# COVID VACCINE INFORMATION FOR LEADERSHIP



NOTE: This FAQ is current as of MAY 14, 2021, however, information is being updated rapidly by the CDC and FDA. Please check the additional links at the bottom of this document for the latest information.

Under a voluntary EUA, personnel may not be compelled to accept the vaccine and commands cannot impose punitive or administrative measures against individuals who exercise the right to decline the vaccine. Commanders should ensure they are not applying undue command influence on individual's decisions.

Updated or added Q&A are highlighted in yellow.

\*\*IMPORTANT UPDATE: The FDA has expanded the emergency use authorization for the Pfizer-BioNTech (Pfizer) vaccine to include adolescents age 12 and above. Once the Advisory Committee for Immunization Practices (ACIP) issues guidance on the vaccine's recommended use, the Department of Defense will issue guidance for DoD beneficiaries 12 to 15 years of age. Parents and guardians that have questions regarding vaccinations are encouraged to discuss their concerns with a medical provider.

Health care providers are asked to report adverse events to the Vaccine Adverse Event Reporting System at <a href="https://vaers.hhs.gov/reportevent.html">https://vaers.hhs.gov/reportevent.html</a>.

### Questions about the Vaccine Itself

- Q. How does a COVID-19 Vaccine Work?
- Q. Is the Vaccine safe?
- Q. What is an Emergency Use Authorization (EUA)?
- Q. How is an EUA different from full approval?
- Q. What has been done to ensure the vaccine(s) being distributed is safe?
- Q. Can someone get COVID-19 from the vaccine?

- Q. Wasn't the vaccine developed too quickly?
- Q. Can a vaccinated person still transmit COVID-19?
- Q. What's the difference between the different vaccines?
- Q. How are the Pfizer, Moderna and Janssen (Johnson & Johnson) vaccines different?
- Q. When should individuals get their second shot of the Pfizer vaccine or the Moderna vaccine?
- Q. Are vaccines interchangeable?
- Q. Is the vaccine safe for pregnant or lactating women?
- Q. When can we eliminate COVID restrictions? Can senior leaders assist? Is there some level of risk we can/should assume?
- Q. Are there any other incentives available for senior leaders to offer to encourage vaccination?
- Q. Latest on when the Emergency Use Authorization will be replaced by an approval which enables mandatory vaccination.
- Q. How long is vaccine good for? If you get it 3 months prior to deployment, is it good for entire deployment?
- Q. Is there public immunity? When will we know?
- Q. Didn't the CDC say people who have COVID should wait 90 days before getting the vaccine?
- Q. Can COVID-19 vaccines affect fertility?
- Q. Will the mRNA vaccine affect my DNA?
- Q. Can the vaccine cause problems if you have an auto immune disease like Lupus?
- Q. Currently, there is no documentation of declination of 2nd dose. Is this something that needs to be tracked?
- Q. What do commands do with the vials of Pfizer vaccine that contain particulates?
- Q. Is there any plan to send Pfizer to Rota to immunize 16-17 year old's since Moderna is >18?
- Q. Why is the Moderna vial a greenish or yellow tint?
- Q. Will variants in the COVID virus change the need to get the vaccine?
- Q. How do I know if the vaccine has expired?
- Q. If in the future there are issues with the vaccine, will volunteering, rather being mandated, change any potential claims with the VA?
- Q. Are the 95% efficacy numbers reflected with real data?

- Q. Does age make a difference in vaccine efficacy—younger being less likely to get the disease after vaccinated?
- Q. Are there any documented cases of an immunized person(s) spreading the virus?
- Q. Do we have the age/risk factor demographics for those who have had a severe reaction?
- Q. What is the efficacy of vaccines after 90 days?
- Q. What is the level of immunity in people who have had the disease after 90/120/150/180 days?
- Q. What is the guidance from FDA regarding the Moderna vaccine for storage/handling and vials?
- Q. How many doses are there in the Moderna vaccine vials?

