



THE ICER MYTH

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Institute for
Patient Access

INTRODUCTION

What stands between patients and the treatment prescribed by their doctors?

In some cases, the barriers are obvious. High co-pays at the pharmacy counter, for instance, or a health insurer's prior authorization requirement that leaves patients waiting for treatment.

In other cases, the barriers are harder to grasp. Nowhere is this truer than with the growing prominence of a Boston-based health economics organization known as ICER, or the Institute for Clinical and Economic Review. Amid widespread debate about pharmaceutical prices, ICER has made a name for itself by generating the unicorn of health care economic analysis: the price at which an innovative drug provides value.

The group has come under scrutiny for its methodology and calculations. Critics have also made an issue of ICER's funding, some of which comes directly from health insurers or from nonprofit foundations supported by health insurers.

But perhaps the organization's biggest drawback is its suggestion that the value of life-altering drugs for individual patients can be lumped into a "one-size-fits-all" calculation.

ICER's "value-based price" is a fallacy, and a dangerous one. In the hands of health plans, these prices can become negotiation tools. If drug manufacturers don't meet health insurers' demands, coverage policies may put new drugs out of patients' reach.

This paper explores the drawbacks of ICER's evidence reports and how those issues affect patients.



ICER EVIDENCE REPORTS


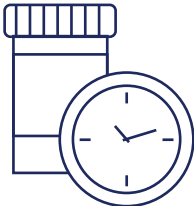
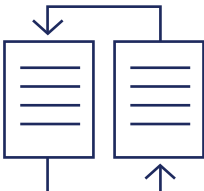

An Overview

ICER’s evidence reports analyze existing studies that have:

- Evaluated the efficacy of a new medicine
- Evaluated the efficacy of comparable medicines currently available
- Reviewed the costs associated with the condition in question.

As a review of studies, ICER’s reports can provide important insights for the health care community. There are important limitations, however, regarding what conclusions can be drawn.

The table below clarifies what ICER does and does not do in its evaluations.

What ICER Does		What ICER DOES NOT Do
Establishes a value-based price benchmark based on what a drug is worth to a generalized patient population		ICER DOES NOT determine a drug’s actual value for a patient based on individualized preferences and health needs
Evaluates a drug’s cost effectiveness before complete data is available		ICER DOES NOT wait to incorporate all pertinent clinical trials data and real-world data for a more complete picture of a drug’s impact
Makes assessments using its “best judgment”		ICER DOES NOT stick to assessment methods that could be replicated by other analysts, a hallmark of scholarly research
Uses QALY methodology, which raises concerns about ethics & fairness		ICER DOES NOT use metrics that accurately reflect the quality-of-life issues that matter to individual patients



A SUMMARY OF SHORTCOMINGS

The limitations of ICER analyses typically stem for one of four issues:

Limitation #1: One-Size-Fits-All Approach

Arguably, the biggest limitation of the ICER evidence reports is the claim that there is one price that ensures that these medicines are worth their costs. This value-based price benchmark is the basis for ICER's determination that certain medications' prices are excessive.

By claiming that there is one cost-effective benchmark, ICER implicitly assumes that the value of a medicine to each individual patient can be evaluated based on the average value of a medicine for the entire population. Put differently, the estimates assume that there is one cost-effective price applicable to all patients.

Such an assumption is wrong.

In attempting to determine what that price is, ICER may compare the drug's current pricetag to different benchmarks of cost-effectiveness. The approach explores varying levels of cost effectiveness but does not stray from the flawed viewpoint that one of these price points is applicable to all patients.

In reality, the value of a medicine to a patient is inherently subjective and will vary across patients based on their individual needs. Patients are remarkably diverse, and factors such as race, ethnicity, and age must be taken into consideration. Furthermore, an individual patient's comorbidities and other medical conditions often have a dramatic impact on the selection and effectiveness of treatment options.

Questions such as whether a drug is delivered orally or via IV, and issues such as how a drug interacts with a patient's other medications, can have a dramatic impact on how effective a drug is for an individual patient.

Consider, for example, ICER's evaluation of targeted immune modulators for treating rheumatoid arthritis. With this analysis, even ICER itself noted that the model's use of a homogenous patient cohort did not reflect the diverse nature of the real-world patient population and its treatment experiences.¹

Important, patient-specific considerations make it simply impossible to calculate a *single price* that reflects a medicine's value to *all patients*.



What it Means for Patients

The fallacy of a single, cost-effective price encourages disingenuous negotiating among manufacturers and health plans that can undermine patients' access to innovative medicine.

Limitation #2: Insufficient Data

Typically, ICER's evaluations are released around the same time the drugs are made available to patients. This is too early. In the case of treatments for atopic dermatitis, ICER actually calculated cost effectiveness even before the drug, or its price, were publicly available.

This timing restricts how much researchers can know about the drug. In some cases, as with treatments for cholesterol-lowering PCSK9

inhibitors, ICER conducted its analysis before clinical trials of the drug were completed.

Even when clinical trials data are available, their use presents certain challenges. Clinical trials are research endeavors designed to test hypotheses about a drug's efficacy and side effects. Health technology assessments, on the other hand, are analyses of how a drug performs in clinical practice.² As a 2007 article in the Journal of

the American Medical Association explains, clinical trials results “might not apply in a straightforward way to individual patients.”³

Further, clinical trials are inherently biased against certain populations, such as senior citizens and ethnic minorities, who tend to be underrepresented. A drug could offer unique risks or benefits to these populations, but such information will be missing from ICER’s assessment.

