ICER's 1/31/2020 Final Release

2020 VALUE ASSESSMENT FRAMEWORK

ICER's Findings In Brief

On January 31, 2020, ICER released its final Value Assessment Framework to guide its reviews through the end of calendar year 2023.

The 2020 Value Assessment Framework continues relying upon the construction of lifetime imaginary worlds that provide "approximate information" to guide health decision makers in formulary decisions. None of the claims made are presented as hypotheses; none are, by design, empirically evaluable. They fail to meet the standards of normal science.

The ICER claims also fail to meet the axioms off fundamental measurement. **The QALY is an impossible construct because the utilities are ordinal scores**. QALY and cost-per-QALY modeled claims are meaningless.

The Patient Voice

ICER's 2020 Value Framework continues using an ordinal utility measure (EQ-5D-3L) that not only fails to take account of interests of patients in various disease states but cannot produce claims for response to therapy. If we are to capture the patient voice within disease states the ICER use of QALYs must be abandoned.

Dogmatic reliance on the EQ-5D-3L demonstrates ICER's continuing ignorance of fundamental measurement. Allied to this is ICER's blind persistence in its disregard for real patients and their real preferences, needs, and experiences. A therapy simply cannot be fully evaluated without a robust mechanism that captures the patient voice – and that gives the patient voice the same consideration as all of the other data being considered.

The focus should be on patient centric measures that not only meet the required standards for measurement and the empirical credibility of claims, but are explicit in defining "quality of life" in terms that patients consider important in fulfilling their health needs in a specific disease state.

Other Issues with ICER's Report

Scientific Credibility: The ICER claims are imaginary, hypothetical, and assumption-driven. They are not measurable or replicable in the real world.

Lack of coherent, disease-specific Quality of Life data: There is no consideration given to disease-specific, credible, evaluable, and replicable claims derived from a coherent Quality of Life construct.

<u>Unprovable claims</u>: Imposing this framework guarantees the recipient cannot test the claims to see if they are right are wrong. They are unprovable because they are hypothetical.

<u>Clinical measures instead of patient-reported measures</u>: The framework relies on generic utility scores that are clinically focused, not patient-reported or informed by patient preference.

<u>Measurement Theory</u>: Ordinal utility scores are inherently imprecise. While we know, for example, that score A is higher than score B, we don't know *how much* higher. An ordinal utility score cannot generate QALYs, but ICER just ignores this.

The Bottom Line:

ICER's 2020 value assessment framework is intended to be a "state of the art" manifesto of the positive and enduring contribution ICER will make, and believes it has indeed been making, to the process of health technology assessment in the US. This is, unfortunately not the case. The ICER value assessment framework adds nothing to our understanding of the impact of new and innovative pharmaceutical products and devices in target patient populations. It cannot support value assessments.

Rather than encouraging discovery to improve the quality of life of patents, particularly those with rare diseases, ICER's fixation on imaginary pricing, affordability and access is the more likely to dampen innovation and discourage patient access. Unfortunately, ICER's failure to understand the simple mathematics of an impossible QALY means that the last five years of evidence reports have been a waste of time.

Further reading: *University of Minnesota Libraries journal INNOVATIONS in Pharmacy Reference: Langley PC. Nonsense on Stilts – Part 1: The ICER 2020-2023 Value Assessment Framework for Constructing Imaginary Worlds. Innov Pharm. 2020;11(1): No. 1* https://pubs.lib.umn.edu/index.php/innovations/article/view/2444