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BRIEF19

A daily review of covid-19 research and policy.

RESEARCH BRIEFING

Diversity, Representation and Covid-19 Clinical Trials.

Racial minorities have a fraught history of inclusion in unethical clinical trials in the United States, and covid-19 has the potential to further complicate the story. One example of exploitation of minorities in clinical trials were the Tuskegee Syphilis experiments, during which Black men were used as subjects to study the natural course of syphilis, despite readily available penicillin. Meanwhile, contemporary examples of racial injustice in clinical trials include *underrepresentation* of Black and other minorities. This is where covid-19 is relevant. Despite a disproportionately high covid-19 disease burden amongst the Black, Latinx and Native American populations, these groups are disproportionately underrepresented in ongoing drug trials. This ultimately asks: will such treatments be generalizable and effective across all populations if studies aren't performed in a population representative of the U.S. as a whole?

In a perspective piece published in the *New England Journal of Medicine*, this continued lack of minority representation in clinical trials is highlighted. In the Adaptive Covid-19 Treatment Trial (ACTT-1), which enrolled 1063 patients, Black, Latinx and Native Americans accounted for only 20 percent, 23 percent, and 0.7 percent of the patients in this study, respectively. Meanwhile, only 11 percent of 397 patients in the Gilead funded Remdesivir study were Black. The crux of the disparity lies in the fact that these studies were conducted in areas where covid-19 related deaths affected these groups at a disproportionately high rate, and their inclusion in these trials were, "substantially underrepresented," according to the article. The authors suggest the lack of diversity in these clinical trials is multifactorial and includes an understandable history of mistrust of the medical community from the perspective of minority communities, as well as the financial cost associated with participating in clinical trials. These problems are further compounded by poor health literacy and language barriers. An additional factor is a lack of diversity amongst the principal investigators. It should also be noted that Remdesivir's "compassionate use" program provided no racial or ethnic data for the 53 patients treated, so no conclusions could be drawn from that subset of patients.

Nevertheless, National Institutes of Health (NIH) policy and federal laws mandate the inclusion of racial minorities in NIH funded clinical trials, as well as transparency of racial and ethnic data in phase 3 clinical trials. And yet the Remdesivir studies failed to have adequate representation or even report proper data. While the ACTT-1 did include demographics for patients enrolled, it still failed to provide outcome data linked to gender, race and ethnicity.

When diverse populations are not adequately represented, it is difficult to extrapolate data to the general population. The authors of this article advocate for prioritizing "inclusion of patient populations that reflect the demographics of the ongoing pandemic." Further, they emphasize the importance of increasing funding for scientists belonging to underrepresented ethnic groups and standardizing the reporting of race and ethnicity data. The authors firmly believe that regulatory agencies, medical journals, funders and peer reviewers have the obligation to ensure that clinical trials meet the standards set in place, not only by federal law but also with respect to NIH policy. Future proposals and manuscripts must be able to account for the demographics of their subjects and commit to reporting more nuanced data. *NEJM*

—Onyeka Otugo, MD, MPH

POLICY BRIEFING

The FDA says it won't cut corners in the race for a coronavirus vaccine. Russia will.

While anxieties created by the covid-19 pandemic have led to hasty journal publications and a public outcry for a vaccine in the near future, the U.S. Food and Drug Administration will not sacrifice their rigorous safety standards. In an article recently published in the *Journal of the American Medical Association,* FDA leadership resoundingly stated that any vaccine candidates will be subject to the same legal and regulatory standards required of all potential medical products. Their piece goes on to enumerate a number of considerations for the vaccine process.

First, all vaccines will be manufactured in accordance with the FDA's quality standards and have their safety and efficacy confirmed prior to distribution. Additionally, to achieve herd immunity, the vaccine will need to be widely distributed. Furthermore, extensive planning will be required before any vaccine can be released in order to establish surveillance and patient follow up. Finally, the authors require that all manufacturing candidates be evaluated by an outside advisory committee.

This statement comes with important underlying context, as Russia recently announced that they have licensed and begun distribution on a vaccine before undergoing Phase III testing, stating, "Russian science is more advanced in this [area] than many other nations." While the adenovirus-based vaccine being proposed has been reportedly tested for safety in previous trials for vaccines like MERS, there is no proof that this particular vaccine works in humans for preventing SARS-CoV-2 infection. *Various.*

—Joshua Lesko, MD

Reimbursement for coronavirus counseling.

In order to encourage healthcare providers to counsel patients regarding social distancing, quarantining and other methods of limiting the spread of coronavirus, the Center for Medicare and Medicaid Services (CMS) and the U.S. Centers for Disease Control and Prevention (CDC) has announced a modification in reimbursement methods.

Using existing evaluation and management (E/M) codes, healthcare providers will be able to bill for these specific educational sessions to encourage wider adoption of safe practices. This policy was announced as part of a broader Fee-For-Service update published by CMS covering various billing changes during the Public Health Emergency (PHE), including broader telehealth, waiving of certain copays and various other changes. *The Center for Medicare and Medicaid Services (CMS)*

—Joshua Lesko, MD