Consideration of value in cost per QALY decision-making – an Extended Value Appraisal proposal

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Introduction

- Cost per QALY is often used as a key decision-making criterion in HTA.
- There are known limitations to the QALY and the value it can capture that is relevant to patients, the NHS and society.
- Without a decision-making framework that can incorporate other value elements in a consistent and transparent way, the broader value of medicines can be systematically under-estimated.

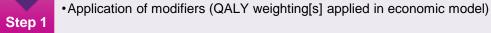
Methods

- Review of work under-taken and reported on during NICE's value-based assessment consultation in 2014 which explored NICE taking account of 'burden of illness' and 'wider societal impact' more explicitly and systematically.
- Targeted literature review to understand the theoretical arguments and empirical evidence that supports the inclusion of the value elements in the proposal.
- Review of global HTA approaches and whether the value elements are considered by other HTA bodies internationally.
- Patient Organisation workshops to review and agree value element definitions and prioritise value elements from a patient perspective.
- Ongoing engagement with ABPI's members to develop an extended value appraisal proposal – an industry position on evolving cost per QALY decision-making frameworks in HTA.

Results

- In considering how value elements (Figure 1) can be consistently captured within decision-making frameworks without introducing undue complexity and retaining room to exercise judgement, we propose two 'modifiers' defined as quantifiable adjustments to the QALY (implemented through QALY weightings) to provide additional weight in decision-making to the value captured within the QALY:
 - 1. Severity there is strong evidence to support a modifier that accounts for severity of disease in terms of quantity and quality of life lost.
 - 2. Rarity a modifier that recognises rarity could help support better access to rare disease medicines.
- The proposed modifiers are incorporated alongside explicit 'value judgements', which are defined as deliberative factors that are considered to account for the value of a technology that cannot be captured within the QALY (Figure 2).

Figure 2: Proposed stepwise approach to HTA decision-making



Consideration of deliberative value judgements

· Consideration of other contextualising factors, e.g. decision risk, uncertainty

•Flexibility in decision-making beyond the ICER to account for significant value not captured by the QALY, as appropriate







Conclusion

Step 2

Decision

- There is scope to include modifiers and deliberative value judgements in cost per QALY centric decision-making frameworks. This approach can provide a structure for decision-making in HTA that is less reliant on the QALY, allowing better realisation of the value medicines provide to patients, their carers and families, the NHS and society.
- When it is not possible to quantify value elements, qualitative/deliberative approaches can be utilised.
- A balance can be struck between appropriate flexibility whilst maintaining transparency of decision-making to stakeholders.

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To view the full Extended Value Appraisal proposal please visit the ABPI $\underline{\text{website}}$ and contact $\underline{\text{vbarrett@abpi.org.uk}}$ for more information