and medium-sized enterprises (SMEs)
- Short production development cycle
- Shorter product life cycle (~18 months)
- Incremental innovation
- Limited research spend
- No extended patent protection
- Health value proposition generally based on costs and resource use

NICE MedTech HTA reflects this context:
…emphasis on early evaluation, early guidance review, expectation of evidence of resource savings

(Chapman 2014)
The Medical Technologies Advisory Committee (MTAC) selects medical devices/diagnostics and *routes* to the appropriate NICE guidance producing programme.

- Diagnostics Assessment Programme
- Technology Appraisal programme
- Interventional Procedures
- The NICE guideline programme
  - Medical Technologies Programme

*Also* NICE Medical Innovation Briefings: information not guidance.

*Cost saving or resource releasing?*
- Manufacturer submission
- External assessment
- Draft guidance from Committee
- Final guidance after public consultation
Methods:

- Evidence underpinning NICE Medical Technologies Guidance and Medical Innovation Briefings will reviewed to characterise limitations with examples

- Implications will be considered
  - for the NICE appraisal process
  - for NICE’s decision-making
  - for realising the potential benefits from medical technology innovation for patients, the NHS and the economy
Examples: available clinical evidence

- Debrisoft monofilament pad for wound debridement
  - Evidence: 15 multiple-patient case-series reports (10 posters), some with retrospective comparators
  - Guidance Recommendation: supported by evidence, estimated to be cost saving

- Parafricta bootees and undergarments to reduce the development of pressure ulcers
  - Evidence: 4 published multiple-patient case-series (3 peer-reviewed papers, 1 with historical controls)
  - Recommendation: more evidence needed, research recommended
Examples: evidence for resource release

- GreenLight XPS for treating benign prostatic hyperplasia
  - clinical evidence from a high quality non-inferiority trial randomised control trial
  - compared to TURP new laser with reduced bleeding produces cost savings in the treatment of men with prostatic hyperplasia
- Cost savings would required service change to facilitate day case surgery
- Feasibility of service change assessed using expert opinion in the absence of RCT evidence
- Guidance: hospitals adopting GreenLight XPS should plan for service redesign
Example: evidence on key outcomes

- Ambu aScope2 (single use intubating fibroscope) for use in unexpected difficult airways
- Limited evidence on equivalent intubation outcomes to multiuse fibroscope
- Safety outcomes (death, brain damage) modelled using modelled scope availability, audit incident reports and medico-legal costs
- Guidance recommendation: use supported
Example: evidence for complex change

- Medical Innovation Briefing: iStat point of care blood testing for use in the emergency department
  - Potential to reduce waits/overcrowding in the ED if used in redesigned service pathway
  - Evidence: 2 single centre pilots before and after service change
  - Evidence requirement: multicentre controlled studies of complex intervention (Cochrane EPOC group)

- Potentially transformational technologies may require care pathway changes in the context of a complex intervention
Key finding: evidence generation

- Evidence used in the appraisal of medical devices may be of poor quality in terms of methodology, execution and reporting, and may not address any identifiable clinical question.
- Poor quality evidence is related to:
  - Lack of understanding product value propositions in the NHS context.
  - Limited industry resource and capacity.
- Consequently guidance decisions may be made in the absence of strong evidence.
Key finding: value proposition

- Problems arising in NICE’s appraisal of medical technologies often arise from lack of manufacturer understanding of the value proposition
  - Value proposition: a clear and credible set of relevant claims capable being evidenced that provide value to healthcare providers and users …our definition

- This often results in:
  - a mismatch between manufacturer commissioned research and accepted standards for clinical evidence
  - research which does not address questions relevant to NHS needs
Key finding: complexity

- Some medical technologies are cost saving and resource releasing only in the context of wider service redesign.
- Evidence generation may therefore be complex and expensive.
- Safety value propositions predicated on preventing very rare events may present particular difficulties.
- This may present barriers to appraisal of promising technologies using the MTEP Methods and Process as evidence may be lacking.
- NICE however published Interim methods guide for developing service guidance in 2014 potentially providing a route for NICE to consider service change.
Conclusion

- Methods to develop NICE advice and guidance are potentially robust but decision-makers may have only poor quality evidence on which to make decisions.

- Industry response to NICE model often shows poor understanding of:
  - value to the NHS
  - clinical evidence
  - Cost consequence analysis data requirements (comparative data, full costs)

- This response reflects industry characteristics (company size, R and D resource, product development cycle and marketing) and potential return on investment
Conclusion continued

- In the context of social decision making paradigm underpinning NICE’s process, positive guidance may be issued without such evidence.
- The risks attached to such guidance may be partially mitigated by research recommendations and a commitment to guidance updates.
Conclusion continued

- Technological change has the potential to improve NHS efficiency,
  - but realisation of savings may require transformational change to care pathways
  - Medical devices may be part of a complex intervention
  - In such cases, research evidence is problematic, multicentre controlled studies of complex interventions may be required

- Assessment of service delivery rather than an individual technology may be a way forward
Conclusion continued

- The NICE process is best suited for products with adequate evidence
  - appropriate product selection by NICE is a key factor
- To realise potential benefits to the NHS and wider economy of NICE’s MedTech process a shared understanding between the NHS and industry is needed of:
  - value propositions in the health context
  - clinical and economic evidence requirements
- This requires knowledge transfer and capacity building, including infrastructure development, tools and targeted consultancy/industry support
Acknowledgements

- Carole Cummins is the Director of the Birmingham and Brunel External Assessment Centre and receives funding from NICE for the EAC
- Rui Duarte, George Bramley, Zulian Liu, Laurence Blake are part of the BBC EAC
- The views expressed are the authors’ own