

March 3, 2022

Dr. Steven D. Pearson
President
Institute for Clinical and Economic Review
Two Liberty Square, Ninth Floor
Boston, MA 02109

Dear Dr. Pearson:

The Partnership to Improve Patient Care (PIPC) appreciates the opportunity to provide feedback on ICER's assessment of treatments for COVID-19. The COVID-19 pandemic has upended the country causing upheaval to many of our most basic institutions, from hospitals to schools. The pandemic is also widely known to have exerted more harm on certain populations, including communities of color, people with disabilities, and individuals living with chronic illness. PIPC urges ICER to capture the far reaching and disparate impact of COVID-19 in its model in order to accurately capture the value of effective treatments. From this vantage point, PIPC asks ICER to consider the following comments:

ICER's Model Omits Multiple Components of the Full Societal Benefit of an Effective COVID-19 Treatment.

ICER's model does not capture the full societal benefits of COVID-19 treatments. The virus has had a shattering impact on society writ large, and for that reason it is even more important than usual that the societal impact is captured in the base case.

Though ICER attempted to capture some minimal societal impacts in one of its scenarios, we strongly recommend including the societal perspective in its base case and urge ICER to explore all avenues to capture the holistic societal burden of COVID-19. The virus does not only impact the productivity of the ill patient, but the productivity of his or her healthy neighbors when they are unable to continue working as usual due to business and school closures. For example, there is a growing body of evidence indicating rising anxiety and depression in the nation's youth following several years of educational and social disruption.¹

COVID-19 has also had a disproportionate impact on our health care system, beyond just capacity of intensive care units. One of the biggest burdens of COVID-19 has been the impact on the health care system's ability to treat routine health problems. Treatments for cancer,² chronic

¹ <https://publications.aap.org/aapnews/news/17718>

² Raymond E, Thieblemont C, Alran S, Faivre S. Impact of the COVID-19 outbreak on the management of patients with cancer. Targeted oncology. 2020 Jun;15(3):249-59.

diseases,³ and scheduled or emergency surgeries⁴ have been delayed or cancelled. This has had a significant and documented effect on health outcomes and non-COVID mortality.⁵ With this in mind, an accurate representation of the value of successful treatments for COVID-19 should include this wider impact on the zero sum of scarce healthcare resources as a marginal public health value as previous studies have shown.⁶

Treatments developed for coronaviruses now may also have considerable additional value in the future. Novel antibiotics not only have great value now because they can treat current infections, but also because they may be the only antibiotic option in the future where resistance to current therapies has been exhausted.⁷ In a similar vein, antivirals cannot be evaluated in a vacuum.⁸ If we have learned anything from the COVID-19 epidemic it is that coronaviruses are not static, they are constantly evolving, and an antiviral that has the potential to keep new variants from being less severe also provides value that should be captured.

ICER's Model Does Not Capture the Impact of Treatment on Health Equity

ICER must be transparent about the fact that the burden of COVID-19 falls more heavily on communities of color, people who are immunocompromised, seniors,⁹ and uninsured populations.^{10,11} Given that the burden of disease in general falls more heavily on these groups, and access to healthcare is also lower in these groups,¹² effective therapeutic interventions can have an impact on reducing underlying health inequities. ICER should examine the fact that not only are effective treatment options impactful for individual patients, but they also have the potential to address systemic health inequalities. We urge ICER to include a specific section on the report addressing health equity and effective treatments' potential impact on health disparities.

³ Maringe C, Spicer J, Morris M, Purushotham A, Nolte E, Sullivan R, Rachet B, Aggarwal A. The impact of the COVID-19 pandemic on cancer deaths due to delays in diagnosis in England, UK: a national, population-based, modelling study. *The lancet oncology*. 2020 Aug 1;21(8):1023-34.

⁴ "Elective surgery cancellations due to the COVID-19 pandemic: global predictive modelling to inform surgical recovery plans." *Journal of British Surgery* 107, no. 11 (2020): 1440-1449.

⁵ Barach P, Fisher SD, Adams MJ, Burstein GR, Brophy PD, Kuo DZ, Lipshultz SE. Disruption of healthcare: Will the COVID pandemic worsen non-COVID outcomes and disease outbreaks?. *Progress in pediatric cardiology*. 2020 Dec;59:101254.

