Unpacking ICER’s Models
Assessing COVID-19 Treatments

July 9, 2020
Partnership to Improve Patient Care: Background

- Coalition of organizations representing patients and people with disabilities, providers, researchers and innovators
- Support PCORI and PCORI Reauthorization
- Support patient-centeredness criteria and patient engagement as drivers of alternative payment models
- Support principles of patient-centeredness in development of value frameworks and shared decision-making tools
ICER Value Assessments

- Conducts cost effectiveness studies for insurers using the cost-per-QALY methodology, with a new emphasis on first-in-class therapies
  - Failure to meaningfully engage patients and often omits outcomes that matter to patients
  - Rushes to conduct premature assessments
  - Relies on the Quality-Adjusted Life Year and other summary metrics
  - Uses a short-term affordability threshold in assessments
ICER’s Models for Assessing Value of Treatments for COVID-19
Panelists

Colin Killick
Disability Policy Consortium

Adolph Falcon
National Alliance for Hispanic Health

Richard Xie, PhD
Innovation and Value Initiative
Colin Killick
Disability Policy Consortium
Quality-adjusted life years (QALYs):
QALYs discriminate against people with disabilities by placing a lower value on their lives.

**What’s the value of your life?**

Death | .1 | .2 | .3 | .4 | .5 | .6 | .7 | .8 | .9 | Perfect Health

0 | .1 | .2 | .3 | .4 | .5 | .6 | .7 | .8 | .9 | 1

Person with Cancer

Person with Rheumatoid Arthritis

Person with Diabetes
Where do QALYs come from?

- Not the views of people who have the disability
- Not experts in the condition
- Not medical data
In short

- QALYs are based on public opinion polls. Random, by phone.
- Given two descriptions—one of a “healthy” life, one of a particular disability.
  - Disability description is based on another highly biased survey
- Asked to choose between X years of life with the disability vs. 10 years of healthy life.
- Value of the life of a person with the disability is 10/X
Meet Bob: 40, non-disabled, white, cis man.
Bob picks up the phone, researchers describe an SCI to him (Listen)
Ask Bob to pick: living 10 years in “perfect health” or X years with an SCI. X increases until he can’t decide.

For Bob, X=20. The researchers decide that because 10/20 is ½, the life of someone with an SCI is half as valuable as a non-disabled person’s life.
What are QALYs used for

• Cost-benefit analysis
  – Treatment A costs $1,000,000, would save the lives of 1000 people. It’s worth buying if 1 life is worth at least $1000
  – If all 1000 of those people have SCIs, QALYs argue that it wouldn’t be worth spending more than $500,000 on Treatment A, because each life it’s saving only counts for half a person.

• Deciding who gets treated
Age-Adjusted Utilities

- ICER’s CEA model exacerbates the flaws that already exist within the QALY by using age-adjusted utilities.
- This further reduces the value of treating older patients.
- It is generally recognized that CEA is biased against older patients, as they have fewer QALYs remaining to gain, but these modeling choices aggravate the issue.
- This speaks directly to why the ACA banned the use of strict cost-effectiveness thresholds.
Direct QALY connection to COVID

- Remdesivir. How much should it cost? Who should get it?
  - Should QALYs be used to decide?
    - Availability
    - Expense
    - Prioritization
- What about a potential vaccine or cure?
“QALY Logic” and COVID

• Crisis standards of care
  – Who lives? Who dies? Who gets a ventilator?
  – Explicit state approach: maximize life years
  – Categorical exclusions, survival threshold
  – Tennessee Decision

• Death of Michael Hickson
  – His life was worth living
Adolph Falcon
National Alliance for Hispanic Health
Implications for Vulnerable Populations

• Communities of color have been disproportionately impacted by COVID-19
• More likely to have underlying health conditions making them more prone to serious complications from COVID-19
• More likely to work at jobs and live in environments that make social distancing harder
Implications for Vulnerable Populations

• ICER’s CEA models largely rely on randomized clinical trials data that lacks minority participants, meaning their models capture data applicable to white, male, non-Hispanic populations.

