Equitably Sharing the Benefits and Burdens of Research: Covid-19 Raises the Stakes

One of the central principles of research ethics is that the benefits and burdens of research with human participants should be equitably distributed. This principle has important implications for questions about where research will be conducted, how participants will be recruited, what questions will be investigated, and who will control the distribution of any innovations that result. In the rush to initiate clinical trials of treatments and vaccines for Covid-19, careful attention to these questions is particularly important. If clinical trials are not designed with equity considerations consciously in mind, the response to the pandemic may exacerbate disparities in health status between population groups.

The question of where Covid-19 clinical trials will be conducted is relevant to both the burdens and benefits of research. On the burdens side, there have long been concerns about the “off-shoring” of studies to low- and middle-income countries (LMICs) to take advantage of looser regulation and of populations eager to participate in research because they have no other good options for accessing health care. This concern explains the outrage sparked by a French doctor’s statement that Covid-19 trials should be conducted in Africa to take advantage of the fact that “there are no masks, treatment, or intensive care” (which would presumably make it easier to determine whether the experimental intervention was working). World Health Organization (WHO) Director-General Tedros Adhanom Ghebreyesus condemned the comment as “a hangover from a colonial mentality.”

At the same time, excluding LMICs from Covid-19 research is clearly not the solution, as doing so would reduce the potential benefits of research for persons in those regions. This is because the results of clinical trials conducted in one part of the world are not necessarily applicable to persons living elsewhere, due to differences in genetic makeups, the prevalence of comorbidities, and local health care infrastructures. It is therefore discouraging that the WHO’s Solidarity Trial, which is comparing the safety and efficacy of four treatment options for Covid-19, currently includes only a few sites in Africa, Latin America, and South or Southeast Asia. The global community must commit to supporting clinical trials in LMICs that contribute to the development of locally relevant interventions, while also ensuring that these efforts do not take resources away from other critical clinical and public health needs.

The manner in which participants are recruited into studies also raises equity considerations. For example, in the United States, there is substantial evidence that African American and Hispanic and Latinx patients are underrepresented among clinical trial participants. This is a problem because, just like people from different parts of the world, people from different racial and ethnic backgrounds may respond differently to medical interventions. While the reasons for racial and ethnic disparities in clinical trial participation are complex, one factor is reliance on recruitment strategies unlikely to generate significant minority enrollment, such as direct recruitment by physician-investigators at academic medical centers. Proven strategies to increase the diversity of clinical trial participants include the development of culturally and linguistically appropriate communication materials, in-person recruitment at free clinics, and the careful use of financial incentives. These and other strategies to overcome racial disparities in research will be particularly important in Co-
vid-19 clinical trials, given that the disease is infecting and killing African Americans at a disproportionately high rate.\(^{11}\)

Also important is support for research specifically focused on the unique needs of certain subpopulations. For example, residents of nursing homes and group homes for the developmentally disabled have been especially hard hit by the Covid-19 outbreak.\(^{12}\) Because these populations have suffered a disproportionate share of the burdens of the pandemic, equity requires support for research specifically designed to reduce risk and improve outcomes in these institutional settings. Similarly, studies should focus on the unique needs of other populations that may be excluded from large-scale clinical trials, such as patients who are pregnant.

The looming issue with respect to research on treatments and vaccines for Covid-19 relates to control over any medical products that are developed. In most cases, companies that develop new medical products are entitled to patent them, even when the research is supported in part by government funds. Patents enable companies to exclude competition and charge high monopoly prices, which effectively blocks large portions of the global population from access to these products. This means that, even when individuals assume risks by participating in research that leads to the development of a medical product, they have no guarantee that, once the product is on the market, it will be made available in their community at a price they can afford.

