Payer perspective: The payers' role in promoting research and innovation

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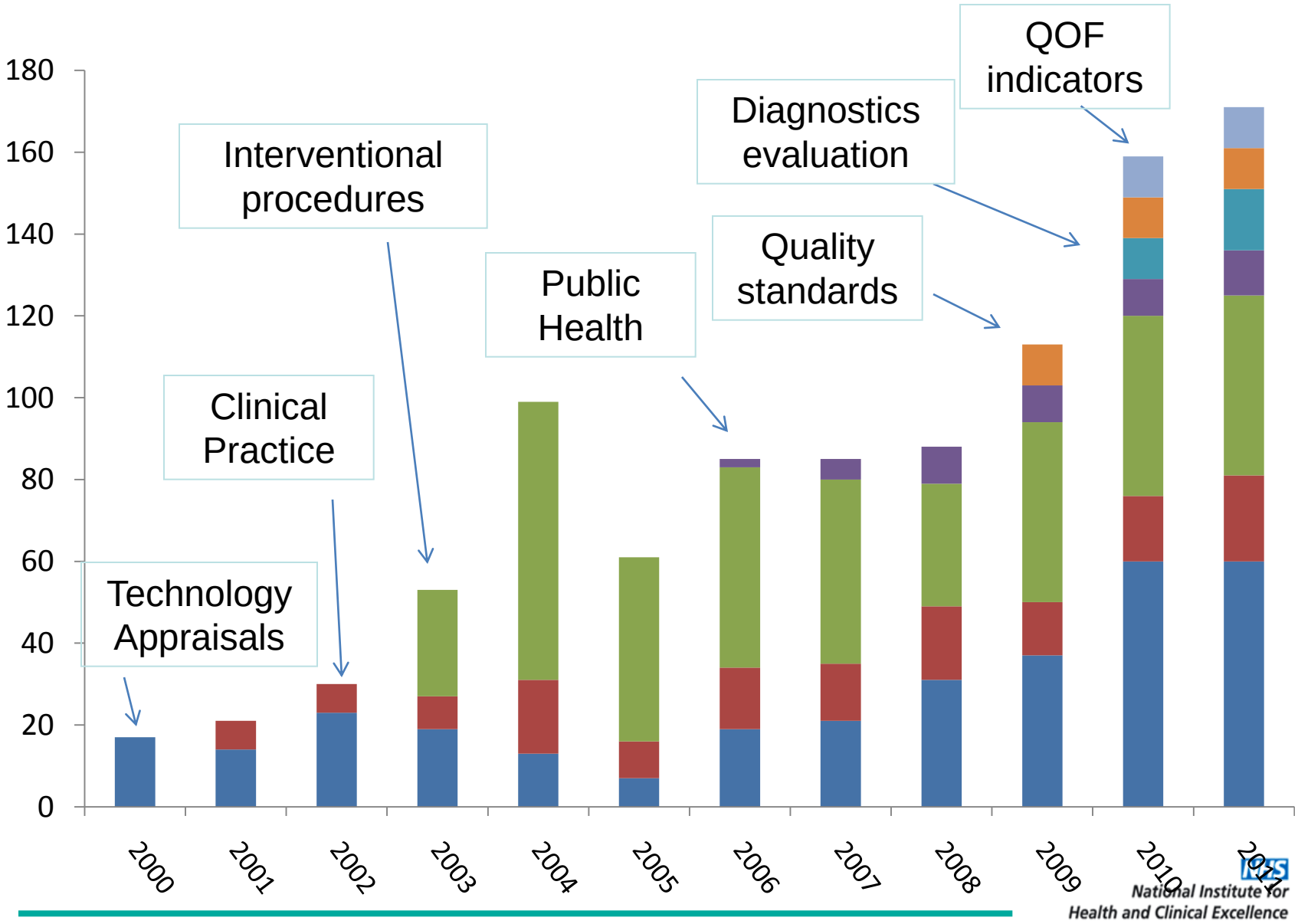
Technology Appraisals NICE

