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(4) Have you had an adverse or allergic reaction to a prior COVID-19 vaccine, or allergic reaction to any other vaccine or injectable therapy?								
(5) Do you have hemophilia or other bleeding disorder or take a blood thinner?								
(6) Are you, or might you be, pregnant or are you nursing (breastfeeding)?								
(7) Do you have an immunocompromising condition (HIV/AIDS, cancer, leukemia, etc.) or take an immunocompromising medicine or treatment (steroids, chemotherapy, radiation therapy, etc.)?								
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## Information about the Screening Checklist Questions

#### (1) Would you like to speak with a healthcare team member about the COVID-19 vaccine?

COVID-19 vaccination is voluntary. These are new vaccines for which there are, understandably, many questions. The potential vaccinee should be afforded ample opportunity to read the FDA-provided EUA Vaccine Fact Sheet and to ask questions prior to vaccination. The staff will not hesitate to refer an individual to an experienced healthcare provider to address questions or concerns regarding the vaccine.

# Do you voluntarily ACCEPT or DECLINE to receive a COVID-19 vaccine?

An individual, after having reviewed the EUA Vaccine Fact Sheet and having had all questions addressed, may accept or decline receipt of a COVID-19 vaccine without any impact upon their future healthcare within the Military Health System or their military career. For declining Service personnel, their declination will be entered into their electronic health record and/or Services' Immunization Tracking System using the exemption code MD (medical, declined).

## (2) Are you currently sick, feel ill, or have a fever over 100°F?

People with moderate or severe illness should not be vaccinated until their symptoms improve. Mild illnesses, even with fevers or requiring antibiotics, should not preclude receipt of COVID-19 vaccine. There is no evidence that acute illness reduces vaccine efficacy or increased vaccine adverse events.

#### (3) Have you received a COVID-19 vaccine before? If so, which one\_\_\_\_

It is important that the 2-dose COVID-19 vaccine series be completed with the same brand of vaccine because the efficacy of a vaccination series is unknown if not completed using the same brand. It is also important to know the date of the first vaccination, as different brands have different recommended dosing intervals. If an individual is a participant in a COVID-19 Vaccine Trial and does not know if they received vaccine or a placebo injection, they should indicate 'yes' to this question and for "which vaccine" state "UNKNOWN". Direct Trial participants to contact their study POC to ask about unblinding and to receive further counseling and guidance from the Study Director before receiving an authorized COVID-19 vaccine.

## (4) Have you had an adverse or allergic reaction to a prior COVID-19 vaccine, or allergic reaction to any other vaccine or injectable therapy?

Patients reporting a serious reaction to a previous dose of COVID-19 vaccine, any vaccine, or injectable therapy (intramuscular, intravenous, or subcutaneous), should be asked to describe their symptoms. There is a remote chance that a COVID-19 vaccine could cause a severe allergic reaction. (1) Persons who have had a severe allergic reaction to the first dose of a COVID-19 vaccine should not receive further doses. (2) An allergic reaction to any other vaccine or injectable therapy (intramuscular, intravenous, or subcutaneous) is a precaution to COVID-19 vaccination. Such individuals should be counseled that the risk of COVID-19 vaccine in such a setting is unknown. Should they elect to be vaccinated, they should be observed for 30 minutes afterward. (3) A history of a significant reaction to a non-injectable medicine, food, latex, or pollen allergy does not preclude receipt of a COVID-19 vaccine. Non-allergic, flu-like symptoms (malaise, myalgia, other systemic symptoms), and vaccination site reactions have been reported with COVID-19 vaccines. These mild-to-moderate reactions are not a reason to withhold future vaccination. However, moderate-to-severe non-allergic reactions should be evaluated by an experienced provider prior to vaccination.

## (5) Do you have hemophilia or other bleeding disorder or take a blood thinner?

People with bleeding disorders or treated with blood thinners should be counseled that they may have an increased risk of developing a hematoma following any intramuscular injection. If feasible, intramuscular vaccination may be delayed until shortly after anti-hemophilia therapy or alternation in their blood thinner regimen. Alternatively, a fine needle (≤ 23 gauge) can be used for vaccination and firm pressure applied to the site (without rubbing) for at least 2 minutes.

# (6) Are you, or might you be, pregnant or are you nursing (breastfeeding)?

If a woman is part of a group (e.g., healthcare personnel) who is recommended to receive a COVID-19 vaccine and is pregnant, she may choose to be vaccinated. However, pregnant or nursing women should be counseled that the new COVID-19 vaccines have not yet been tested for safety or efficacy during pregnancy or nursing (breastfeeding).

- (a) Pregnancy. Safety and Efficacy of COVID-19 vaccines in pregnant women is as of yet unknown. Animal developmental and reproductive toxicity studies are ongoing. In general, there is no evidence that inactivated vaccines pose a risk to a fetus or pregnant woman. Currently, COVID-19 vaccines approved for use by the FDA are considered inactivated vaccines. Nonetheless, a cautious approach is warranted with COVID-19 vaccines in pregnancy. An individualized risk/benefit analysis should take into account the pregnant woman's risk of exposure to COVID-19, the risks of COVID-19 to her and potential risks to the fetus, and the unknown risks associated with the vaccine. Routine testing for pregnancy prior to receipt of a COVID-19 vaccine is not recommended. A vaccinated pregnant woman should be encouraged to speak with her OB Provider about enrolling in a COVID-19 Pregnancy Registry.
- (b) Breastfeeding. No vaccines are considered a risk to a woman or her breastfeeding child, with the special exceptions of smallpox and yellow fever vaccines. However, because COVID-19 vaccines are new, patients should be counseled that these vaccines have not been tested in breastfeeding women. Counseling may include noting that CDC/ACIP does not require breastfeeding-specific data to consider other vaccines safe in breastfeeding. In general, the benefits of vaccinating nursing women usually outweigh potential risks when the likelihood of disease exposure is high and when infection would pose a risk to the mother.

#### (7) Do you have an immunocompromising condition (HIV/AIDS, cancer, leukemia, etc.) or take an immunocompromising medicine or treatment (steroids, chemotherapy, radiation therapy, etc.)?

Immunocompromised individuals should be counseled that neither the safety nor efficacy of the COVID-19 vaccines have been studied in individuals with weakened immune systems resulting from congenital defect, disease, medications, or treatments. Non-live COVID-19 vaccines (those currently approved or under study in the US) may be administered to immunocompromised patients, although the protective benefit may be suboptimal. Vaccinated immunocompromised individuals need to continue to follow all current guidance to protect themselves against

# (8) Will you be TDY/TAD/PCS OCONUS for > 30 days within the next 30 days?

Most COVID-19 vaccines require two doses 21-28 days apart for optimal efficacy. Unfortunately, different brands of COVID-19 vaccine CANNOT be mixed. Therefore, to receive the first shot of one brand of vaccine requires that a vaccinee be able to receive the same brand about 21-28 days later. Extended OCONUS travel within 30 days of the first vaccination generally precludes this. Therefore, if such travel is planned, if the screener cannot ensure the 2nd dose with same brand can be administered at new location, initiation of vaccination should be deferred to the

The Defense Health Agency-Immunization Healthcare Division (DHA-IHD) is available to assist patients and healthcare providers with treatment of health problems before and after vaccinations, and with medical exemptions. Please contact the DHA-Immunization Healthcare Division 24/7 Support Center at 877-438-8222, DSN 761-4245.