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Social Justice in Clinical Research

By Norman M. Goldfarb

The year 2020 experienced a level of social upheaval the U.S. has not seen since the 1960s. Among other things, the weight of public opinion has become very clear: The time for social injustice has passed. Lip service is no longer adequate. Concrete action must be taken. The price must be paid. Inertia must be overcome.

Clinical research has always been haunted by a lack of broad participation from all segments of society. Choose your favorite word — disfavored, disadvantaged, marginalized, disempowered, minority, underprivileged, deprived, subordinated, unequal, oppressed, discriminated against, etc.— they have all been left out.

The Belmont Report addressed the equitable distribution of risks. For example, it is unfair to test a risky, new drug on a population that will not have access to the marketed product. Fairness requires that we determine safety and effectiveness across the entire population, but that goal creates a conundrum: if we do not test a drug on pregnant women, for example, we will not know if it is safe for them; but who wants to risk that study?

When the focus is on risk rather than benefit, not including disfavored populations in clinical studies can be considered benign, since it would not be fair to risk disadvantaged subjects’ health for the benefit of advantaged white males.

But the situation has changed. Rapidly advancing technology makes clinical research as a care option (CRAACO) a very legitimate branch of medicine. For many diseases, especially cancers, clinical research studies now offer the superior, or only, treatment. As a result, excluding disfavored populations in clinical studies is no longer benign; it is malignant.

As a result, equity in clinical research now means going the extra mile to give disfavored populations access to clinical study benefits. Because of past horrors, such as the Tuskegee Study of Untreated Syphilis in the Negro Male, disfavored populations, especially Blacks, are understandably wary of participation in clinical studies. U.S. immigration policies have created a fundamental level of mistrust of the U.S. government and institutions in general in the Latino population. It will take many years of educating and engaging with disfavored populations before we will be successful in consistently creating representative trials.

Economic, social, language and location factors create other barriers to equitable access to medical care, and even more to clinical studies. We must pay more attention to access and less to undue influence. Clinical studies can offer fair compensation, transportation, flexible hours of operation, interpretation services, etc., to help address these issues. It is not enough to make information available about clinical studies. We cannot expect the disempowered to take the initiative. They must be empowered as equals, not just recipients of our largess. It is *they* that are doing *us* the favor.

Opening clinical studies to the disfavored is not just a matter of altruism and social justice. It also serves our interests by expanding the accessible study-participant population, broadening the markets for our medical products, and developing new political allies. Wouldn’t it be nice to be on the agenda of social activists?

Addressing injustice in clinical research requires connecting, engaging, listening, learning and educating. We know how to do these things. While it will take years to right the clinical research social justice ship, it will not take forever. We can then look forward to all the benefits of social justice with none of the costs.

Social reformers led the movement to create the Food and Drug Administration and federal regulations to protect the public from unsafe and ineffective medical products. HIV/AIDS activists led the movement to accelerate the FDA's process for approving drugs in a crisis. But, we cannot expect marginalized populations to lead the charge for access to clinical studies that meet their needs. We must do that ourselves. We know what to do. We've already started doing it. Over time, we will get better and better at it. Let's work together to make clinical research a model of social justice for the nation and the world.

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