ICER's CLAIMS: QUESTIONS DECISION MAKERS SHOULD ASK

ICER's value assessment framework is intended to support recommendations for pricing and affordability. That means ICER must be held responsible for the credibility of its claims. Without accountability, ICER will continue to make claims that fail the standards of normal science, relying on evidence models and the construction of quality of life claims that are mathematically impossible. Here are some questions that decisionmakers can ask ICER on the relevance of the value assessment framework.

The Pseudoscience Position

Previous Current Issues Reports have made the case that the value assessment framework embraced by the Institute for Clinical and Economic Review (ICER) is an analytical dead end. The framework not only fails to meet the standards of normal science in developing claims that at are credible, evaluable and replicable, but fails at a more basic level in a failure to meet the axioms of fundamental measurement [1].

Measurement is central to both the physical and social sciences. Unless the instruments that are developed actually accommodate the axioms of fundamental measurement, any claims based on those instruments should be rejected. This is where the ICER value assessment framework falls short: it makes assumptions about utilities which are clearly false. Multiplying time spent in a disease state by a utility score from the EQ-5D-3L generic instrument to create a quality adjusted life years (QALYs) is mathematical nonsense because the utility score is an ordinal, multi-attribute manifest score. It cannot be used to multiply time spent. The only scale that can do this is a ratio scale.

Let ICER Respond

Policy and health system decisionmakers need to understand the consequences of taking ICER pricing and access recommendations at face value. Unfortunately, because the technical issues relating to measurement theory and imaginary world modeling methods may be unfamiliar, ICER is not held accountable at all – and until questioned and forced to back up its claims, ICER will continue unopposed.

The questions PAAP proposes decisionmakers should ask ICER before accepting its recommendations are straightforward, and set out in a logical sequence to cover these fundamental issues:

- ICER's commitment to approximate information rather than hypothesis testing
- The impossibility of ever assessing empirically ICER's claims
- ICER's claims are model-specific; alternative models will give other claims
- ICER provides, without definition, "approximate information"

- ICER fails to recognize axioms of fundamental measurement
- ICER applies utilities that are manifest scores and cannot support arithmetic operations
- ICER's QALY is an impossible mathematical construct
- ICER's models are based on assumptions that cannot logically be supported for future events

Questions for ICER

1. Does ICER agree with the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) that the task of health technology assessment is **not** to test hypotheses, but to provide information to decision makers?

2. The standards of normal science – all claims must be credible, evaluable and replicable – have been in place for centuries. Normal science supports the discovery of new facts through conjecture and refutation or confronting theory with evidence. So why has ICER put hypothesis testing aside?

3. If a lifetime Markov simulation drives claims (e.g., lifetime QALYs), then none of these claims would meet the standards of normal science, and cannot be evaluated empirically. In the absence of such an evaluation, how can decisionmakers judge these claims?

4. If claims cannot be evaluated or validated, why should decisionmakers pay any attention to ICER where alternative models can produce different imaginary claims?

5. If the purpose of ICER's model is to provide "approximate information," how does ICER define the term "approximate" and what is it approximate in relation to?

6. Critical to any scientific progress is accurate measurement. Does ICER agree this means that in order for ICER's claims to be valid, the instruments (e.g., the EQ-5D-3L) that are developed must meet the axioms of fundamental measurement theory?

7. Is it correct that a key part of ICER's model is to create QALYs to support recommendations for value from incremental cost-per-QALY claims?

8. Following the ICER reference framework for value assessment, is it correct that a Quality Adjusted Life Year (QALY) is created by multiplying time spent in a disease state by a utility score on a scale of 1 (perfect health) and 0 (death)?

9. Following the axioms of fundamental measurement theory, if we are to multiply time spent by a utility score, then that utility has to be on a ratio scale (i.e., the scale has a true zero; there can be no values below zero), correct?

10. Because they have negative values (lowest EQ-5D-3L score is -0.59), and they lack a fundamental requirement of uni-dimensionality (measurement of one attribute), does ICER agree that this means these utility scores do not have ratio properties?

11. Does ICER agree that utility instruments such as the EQ-5D-3L are multi-attribute, and therefore do not have a latent construct that supports a unidimensional measure such as quality of life?

12. Does ICER agree that because the EQ-5D does not have ratio properties, the creation of a QALY is mathematically impossible? And if so, how does ICER justify modeling incremental cost-per-QALY claims?

13. We have known for 40 years that generic utility instruments such as the EQ-5D-3L create only ordinal manifest scores. The only mathematical operations permitted are estimating medians and modes. How does ICER

justify its continued creation of mathematically impossible entities?

15. Does ICER believe that assumptions from the past can create a 'realistic' assumed future world extending 10, 20, or 30 years to support non-evaluable claims? Could ICER explain this approach?

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[1] Langley PC. Nonsense on Stilts Part 1: The ICER 20209-2023 Value assessment Framework for Constructing Imaginary Worlds. *InovPharm*. 2020;11(1).No. 12
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