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# **Discrimination in Cost Effectiveness**

Summary: While cost-effectiveness analyses are commonly used to compare interventions, their use can perpetuate health inequities.

Traditional quality-adjusted life years gained (QALY)-based cost-effectiveness analyses (CEA) are commonly conducted by HTA bodies and researchers to compare the value of medical interventions. These analyses, which also serve as the basis for value assessments, are subsequently leveraged by payers in the commercial market to help inform resource allocation decisions. Conventional QALY-based CEA methods are designed to generate a population-level outcome (e.g., average expected benefits in relation to expected costs), however this approach is not well equipped to address an increasingly diverse patient population. This can particularly impact vulnerable communities, who experience worse health outcomes compared to the general population. Instead, traditional value assessment focuses on providing insights relative to the 'average' patient, regardless of the heterogeneity of the population who could benefit from an intervention under review.<sup>1</sup> In cases where there are patient-level differences that could impact outcomes, this one-size-fits-all approach could lead to a miscalculation of value across subpopulations and exacerbate disparities if these differences are also associated with existing inequities (e.g., by race, ethnicity, or disability). There are a number of key reasons that CEA can perpetuate inequities:

- 1. Typical QALY-based CEA assume a homogenous group, often ignoring important differences influenced by social determinants of health. One-size-fits-all approaches to assessing value using a generalized population may over- or underestimate true value of said intervention on subpopulations.
- 2. CEA that rely on stratified quality of life or life expectancy inputs would systematically undervalue interventions for populations with lower estimated life expectancies and quality of life (QoL), including racial and ethnic minorities, elderly, and individuals with disabilities.

## Section 1: One-Size-Fits-All Approaches to Value Assessment Fail to Account For an Increasingly Diverse Patient Population

When conducting traditional QALY-based CEA, researchers typically assume all patients have a population-wide average risk of disease, utilization of treatment, and efficacy of therapy. However, this assumption fails to account for the racial and ethnic health disparities known to exist in the US. For example, the average rate of hypertension in all US adults is 47.3%, however this ranges from 38.9% in the Hispanic population to 56.2% in the non-Hispanic Black population.<sup>2</sup> The higher the incidence of a disease in a subpopulation, the higher potential value an intervention may have on that particular population compared to that of the general population. Therefore, the value of preventive measures, such as educational interventions related to limiting sodium intake and encouraging exercise, or anti-hypertensive pharmaceutical treatments would be deemed of lower value to the 'average' population despite offering a potential higher value to the Black population. For an example, see Figure 1.

 <sup>&</sup>lt;sup>1</sup> Williams A. Cost-effectiveness analysis: is it ethical? *Journal of Medical Ethics*. 1992;18(1):7-11. doi:<u>10.1136/jme.18.1.7</u>
 <sup>2</sup> Centers for Disease Control and Prevention. Table 1. Published March 22, 2021. <u>https://millionhearts.hhs.gov/data-reports/hypertension-prevalence-tables.html</u>

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Figure 1: Impact of Incidence on Benefit of an Intervention

| POPULATION A   | POPULATION B  |
|--|---|
| 100 people in the population   | 100 people in the population  |
| 50% with disease = 50 patients   | 10% with disease = 10 patients  |
| • Drug is life-saving 50% of the time = 25 lives saved   | • Drug is life-saving 50% of the time = 5 lives saved   |
| <ul> <li>100 people in the population</li> <li>50% with disease = 50 patients</li> <li>Drug is life-saving 50% of the time = 25 lives saved</li> </ul> | <ul> <li>100 people in the population</li> <li>10% with disease = 10 patients</li> <li>Drug is life-saving 50% of the time = 5 lives saved</li> </ul> |

There are more examples which showcase that using a single population in cost-effectiveness fails to reflect the diversity in patient outcomes and experiences. In breast cancer, the risk of disease ranges from 8% in American Indian and Alaskan Native women to 12% in Black women, and the proportion of women over 40 who had undergone mammography in the previous two years ranged from 57.8% among Asian women to 67.3% in white women.<sup>3,4</sup> All of these disparities are masked in the general population averages within traditional QALY-based CEA models. These differences in risk of disease and treatment uptake, if not accounted for, have the potential to bias the true benefit of treatments among racial/ethnic subgroups.

The impact of not accounting for patient differences in CEA can be seen in recent published literature. A review by the Institute for Clinical and Economic Review (ICER) which assessed the cost-effectiveness of outpatient treatments for COVID-19 assumed a homogenous patient population.<sup>5</sup> While ICER found the treatments to be cost-effective for the general population, the assessment failed to account for the unique impact the COVID pandemic has had on racial and ethnic minority populations and individuals with disabilities due to a myriad of long-standing issues such as, racism, discrimination, social and economic inequities.<sup>6,7,8</sup> Through its one-size-fits-all approach to assessing value, ICER's report likely undervalued the true clinical benefit and impact of COVID treatments on certain racial and ethnic minority and disability populations who have experienced a disproportionate burden of the COVID-19 pandemic including in terms of prevalence, hospitalization, and mortality as compared to the white or non-disabled population.<sup>9,10</sup> CEA findings using data from homogenous populations could lead to inappropriate access determinations.

