NICE methods review: Modifiers in HTA decision-making

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ISPOR 2021: When is a QALY not a QALY? Challenges in introducing and applying modifiers in HTA decision-making

NICE National Institute for Health and Care Excellence
The voluntary scheme for branded medicines pricing and access in England:
The voluntary scheme commits us to reviewing our methods for technology appraisals and highly specialised technologies. We’ve extended this exercise to include the methods and processes of the Medical Technologies Evaluation Programme and the Diagnostics Assessment Programme.

Future proofing
NICE’s HTA programme must continuously pursue excellence in the application of new methods and reflect technological innovation – to ensure the right access, for the right patients, at the right value

The regulatory landscape is changing
As the UK regulatory and access environment evolves, it is important to clearly show how NICE’s methods can support early patient access to valuable health technologies

Post-EU exit
We want to ensure the UK remains a destination of choice for the life sciences sector
Methods review – modifiers

Stage 1
• What are the relevant modifiers for decision-making?

Stage 2
• How should modifiers be applied in decision-making?
A factor is considered a modifier if:

- It has not been included in the QALY because it cannot be, i.e., issues that go over and above the QALY calculation → technical "adjustment"
- Value judgements

A factor is NOT considered a modifier if it has not been included in the ICER/QALY but should have been → technical correction
Opportunity cost and moral case

**QALY = QALY = QALY**

**A deviation/modifiers means**

- Some characteristics/populations valued more and others less
- There needs to be a moral and ethical reflection supported by reason, coherence and available evidence.
Factors to take into account in decision making (current methods guide)
Reviewing the evidence

Scientific, economic and methodological evidence
→ NICE’s objectives and principles: commitments to patients, the NHS and industry
→ Legislative and policy commitments
→ Ethical and legal duties to equalities and human rights
There seems to be a moral case to place a higher value on the life of the patients with terminal conditions. However, these extensions of life should be replaced by or accompanied by improvements in quality of life. This would prevent prioritising specific conditions (such as cancer) versus others.

Evidence supporting severity as an important value element

No moral case

Innovation important to prioritise, but no evidence that society values health benefits more highly than equivalent benefits from less innovative interventions

Clear case to amend, because of challenges of interpretation of the current method
Modifiers: case for change (2)

Health inequalities

- Case for considering, where a technology has the potential to give important benefits to disadvantaged groups that are not otherwise captured (e.g. in the QALY, severity modifier)
- Consistent finding that members of the general population would be willing to trade total (QA)LYs to reduce inequity in the social distribution of (QA)LYs

Uncertainty

- No moral case
- Fundamental aspect of committee’s decision-making
- Committees should retain flexibility to consider higher degrees of uncertainty for specific situations including:
  - Conditions or technologies where it is recognised that evidence generation is complex and difficult e.g. rare diseases or children
  - Innovative or complex technologies
Modifiers: case for change (3)

Children

• NICE Citizen’s Council and Social Value Judgements do not support additional weight by age
• Evidence not sufficient to support a case for change now – further research needed but higher degrees of uncertainty accepted for technologies indicated in children

Rarity

• There may be a moral and ethical justification for applying a greater weight where there is an unmet need or health inequality arising from the fact a disease is rare
• Evidence does not support an application of modifier
• Other decision-making modifiers should consider whether any additional adaptation or weighting should be applied/is needed if a disease is also rare. → higher degrees of uncertainty
Proposed factors to take into account in decision making

- Clinical effectiveness
- Cost effectiveness
- Uncaptured benefits
- Non-health benefits
- Severity of the condition
- Uncertainty: - Rarity - Children - Innovative or complex
- Health inequalities

NICE
From case for change to draft manual

- Review consultation response
- Developing the manual and structured decision-making framework
- Realising the benefits
- Draft programme manual: consultation, review and finalisation

NICE

Process review
What happens next?

Methods consultation: Completed December 2020

Second stage: January - December 2021
- Case for change for process consultation (Feb-Apr)
- The how: from case for change to programme manual (Ongoing)
- Consultation on unified manual (July-Aug)

Publication and implementation: December 2021 onward

Thank you.

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