



ACMT/AAEM/ACEP Joint Statement in Support of COVID-19 Vaccines

March 19, 2021

As experts in toxicology, pharmacology, emergency medicine, and public health, the American College of Medical Toxicology (ACMT), American Academy of Emergency Medicine(AAEM), and the American College of Emergency Physicians (ACEP) highly recommend vaccination against COVID-19 with the currently authorized vaccines.

In December 2020, the United States Food and Drug Administration (FDA) authorized two vaccines (Pfizer-BioNTech BNT162b2) and (Moderna mRNA-1273) for prevention of COVID-19 [1,2]. Both vaccines are highly effective, preventing up to 95% of cases of symptomatic COVID-19. These vaccines contain mRNA (m stands for messenger), which is genetic material that contains instructions for making proteins. mRNA is not infectious, cannot cause COVID-19, and cannot become part of the permanent DNA genome. To promote mRNA stability and uptake after administration, the vaccines also contain salts, sugars, and lipids. Although the specific mRNA sequence in these COVID-19 vaccines is novel, other mRNA vaccines were first evaluated in the 1990s [3]. Following an unprecedented investment in resources, researchers have rapidly developed these vaccines without compromising scientific integrity or safety.

In February 2021, FDA authorized a third vaccine: Janssen Ad26.COV2.S [4]. This vaccine uses an adenovirus to trigger production of proteins which will, in turn, allow the immune system to better respond to coronavirus infection. This adenovirus cannot reproduce and cannot cause COVID-19. This one-shot vaccine was 66% effective in preventing moderate to severe COVID-19 at 14 and 28 days.

The clinical trials showed excellent safety profiles for all vaccines. The most common adverse events for these vaccines include injection site pain, fatigue, headache, muscle aches, joint pain, and fever. These mild effects generally lasted only a day or two. The incidence of serious adverse events for all vaccines was low (less than 1%) and similar to the placebo groups [1,2,5].

To date, the most significant adverse event is anaphylaxis- a severe but treatable allergic reaction. At present, the incidence of anaphylaxis is 2.8 cases per million doses of the Moderna vaccine and 5 cases per million doses of Pfizer-BioNTech vaccine [6]. For comparison, the incidence of severe allergic reaction from penicillin is 3 per 10,000 and for other vaccines is 1.3 per million [7,8]. There have been no deaths due to anaphylaxis from the COVID vaccines.

The extremely low risk of severe adverse effects related to vaccination should be considered against the risk associated with contracting COVID-19. The risk of mortality following SARS-CoV-2 infection ranges from about 1 in 5,000 (20-49 years old) to about 1 in 20 (>70

years-old) [9]. Treatment of COVID-19 may require endotracheal intubation and prolonged hospital stay. Survivors may experience complications such as myocarditis or blood clots. Even a mild course of illness will require isolation and missed work. Many individuals, described as “long-haulers,” have persistent symptoms for weeks or months after infection [10]. In short, the risk of becoming seriously or persistently ill from the virus is an order of magnitude greater than from the vaccine.

To monitor vaccine safety, adverse events are obtained through several passive and active reporting mechanisms. The CDC, FDA, VA, DoD, and others are collecting adverse event reports. Reporting is voluntary for patients. Reporting of certain events is required for healthcare professionals and reporting of all events is required for vaccine manufacturers [11]. V-Safe, a voluntary smartphone-based tool, actively checks in with patients to identify adverse effects [12]. CDC also collects data from direct consultation on complex cases using the Clinical Immunization Safety Assessment project [13].

There are many populations that may benefit from focused support. People who are pregnant or breastfeeding may have concerns about receiving the vaccine. This population was excluded from the initial clinical trials, yet they are at increased risk of severe illness from COVID-19. These patients should work with their healthcare providers to help guide their decisions. However, reproductive toxicity studies thus far are reassuring and both the American College of Obstetricians and Gynecologists and the Society for Maternal-Fetal Medicine support pregnant patients' access to vaccines [14].

ACMT recognizes that many people are apprehensive about receiving a new vaccine. This may be especially true in communities of color, which have historically well-founded reasons to mistrust health care and have been disproportionately affected by the pandemic. Our hope is to reassure the public that the speed in which the vaccines were developed did not compromise safety. No steps were skipped in its development. With widespread vaccination we can stop the loss of life and suffering caused by COVID. In order to end the pandemic, it is essential that we reach vulnerable and underserved populations, instill confidence in vaccinations, and empower everyone to choose to be vaccinated and protected from this disease. ACMT strongly encourages and fully supports all efforts to engage all communities and ensure equitable access to the vaccine.

The risk of COVID-19 vaccination is far less than the risk of contracting the disease. The currently authorized vaccines prevent moderate and severe COVID-19, reducing the risk of death and long-term disability. Large-scale vaccination is the safest path to a return to our normal lives. We strongly support the use of the authorized COVID-19 vaccines and urge Americans to receive a vaccine when eligible.

Sincerely,

American College of Medical Toxicology, Board of Directors
American Academy of Emergency Medicine

American College of Emergency Physicians

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