Throughout the published literature there are many cases that demonstrate differences in value that are revealed when results are stratified by race and ethnicity. For example, a 2019 CEA assessed the pneumococcal vaccine in individuals 50-64 years old. In this study, when the

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<sup>&</sup>lt;sup>3</sup> National Cancer Institute. Breast: SEER Age-Adjusted Incidence Rates, 2014-2018, By Sex, Delay-adjusted SEER Incidence Rate, All Races, All Ages, All Stages. SEER\*Explorer Application. <u>https://seer.cancer.gov/explorer/</u>

<sup>&</sup>lt;sup>4</sup> National Center for Health Statistics. Health, United States, 2019: Table 033. Hyattsville, MD. 2021. Available from: <u>https://www.cdc.gov/nchs/hus/contents2019.htm</u>.

<sup>&</sup>lt;sup>5</sup> Institute for Clinical and Economic Review (ICER). Special Assessment of Outpatient Treatments for COVID-19. Published online February 3, 2022. <u>https://icer.org/wp-content/uploads/2021/08/ICER\_COVID\_19\_Draft\_Evidence\_Report\_020322.pdf</u>

<sup>&</sup>lt;sup>6</sup> Thoumi A, Hendel K, Gutierrez S, Chaudrey N, Martinez-Bianchi V. Bridging The Health Equity Gap: Strategies To Create An Equitable Health System For Latinx Communities. Health Affairs. Published November 19, 2021. https://www.healthaffairs.org/do/10.1377/forefront.20211115.823757

<sup>&</sup>lt;sup>7</sup> NIHCM Foundation. Disability, Health Equity & COVID-19. Published September 21, 2021. <u>https://nihcm.org/publications/disability-health-equity</u>

<sup>&</sup>lt;sup>8</sup> Artiga S, Tolbert J, Kates J, Michaud J, Orgera K. Growing COVID-19 Hotspots in the U.S. South and West will Likely Widen Disparities for People of Color. KFF. Published July 10, 2020. <u>https://www.kff.org/policy-watch/growing-covid-19-hotspots-in-south-and-west-likely-widen-disparities-people-of-color/</u>

<sup>&</sup>lt;sup>9</sup> Centers for Disease Control and Prevention. COVID-19 Information for People with Disabilities. Published October 26, 2021. https://www.cdc.gov/ncbddd/humandevelopment/covid-19/people-with-disabilities.html

<sup>&</sup>lt;sup>10</sup> COVID-19 Deaths By Race And Ethnicity In United States. Health Equity Tracker. https://healthequitytracker.org

authors assume that the vaccine is effective against nonbacteremic pneumococcal pneumonia, the general population had a mean ICER value of \$81,002 (notably above another commonly used threshold of \$50,000/QALY), however the Black population had a mean ICER value which was almost half the general population value (\$43,957).<sup>11</sup> So, based on the average cost effectiveness, the results may be interpreted as suggesting that the intervention is not worth covering for patients to access, despite the fact that it is estimated to have a favorable cost-effectiveness ratio for Black patients.

Given the challenges of relying on average cost-effectiveness calculations due to differences in patient risk, and treatment effectiveness, driven by societal factors outside the healthcare system, stratifying estimates by subgroups may offer one solution. However, additional limitations remain when CEA are stratified and relies on the QALY or life-years gained. In Section 2 of this brief we describe why CEA that rely on stratified quality of life or life expectancy inputs can do more harm than good.

### Section 2: Value Assessments Stratified by Race Could Also Undervalue Treatments For Certain Populations

As mentioned previously, the CEA result (incremental cost-effectiveness ratio) is estimated by dividing the costs of an intervention by the clinical benefits. **That clinical benefit is typically measured in either life years gained or quality-adjusted life years gained (QALYs).** These measures of benefit reflect the patient outcomes due to receiving the intervention compared with their outcomes in the absence of the intervention. However, this difference can be influenced by differences between groups that are not reflective of the intervention of interest, and to the extent those differences are due to underlying health inequities the results can be biased and discriminate against treatments for disadvantaged populations.

For example, there are well documented disparities in life expectancy between racial groups, whether it is measured from birth or from a specific age. As of 2020, white individuals are expected to live 77.6 years, with those surviving until age 65 being expected to live an additional 18.8 years. In comparison, life expectancy for Black individuals averages 71.8 years from birth, and those surviving to 65 only expect to live another 16.6 years.<sup>12</sup> When considering an intervention that can reverse a fatal condition, each subgroup would have their benefit measured as the additional years gained from the time of the intervention until their age of expected death. Given the differences in life expectancy, less value would therefore be assigned to an intervention given to a Black individual as would the same intervention in a white individual. For example, conducting racial/ethnic subgroup analyses on the value of COVID-19 vaccines may result in discrimination due to these unfortunate disparities in life expectancy among Black as compared to white individuals.

