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BRIEF19

A daily review of covid-19 research and policy.

RESEARCH BRIEFING

Minorities account for an outsized proportion of covid-19 hospitalizations.

Differences in social determinants of health (SDOH), the social and economic conditions that contribute to health, may explain why covid-19 has affected some racial and ethnic groups more than others. The authors of a recent study in *JAMA* characterized the racial and ethnic covid-19 hospitalizations across 12 states, and found that covid-19 positive White patients accounted for a smaller proportion of hospitalizations, compared to the Black, Native American, Asian and Hispanic populations.

Particular examples included in the data clarify this finding. For example, in Minnesota the state population is 84 percent White, but the hospitalized population was 53 percent White. The difference in proportion of hospitalizations and the state population of Black individuals were greatest in Ohio (32 percent versus 13 percent), Minnesota (25 percent vs 7 percent), Indiana (28 percent versus 10 percent) and Kansas (22 percent versus 6 percent). The authors observed similarly disproportionate hospitalization rates for Hispanic and Native American populations in most states.

The underlying context of this study becomes more interesting when compared to another recent *JAMA* study covered in *Brief19*, which found no difference in all-cause mortality between Black and White Americans once hospitalized.

There are a number of key takeaways in comparing these two studies. First, it seems clear there are disparities in how different groups access healthcare during covid-19. if not always. Even if SDOH do not specifically affect mortality from covid-19, they may affect other aspects of health and quality of life. A greater rate of hospitalization during a pandemic could also reflect decreased availability to outpatient services, such as a patient needing to be hospitalized for uncontrolled diabetes because they could not reach their doctors or receive refills on medication in a timely manner. It is also important to remember that while the second study we mentioned found no difference in all-cause mortality of hospitalized patients, understanding that a greater proportion of minorities were hospitalized means that there is a higher degree of mortality among minorities as a proportion of the total population.

There were a number of limitations to this study, however, as there was no adjustment for age, sex, comorbidities and socioeconomic factors. Furthermore, SDOH can vary from state to state. A helpful follow-up analysis could identify factors that drive the difference in hospitalizations. It would be informative to consider the differences between access to care in rural settings as compared to urban venues and an analysis of the rates of rehospitalization.

—Michael Chary, MD PhD

POLICY BRIEFING

Emergency use authorization for convalescent plasma granted over experts' concerns.

On Sunday, the U.S. Food and Drug Administration (FDA) granted an Emergency Use Authorization (EUA) for convalescent plasma as a treatment for covid-19. On Friday, *Brief19* covered a developing story in which a group of experts from the National Institutes of Health (NIH) and National Institutes of Allergy and Infectious Disease (NIAID) including Dr. Anthony Fauci and Dr. Francis Collins opposed this designation due to insufficient evidence demonstrating benefit. But on Sunday the administration moved forward. The White House Chief of Staff hailed the move, saying that the FDA had been made by President Trump and his team to "see the light." Under the Authorization, the FDA determined that the potential gains of plasma outweighs the known and potential risks. The premise behind the use of such plasma is that individuals who have recovered from the coronavirus have circulating antibodies that may be able to stimulate the recipient's immune system into mounting a more effective defense.

However, the FDA's decision memorandum relies mainly on retrospective data. In a press briefing, it was claimed that plasma was associated with a 35 percent lowering of the death rate from covid-19. This is a misleading claim. In a subset of a subset (patients under 80 years old who received plasma in the first three days of hospitalization, who were not on mechanical ventilators), death rates fell from around 10 percent to around 6.5 percent. Even if those data are found in a true trial, this implies that nearly 30 such patients would need to be treated to save one life. Nevertheless, that would be a significant victory, if it were found to be true in a clinical trial.

Meanwhile, the only two randomized clinical trials studying the effect of plasma in treating covid-19 have been disappointing. Both showed no statistical benefit. *The FDA.*

—Joshua Lesko, MD

Decreased oversight of laboratory tests.

The Department of Health and Human Services (HHS) has announced a change in their premarket review process for laboratory developed tests (LDTs). It will no longer require a premarket review. Stating compliance with Executive Order 13771 (each agency must repeal two regulations for every regulation issued and must not exceed incremental regulatory costs determined by the Office of Management and Budget) and Executive Order 13924 (regulations should be reduced in the face of the public health emergency to hasten economic recovery), these changes allow requests for review by the FDA for approval or Emergency Use Authorization without the same robust data as prior applications. According to the FDA, the premarket approval process is "the most stringent" review and is required before some medical devices can be marketed. Requesting the review is a voluntary process, and the caveat for foregoing it is that products will not be eligible for protection under the Public Readiness and Emergency Preparedness (PREP) Act, which offers liability protections for covered entities. *Various.*

—Joshua Lesko, MD