### **Questions about Vaccine Distribution**

- Q. How old do you have to be to receive a vaccine?
- Q. How will the vaccine be distributed and administered?
- Q. Where can you sign up to get the COVID-19 vaccine?
- Q. Will vaccines be available at MTFs? When will they be available?
- Q. Why is the plan phase driven and not population or hot spot focused?
- Q. Who in the Navy and Marine Corps is determining which units are in which priority level?
- Q. How will the Navy and Marine Corps work with host nations, who may have not approved COVID 19 vaccines for their national populations, to distribute and administer vaccines to Naval personnel stationed in overseas locations?
- Q. For foreign nationals who quality for COVID vaccine, does it matter if their HN did or did not approve the vaccine?
- Q. When will ships at sea get the vaccine?
- Q. Is the DoD considering purchasing vaccine from foreign governments?
- Q. How much does the COVID-19 vaccine cost?
- Q. How are we doing on vaccination rates?
- Q. What should CNO or other senior leaders say when asked "why should I get the vaccine?"
- Q. Anything else the team recommends for leaders to know/understand.
- Q. If we were to vaccinate 70% of a crew, then ROM-S the other 30% and combine to form a bubble, can we say the risk is driven low enough? Can we use rapid testing and vaccine to get rid of ROM while keeping risk low?
- Q. Can ROTC personnel get DOD vaccine?

- Q. Any prohibition on dependents getting vaccine from host nation if outside the US?
- Q. How will you know when a command is in need of an allotment to cover 2nd doses from week to week?
- Q. Who sets priority for DoN personnel to receive the vaccine? And are recruiters 1b personnel?
- Q. Is there any guidance on transporting the vaccine?
- Q. Should a ship vaccinate if they are currently having an outbreak?
- Q. Is there any guidance on vaccinating American citizens living abroad if they are not otherwise eligible for care at our overseas MTFs?

### Questions about MY Vaccine

- Q. Am I at risk for serious adverse events if I receive the Janssen COVID-19 vaccine?
- Q. What activities can I participate in if I have been fully vaccinated?
- Q. Are individuals required to get the vaccine?
- Q. Why should I get the vaccine?
- Q. How will I know when I am eligible to get the vaccine?
- Q. Which iteration of the vaccine will I get?
- Q. Where should I be vaccinated?
- Q. Where can I get the COVID-19 vaccine?
- Q. How will the Navy and Marine Corps track personnel who receive a COVID vaccine?
- Q. If I already had COVID-19, should I still get a vaccine?
- Q. Will I still need to wear masks and practice physical distancing once a vaccine is available?
- Q: How soon does the vaccine take effect after getting the first shot?
- Q: Can I still get COVID once I have been vaccinated?
- Q: How long will protection last following vaccination?
- Q. Should I get the vaccine for influenza (flu shot)?
- Q. Can I get the flu vaccine and the COVID vaccine at the same time?
- Q. Should I get the flu vaccine or the Pfizer vaccine? Alternately, should I hold off on required vaccines so that I can get the Pfizer vaccine?
- Q. If I get the vaccine do I still need to ROM, guarantine, or wear a mask?
- Q. Will DoD require all service members to receive the vaccine?

- Q. Why should we receive the first-available vaccine when there are several other vaccines still in trials?
- Q. How will the vaccine be administered?
- Q. If the vaccine is voluntary does it change the guidance for masks and social distancing?
- Q. Would a command need to put out guidance for work? Such as 'if you do not get the vaccine you continue to telework, if you do get the vaccine you must return to normal work schedules'.
- Q. If someone declines to receive the vaccine, how is it noted in their record?
- Q. What are the consequences of declining vaccination?
- Q. What can I do to encourage vaccination by members of my command?
- Q. Under what circumstances could the vaccine become mandatory?
- Q. How would a command know who got the vaccine and who did not?
- Q. For platforms such as ships and submarines would there still be an opt out for the vaccine?
- Q. What exemptions will be made when the vaccine is required?
- Q. Will the manufacture of the vaccine be disclosed to the patient prior to immunization?
- Q. Will a prescription be necessary for a vaccine under an EUA?
- Q. Can I pick which vaccine to get?
- Q. Can I test positive due to the COVID-19 Vaccine?
- Q. After getting a COVID-19 vaccine, will I test positive for COVID-19 on a viral test?
- Q. What changes for me when I get inoculated?
- Q: Why should I get vaccinated if it doesn't change the rules for what I can and cannot do?
- Q. Can a vaccinated individual transmit to a non-vaccinated individual?
- Q. Can I get the COVID vaccine if I recently had COVID?
- Q. Can I get the COVID vaccine if I currently have COVID?
- Q. Is there any evidence of passing the virus or the immunity from mother to child in a pregnant woman?
- Q. Are there any issues with persons receiving chemotherapy and the effectiveness of the vaccine?
- Q. I received my first dose of the vaccine. Will I be notified for the 2nd dose

