INFORMATION PAPER

DHA-IHD 23 AUG 2024

SUBJECT: COVID-19 Disease and COVID-19 Vaccines

Purpose. To describe COVID-19 disease and the vaccines that are used for protection

- 1. Facts.
 - a. Microbiology.

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes coronavirus disease 2019 (COVID-19), is a single-stranded, positive-sense RNA virus that belongs to the large family Coronaviridae.

b. Disease.

SARS-CoV-2 is transmitted from person-to-person by airborne particles and droplets. Infection from contaminated surfaces or objects is also possible but a less common source of illness. People with COVID-19 can be infectious from 1–2 days before, and up to 8–10 days after, symptoms begin.

Signs and symptoms of COVID-19 may include fever, sore throat, congestion, cough, shortness of breath, headache, body aches, loss of taste or smell, and/or fatigue. Illness can range from mildly symptomatic to severe.

Severe disease may include pneumonia, cardiac complications, neurologic complications, and/or blood clotting problems. Severe disease occurs more often in people who are ages 50 years and older, with risk increasing substantially at ages older than 65 years. Risk of severe illness is also increased in people who are immunocompromised or with certain underlying medical conditions. People who are pregnant are at increased risk of severe illness from COVID-19 and of having pregnancy complications.

c. Epidemiology.

The first cases of COVID-19 were reported in late 2019 in Wuhan, China, then rapidly reported in other countries. On January 30, 2020, the World Health Organization (WHO) declared the outbreak a Public Health Emergency of International Concern, and on March 11, 2020, the WHO declared COVID-19 a global pandemic. As of early 2024, more than 774,000,000 confirmed cases and more than 7,000,000 deaths have been reported.

SARS-CoV-2 viruses have ongoing circulation worldwide with no clearly predictable or seasonal patterns of transmission. The viruses that cause COVID-19 have evolved over time as new genetic variants emerge.

As of 2024, SARS-CoV-2 causes less severe illness than when it first emerged, likely due to background immunity of the population and reduced pathogenesis of newer viral variants. COVID-19 remains a significant public health threat, especially to medically vulnerable persons. SARS-CoV-2 viruses will continue to evolve, and new variants could emerge that are more infectious or cause more severe illness.

d. Vaccines.

Vaccines to prevent COVID-19 became available in the United States in December 2020. Since that time, COVID-19 vaccines have been updated periodically to better cover the circulating variants of SARS-CoV-2.

COVID-19 vaccines have undergone and will continue to undergo the most intensive monitoring in US history. Evidence from the hundreds of millions of COVID-19 vaccines administered in the US, and the billions of vaccines administered globally, demonstrates that these vaccines are safe and effective.

There are two types of COVID-19 vaccines that are currently licensed or authorized for use in the United States.

mRNA vaccines

Moderna COVID-19 vaccines are authorized for children ages 6 months to 11 years. SPIKEVAX[®] is the licensed Moderna product for people ages 12 years and older.

Pfizer-BioNTech COVID-19 vaccines are authorized for children ages 6 months to 11 years. COMIRNATY[®] is the licensed Pfizer-BioNTech product for people ages 12 years and older.

Protein subunit vaccine

Novavax COVID-19 Vaccine, Adjuvanted is authorized for people ages 12 years and older.

e. Immunization.

Everyone ages 6 months and older in the United States is eligible and recommended to receive COVID-19 vaccination.

Centers for Disease Control and Prevention (CDC) provide additional details regarding vaccine schedules, vaccine safety, and vaccination recommendations for people who are moderately to severely immunocompromised.

Vaccine development and recommendations are likely to continue to change, and the CDC website will have the most current recommendations. https://www.cdc.gov/vaccines/covid-19/

People who are up-to-date on their COVID-19 vaccine have a lower risk of severe illness, hospitalization, and death from COVID-19 than people who are unvaccinated or who have not completed all the doses recommended for them by CDC.

f. Contraindications and Precautions.

Severe allergic reaction. COVID-19 vaccines are contraindicated in persons with a history of severe allergic reaction (e.g., anaphylaxis) to a previous dose of COVID-19 vaccine or any component of the vaccine.

Non-severe allergic reaction. These reactions include, but are not limited to: urticaria beyond the injection site; angioedema involving lips, facial skin, or skin in other locations. People with a non-severe allergy-related precaution to one COVID-19 vaccine type may receive the alternative COVID-19 vaccine type in the usual vaccination setting. Vaccination with the same COVID-19 vaccine type may be considered on an individual basis; the same vaccine type should be administered under the supervision of a health care provider experienced in the management of severe allergic reactions. An observation period of 30 minutes post-vaccination should be considered. Referral to an Allergist-Immunologist should be considered.

