

# **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



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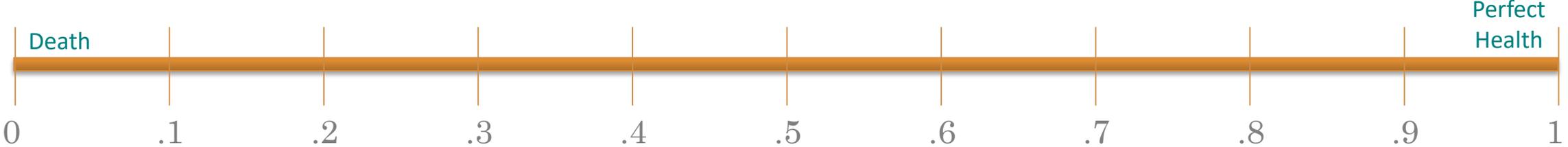
Colin Killick  
Disability Policy Consortium

# **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?*



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  $10/X$

# An example

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  $\frac{1}{2}$ , 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

In Focus Blog – Published on: June 23, 2020

## Medicare Claims Data Further Highlight Pandemic's Toll on Racial Minorities

Gianna Melillo

Preliminary data released by CMS show black Americans with Medicare coverage are nearly 4 times more likely than their white counterparts to be hospitalized for coronavirus disease 2019 (COVID-19).

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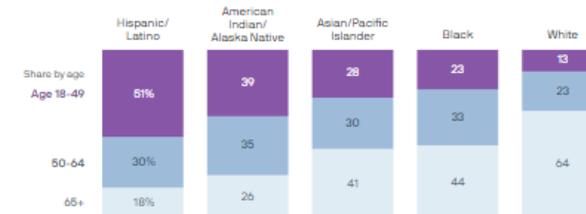
## Young people of color more likely to be hospitalized for coronavirus

 Darlin Owens, author of [Vital](#)



### U.S. COVID-19-associated hospitalizations by race/ethnicity and age

As of June 20, 2020 among 14 states in the COVID-NET surveillance network



Reproduced from [COVID-NET](#). Chart: Aesha Vasudek

# Implications for Vulnerable Populations

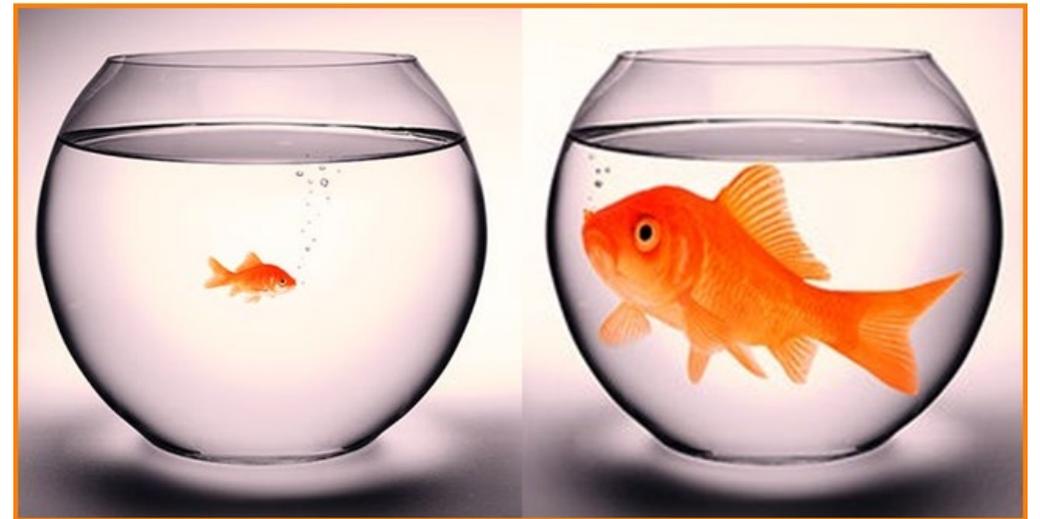
- ICER's CEA models largely rely on randomized clinical trials data that lacks minority participants, meaning their models capture data applicable to white, male, non-Hispanic populations
- ICER's model omits attention to the evidence that differential triggers, like pollution and food insecurity has 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

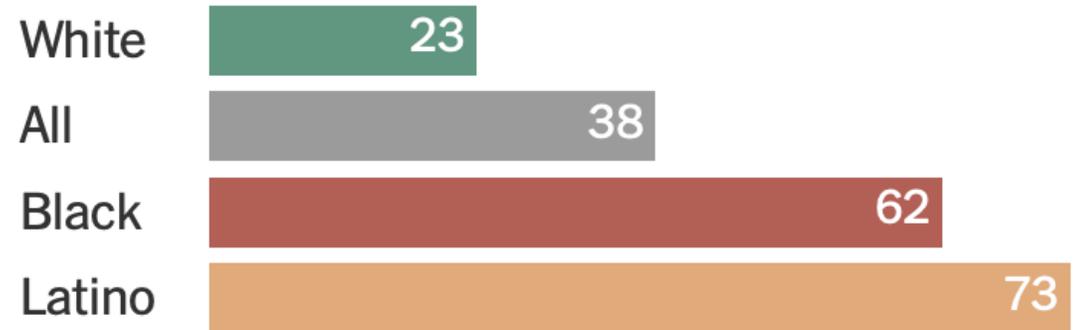
One Size Does Not Fit All!



# 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





Richard Xie, PhD  
Innovation and Value Initiative

# 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?

[www.valueourhealth.org](http://www.valueourhealth.org)

[www.pipcpatients.org](http://www.pipcpatients.org)

[Thayer@pipcpatients.org](mailto:Thayer@pipcpatients.org)

# **Bonus Slides**

*QALY Explainers*

# 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

Levels of perceived problems are coded as follows

1

2

3

Level = 1

## 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

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”

	“Perfect Health”	“Spinal Cord Injury”
Survey Answers	1,1,1,1,1	3,3, 2,2,1
Years remaining	5	10

- 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  $(100) \times (0.5) = 50$  “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.