Serving as Trusted Messengers about COVID-19 Vaccines and Therapeutics

Leon McDougle, M.D., M.P.H., Dial Hewlett, Jr., M.D., Sonja S. Hutchins, M.D., M.P.H., Dr.P.H., Rodney G. Hood, M.D., Lakesha M. Butler, Pharm.D., B.C.P.S., L. Kadijah Lang, M.D., Oliver T. Brooks, M.D., Virginia A. Caine, M.D., Patricia N. Whitley-Williams, M.D.

Author affiliations: Leon McDougle, NMA 121st President, Professor of Family Medicine, The Ohio State University College of Medicine, Columbus, OH; Dial Hewlett, Medical Director, Disease Control Division, Deputy Commissioner, Westchester County, Department of Health, NY; Sonja S. Hutchins, Professor of Community Health & Preventive Medicine, Morehouse School of Medicine, Atlanta, GA; Rodney G. Hood, General Internist, San Diego, CA; Lakesha M. Butler, Clinical Professor, Department of Pharmacy Practice, Southern Illinois University Edwardsville, Edwardsville, IL; L. Kadijah Lang, Family Physician, Los Angeles, CA; Oliver T. Brooks, Chief Medical Officer, Watts Healthcare Corporation, Los Angeles, CA; Virginia A. Caine, Associate Professor of Medicine, Indiana University School of Medicine, Director, Marion County Public Health Department, Indianapolis, IN; Patricia N. Whitley-Williams, Professor and Chair, Department of Pediatrics, Division Chief, Allergy, Immunology, and Infectious Disease, Rutgers Robert Wood Johnson Medical School, New Brunswick, NJ

The COVID-19 pandemic has served as a stress test for communities made vulnerable by racism, bias, geography, disability, and socioeconomic status. Science and innovation are central to any solutions that enable communities to overcome a failed stress test and barriers to health parity. Operation Warp Speed and scientific advancements have led to the development of COVID-19 vaccines in an unprecedented time-frame; however, the project's name and speed of the clinical trial process have resulted in some skepticism about vaccine safety and effectiveness. According to the Kaiser Family Foundation (KFF) vaccine monitor, the willingness of the Black community to receive a COVID-19 vaccine has improved from 50% in September to 62% in December. Although, 35% of Black *people* surveyed reported unwillingness to receive the vaccine in December, which is the highest rate among racial/ethnic groups. The importance of the KFF findings are magnified when juxtaposed with the Black community COVID-19 hospitalization rate of nearly 4 times greater and a death rate of nearly 3 times greater than the White community.[1,2] Furthermore, 29% of healthcare workers reported unwillingness to receive COVID-19 vaccination in December.[1]

Serving in our role as trusted messengers in the Black community and a leading voice for health parity, a resolution to establish a COVID-19 Task Force on Vaccines and Therapeutics was introduced by Rodney G. Hood, MD, NMA Past President and delegate from California, and Jennifer R. Walton, MD, MPH, Chair Pediatric Section and delegate from Ohio, that was unanimously passed by the House of Delegates on August 4, 2020. Members of the task force were appointed by President Leon McDougle, MD, MPH, (Chair) and include Patricia N. Whitley-Williams, MD, pediatric infectious disease specialist; Dial Hewlett, Jr, MD, and Virginia A. Caine, MD, who are both infectious disease specialist; Sonja S. Hutchins, MD, MPH, DrPh, community medicine and preventive health specialist; Lakesha M. Butler, PharmD, BCPS, immediate-past President of the National Pharmaceutical Association; Khadijah Lang, MD, family medicine physician; Oliver T. Brooks, MD, immediate-past President of the NMA, pediatric and adolescent medicine specialist; and Rodney Hood, MD, internist. The Task Force was charged with advising NMA members, healthcare partners and patient constituents about the safety and efficacy of COVID-19 vaccines and treatments.

Since October of 2020 the task force has been meeting with Pfizer-BioNTech and Moderna clinical scientist and reviewing clinical trial outcomes data made available to the United States Food and Drug Administration (FDA) and the CDC ACIP concerning the messenger RNA vaccines.

The task force reviewed the clinical trial data in search of differences in health outcomes that would place the Black community at higher risk of unfavorable outcomes from the vaccine. It was determined that the number and percentage of Black people enrolled in the Pfizer-BioNTech and Moderna phase 3 clinical trials were sufficient to have

https://doi.org/10.1016/j.jnma.2021.01.003

confidence in the health outcomes. Ten percent of participants in both clinical trials were Black equaling more than 4400 and 3000 people, respectively. Persons receiving the vaccine were >94% less likely to develop COVID-19 infection as compared to the placebo group. Efficacy and safety were observed and consistent across race, ethnicity, gender, and age including adults over 65 years of age.

