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EDITORIAL

Is ICER NICEr?

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With the exception of 9.2% of the population who remain uninsured, US citizens with health insurance have coverage for prescription drugs; yet, a report in The Huffington Post states "Over one in five Americans say that they have been forced to leave a prescription unfilled due to high costs" [1]. The US has the highest pharmaceutical costs in the world and the rate of increase is also the highest. Furthermore, a report on national trends in drug expenditures shows that total drug expenditures are expected to increase by 6.0–8.0% in 2017 [2]. Pharmaceutical expenditures are increasing more rapidly than overall healthcare expenditures, which is partly due to the opaque nature of the drug pricing process in the US. US drug companies determine their own list prices and negotiate rebates and discounts with government plans, private insurers, and pharmacy benefit managers. Pharmaceutical benefits managers who negotiate the provision of drugs for most private insurers have also been unable to arrest increases in the cost of prescription medicines and are often accused of not providing access to important medicines through their formularies [3]. All in all, patients in the US are expected to pay more for drugs whose accessibility and expected benefit remain uncertain. A potential solution to this crisis may be to provide an independent appraisal of drugs based on efficacy and cost effectiveness in producing better health in comparison to other treatment options, thus enabling the construction of a value-based price for reimbursement.

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Similar to the National Institute for Health and Care Excellence (NICE) in the UK and The Pharmaceutical Benefits Advisory Committee (PBAC) in Australia, the Institute for Clinical and Economic Review (ICER) is the first organization in the US to address drug prices using cost-effectiveness methods, and to gain the attention of important stakeholders. ICER is organized differently than NICE and PBAC; ICER is an independent, non-profit, non-governmental organization that is funded by foundations to conduct evidence reviews on drugs that combine analyses of comparative clinical effectiveness and cost effectiveness in a way that produces recommendations for 'value-based' price benchmarks.

An ICER report is composed of six main parts: comparative clinical effectiveness, incremental cost effectiveness, potential benefits or disadvantages that lie outside the scope of clinical or cost effectiveness, contextual considerations, budget impact analysis, and a section in which the value-based price benchmark is calculated [4]. ICER's report on proprotein convertase subtilisin/kexin type 9 (PCSK9) drugs, which offers a value-based price benchmark that is much lower than the list price set by the manufacturers, is one prominent example [5]. The calculation of the price benchmark is done by establishing the price range to achieve an incremental cost-effectiveness ratio between $100,000 and $150,000 per quality-adjusted life-year (QALY). Although cost-effectiveness thresholds are often debated, ICER justifies its range on the basis of academic studies from past several decades, and its value-based price benchmarks have achieved a growing sense of validity among payers and policymakers. ICER's standard cost-effectiveness analyses are conducted from the payer perspective. In addition, societal perspective analyses are routinely provided as sensitivity analyses, and ICER has recently announced that for treatments of ultra-rare

conditions, it will elevate the societal perspective analysis into a co-equal status with the base-case payer perspective, using both to generate value-based price benchmarks.

From the outset of the preliminary scoping phase of every review, ICER reaches out to engage with the patient community, clinical experts, drug makers, and other stakeholders in order to get their input on what living with a specific condition is like for patients, how well available outcome measures capture what matters most to patients, and how the structure of the cost-effectiveness analysis can best mirror the clinical and economic features of care. This process of reaching out to interested parties culminates in a public hearing at which ICER convenes an independent appraisal committee to debate each report, hear testimony from stakeholders, and hold votes on the strength of the clinical evidence and the overall value of each treatment. Once all groups have been heard, ICER posts all reports for free public access—such transparency is rare.

An important element of ICER's approach is to launch the review for each drug approximately 8 months before the US FDA approval is expected in order that the final report and public hearing can coincide with the time frame during which initial insurance coverage and pricing negotiations are taking place. ICER reports are being incorporated into formulary decision making by many state Medicaid programs, the Veterans Administration, and a number of major pharmaceutical benefit managers. In one publicly noted case, ICER's report was used by drug makers Sanofi and Regeneron to help determine the launch price for Dupixent, a new treatment for atopic dermatitis, prior to FDA approval [6].

Like NICE and the PBAC, ICER is the first organization to bring direct use of cost-effectiveness analysis into decision making. ICER has received much attention, followed by concerns on its value assessment methods. For one, contention remains regarding the appropriate time horizon for short-term affordability analysis. Some analysts indicate that 5 years is far beyond the budget horizon expected for PBMs, insurers, and employers [7], or that it is too short to take into account downstream benefits. Similarly, others point out that ICER does not take into account the fact that new benefits of a particular drug may accrue over time, and also provide downstream benefits to caregivers and family members [8]. Both of these are issues that need to be addressed going forward. In response to concerns raised, the newly updated ICER value framework for 2017–2019 states that ICER reports will consider seven possible 'other benefits or disadvantages' and five 'contextual considerations' for the next year that may be able to take into account the direct and indirect benefits to non-patients that accrue both now and downstream [9].

ICER's impact is growing concurrently with increasing concerns over drug costs and pricing among patients and payers. Independent analysis of effectiveness and value will be a critical element of any future policy approach to address these concerns. In the future, potential applications to formularies might include using cost-effectiveness thresholds to set value-based reference prices. By using reference pricing, many European countries have succeeded in lowering drug prices [10].

ICER will never be NICE or the PBAC as it should remain independent and not regulatory. Through transparency, stakeholder engagement and cutting-edge methods, ICER will successfully lead to evidence-based policymaking in the US.

Compliance with Ethical Standards

Deborah Freund is a former member of the Board of Directors of ICER. Neither she nor Jennifer Choi have received any funding or money from ICER.

References

1. Alex L, Stephanie C. Americans demand lower drug prices: this senate bill would deliver. https://www.huffingtonpost.com/entry/americans-demand-lower-drug-prices-this-senate-bill_us_58dbee85e4b0487a198a5672. Accessed 25 Oct 2017.
2. Schumock G, Li E, Suda K, et al. National trends in prescription drug expenditures and projections for 2016—projecting future drug expenditures. Am J Health Syst Pharm. 2016;73:e357–73.
3. Lyles A. Pharmacy benefit management companies, do they create value in the US Healthcare System? Pharmacoeconomics. 2017;35(5):493–500.
4. Institute for Clinical and Economic Review. Methodology. https://icer-review.org/methodology/. Accessed 25 Oct 2017.
5. Dan M, Meg T. Pricey new cholesterol Rx covered by big drug plan, but…. https://www.cnbc.com/2015/10/06/pricey-new-cholesterol-rx-covered-by-big-drug-plan-but.html. Accessed 25 Oct 2017.
6. David F. Wired. The new war on (overpriced) drugs. https://www.wired.com/story/fighting-high-drug-prices/. Accessed 25 Oct 2017.
7. Neumann PJ, Cohen JT. ICER's revised value assessment framework for 2017–2019: a critique. Pharmacoeconomics. 2017;35:977–80.
8. Philipson TJ, Kamal-Bahl S, Jena AB. Defining value: the need for a longer, broader view. Pharmacoeconomics. 2017;35:669–72.
9. Institute for Clinical and Economic Review. Overview of the ICER assessment framework and update for 2017–2019. https://icer-review.org/wp-content/uploads/2017/06/ICER-value-assessment-framework-update-FINAL-062217.pdf. Accessed 24 Jul 2017.
10. Austin F. To reduce the cost of drugs, look to Europe. https://www.nytimes.com/2015/10/20/upshot/to-reduce-the-cost-of-drugs-look-to-europe.html. Accessed 25 Oct 2017.