Massachusetts COVID-19 Vaccine Safety and Efficacy Evaluation Task Force

MEMORANDUM

To: Paul Biddinger, MD
Chair, Massachusetts COVID-19 Vaccine Advisory Group

From: Massachusetts COVID-19 Vaccine Safety and Efficacy Task Force:
Daniel Kuritzkes, MD, Brigham & Women's Hospital, Task Force Chair
Tamar Barlam, MD, Boston Medical Center[1]
Helen Boucher, MD, Tufts Medical Center
Rajesh Gandhi, MD, Massachusetts General Hospital
Toni Golen, MD, Beth Israel Deaconess Medical Center
Douglas Golenbock, MD, UMass Memorial Medical Center
Mary LaSalvia, MD, Beth Israel Deaconess Medical Center
Richard Malley, MD, Boston Children's Hospital[2]
Armando Paez, MD, Baystate Health
Kenneth Wener, MD, Lahey Hospital & Medical Center

Re: Evaluation of safety and efficacy data for the Pfizer-BioNTech COVID-19 Vaccine

Date: December 14, 2020

We convened this Task Force with the goal of providing the Baker-Polito Administration, including the Massachusetts Department of Public Health, with an independent, non-governmental evaluation of each COVID-19 vaccine approved under Emergency Use Authorization (EUA) by the US Food and Drug Administration (FDA). Composed of Infectious Disease experts from the major academic hospitals across the Commonwealth, the Task Force will review the safety and efficacy of each vaccine using the data packages presented by the FDA and Sponsor.[3]

Following its review of the safety and efficacy data for the Pfizer-BioNTech COVID-19 Vaccine (Pfizer vaccine), the Task Force unanimously recommends that the Commonwealth deploy the Pfizer vaccine under the EUA as per FDA guidance. Based on the totality of scientific evidence available, we believe the known and potential benefits of the Pfizer vaccine outweigh its known and potential risks in individuals 16 years of age and older. Our recommendation is based on the vaccine's high efficacy and acceptable safety profile and the finding that the vaccine is similarly safe and effective in all groups studied regardless of age, sex, race, and ethnicity.

We further recommend the following:

- The Pfizer vaccine should be offered to pregnant individuals at all gestational ages, lactating individuals, and individuals of childbearing age. Pregnant individuals should make the decision regarding whether to receive the vaccine in consultation with their health care provider.

- The Pfizer vaccine should be offered to immunocompromised individuals. Though we recognize that immunocompromised individuals were not included in the Phase 3 trial and may have a

[1] Due to a prior commitment, Dr. Barlam was unable to attend the meeting. Dr. Manish Sagar served as her alternate for this meeting.
[2] Due to a prior commitment, Dr. Malley was not able to participate in the entire meeting.
[3] Dr. Golen is Interim Chair of the Department of Obstetrics and Gynecology at BIDMC and serves as an ad hoc member of the Task Force.

diminished response to vaccination, they are an important population to protect against COVID-19 and we see no reason not to offer the vaccine to them. Optimal timing of vaccination for such individuals in the course of their treatment should be discussed between these individuals and their health care providers.

- The Pfizer vaccine should not be offered to individuals with a history of severe allergic reaction to components of the Pfizer vaccine.

- The Pfizer vaccine should be offered to individuals with a history of severe allergic reactions, including anaphylaxis, to other allergens such as foods, bee stings, etc. Such individuals who have concerns about the vaccine should consult with their health care provider.

- The Pfizer vaccine should be offered to individuals without regard to prior COVID-19 infection. Data suggest that individuals are unlikely to become re-infected within 90 days of symptom onset of their preceding infection so it is reasonable to schedule vaccination at least 90 days following infection.[4]

- The Pfizer vaccine should be offered to individuals without regard to prior receipt of convalescent plasma or monoclonal antibody therapy. However, vaccination should be scheduled at least 90 days following plasma or monoclonal antibody therapy in order to avoid interference with the immune response.

- Individuals should receive the second dose of the Pfizer vaccine 21 days after the first dose or as close as to that timeframe possible.

We note that safety review is ongoing by the external Data Monitoring Committee and that robust safety monitoring programs are in place. It is expected that the study will continue to completion in order to support licensure and ultimately to completion at the 2-year follow-up time point as planned. Additional studies are planned to understand the risks and benefits of the vaccine in younger individuals, pregnant individuals, and immunocompromised individuals, as well as other at-risk groups.

[4] https://www.cdc.gov/coronavirus/2019-ncov/hcp/duration-isolation.html