Acute illness. Defer vaccination of patients with moderate or severe acute illness until after they have recovered. People who recently had SARS-CoV-2 infection may consider delaying a COVID-19 vaccine dose by 3 months from symptom onset.

History of Multisystem Inflammatory Syndrome in Children (MIS-C) or Multisystem Inflammatory Syndrome in Adults (MIS-A). Persons with a history of MIS-C or MIS-A should talk to their healthcare provider before receiving a dose of COVID-19 vaccine see CDC guidance on "Considerations for initiating COVID-19 vaccination in people with a history of MIS-C or MIS-A" for more information.

History of myocarditis or pericarditis. Development of myocarditis or pericarditis within 3 weeks after a dose of any COVID-19 vaccine is a

precaution to a subsequent dose of any COVID-19 vaccine, and subsequent doses should generally be avoided. If, after an appropriate risk assessment, the decision is made to administer a subsequent COVID-19 vaccine dose, wait until the episode of myocarditis or pericarditis has resolved (resolution of symptoms, no evidence of ongoing heart inflammation or sequelae as determined by patient's clinical team) before administering a COVID-19 vaccination.

Pregnancy and breastfeeding. Staying up to date with COVID-19 vaccinations is recommended for people who are pregnant, trying to get pregnant, or who might become pregnant in the future. A growing body of evidence on the safety and effectiveness of COVID-19 vaccination indicates that the benefits of vaccination outweigh any potential risks of COVID-19 vaccination during pregnancy. Staying up to date with COVID-19 vaccinations is recommended for people who are breastfeeding.

g. Adverse Events.

The most common adverse events following immunization (AEFIs) with COVID-19 vaccines are: local pain, swelling, or redness at the injection site, or systemic fever, fatigue, headache, body aches, or swollen lymph nodes. Most local or systemic AEFIs are attributable to robust immune responses and these reactions resolve in 2-3 days.

Fainting (syncope) can occur with any vaccination. Clinics must be prepared to evaluate and manage syncope.

Patients who are suspected of developing myocarditis or pericarditis after COVID-19 vaccination should receive clinical care in accordance with the algorithm developed by DHA IHD and Cardiology consultants. https://health.mil/Reference-Center/Fact-Sheets/2024/02/01/Post--Vaccination-Associated-Myopericarditis-Algorithm

Healthcare providers are strongly encouraged to report to VAERS any adverse event that occurs after the administration of a vaccine licensed in the United States, whether or not it is clear that a vaccine caused the adverse event. It is also required to report COVID-19 vaccine administration errors, whether or not associated with an adverse event. See VAERS Reporting Requirements for COVID-19 Vaccines for more information.

Clinicians and/or vaccine recipients may contact DHA Immunization Healthcare Division with questions about AEFIs at 1-877-GET-VACC (1-877-438-8222), Option 1.

h. Special Considerations.

People who have a history of myocarditis or pericarditis that occurred before COVID-19 vaccination or more than 3 weeks after a COVID-19 vaccine dose may receive any COVID-19 vaccine after the episode of myocarditis or pericarditis has completely resolved (i.e., resolution of symptoms, no evidence of ongoing heart inflammation or sequelae as determined by the person's clinical team). This includes people who had myocarditis or pericarditis due to SARS-CoV-2 infection.

COVID-19 vaccines may be given at the same time as other vaccines. However, out of an abundance of caution, CDC suggests that people at increased risk of myocarditis, including adolescent or young adult males, may consider waiting 4 weeks between administration of COVID-19 vaccine and JYNNEOS vaccine.

- i. DoD policy. Administration of COVID-19 vaccine is not mandatory for military service members. Administer COVID-19 vaccines to DOD beneficiaries as per current CDC/ACIP recommendations, local public health guidance for outbreak prevention, or IAW service specific guidelines.
- 2. References.
 - a. Centers for Disease Control and Prevention (CDC). COVID-19 Vaccination Clinical and Professional Resources. Last updated 23 Aug 2024. <u>https://www.cdc.gov/vaccines/covid-19/</u>
 - b. CDC. Use of COVID-19 Vaccines in the United States. Interim Clinical Considerations. Last updated 23 Aug 2024. <u>https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html</u>
 - c. CDC Yellow Book 2024, COVID-19. Last updated 15 Apr 2024. https://wwwnc.cdc.gov/travel/yellowbook/2024/infections-diseases/covid-19.
 - d. Multiple resources (e.g., COVID-19 product inserts and CDC Vaccine Information Statements) assembled by Immunization Healthcare Division. <u>https://www.health.mil/Military-Health-Topics/Health-</u><u>Readiness/Immunization-Healthcare/IHD-COVID-19-Vaccine-Resource-Center-for-Health-Care-Personnel</u>

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