NHS
National Institute for
Health and Clinical Excellence

NICE guidance over the years



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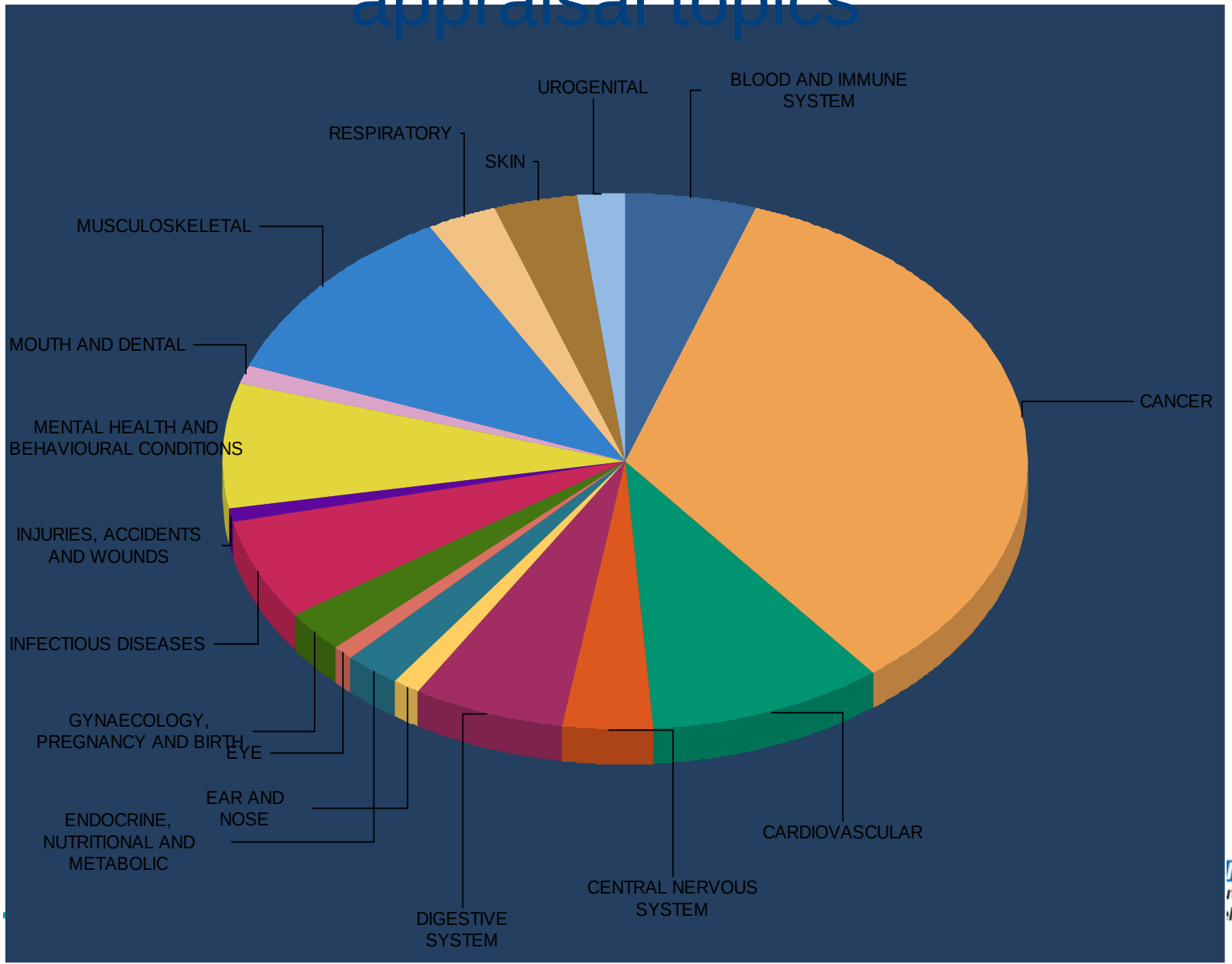
Therapeutic areas in technology appraisal topics