Moreover, invaluable post-marketing data on efficacy, risks, and side effects are still unknown when ICER conducts its analysis. ICER’s timing means that the potential risks and benefits that

derive from long-term use of a drug, which may be further identified during post-marketing studies cannot be incorporated into the assessment.

This timing significantly limits the data upon which ICER bases its conclusions.

What it Means for Patients



ICER’s timing denies patients, health care providers, and health insurers a comprehensive understanding of a medicine’s potential benefits and risks.





Limitation #3: Inability to Replicate

A basic principle of scholarly research is that other researchers should be able to replicate the results of a study. This is not possible with ICER's reports.

Take, for example, ICER's Evidence Rating Matrix, a fundamental part of its assessments. The matrix is meant to help determine a letter grade that reflects a drug's "net health benefit."

A letter grade suggests precise, objective calculations. Yet the grade assigned by ICER does not reflect a quantitative, evidence-based methodology. Instead, these are *qualitative* opinions offered by ICER-selected "experts" who are evaluating the data selected by ICER employees.

ICER's evaluation of abuse-deterrent opioids reveals how this seemingly quantitative methodology is inherently qualitative. In defending the C+ rating it gave abuse-deterrent opioids, ICER explains that its

"judgment is that the evidence can only demonstrate a 'comparable or better' net health benefit."

Such judgments are nothing more than opinions; they may be valid, or they may be invalid. Moreover, other experts could evaluate the same evidence but reach a different conclusion. Thus, ICER's methodology lacks the reproducibility that characterizes reliable scholarly research.

What it Means for Patients



Patient's health plan coverage for innovative medicines may be influenced by ICER's reports, even though the findings lack a hallmark of academic legitimacy.

Limitation #4: Inadequate Metrics

The Quality-Adjusted Life Year, or QALY, is a metric that assigns a value to the benefits a medicine may provide a patient population. It is an integral part of ICER's methodology.

Yet QALYs have important limitations. In particular, QALYs raise ethical concerns because they assign the highest value of life to a state of perfect health.⁴ This can be considered discriminatory when applied to people with disabilities, whose normal state may not align with QALY's definition of "healthy."⁵ Given these concerns, use of QALYs has been restricted in several instances, such as:

- The Department of Health and Human Services has stated that health plans' use of QALYs to determine coverage could violate the Americans with Disabilities Act.
- Congress voted to ban the Patient Centered Outcomes and Research Institute from using QALYs to assign a value to treatments.⁶
- Medicare is not allowed to use QALYs to restrict coverage.⁷

Trying to assign a value to inherently qualitative considerations is complex. ICER's reliance on the QALY methodology is particularly troubling because ICER often evaluates medicines for diseases that are largely qualitative. This includes diseases

such as migraine, the movement disorder known as tardive dyskinesia, and rheumatoid arthritis, which inflict pain, discomfort, and social stigma – symptoms that don't neatly correspond to objective forms of measurement.

While quality-of-life concerns may generate a sympathetic paragraph or two at the beginning of an ICER analysis, these crucial patient considerations do not alter ICER's conclusions in a meaningful way. Instead, ICER inappropriately emphasizes a metric that's subject to widespread criticism for its ethical shortcomings and impact on disabled populations.



What it Means for Patients

Because ICER analyses rely on QALYs, they significantly undervalue potential benefits of innovative medicines.





CONCLUSION

If done correctly, ICER analyses could help medical professionals better understand the potential clinical benefits of innovative medicines as compared to current medical options. Further, these analyses can put these benefits into perspective relative to the current costs of the disease, as well as any potential reduction in the disease costs that the medicines can enable.

ICER analyses cannot, however, accurately and responsibly achieve one of the organization's main goals – to calculate a price that fairly represents the value innovative medicines hold for a wide range of patients. This calculation is predicated on insufficient data and methodology that has significant limitations. **Therefore, ICER conclusions often introduce fundamental misunderstandings of the value these medicines hold for individual patients.**

REFERENCES

1. Institute for Clinical and Economic Review. (2017) "Targeted Immune Modulators for Rheumatoid Arthritis: Effectiveness & Value." https://icer-review.org/wp-content/uploads/2016/08/NE_CEPAC_RA_Evidence_Report_FINAL_040717.pdf
2. Jönsson, B. (2015) "Bringing in health technology assessment and cost-effectiveness considerations at an early stage of drug development." *Molecular Oncology*, May, 9(5): 1025-1033.
3. Kent, D.M. and Hayward, R.A. (2007) "Limitations of Applying Summary Results of Clinical Trials to Individual Patients: The Need for Risk Stratification" *JAMA*, 298(10):1209-1212 September 12.
4. Pettit, D.A. et al. (2016) "The Limitations of QALY: A Literature Review." *Journal of Stem Cell Research & Therapy*, March, <https://www.omicsonline.org/open-access/the-limitations-of-qaly-a-literature-review-2157-7633-1000334.php?aid=70859>
5. Neumann, P.J. and Greenberg, D. "Is the United States Ready for QALYs?" *Health Affairs*, September 2009, 28:5. <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.28.5.1366#R15>
6. Social Security Administration. "Compilation of the Social Security Laws." https://www.ssa.gov/OP_Home/ssact/title11/1182.htm
7. Coehlo, T. (2017) "Prioritizing Health Care: Patient or Payer First?" *Real Clear Health*, September 2017. https://www.realclearhealth.com/articles/2017/09/05/prioritizing_health_care_patient_or_payer_first__110720.html

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