JOURNAL OF CLINICAL RESEARCH BEST PRACTICES
Vol. 17, No. 3, March 2021 “Happy Trials to You”

Justice in Research: Reflections on the Lessons of 2020

By Elisa A. Hurley

Last year, Heather H. Pierce and I shared some thoughts about the “Belmont Report at 40” and about the evolution and flexibility of the Belmont principles of respect for persons, beneficence and justice in the face of changing circumstances.[1,2] As we leave behind the extraordinary year of 2020, I have been thinking about how the pandemic, together with the Black Lives Matter social justice movement, has shone new, and I would say, welcome light on the principle of justice in research.

People talk about the murder of George Floyd at the hands of police last spring as occasioning a long-overdue moment of reckoning in this country about our legacy of racism and racial injustice. I think 2020 also presented a moment of reckoning for the research enterprise and its own role in perpetuating or benefitting from that injustice. We in the research oversight field have an important opportunity to examine not just our research practices but also the ways in which the research enterprise is embedded within a society that is unjust in fundamental ways.

We know that the novel coronavirus is disproportionately affecting people from racial and ethnic minority groups.[3] Black people make up 13% of the U.S. population but represent about 21% of the deaths from COVID-19. A recent study out of Stanford University found that Blacks and Hispanics account for 58% of COVID-19 hospitalizations and 53% of deaths.[4] According to the Centers for Disease Control and Prevention, Black Americans are dying at two times the rate of whites from the virus, Hispanics and Latinos are almost three times as likely to become infected as whites, and American Indian/Alaska Native people are more than five times as likely as whites to be hospitalized for COVID-19.[5]

These are, of course, just the most recent manifestations of longstanding health inequities in our country.

We also know that these are the very same groups who are historically underrepresented in clinical trials; treatment and vaccine trials for COVID-19 are no different. By some accounts, only 3% of coronavirus vaccine trial participants are Black.[3] (Although it’s worth noting that volunteers from communities of color make up 37% of the Moderna vaccine trial — a figure to be applauded).[6] In other words, many of those who are most at risk from the virus are not represented in treatment or prevention trials. The problem, then, is that the findings of these trials may not be generalizable to those who could most benefit. This may in turn actually exacerbate health inequities.

These are the bleak, and familiar, facts. The pandemic and 2020’s racial justice movements have together brought these inequities — along with the range of social, economic and other factors that contribute to them — into stark relief. But precisely because they have done so, they also present us with an opportunity to reconsider justice in research.

Conversations are already happening about how the pandemic and the creative ways the research community has adapted to it are helping us rethink how we conduct, oversee and regulate research to make research participation more accessible and equitable.[7] Some examples include the increased use of telemedicine study visits, remote auditing, and trial monitoring through use of electronic health records, further development of remote consent processes, and the use of wearables for data collection during studies — all strategies that might support the participation of underrepresented groups for whom trial participation has in the past been impracticable.

In addition, the Multi-Regional Clinical Trials (MRCT) Center of Harvard and Brigham and Women's has released an extraordinarily comprehensive guidance document and toolkit outlining how research stakeholders, including IRBs, can help achieve diversity, inclusion and equity in clinical trials.[7], These tools, the culmination of the first phase of a project that has been in the works for several years, could not have come at a better time for the research community. MRCT's guidance and toolkit cover everything from strategies for partnering with communities and research workforce development to considerations for data collection, reporting and analysis to eligibility criteria and subject recruitment.

The FDA has also published its final guidance on enhancing diversity in clinical trial enrollment, using the voice and leadership of the FDA to encourage the broadening of clinical trial eligibility criteria and other inclusive trial practices, so as not to unjustifiably and unjustly exclude individuals from trial participation.[8]

The Department of Health and Human Services (HHS)'s Secretary's Advisory Committee on Human Research Protection (SACHRP) has recently taken up consideration of the role of justice as an ethical principle in the Common Rule, examining how it can provide more guidance to IRBs about operationalizing justice concerns.[9]

These are just some of the exciting, important current efforts to identify and implement real, meaningful steps within the research and research oversight enterprises to make them more just.

The twin crises we've faced the past year are also forcing us to confront in new or maybe starker ways the extent to which the research enterprise is embedded in a society characterized by various forms of injustice and inequity.

For example, we are more aware than ever of the extent to which inequities in COVID-19 outcomes are products of social determinants of health — factors such as whether and where one is employed; whether one lives in close proximity to others, takes public transportation, has access to regular healthcare, speaks English, has insurance, or has childcare help, to name just a few. The pandemic has also drawn attention to the fact that many of these same factors also serve as structural barriers to research participation, even for people who might otherwise be willing to participate.

At the same time, the lack of representation in COVID-19 clinical trials has also once again made plain the continued legacy of distrust in the healthcare and research enterprise among Black Americans and other racial and ethnic minorities, given historical wrongs perpetrated on these communities. We can see this effect in data about willingness to take a vaccine. In late November 2020, a study was released that illuminates this "trust gap," showing that just 14% of Black and 34% of Latinx people trust that a vaccine will be safe, and 18% and 40%, respectively, trust that it will be effective.[10] Less than half of the African Americans included in the survey said they would definitely or probably get the vaccine.

A recent article in the *New England Journal of Medicine* suggests that the way to address this distrust is for the research enterprise to take steps to become more trustworthy.[3] For instance, Black people may be more willing to enroll in vaccine trials if they have assurances that Black communities will have fair access to vaccines once they become available — where fair access means they will be prioritized, given the disproportionate effect of the pandemic on them.

The circumstances of the past year have also forced us to look anew at how implicit bias (i.e., the attitudes and stereotypes we all carry around that affect our understanding, actions and decisions in an unconscious manner) plays out in the research context, for instance, in recruitment practices.[11] They are also giving rise to important conversations about lack of diversity in the research workforce, especially the underrepresentation of principal investigators (PIs) of color who might counteract recruitment biases and enhance trust in the research enterprise generally and in specific research projects in particular.

These issues aren't new, and they certainly aren't simple. Some of them — such as access to insurance, priority access to vaccines, and increased funding for PIs of color — are clearly outside our ambit in the research oversight community. Addressing them will take larger structural changes. But I think there is value in being clear eyed about the multiple ways that injustice infiltrates and affects the research enterprise.

And, I am hopeful that, unsettling and difficult as this past year has been, we are at a turning point, not just in terms of our collective recognition of the problems of injustice in research but in terms of our collective will to take action to address these problems. We have a lot of work to do; but as my colleague Barbara Bierer put it recently, the community is, perhaps more than ever, motivated and ready to do that work.

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This piece first appeared on PRIM&R’s blog Ampersand (adapted from Elisa A. Hurley’s opening remarks at the 2020 Advancing Ethical Research Conference). It has been published here with permission.