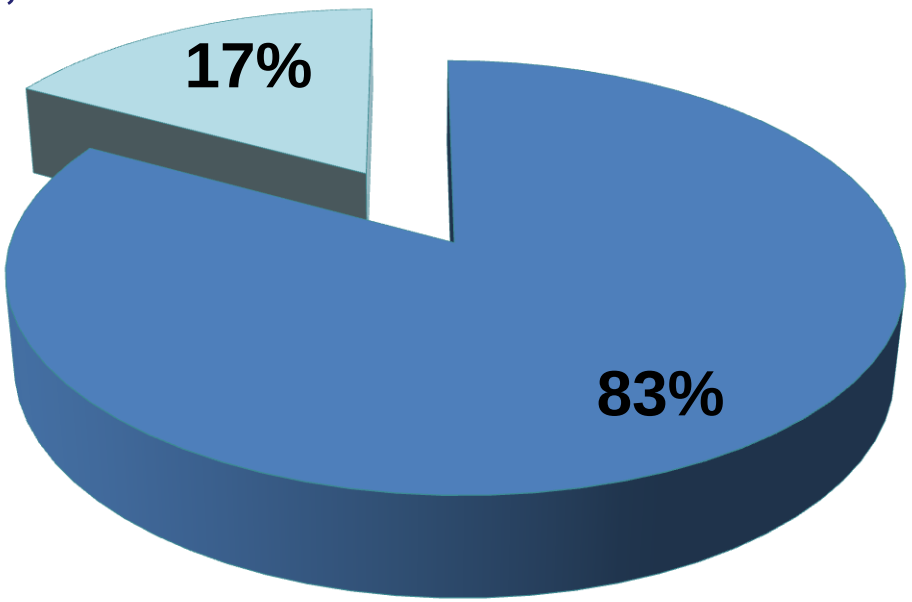


Breakdown of appraisal recommendations

213 appraisals published up to Jan 2011

421 individual decisions

‘no’ or
‘only in research’



recommended for routine use
or under specific circumstances

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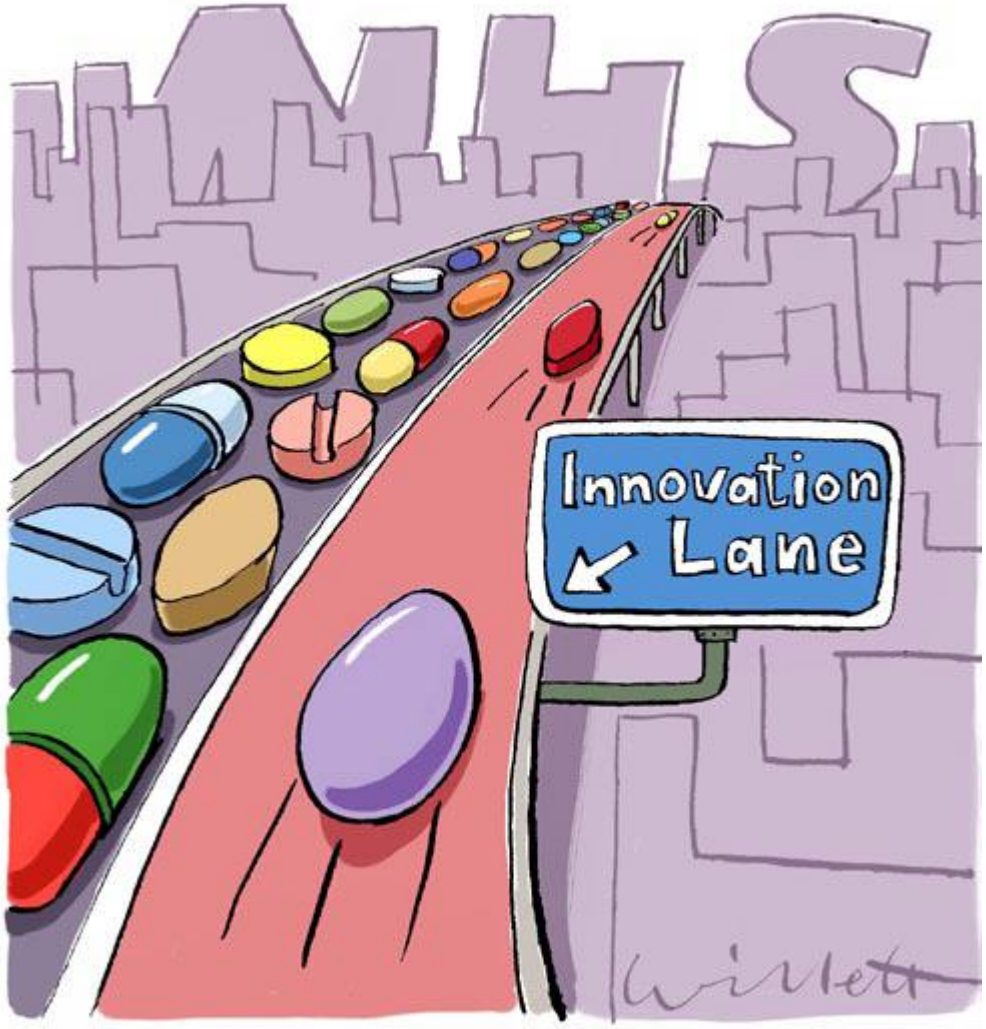
Research recommendations

- 6% of decisions: ‘only in research’
  - *‘… not recommended except in the context of a clinical trial ‘*
  - *‘…recommended only as part of a research study‘*
- Methods guide 6.2.12: “Recommendations on the use of technologies only in the context of research will not include consideration of which organisation (public or private) will fund the research”
- Responsibility to fund any research does not automatically fall on the NHS
- Liaison with NIHR