When comparing the outcomes of people receiving the vaccine versus the placebo injection there were no significant differences in the occurrence of Serious Adverse Events (SAE). In England, two people with a prior history of severe allergies developed anaphylaxis immediately after receiving the Pfizer-BioNTech vaccine outside of the clinical trial. They did recover from the allergic reaction. While these reports are being investigated, caution should be observed for any person with history of severe allergy to vaccines or other injectable therapy. Patients with a severe allergic reaction (anaphylaxis) to the vaccine components have a contraindication to receiving these vaccines. Please refer to the CDC ACIP recommendations for more details.[3–6]

The messenger RNA vaccines cannot transmit COVID-19 infection. These vaccines enable the immune system to develop antibodies to a segment of the coronavirus called the spike protein. Immunity should be achieved about 7–14 days following the 2nd dose of the vaccine. Short-term symptoms are commonly experienced following the Pfizer-BioNTech and Moderna vaccinations and last an average of 1–3 days and include pain and redness at injection site, fatigue, muscle aches and pains, joint pain and headache.

The task force review also included questions about safety of vaccine administration in special populations, such as persons with sickle cell disease or sickle cell trait, autoimmune diseases like systemic lupus erythematosus, and HIV that disproportionately impact Black populations. In general, persons with chronic diseases that are controlled, and stable do qualify for receiving the vaccines. Consultation with one's healthcare provider beforehand is advisable. A request for analysis of data for participants with sickle cell disease or sickle cell trait was submitted by the NMA COVID-19 Task Force and is pending. Participants with controlled autoimmune diseases were enrolled in the clinical trials and an increased risk to receiving the vaccines was not observed. Participants with controlled HIV with CD4 counts of more than 200 and undetectable viral load were enrolled in the clinical trials. Data will be reported during or before the 1st quarter of 2021 with the Biologics License Applications.

In addition, reproductive toxicology studies in animals did not reveal increased risk of vaccines to the fetus during pregnancy. Expanding clinical trial enrollment to include pregnant women is planned along with descending enrollment ages to include adolescents and children. The Task Force is supportive of post-licensure surveillance plans including the Vaccine Adverse Event Reporting System https://vaers.hhs.gov/and V-safe https://www.cdc.gov/to monitor for Serious Adverse Events in persons who receive the vaccines and inform precautions as needed for future vaccine administration. The planned 2-year Phase 4 follow-up of clinical trial participants was also thought to be important.

CONCLUSION

The U.S. FDA approval for emergency use authorization (EUA) of the Pfizer-BioNTech and Moderna vaccines is supported by findings of the NMA COVID-19 Task Force on Vaccines and Therapeutics. In addition, emphasis must also be placed on building parity into dissemination plans for the vaccines that include culturally sensitive, multilingual outreach tailored for local communities to help decrease vaccination hesitancy and close gaps in health outcomes.

REFERENCES

1. Hamel, L., et al. (2020). Kaiser family foundation vaccine monitor: December 2020. https://www.kff.org/coronavirus-covid-19/report/kff-covid-19-vaccine-monitor-december-2020/.
2. COVID-19 hospitalization and death by race/ethnicity. National center for immunization and respiratory diseases (NCIRD), division of viral diseases. https://www.cdc.gov/coronavirus/2019-ncov/covid-data/investigations-discovery/hospitalization-death-by-race-ethnicity.html, (2020).
3. Interim clinical considerations for use of mRNA COVID-19 vaccines currently authorized in the United States. National center for immunization and respiratory diseases (NCIRD). https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html, (2020).
4. Interim considerations: preparing for the potential management of anaphylaxis after COVID-19 vaccination. National Center for Immunization and Respiratory Diseases (NCIRD). https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html, (2020).
5. Oliver, S. E., et al. (2020). The advisory committee on immunization practices' interim recommendation for use of pfizer-BioNTech COVID-19 vaccine — United States, December 2020. *MMWR Morb Mortal Wkly Rep*, 69(50), 1922–1924. https://www.cdc.gov/mmwr/volumes/69/wr/mm6950e2.htm?s_cid=mm6950e2_x.
6. Oliver, S. E., et al. (2020). The advisory committee on immunization practices' interim recommendation for use of Moderna COVID-19 vaccine — United States. *MMWR Morb Mortal Wkly Rep*, 69, 1653–1656. https://www.cdc.gov/mmwr/volumes/69/wr/mm695152e1.htm?s_cid=mm695152e1.

Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.