OFFICE OF LEGISLATIVE RESEARCH
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ResearchReport

Institute for Clinical and Economic Review

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Issue

This report answers a series of questions about the Institute for Clinical and Economic Review (ICER).

Summary

ICER was founded in 2006 as a Harvard Medical School research project. It moved to Massachusetts General Hospital in 2007, and became an independent nonprofit organization in 2013. Currently, it analyzes pharmaceutical drugs and other medical services and reports on their effectiveness and cost. Generally, ICER's reports consider a drug's or service's cost, expected patient improvement, and impact on the health care system. The institute runs an assessment program on new drugs, operates three regional collaborative groups, acts as a health technology assessment program for the state of Washington, and establishes various initiatives, such as the Proven Best Choices program to assess high and low value health care initiatives.

ICER indicates that its voting bodies, funding, and governing procedures are independent from healthcare payers (i.e., insurers). According to its website, "all ICER reports are produced with funding exclusively from non-profit foundations and other sources that are free of conflicts of interest from the life science industry or insurers." ICER's full Conflict of Interest Policy is available here.

General Information

What is ICER's legal business entity name?

According to ICER's federal tax filings, its legal business name is "Evidence for Healthcare Improvement."

Funding

What large health insurers, insurance related trade associations, and nonprofits fund ICER? How much have they contributed since ICER's formation?

ICER must disclose its total funding because of its nonprofit status, but the organization does not appear to disclose funding by specific source. Thus, we were unable to determine the total contributions from each organization type.

However, ICER does report funding by general category (although it is not clear if it is annual or cumulative funding). According to its website, ICER receives 77% of its funding from nonprofit foundations and 2% from government grants and contracts. The website also indicates that "funding is not accepted from manufacturers or private insurers to perform reviews of specific technologies." However, the institute acknowledges that 21% of its total funding is used for its ICER Policy Summit and comes from manufacturer grants and contributions (13%) and from health plans and provider groups (8%).

ICER indicates that it has received funding from the following sources since June 2018:

Apex Healthcare Consulting	Commonwealth Fund	NESCSO/University of Massachusetts
Blue Cross Blue Shield of Massachusetts	Harvard Pilgrim Health Care	Network for Good
Blue Shield of California Foundation	Jeffries	Partners Healthcare
Boston University School of Public Health	Laura and John Arnold Foundation	RBC Capital Markets
California Health Care Foundation	National Institute for Health Care Management	University of Colorado

For the annual ICER Policy Summit and other membership activities, ICER receives support from pharmaceutical companies and health insurers.

Does ICER receive funding from the California Health Care Foundation or the Blue Shield of California Foundation. If so, what percentage of its budget do these contributions account for?

Yes. The California Health Care Foundation and the Blue Shield of California Foundation both contribute, according to ICER's website. ICER does not indicate how much funding it receives from these sources.

Where did ICER's early financial support come from?

According to a report titled "Addressing the Myths About ICER and Value Assessment," the organization was initially founded in 2006 as an academic research project based out of Harvard Medical School. The next year it moved to Massachusetts General Hospital. It did not become an independent nonprofit organization until 2013. (The report appears to be from 2016 and is no longer available on the ICER website).

According to the report, from 2006 to 2009, the largest funding support came from unrestricted contributions from the National Pharmaceutical Council. The report notes that "during its early years" funding came from the National Pharmaceutical Council (~40%); federal grants (~25%); nonprofit grants, including from the Robert Wood Johnson Foundation and the Blue Shield of California Foundation (~25%); and unrestricted support from health insurers (10%).

Membership

Provide the names of the health insurers, pharmacy benefit managers, and pharmaceutical companies that are ICER members.

ICER's current membership, as listed on its website, is provided in the table below. Several members appear to be insurers, pharmacy benefit managers, or pharmaceutical companies.

ICER Current Membership

Aetna	Editas	Mallinckrodt Pharmaceuticals
Allergan	Express Scripts	Merck & Co.
Alnylam	Genentech	National Pharmaceutical Council
America's Health Insurance Plans	GlaxoSmithKline	Novartis
Anthem	Harvard Pilgrim Health Care	Premera Blue Cross
AstraZeneca	Health Care Service Corporation	Prime Therapeutics
Biogen	HealthPartners	Regeneron
Blue Shield of CA	Johnson & Johnson	Sanofi
Cambia Health Solutions and MedSavvy	Kaiser Permanente	United Healthcare
CVS Caremark	LEO Pharma	

Are any patient groups ICER members?