NICE-related Medical Research Council projects

- Widening the spectrum of health outcomes used in health technology assessment: integrated synthesis and mapping to QALYs [**Ades**]
- Use of generic and condition-specific measures in NICE decision-making [**Longworth**]
- Preparatory study for the re-evaluation of the EQ-5D tariff [**Tsuchiya**]
- Properties of statistical methods for indirect and mixed treatment comparison - a computer simulation evaluation [**Song**]
- Methodological search filter performance: assessment to improve efficiency of evidence information retrieval [**Lefebvre**]
- Methods to estimate the NICE cost-effectiveness threshold [**Sculpher**]
- Methods for the Indirect estimation of health state utilities [**McCabe]**



Ferner R., Hughes D. and Aronson J. 'NICE and new: appraising innovation' BMJ 2010; 340: 245-247.

"different ways of doing things which bring improved outcomes" (Cooksey)

"new, constitutes an improvement on existing products , step-change" (Kennedy)

"…a plausible gain of at least 1 QALY would be a reasonable threshold for judging the usefulness of a supposedly innovative technology…" (Ferner et al, 2010)

"…..whether a new medicine represented a significant improvement relative to existing treatments..." (DH Consultation Paper on VBP)

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How much improvement do new medicines bring?

- Analysis carried out by Prof Ken Peterson and colleagues at the Scottish Medicines Consortium
- Gains in quality adjusted life years taken from manufacturer's submissions to the SMC
- 256 medicines reviewed between 2002 and 2009
- HTAi 2010, ISPOR 2010

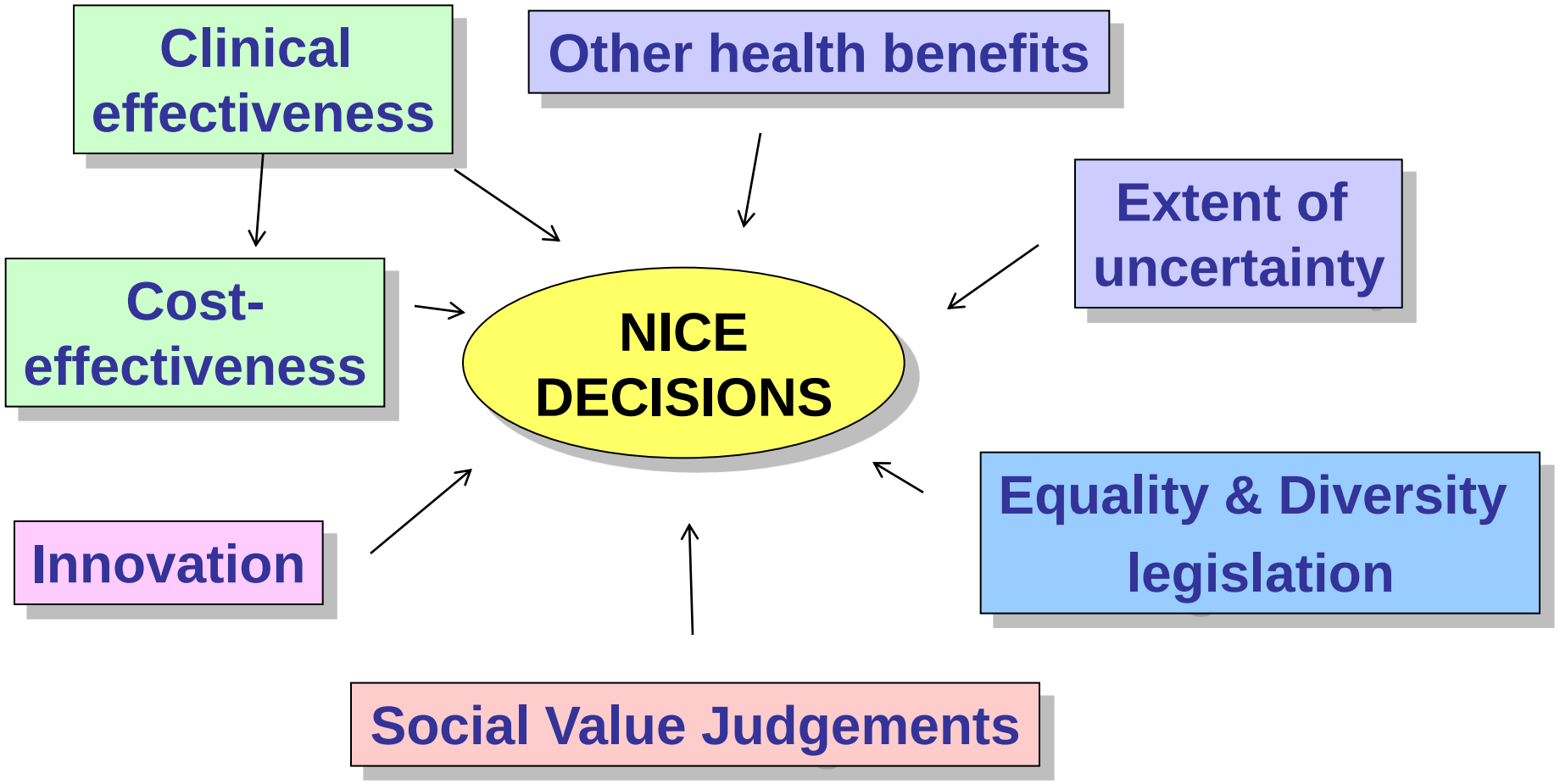
Guide to the Methods of Technology Appraisal (2008)

