

How have surrogate outcomes been dealt with in existing HTA evaluations by different HTA bodies and what lessons can be learnt?

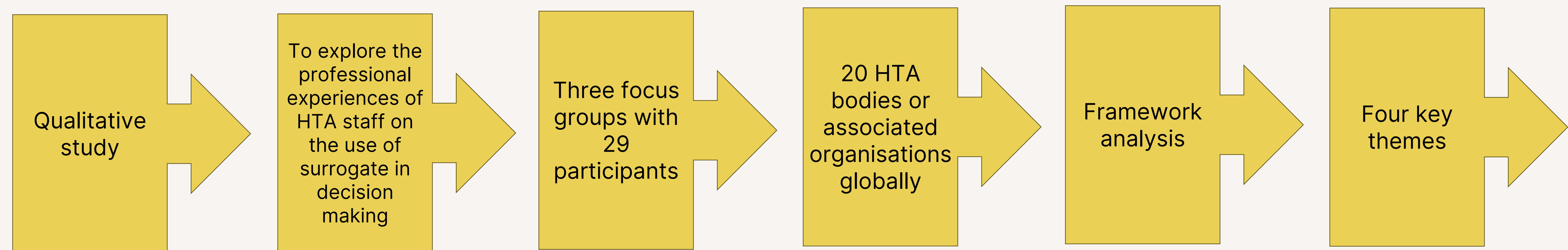
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Background

- Surrogate outcomes pose challenges to health technology assessment (HTA) bodies and payers when used to inform the clinical and cost-effectiveness of technologies
- Some HTA bodies have published methodological guidance on the use and validation of surrogates
- It is not uncommon that decision makers must make recommendations in the absence of well-established evidence on the validation of surrogates

What we did




Key themes




Challenges of using surrogates in economic modelling for HTA

- **Limited guidance** on how to manage surrogates in HTA with economic models often designed around the surrogate
- Evidence and previous decisions made in the same technology, same disease or using same surrogate can be unclear
- **Lack of alignment** in expectations between regulators, HTA bodies and technology developers regarding the level of information required for decision making
- Validation processes are **complex, time consuming and costly**




Experience of using surrogates in economic modelling for HTA

- Lack of standard definition of surrogates
- Surrogates are used in the majority of evaluations



Guidance for use of surrogates in economic modelling to inform HTA decisions

- Guidance needs to
 - Be flexible, adaptable and consistent
 - Outline how to report methods and results transparently
 - Include how to validate surrogacy relationship including methods, presentation and minimum standards
- Consider patient needs and acknowledge scenarios where standards of evidence may be hard to meet (e.g. rare diseases)



Suggested recommendations for future use of surrogates in economic modelling for HTA


- **Transparent reporting** to understand the evidence and uncertainties associated with the use of a surrogate in economic modelling
- **Model conceptualisation, design and structure**
 - Model the disease not the surrogate
 - Facilitate future data relating to surrogacy relationship
 - Allow removal of surrogate to explore its impact
- **Validation of surrogate**
 - Include clinical and patient expertise and real-world evidence where appropriate
 - Review all evidence of surrogacy relationship
- **Assessing uncertainty**
 - Test assumptions in surrogacy relationship using scenario analysis and value of information analysis (if appropriate)

What we learnt

- Decision making using surrogates is a frequent and challenging problem faced by HTA bodies globally
- This work informed a wider project aimed at developing recommendations and considerations for the use of surrogates in economic modelling for HTAs

For further information please visit:

<https://www.nice.org.uk/news/blogs/how-surrogate-outcomes-influence-long-term-health-outcomes>



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