- Q. Do I go back to the where I received my first dose on the day highlighted on my vaccination card, or will I be sent to an alternate location?
- Q. Do I need to receive my second dose from the same entity (i.e. DoD, VA, private healthcare provider) that provided my first dose?
- Q. Do my first and second doses need to be the same vaccine (i.e. Pfizer or Moderna)?
- Q. What should you do if you get COVID between the two doses of the vaccine?
- Q. Can you provide more information / clarification on the mutations of the virus and if the vaccine will protect against the new forms/variants?
- Q. What if I can't get the 2nd dose of my vaccine exactly 21 or 28 days after my first dose?
- Q. Do we have guidance on acceptability of giving the 1st dose to deployers without a guarantee of getting the 2nd dose?
- Q. Can people finish vaccine series with DoD if started at civilian location (or the reverse)?
- Q. Will the Navy and Marine Corps follow the same recommendation from the CDC about the need to quarantine if exposed after vaccination?
- Q. Can I take Tylenol, Motrin or antihistamines after I get my vaccine?
- Q. Are there any documented cases of immunized personnel (14 days following both doses) getting COVID 19?

### Questions about who can get the Vaccine

- Q. I previously declined to take a vaccine, but now I would like to get vaccinated. Is a vaccine still available to me?
- Q. Will TRICARE beneficiaries including military retirees have access to the vaccine?
- Q. Which Select Reserve and National Guard personnel will receive the vaccine?
- Q. I don't live near a military treatment facility or DoD vaccination site. Can I get the COVID-19 through my county health department or civilian employer?
- Q. I am a NAF employee (or DoD Contractor) but can't be treated by a military treatment facility normally. Can I still get my COVID-19 vaccine at my installation MTF or site?
- Q. I am an employee of a DoD contractor supporting DoD efforts. Can I get the vaccine from the DoD?
- Q. Can OCONUS DoD Contractor dependents receive their COVID vaccine from military treatment facilities?
- Q. Is the vaccine safe for pregnant or lactating women?

- Q. Should children get the vaccine?
- Q. Are our contractor HCWs eligible to receive the vaccine?
- Q. I've heard people with allergies should not get the vaccine, is that accurate?
- Q. Should aviators or other personnel in a special medical status (i.e. flight status) get the vaccine?
- Q. If aviators or other personnel do get the vaccine, are they medically down for a period of time?
- Q. Can Allied and Partner personnel stationed on DOD installations get the vaccine?
- Q. What about individuals not covered in the list of eligible foreign nationals?
- Q. Will foreign nationals then be eligible for follow-on care?

### Provider/CO Questions on Vaccine

- Q. What should health care providers look for in evaluating Janssen COVID-19 vaccine recipients for these serious adverse events?
- Q. What information can be released if a state official requests information on COVID-19 vaccination at a MTF or vaccination site?
- Q. What information can be released if a US Senator or Member of the House of Representative requests information on COVID-19 vaccination at a MTF or vaccination site?
- Q. How many doses are there in each vial of vaccine?
- Q: Can remainder doses of vaccine in vials, after the prescribed 5 doses, be used by providers?
- Q: How should we manage anaphylaxis if something happens as a result of giving the vaccine?
- Q. Is there a safety mechanism in place to ensure the same vaccine is used for the second dose once vaccine distribution expands and there could potentially be more than vaccine at a location?
- Q. Do all MTFS and tracking authorities need ADVANA? It says DHA will be required to use ADVANA, but will the MTFS need to use to report up to DHA?
- Q. When it lists "1000 doses," in a shipment, is that all for immediate use or should we save half for the second dose?
- Q. Does an EUA have any impact on standing orders?
- Q. Can a COVID-19 vaccine be administered to populations not included in the authorized use of the vaccine under its EUA?
- Q. Is there a standing order for the Pfizer vaccine?
- Q. Is there a standing order for the Moderna vaccine?