6.1.3 "….. the Institute is expected to take into account .....the potential for long-term benefits to the NHS of innovation. "

6.2.23:

- "Above a most plausible ICER of £20,000 per QALY gained, judgements about the acceptability of the technology as an effective use of NHS resources will specifically take account of the following factors.
  - .....
  - The innovative nature of the technology, specifically if the innovation adds demonstrable and distinctive benefits of a substantial nature which may not have been adequately captured in the QALY measure.

Making the decision



Appraising life-extending, end of life treatments 2009 Supplementary Advice

- Permits and encourages a positive use of discretion where otherwise a positive recommendation would very probably not be made
- Assessed by magnitude of the additional weight placed on the QALY benefits
- Criteria
  - Patients have a short life expectancy (<24months)
  - Life extension (at least 3 months)
  - Small patient population
  - Robust evidence and plausible assumptions

….the meaning of the ‘small patient population’ criterion…

- Recognises that treatments developed for small patient populations often have higher prices (and therefore reduced cost effectiveness)
- Higher prices are more likely to be justified given the need to recoup costs for the development of a technology with a more limited marketing authorisation
- Encourage the development of treatments for small populations

Application of the ‘end-of-life medicines’ advice

Total technologies appraised	**67**
End-of life criteria considered	17
All criteria met	10
Recommended	7

Kennedy study on Innovation (2009)

- What approach should NICE adopt to ensure that innovation is properly taken into account.
- Stakeholder submissions, workshops, report
- *'.....Where innovation becomes important is when Pharma states that a product*
    - *is new*
    - *constitutes an improvement on existing products*
    - *offers something more: a step-change in terms of outcomes for patients'*
- Innovation = potential to make a significant and substantial impact on health-related benefits

NICE response to Kennedy's report

- Amended our processes to
  - To ensure that all health-related benefits are captured
  - To explore if all health-related benefits have been taken into account in the QALY calculation and if not, how these were evaluated.
- Additional specific questions during scoping and the appraisal
- Questions introduced early in 2010

How often was the technology associated with a possible step change?

30 published appraisals or consultation documents

9 possibly innovation or step change

Examples:

- Less frequent dosing than with current care and better adherence
- Targeted treatment for a patient group with a particular genetic marker, therefore increasing the likelihood of response to treatment.
- No alternative treatment available
- Different side effect profile/ no side effects compared with current care

How often were the HR-benefits not captured in the QALY?

30 published appraisals or consultation documents

↓

7 Some HR-benefits not captured in the QALY

↙ ↘

2
Impact on decision

HR-benefits of reduced hospital visits in last year of life
HR- benefits of delaying toxic chemotherapy

5
No impact on decision

(changing utility values had little effect on ICERs)

How often is a technology flagged as innovative by the manufacturer during scoping?

28 topics

8 potential innovation as described by manufacturer

7 data identified by manufacturer

Weights for therapeutic innovation and improvement

- Value of innovation *per se*
- Social weights/ adjustments
- Does this incentivise innovation?
- Social valuation studies of other factors not conclusive

Conclusions

- Innovation is seen with new health technologies
  - ➢ but not very often
- Changes made to explicitly address innovation
  - Eliciting input from stakeholders/ manufacturers
  - Part of Committee considerations
  - Useful information about what is seen as innovation associated with new technologies
  - Valuable experience for any future work on capturing the value of new innovative medicines