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
Helen Boucher, MD, Tufts Medical Center
Rajesh Gandhi, MD, Massachusetts General Hospital
Toni Golen, MD, Beth Israel Deaconess Medical Center[1]
Douglas Golenbock, MD, UMass Memorial Medical Center[2]
Mary LaSalvia, Beth Israel Deaconess Medical Center[3]
Richard Malley, MD, Boston Children's Hospital
Armando Paez, MD, Baystate Health
Kenneth Wener, MD, Lahey Hospital & Medical Center

Re: Evaluation of safety and efficacy data for the Ad26.COV2.S COVID-19 Vaccine

Date: March 5, 2021

This Task Force was convened 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.[4]

Following its review of the safety and efficacy data for the Ad26.COV2.S COVID-19 Vaccine ("Janssen vaccine"), the Task Force unanimously recommends that the Commonwealth deploy the Janssen 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 Janssen vaccine outweigh its known and potential risks in individuals 18 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.

Moreover, we conclude that the Janssen vaccine is highly effective in preventing severe/critical illness due to COVID-19 and in preventing hospitalizations and deaths due to infection with SARS-CoV-2. Given the clinical trials data for all three COVID-19 vaccines with EUA approval (Janssen, Pfizer,

[1] Drs. Golen and LaSalvia, BIDMC physicians, recused themselves from the review of and determination of whether to move forward with Janssen COVID-19 vaccine due to a potential conflict, or perceived conflict, because of BIDMC's collaboration with J&J to develop the COVID-19 vaccine.
[2] Due to a prior commitment, Dr. Golenbock was unable to attend the meeting. Dr. Peter Rice served as his alternate for this meeting
[3] See footnote #1.
[4] Dr. Toni Golen is Interim Chair of the Department of Obstetrics and Gynecology at BIDMC and an ad hoc member of this Task Force. Dr. Khady Diouf of the Department of Obstetrics and Gynecology at Brigham and Women's Hospital served as an alternate for Dr. Golen.

Moderna), there is no basis for preferring one vaccine over another; each was studied at different times in different populations and regions with varying prevalences of COVID-19 and SARS-CoV-2 variants. All three vaccines should be deployed by the Commonwealth to ensure vaccination of the largest number of people as rapidly as possible.

We further recommend the following:

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

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

- The Janssen 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 Janssen vaccine should be offered to individuals without regard to prior COVID-19 infection. While vaccine supplies are limited, it may be appropriate to delay vaccination of this population for up to 90 days. Among patients with prior COVID-19 infection, "the risk of reinfection, and thus the need for vaccination, might increase with time following initial infection."[5]

- The Janssen 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 possible interference with the immune response.

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.

[5] https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html