- Q. Is there a standing order for the Janssen (Johnson & Johnson) vaccine?
- Q. Will NMRTUs receive their own shipment or will it go through the NMRTCs?
- Q. What system should be used for submitting adverse events as noted in the DHA-IPM?
- Q. How will my command order vaccines?
- Q. How will my command receive vaccines?
- Q. Does COVID-19 impact readiness?
- Q. Who is eligible to decline a vaccine? Alternately, can I defer/decline my entire command to get rid of the requirement?
- Q. What is the process/documentation needed to be able to certify a ship to directly receive and administer the vaccine?
- Q. If there is a full 0.5 mL 6th (extra) dose from a Janssen (Johnson & Johnson) vial can I use it?

### **Addressing Counter Narratives**

- 1. It's voluntary, I don't need to get it.
- 2. Concern about fertility if I get the immunization.
- 3. The mission doesn't require that I get it.
- 4. I shouldn't get it before older people, so I'll wait.
- 5. This vaccine was not designed taking minorities into account.
- 6. I've had COVID so I'm immune already.

**Additional Information** 

### Questions about the Vaccine Itself

#### Q. How does a COVID-19 Vaccine Work?

A. Vaccines fight disease by producing an immune response within the body. Sometimes that means flu-like symptoms, such as aches, headache and fever. This is normal and a sign that your body is creating antibodies to protect you from COVID-19.

#### Q. Is the Vaccine safe?

**A.** COVID-19 vaccines are safe and effective. COVID-19 vaccines were evaluated in tens of thousands of participants in clinical trials. The vaccines met FDA's rigorous scientific standards for safety, effectiveness, and manufacturing quality needed to support emergency use authorization (EUA). Millions of people in the United States have received COVID-19 vaccines, and these vaccines are undergoing the most intensive safety monitoring in U.S. history. This monitoring includes using both established and new safety monitoring systems to make sure that COVID-19 vaccines are safe.

As of April 2021 the FDA added a warning to the Janssen COVID-19 vaccine EUA and fact sheets regarding the rare clotting events. Despite the warning, the FDA and CDC have confidence that this vaccine is safe and effective in preventing COVID-19.

Since early March, DOD is tracking 17 reports of cardiac inflammation/myocarditis in recipients of the Pfizer and Moderna COVID-19 vaccines, out of more than 2.7 million shots administered. These 17 individuals were identified through the CDC's Vaccine Adverse Event Reporting System (VAERS). This thorough vaccine safety monitoring system is designed to notice unexpected or unusual side effects which may be associated with vaccination for further investigation.

It's important to note that just because an adverse event occurs near time of vaccination does not mean that it is caused by the vaccine. At this time, it is unclear if these events are related to vaccination. We continue to believe that these vaccines are safe and effective. We are confident in these vaccines and encourage vaccination.

The risk of adverse health effects from COVID-19 far exceed the mostly minor events shown to be associated with vaccination. The FDA has determined that the available data show that the vaccine's known and potential benefits outweigh its known and potential risks in individuals 18 years of age and older.

### Q. What is an Emergency Use Authorization (EUA)?

**A.** Drugs and vaccines have to be approved by the Food and Drug Administration (FDA) to ensure that only safe and effective products are available to the American public. In situations when there is good scientific reason to believe that a product is safe and is likely to treat or prevent disease, the FDA may authorize its emergency use under specific circumstances. Vaccines authorized for emergency use are offered on a voluntary basis.

#### Q. How is an EUA different from full approval?

A. According to the FDA EUA announcement, the issuance of an EUA is different than an FDA approval (licensure) of a vaccine, in that a vaccine available under an EUA is not approved. In determining whether to issue an EUA for a product, the FDA evaluates the available evidence to determine whether the product may be effective and also assesses any known or potential risks and any known or potential benefits. If the product meets the effectiveness standard and the benefit-risk assessment is favorable, the product is made available during the emergency.

The EUA also requires that fact sheets that provide important information, including dosing instructions, and information about the benefits and risks of the Vaccine, be made available to vaccination providers and vaccine recipients.

The manufacturers of the vaccine have submitted a pharmacovigilance plan to the FDA to monitor the safety of their vaccines. The pharmacovigilance plan includes a plan to complete longer-term safety follow-up for participants enrolled in ongoing clinical trials. The pharmacovigilance plan also includes other activities aimed at monitoring the safety

profile of the vaccine and ensuring that any safety concerns are identified and evaluated in a timely manner.