It does not appear that any patient groups are ICER members, although patient advocacy groups may be members (e.g., MedSavvy is a healthcare transparency company that appears to help patients find lower-cost prescription services).

Value Metrics

What specific metrics does ICER use when determining a medication's value and value to patients? Does ICER take into account patient quality of life?

ICER's value assessment framework for 2017-2019 is available here. Generally, the framework considers a drug's long-term value for money and its short-term affordability, with specific adjustments depending on whether the assessed intervention is a drug, test, service, medical device, procedure, or an ultra-orphan drug (i.e., drug used to treat a very rare disease). The framework considers a patient's quality of life, primarily through the use of QALY metrics (which measure cost per quality-adjusted life year) and patient-centered input (which helps derive the comparative clinical effectiveness (see below)).

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Long-Term Value for Money. The long-term value incorporates the following four measures:

1. comparative clinical effectiveness, including information from patient groups on health outcomes, severity, and other data;
2. incremental cost-effectiveness, including computer modeling of long-term clinical outcomes and costs and QALY assessments,
3. other benefits or disadvantages, including additional factors such as whether a health intervention reduces racial, gender, or ethnic health disparities; and
4. contextual considerations, including additional factors such as whether a condition is of high severity or the intervention is the first to offer any improvement for patients.

Short-Term Affordability. Short-term affordability refers to a high value product, the cost of which may have a negative impact on the health system as a whole (e.g., the high cost of Sovaldi as a hepatitis C treatment). ICER performs an evaluation of a drug's or service's short-term affordability which, includes the impact on health expenses.

Officer Compensation and Staff Background

Provide information on the backgrounds of ICER staff.

ICER's senior management team consists of its President, Executive Vice President and Chief Operating Officer, Chief Medical Officer, Vice President of Development, and Vice President of Communications and Outreach. According to biographies available on the organization's website, senior management team members appear to have experience that qualifies them for their position. For example, ICER's President (Dr. Steven Pearson) is a lecturer in the Department of Population Medicine at Harvard Medical School, a Visiting Scientist in the Department of Bioethics at the National Institutes of Health, and previously served as Special Advisor on Technology and Coverage Policy within the Coverage and Analysis Group at the Centers for Medicare and Medicaid Services, among other things. A full list of ICER's senior management, including their background information, is available here.

In addition to senior management, ICER appears to employ at least 20 staff members and to work with several "affiliated researchers." Additional information about staff members is available here.

What was the most recently reported compensation of ICER's officers?

The table below provides the most recently reported compensation of ICER's senior officers, according to its IRS Form 990 (2017).

Officer and Title	Reportable Compensation
Steven Pearson, President	$ 456,004
Sarah Emond, Treasurer, Secretary, COO	181,553
Dan Ollendorf, Chief Scientific Officer	219,646
David Rind, Chief Medical Officer	226,602
Richard Chapman, Director of Health Economics	195,364
William Dreitlein, Director of Pharmaceutical Intelligence	129,852
Varun Kumar, Health Economist	108,829
Sonya Kham, Program Director	105,778

The reportable compensation does not include the estimated amount of other compensation from ICER or other related organizations (e.g., employer-provided health benefits not included in reportable compensation).

Governance

Who is on the ICER Governance Board and what are their backgrounds? How many members have ties to the insurance industry?

According to ICER's website, the governing and advisory boards consist of the members listed in the tables below. It appears that many members have direct or indirect connections to the insurance industry.

ICER Governance Board

Ellen Andrews, PhD,	Executive Director, Connecticut Health Policy Project
Carmella Bocchino, RN, MBA	President and CEO, CRB Strategies, LLC
Tanisha Carino, PhD	Executive Director, FasterCures
Wendy Everett, ScD	Special Advisor, NEHI
Ron Pollack, JD	Chair Emeritus, Families USA
Murray Ross, PhD (Chair)	Vice President and Director, Kaiser Institute for Health Policy Kaiser Permanente
Lewis Sandy, MD	Executive Vice President, Clinical Advancement, UnitedHealth Group
Mark Skinner, JD	President and CEO, Institute for Policy Advancement

Anya Rader Wallack, PhD	Associate Director, Center for Evidence Synthesis in Health at Brown University
Frances Visco, JD	President, National Breast Cancer Coalition