⁶ Jena AB, Stevens W, Gonzalez YS, Marx SE, Juday T, Lakdawalla DN, Philipson TJ. The wider public health value of HCV treatment accrued by liver transplant recipients. *The American journal of managed care*. 2016 May;22(6 Spec No.):SP212-9.

⁷ Luepke, K.H., Suda, K.J., Boucher, H., Russo, R.L., Bonney, M.W., Hunt, T.D. and Mohr, J.F., 2017. Past, present, and future of antibacterial economics: increasing bacterial resistance, limited antibiotic pipeline, and societal implications. *Pharmacotherapy: The Journal of Human Pharmacology and Drug Therapy*, 37(1), pp.71-84.

⁸ Rusic D, Vilovic M, Bukic J, Leskur D, Seselja Perisin A, Kumric M, Martinovic D, Petric A, Modun D, Bozic J. Implications of COVID-19 pandemic on the emergence of antimicrobial resistance: Adjusting the response to future outbreaks. *Life*. 2021 Mar;11(3):220.

⁹ Tai DB, Shah A, Doubeni CA, Sia IG, Wieland ML. The disproportionate impact of COVID-19 on racial and ethnic minorities in the United States. *Clinical Infectious Diseases*. 2021 Feb 15;72(4):703-6.

¹⁰ Lodge W, Kuchukhidze S. COVID-19, HIV, and migrant workers: the double burden of the two viruses. *AIDS patient care and STDs*. 2020 Jun 1;34(6):249-50.

¹¹ Miller IF, Becker AD, Grenfell BT, Metcalf CJ. Disease and healthcare burden of COVID-19 in the United States. *Nature Medicine*. 2020 Aug;26(8):1212-7.

¹² Ward MM. Access to care and the incidence of endstage renal disease due to systemic lupus erythematosus. *The Journal of rheumatology*. 2010 Jun 1;37(6):1158-63.

ICER Continues to Use the Quality-Adjusted Life Year, which is widely known to discriminate against people with disabilities, patients with chronic conditions, and older adults – populations hit hardest by the pandemic.

Multiple studies have shown that cost-effectiveness models that use the quality-adjusted life year (QALY) discriminate against patients with chronic conditions¹³ and people with disabilities.¹⁴ There is widespread recognition that the use of the QALY is discriminatory. The QALY has historically been opposed by the American public and policy makers. The National Council on Disability (NCD), an independent federal agency, concluded in a 2019 report that QALYs discriminate by placing a lower value on treatments which extend the lives of people with chronic illnesses and disabilities. NCD recommended that policymakers and insurers reject QALYs as a method of measuring value for medical treatments.¹⁵ Throughout the pandemic, people with disabilities and chronic conditions have been hit hardest by COVID-19. They have experienced worse health outcomes, been subjected to discriminatory crisis standards of care, and too often have been viewed as disposable.¹⁶ Effective treatments for COVID-19 have the potential to be most meaningful to these individuals. Therefore, the QALY, which is known to undervalue treatments for people with disabilities, should not be used in this assessment.

Recent work shows that due to diminishing returns, traditional cost utility methods, like those ICER uses, overvalue treatments for mild illnesses and undervalue treatments for highly severe illnesses, and as a result such studies recommend underpaying for treatment of severe illnesses. ICER should be evolving away from use of the QALY, and, instead, measuring value based on the most up to date science and improved health utilities reflecting the value to the patient.

ICER Should Use a Transmission Model When Assessing Treatments for Infectious Diseases.

Markov models and decision trees are commonly used for non-communicable diseases, as they are loosely based around disease progression over the course of the disease. Models used to represent communicable diseases have a very different structure. The population of interest is not just those with the disease at the onset of the model timeline, but also others within the population who may become infected. Even if the agents being evaluated are for treatment, not prevention, more effective treatment tends to mean lower periods of incubation and infection, which impacts transmission. Transmission models are regarded as best practice for estimating

¹³ Paulden M. Recent amendments to NICE's value-based assessment of health technologies: implicitly inequitable?. Expert review of pharmacoeconomics & outcomes research. 2017 May 4;17(3):239-42.