This discriminatory characteristic in CEA also arises when considering the values of interventions that can be used in individuals of different ages. A life-saving intervention administered to an infant would result in many decades of additional life, whereas an alternative intervention in an elderly individual would be viewed less positively by CEA because the

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<sup>&</sup>lt;sup>11</sup> Wateska AR, Nowalk MP, Lin CJ, et al. Cost-effectiveness of adult pneumococcal vaccination policies in underserved minorities aged 50–64 years compared to the US general population. *Vaccine*. 2019;37(14):2026-2033. doi:10.1016/j.vaccine.2019.01.002

<sup>&</sup>lt;sup>12</sup> Arias E, Betzaida TV, Ahmad F, Kochanek K. Provisional Life Expectancy Estimates for 2020. National Center for Health Statistics (U.S.); 2021. doi:10.15620/cdc:107201

potential gains in life expectancy would be far fewer.

Similarly, when benefits of an intervention are measured in terms of QALY, they are estimated by considering the increase in both length and QoL gained from the intervention. The biases that could arise related to length of life have been discussed, but the same issues apply to the QoL when considering interventions that could be used amongst populations whose baseline QoL is low due to severe illness or disability.

As an example, imagine a condition reduces the health utility of an individual to 0.30 (with 1 representing perfect health, 0 representing death, and values in between reflecting the health-related QoL for those with illness). If a curative treatment existed for this condition and was used on an otherwise healthy individual, their health utility could improve by 0.70 (1.0 - 0.30), and would be reflected in higher QALY gains. If the same treatment was given to an individual with severe illness or disabilities such that curing the condition would only result in their utility increasing from 0.30 to 0.50 (due to the impact of their unrelated disability), the same intervention would be assigned less value. When choosing between interventions, those that are more commonly given to individuals with disabilities would therefore be penalized due to providing less potential benefit. A similar issue arises when considering groups that may have more co-morbidities and worse overall health in the absence of disease, whether these groups are defined by race, socioeconomic status, or age. Therefore, the very nature of how QALYs are calculated devalues the lives of certain subgroups who experience health inequities and unfortunately have less time to "survive."

### Conclusion

The lack of diversity and potential discrimination when employing current methodologies may be disturbing and are a step back in the progress towards health equity. Average estimates of value based on the QALY or life expectancy fail to reflect important differences in patient populations, which are often driven by underlying health disparities. Stratifying CEA results using data representative of different subgroups can better represent these differences. However, challenges remain in relying on QALY-based CEA based on stratified inputs given its potential to discriminate against disadvantaged communities with lower life expectancy or quality of life, including the disabled, severely ill, and select communities of color.

However, efforts are underway to employ innovative approaches to assess the value of health interventions that do not incorporate QALYs.<sup>13</sup> Comparative effectiveness research that is not reliant on the QALY or life expectancies provides a method to evaluate treatment effectiveness on distinct and important health-related outcomes while adjusting for disparities. Additionally, multi-criteria decision analysis (MCDA) is a viable methodology in which multiple outcomes can be reported separately or combined to generate a single measure of value while incorporating input from diverse patients.<sup>14,15,16</sup> This ensures that health outcomes can be captured along with

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<sup>&</sup>lt;sup>13</sup> Diaby V, Ali A, Babcock A, Fuhr J, Braithwaite D. Incorporating health equity into value assessment: frameworks, promising alternatives, and future directions. 2021;27(9):8.

<sup>&</sup>lt;sup>14</sup> AJMC. Expanding Use of Multi-Criteria Decision Analysis for Health Technology Assessment. Published December 11, 2019. <u>https://www.ajmc.com/view/expanding-use-of-multicriteria-decision-analysis-for-health-technology-assessment</u>

<sup>&</sup>lt;sup>15</sup> National Pharmaceutical Council. Empowering the Patient Voice in Value Assessment: Paving the Way for MCDA. Published November 29, 2020. <u>https://www.npcnow.org/resources/empowering-patient-voice-value-assessment-paving-way-mcda</u>

<sup>&</sup>lt;sup>16</sup> McQueen RB. How MCDA Can Drive Better Value Assessment. PhRMA Foundation. Published April 28, 2021. https://www.phrmafoundation.org/2021/04/how-mcda-can-drive-better-value-assessment/

equity and other societal priorities to develop a full measure of value.

While there may be no "one-size-fits-all" approach to CEA that can adequately inform the value of interventions for the general population and across subgroups, alternative approaches need to be both more refined and adopted to be seen as a potential solution to the current problems. While CEA was not designed to be discriminatory, by ignoring the impact of interventions on inequities, it is implicitly allowing these differential outcomes to persist.

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