ICER Advisory Board

Robert W. Dubois, MD, PhD	Chief Science Officer, National Pharmaceutical Council
Stephen Friedhoff, MD	Senior Vice President, Clinical Strategy and Programs, Anthem, Inc.
Jon Gavras, MD	Senior Vice President, Chief Medical Officer, Prime Therapeutics
Vivian Herrera	Executive Director, Head Immunology & Dermatology and Medical Access, US Health Economics & Outcomes Research, Novartis Pharmaceuticals Corporation
Bryan Johnstone, PhD	Vice President, Global HEOR, Sanofi
Andreas Kuznik	Senior Director, Health Economics and Outcomes Research, Regeneron Pharmaceuticals
Carolyn Langer, MD, JD, MPH	Chief Medical Officer, Office of Medicaid (MassHealth) Commonwealth of Massachusetts
Martin Marciniak, PhD	Vice President, US Medical Affairs, Customer Engagement, Value, Evidence, and Outcomes, GlaxoSmithKline
Kendra Martello, JD	Senior Director, Public Policy, Government Affairs & Public Policy, Mallinckrodt Pharmaceuticals
Michael Sherman, MD, MBA, MS	Senior Vice President and Chief Medical Officer, Harvard Pilgrim Health Care
Susan Shiff, PhD, MBA	Senior Vice President, Center for Observational and Real-World Evidence, Merck & Co., Inc.
Sean D. Sullivan, PhD, MSc	Professor and Dean, University of Washington School of Pharmacy
Marcus Thygeson, MD	Chief Health Officer, Bind Benefits
John Watkins, PharmD, MPH, BCPS	Pharmacy Manager, Formulary Development, Premera Blue Cross

In addition, ICER has an advisory board for each of its three regional programs. Membership information for these boards is available here, under "Program Advisory Boards."

ICER Myth Report

Summarize the April 5, 2018 "ICER Myth Report" by the Institute for Patient Access.

"The ICER Myth," published by the Institute for Patient Access (IfPA), identifies four limitations in ICER's methodology. It starts of by stating the following:

> [t}he 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.

According to the report, ICER establishes a value-based price based on what a drug is "worth" to the entire patient population without determining the drug's actual value for a specific patient (or set of patients) based on individual preferences and health needs.

The report goes on to indicate that ICER also (1) evaluates drugs before complete data is available, (2) uses subjective "best judgement" assessments that cannot be replicated by other researchers, and (3) uses a QALY (quality-adjusted-life-year) methodology, which raises ethical and moral concerns and fails to reflect quality-of-life issues that matter to individual patients.

Below, we summarize the four limitations, according to the report. Because ICER responded to the report's assessment of QALY, we summarize that response as well.

One-Size-Fits-All Approach. According to the report, ICER claims that there is one price at which medicines are worth their cost. This assumes that a medicine's value to each individual patient can be expressed as an average value. Instead, according to the report, "the value of a medicine to a patient is inherently subjective and will vary across patients based on their individual needs." As a result, "patient-specific considerations make it simply impossible to calculate a single price that reflects a medicine's value to all patients."

Incomplete Data. The report argues that, since ICER's reports are released simultaneously with new drugs, ICER's data is incomplete. It notes at least one instance in which ICER conducted a drug analysis before clinical trials were completed. Additionally, the report notes that clinical trials are "inherently biased against certain populations" and as a result, the full risks or benefits are not known until the drug is assessed on the general population.

Subjective Data. According to the report, ICER relies on qualitative opinions of ICER-selected experts, instead of objective data that can be replicated by other researchers. Specifically, ICER's "Evidence Rating Matrix" uses a letter grade to represent a drug's net health benefit. The letter grade, according to IfPA, is arrived at based on an expert's judgement. "Such judgements" IfPA

writes, “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.”

QALY Metrics. Generally, QALY is an assessment tool that weighs a medicine’s benefit and includes the quality and length of the life. According to the report, QALY raises significant ethical concerns because it assigns the highest possible value to perfect health and as a result, inherently discriminates against disabled and other individuals whose “normal state” is not perfect health. Due to this, the report notes instances of Congress, the federal Department of Health and Human Services, and Medicare restricting or prohibiting the use of QALY in determining coverage or evaluating treatments.

ICER Response on QALY. According to ICER’s “Addressing the Myths About ICER and Value Assessment” report, QALY “is used throughout the world as the gold standard measure of how much better a treatment makes patients through extending life and/or improving the quality of life.” In noting how it works, ICER argues that “QALY measures relative improvement from wherever patients start out.” ICER notes that it is aware of the potential ethical problems, and takes two steps to minimize their effect. First, it uses quality of life scores, when possible, from individuals who have a specific condition in order to form a base-line score of “how bad” the condition is. Second, ICER “repeats analyses using different quality of life assumptions in order to understand whether a change in baseline quality of life makes an important difference in the final results.” According to ICER, these repeat analyses are considered when evaluating a drug’s effectiveness.

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