Efforts are already underway to ensure more equitable access to Covid-19 treatments and vaccines. The WHO and some prominent government and industry leaders recently pledged to work together to ensure that “all people have access to all the tools to prevent, detect, treat and defeat Covid-19.”\(^{13}\) Some companies have committed to making any such products that they develop available on a nonprofit basis.\(^{14}\) One idea that will be considered at this year’s World Health Assembly is a proposal to establish a mechanism for companies to “pool” patents and other intellectual property rights over Covid-19 products, making it easier for developers to access new technologies and for generic manufacturers to produce needed products at an affordable price.\(^{15}\)

Yet, while these are encouraging developments, they remain insufficient. The Trump administration has made clear that it has no interest in supporting any WHO-led initiatives, and, in any event, the WHO lacks the authority to override national intellectual property laws. While voluntary corporate philanthropy is admirable, with more than 100 vaccine candidates currently in development, there is no assurance that the companies making philanthropic pledges will be the ones whose candidate vaccines ultimately succeed.

What is needed is an international governance system to oversee access to Covid-19 vaccines and treatments. Given the fundamental ethical principle of equity in research, advocating for such a system should be a priority for everyone involved in designing, conducting, and funding clinical trials.

Carl H. Coleman, JD, is a professor of law at Seton Hall University School of Law.

1. Council for International Organizations of Medical Sciences (CIOMS), *International Ethical Guidelines for Health-Related Research Involving Humans* (Geneva: CIOMS, 2016), guideline 3.
2. National Bioethics Advisory Commission, *Ethical and Policy Issues in International Research: Clinical Trials in Developing Countries* (Rockville, MD: National Bioethics Advisory Commission, 2001).
3. Folley, A., "French Doctor Apologizes after Suggesting Africa for Coronavirus Tests," *The Hill* (blog), April 7, 2020.
4. Ibid.
5. Presidential Commission for the Study of Bioethical Issues, *Moral Science: Protecting Participants in Human Subject Research* (Washington, DC: Presidential Commission for the Study of Bioethical Issues, 2011), 91.
6. Roussi, A., and A. Maxmen, "African Nations Missing from Coronavirus Trials," *Nature* (April 3, 2020): doi:10.1038/d41586-020-01010-7.
7. Loree, J. M., et al. "Disparity of Race Reporting and Representation in Clinical Trials Leading to Cancer Drug Approvals from 2008 to 2018," *JAMA Oncology* 5, no. 10 (2019): e191870.
8. "Racial and Ethnic Minorities in Clinical Trials," U.S. Food and Drug Administration, March 18, 2020, https://www.fda.gov/consumers/minority-health-and-health-equity/racial-and-ethnic-minorities-clinical-trials.
9. Borno, H. T., et al., "A Step towards Equitable Clinical Trial Recruitment: A Protocol for the Development and Preliminary Testing of an Online Prostate Cancer Health Information and Clinical Trial Matching Tool," *Pilot and Feasibility Studies* 5 (2019): article 12.
10. Taani, M. H., et al. "Lessons Learned for Recruitment and Retention of Low-Income African Americans," *Contempo*...
The Coronavirus Is Infecting and Killing Black Americans at an Alarmingly High Rate,” *Washington Post*, April 7, 2020.

12. Hakim, D., “‘It’s Hit Our Front Door’: Homes for the Disabled See a Surge of Covid-19,” *New York Times*, April 8, 2020.

13. “Global Leaders Unite to Ensure Everyone Everywhere Can Access New Vaccines, Tests and Treatments for COVID-19,” World Health Organization, April 28, 2020, https://www.who.int/news-room/detail/24-04-2020-global-leaders-unite-to-ensure-everyone-everywhere-can-access-new-vaccines-tests-and-treatments-for-covid-19.

14. “Our Efforts to Develop a Vaccine and Identify Therapies for COVID-19,” Johnson & Johnson, accessed April 28, 2020, https://www.jnj.com/coronavirus/prevention-and-treatment.

15. ‘t Hoen, E., “How the World Can Put Sharing above Profits in the Race for a Vaccine,” *Barrons*, April 16, 2020, https://www.barrons.com/articles/a-vaccine-for-all-not-if-these-companies-and-countries-have-their-way-51586976476.