¹⁴ Nord E, Pinto JL, Richardson J, Menzel P, Ubel P. Incorporating societal concerns for fairness in numerical valuations of health programmes. Health economics. 1999 Feb;8(1):25-39.

¹⁵ https://www.ncd.gov/sites/default/files/NCD_Quality_Adjusted_Life_Report_508.pdf

¹⁶ https://www.aapd.com/wp-content/uploads/2022/01/CDC-Letter_FINAL.pdf

cost-effectiveness in infectious diseases with recent examples in HCV,¹⁷ HIV,¹⁸ HPV,¹⁹ influenza,²⁰ pneumonia,²¹ and COVID-19.²²

The impact of effective treatments on behavioral aspects of the population that impact how public health systems are able to manage the pandemic is also documented. The availability of effective treatments is known to have a positive effect on the probability of cases being diagnosed,²³ and how early they are diagnosed due to an increased propensity to seek testing by the general population.²⁴ This can result in a population level health benefit that can only be measured with the use of a transmission model.

Using a transmission model would also allow the report to more ably assess the wider economic burden of failing to control an epidemic and its impact on economic and social wellbeing more broadly.²⁵ Numerous commentators have made the point that where there are no therapeutic interventions available, the only options are to enforce considerable behavioral restrictions on society, which comes at great economic and mental health cost.²⁶

Conclusion

PIPC urges ICER to revisit its modeling choices to ensure it is capturing the full benefit of effective COVID-19 treatments on society, including health equity considerations.

¹⁷ Scott N, McBryde ES, Thompson A, Doyle JS, Hellard ME. Treatment scale-up to achieve global HCV incidence and mortality elimination: a cost-effectiveness model. *Gut*. 2017 Aug 1;66(8):1507-15.

¹⁸ Chesson, H.W. and Pinkerton, S.D., 2000. Sexually transmitted diseases and the increased risk for HIV transmission: implications for cost-effectiveness analyses of sexually transmitted disease prevention interventions. *Journal of acquired immune deficiency syndromes (1999)*, 24(1), pp.48-56.

¹⁹ Jit M, Brisson M, Laprise JF, Choi YH. Comparison of two dose and three dose human papillomavirus vaccine schedules: cost effectiveness analysis based on transmission model. *Bmj*. 2015 Jan 7;350.

²⁰ Pitman RJ, Nagy LD, Sculpher MJ. Cost-effectiveness of childhood influenza vaccination in England and Wales: results from a dynamic transmission model. *Vaccine*. 2013 Jan 30;31(6):927-42.

²¹ Tilahun GT, Makinde OD, Malonza D. Modelling and optimal control of pneumonia disease with cost-effective strategies. *Journal of Biological Dynamics*. 2017 Aug 11;11(sup2):400-26.

²² Aldila D. Cost-effectiveness and backward bifurcation analysis on COVID-19 transmission model considering direct and indirect transmission. *Commun. Math. Biol. Neurosci.*. 2020 Mar 8;2020(3)8

²³ Zhai P, Ding Y, Wu X, Long J, Zhong Y, Li Y. The epidemiology, diagnosis and treatment of COVID-19. *International journal of antimicrobial agents*. 2020 May 1;55(5):105955.

²⁴ Hunter E, Price DA, Murphy E, van der Loeff IS, Baker KF, Lendrem D, Lendrem C, Schmid ML, Pareja-Cebrian L, Welch A, Payne BA. First experience of COVID-19 screening of health-care workers in England. *The Lancet*. 2020 May 2;395(10234):e77-8.

²⁵ Miles D, Stedman M, Heald A. Living with COVID-19: balancing costs against benefits in the face of the virus. *National Institute Economic Review*. 2020 Aug;253:R60-76.

²⁶ Atalan A. Is the lockdown important to prevent the COVID-19 pandemic? Effects on psychology, environment and economy-perspective. *Annals of medicine and surgery*. 2020 Aug 1;56:38-42.



Partnership to Improve Patient Care

Sincerely.

A handwritten signature in black ink that reads "Tony Coelho". The signature is enclosed in a thin black rectangular border.

Tony Coelho, Chairman
Partnership to Improve Patient Care