



ABANDONING ICER LIFETIME QALYs

abandoned, *adj.* Left and no longer wanted, used or needed. "There was an abandoned supermarket trolley in the middle of the road." – *Oxford English Dictionary (OED)*

A recent Patient Access and Affordability Project [commentary](#) on the Institute for Clinical and Economic Research's (ICER's) [Value Assessment Framework](#) made case that not only were ICER and its evidence reports an unnecessary distraction, but that the notion of a quality adjusted life year – or QALY – might also be usefully abandoned.¹

The purpose of this report is to explain *why* the lifetime QALY should be abandoned – and why ICER's reliance upon this construct makes that organization an unnecessary distraction.

QALY Foundations

The QALY, a measure that is intended to combine mortality and morbidity, a global standard for assessing the cost-effectiveness of competing pharmaceutical products and devices, rests on a flimsy if not a fatally flawed base. While there is no objection to claims expressed in terms of QALYs that are disease specific, credible, evaluable, and replicable across treating settings, the notion of a lifetime QALY has no scientific merit.

The conclusion that lifetime QALYs are pseudoscience is based on three considerations:

- The QALY as a centerpiece to claims by ICER on the construction of reference case imaginary worlds is nonsensical; imaginary constructs for "approximate information" have no role in formulary decision making.
- Modeled claims for lifetime imaginary QALYs rests on the ability of the

modelers to construct estimates of different time spent by hypothetical patients over their lifetimes in disease states to which utilities can be applied.

- Utilities typically employed by model builders to generate QALYs (utility multiplied by time) are ordinal rather than cardinal measures, meaning they fail standards for fundamental measurement; the resulting QALY "measure" is logically absurd.

Measurement

The failure to appreciate the importance of measures that meet cardinal or interval standards versus ordinal measures is the fatal flaw in QALY claims. It has long been recognized that ordinal measures that characterize generic multi-attribute utility systems (e.g., EQ-5D) cannot be used to support statistical options such as means, standard deviations, and change and effect sizes. They cannot be applied to estimated periods of time (years) to create

QALYs. In the reference case model, claims for lifetime QALYs are, therefore, invalid.

Developing an instrument with the necessary interval properties means starting from scratch. The developer has to consider the construct or latent attitudes the instrument is intended to capture (e.g., Quality of Life in a specific disease state) and, through a process of item development and assessment that meet Rasch measurement standards, construct the appropriate instrument. As this development would typically start with patient-centric qualitative interviews, the product is an instrument that “captures the patient voice.”

Few instruments that are found in health technology assessment meet these development standards. The overwhelming majority of them are “clinically operational.” *They capture symptoms and responses that typically reflect the interest of physicians and “expert groups” rather than patients.* The EQ-5d-3L is an example: it has five health or symptom dimensions and three response levels for each dimension. These are aggregated to generate a utility raw score through an algorithm that reflects community – not patient – preferences for a health or symptom-level state. The responses by health state are ordinal; we know one response is “better” than another but the differences are unknown. At best these response levels can yield estimates of modes or medians but not means.

Unless you have access to the original patient data that were used to create the ordinal utility measure (or raw score from other Patient Reported Outcome measures) it is virtually impossible to make the case, *ex post facto*, that the utility or raw score meets Rasch standards for an interval measure. By default, you have to assume the measure is ordinal. If you want a measure that has any meaning, you have to start from scratch and adhere to Rasch development standards. This means that the overwhelming majority of disease specific outcome measures fail the standards of fundamental measurement,

with the same point made in respect of generic measures. The instruments gave no thought to fundamental measurement and its implications for evaluating change.

Modeling Disease Stages

The second step in generating imaginary QALYs is to provide estimates of the time spent in each hypothetical disease state over the lifetime of the modeled patient cohort. This is open to a number of techniques and there is no agreement, in the context of imaginary worlds, as to a “preferred” method. Given this, there estimates of time spent before transitioning to the next disease stage, is entirely by assumption.

At this stage, the reviewer might well raise the issue of “interpretation.” What should we infer, if anything, from a lifetime QALY construct that applies ordinal utilities to assumed time spent in a disease stage where *different* ordinal utilities are applied? These utilities may differ, presumably declining as the disease progresses, but we cannot say by how much as the utility has only ordinal properties. Nor can we compare utilities (and QALYs) between different arms of the model to give imaginary claims of incremental benefit.

Modeling Costs

This triumvirate supporting the imaginary cost-per-QALY construct is complete with the cost assumptions. Again, looking to the future costs assumed to be incurred over the course of a disease, the world is our oyster. We can choose, essentially, anything we like. Are we imagining the future 10, 20 or 30 years of direct medical costs, assiduously assembled for each imaginary stage of the disease? Or are we more ambitious in extending this to social costs? The beauty of this is that there is no way to know.

Interpreting Imaginary QALYs

Knowing what we know, can imaginary QALYs be interpreted? Can we put any credence in claims based upon: (i) ordinal scores for utilities; (ii) one

of many possible model estimates of time spent in successive modeled disease stages; and (iii) one of many possible modeled crystal ball scenarios of future costs? The obvious answer is “no.” Yet we are asked to believe that this one of a possible multiverse of modeled worlds – all of which fail the standards of fundamental measurement – somehow play a decisive role in formulary decisions. Any change in assumptions regarding model structure, choice of ordinal utility, time spent in a disease stage and choice of costs would all impact the final incremental cost-per-QALY calculation. A threshold claim is specific to a model. Of course, ICER could argue that like NICE in the UK, this is the only relevant model for the US health system. Then it might claim relevance to its “for information” imaginary threshold price discounting and product access claims. Given the lack of scientific merit in the ICER value assessment frame, it is difficult to see how anyone could take that claim seriously.

Abandonment

While “abandonment” has a certain Dickensian flavor, the case presented in the ICER commentary is that it is inevitable. In the case of the supermarket trolley, this may be because the wheels fell off; in the case of lifetime QALYs, the wheels were never attached in the first place. We cannot continue to base formulary decisions on a methodology that fundamentally and fatally flawed. Health care systems who have embraced the ICER pseudoscience as inputs to their decisions on pricing and access, might be advised to have second thoughts.

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REFERENCES

¹ Langley PC. Nonsense on Stilts – Part 1: The ICER 2020-2023 Value Assessment Framework for Constructing Imaginary Worlds. *InovPharm*, 2020;11(1): No. 12
<https://pubs.lib.umn.edu/index.php/innovations/article/view/2444>