• ICER’s model omits attention to the evidence that differential triggers, like pollution and food insecurity, has on the expression of disease and illness.
ICER Omits Societal Perspective

• Trying to alleviate widespread fear
• Putting hospital system back on stable footing
• Alleviate healthcare worker burden
• Time spent home versus in hospital has value to patients
• Holistic public health good

One Size Does Not Fit All!
Impact on Health Disparities

If we base our assessment of care and treatments for COVID-19 on averages, as ICER does in this model, we will continue to exacerbate instead of ameliorate the pervasive health disparities in our country.

Coronavirus cases per 10,000 people

- White: 23
- All: 38
- Black: 62
- Latino: 73
Let’s Look at the Models

- ICER modeled value of COVID-19 treatments using two different types of models
  - Cost-effectiveness analysis
  - Cost Recovery
Assessment Premature

> Uncertainty in the underlying evidence regarding prevalence of COVID-19 and treatment effectiveness of remdesivir

> Do not have a strong indication of when and for whom this therapy will work most effectively

> Do not know what proportion of patients will benefit because we lack comprehensive data on patient characteristics
Lack of Flexibility in Model

> Lack of flexibility in the structural assumptions of the two models

> Evaluating a range of assumptions would give yield to a more comprehensive and nuanced discussion
CEA Model Threshold for Pricing

> ICER scaled down threshold for pricing to $50,000 per QALY

> Ideally this type of change would be based on comprehensive stakeholder dialogue, particularly during a public health crisis
Societal Impact

> Omitted impacts of health systems capacity and healthcare personnel

> In 2018, **ISPOR’s Special Task Force on Value Assessment Frameworks** published recommendations for vigorous testing to incorporate benefits beyond net costs and net QALYs into value assessments
  - Fear of contagion
  - Severity of illness
  - Insurance Value
  - Value of Hope
Long Term Impact

> How “value” is determined will have long-term consequences on the future investments in COVID-19 treatments

> Narrow assessments could create disincentives for investment in novel treatments

> There needs to be a balance between access and incentives to innovate.
Principles of Value Assessment

> IVI advocated the following key principles in value assessment
  > Consensus
  > Flexibility
  > Transparency
  > Open-source
Beyond Value Assessment

- Value assessment is just the first step
- Distribution of treatments
  - Who should get it first?
  - How do we ensure access for vulnerable communities?
- Long-term public health investments
  - Infrastructure
  - R&D for infectious diseases
Questions?

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Survey #1: EQ-5D

- Given to PWD. Usually same survey for every condition.
- 5 questions (Mobility, Self-Care, “Usual Activities,” Pain, Depression), 3 options each.
- You must answer every question.

By placing a check-mark in one box in each group below, please indicate which statements best describe your own state of health today.

**Mobility**
- I have no problems in walking about
- I have some problems in walking about
- I am confined to bed

**Self-Care**
- I have no problems with self-care
- I have some problems washing or dressing myself
- I am unable to wash or dress myself

Levels of perceived problems are coded as follows:

- 1
- 2
- 3

Level = 1
Survey #2: Random Phone Calls

- Few thousand phone numbers are called at random.
- Given a choice between two “possible lives”

<table>
<thead>
<tr>
<th></th>
<th>“Perfect Health”</th>
<th>“Spinal Cord Injury”</th>
</tr>
</thead>
<tbody>
<tr>
<td>Survey Answers</td>
<td>1,1,1,1</td>
<td>3,3,2,2,1</td>
</tr>
<tr>
<td>Years remaining</td>
<td>5</td>
<td>10</td>
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</tbody>
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- If they couldn’t choose, Spinal Cord Injury would get a 0.5 score—meaning the life of someone with a SCI would be worth half as much as a non-disabled person’s life.
How are QALYs Used

• Cost-effectiveness decisions. For example:
  – Treatment X costs Massachusetts $1 million dollars and saves 100 lives. Using it to save one life costs $1,000,000/100 = $10,000.
  – However, what if all 100 people had spinal cord injuries? According to the QALY approach, the value of their lives is (100) X (0.5) = 50 “normal” lives. The treatment only gets credit for saving half as many lives, so the cost per “life” becomes $20,000.
QALYs Have Historically Been Rejected by Policymakers

- The ACA explicitly prohibits PCORI from using the cost-per-QALY to determine effectiveness, and further restricts use in Medicare to determine coverage, reimbursement, or incentive programs.

- In 1992, HHS rejected Oregon’s prioritized list of covered services for Medicaid citing the potential for violating the ADA due to use of QALYs and cost effectiveness.