The FDA also expects manufacturers whose COVID-19 vaccines are authorized under an EUA to continue their clinical trials to obtain additional safety and effectiveness information and pursue approval (licensure).<sup>1</sup>

#### Q. What has been done to ensure the vaccine(s) being distributed is safe?

A. Vaccines and therapeutics to prevent and treat diseases are developed in stages. In Phase 1 Trials researchers test an experimental drug or treatment in a small group of people for the first time. In Phase 2 Trials the experimental drug or treatment is given to a larger group of people to see if it is effective and to evaluate its safety further. In Phase 3 Trials the experimental study drug or treatment is given to very large groups of people. Researchers confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the experimental drug or treatment to be used safely. Manufactures are required to submit their raw data for the FDA to review. Safety, immune response, and efficacy data from the trial stages are submitted to the FDA before they are authorized for use and distribution.

#### Q. Can someone get COVID-19 from the vaccine?

**A.** No, it is not possible to get COVID-19 from vaccines. Vaccines against COVID-19 use inactivated virus, parts of the virus, or a gene from the virus. None of these can cause COVID-19.

### Q. Wasn't the vaccine developed too quickly?

**A.** Through a whole-of-nation effort and unprecedented coordination in the medical and scientific communities, significant breakthroughs made possible an accelerated vaccination schedule. While these vaccines are being made available as quickly as possible, routine processes and procedures remain in place to ensure the safety of any vaccine that is authorized or approved for use.

#### Q. Can a vaccinated person still transmit COVID-19?

**A.** Currently there is no data on transmission blocking for the vaccines. The vaccines work to protect individuals from disease symptoms, but it is unknown at this time whether vaccinated people can still transmit the virus as an asymptomatic infection. It is recommended by both the CDC and the DOD to continue to practice public health protective measures like washing your hands, wearing a mask and frequently cleaning common areas.

#### Q. What's the difference between the different vaccines?

**A.** All the vaccines that will be approved by the FDA will provide a period of immunity from COVID-19. The difference is in how they turn on your body's immune system to produce antibodies.

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<sup>&</sup>lt;sup>1</sup> https://www.fda.gov/news-events/press-announcements/fda-takes-additional-action-fight-against-covid-19issuing-emergency-use-authorization-second-covid and https://www.fda.gov/news-events/pressannouncements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19

### Q. How are the Pfizer, Moderna and Janssen (Johnson & Johnson) vaccines different?

**A.** All three vaccines have a high level of effectiveness in preventing serious COVID-19 symptoms in individuals. The Pfizer and Moderna vaccines use mRNA technology to initiate an immune response and require two doses for full effectiveness. The Janssen (Johnson & Johnson) vaccine only requires a single shot and uses a specific type of virus called adenovirus type 26 (Ad26).

While adenoviruses are a group of viruses that are relatively common, the Ad26 has been modified by Janssen for the vaccine so that it cannot duplicate in the human body to cause illness. After a person receives this vaccine, the body can temporarily make a spike protein to trigger an individual's immune system to learn to react defensively, producing an immune response against SARS-CoV-2.

All three have similar minimal side effects.

### Q. When should individuals get their second shot of the Pfizer vaccine or the Moderna vaccine?

**A.** Two of the COVID-19 vaccine series (Pfizer and Moderna) consist of two doses. The Pfizer-BioNTech doses should be three weeks (21 days) apart and the Moderna doses should be 28 days apart. Second doses administered within a grace period of ≤4 days from the recommended date for the second dose are considered valid; however, doses administered earlier do not need to be repeated. The second dose should be administered as close to the recommended interval as possible. However, there is no maximum interval between the first and second dose for either vaccine.

### Q. Are vaccines interchangeable?

**A.** All efforts should be made to ensure that the second dose is from the same manufacturer as the first. This may include planning vaccination around PCS – e.g. deferring vaccination until you arrive at your destination to ensure both doses are the same.

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

Using the above strategies, every effort should be made to determine which vaccine product was received as the first dose to ensure completion of the vaccine series with the same product. In exceptional situations in which the vaccine product given for the first dose cannot be determined or is no longer available, any available mRNA COVID-19 vaccine may be administered at a minimum interval of 28 days between doses to complete the mRNA COVID-19 vaccination series.

In situations where the same mRNA vaccine product is temporarily unavailable, it is preferable to delay the 2<sup>nd</sup> dose (up to 6 weeks) to receive the same product than to receive a mixed series using a different product. If two doses of different mRNA COVID-

19 vaccine products are administered in these situations (or inadvertently), no additional doses of either product are recommended at this time.

Although CDC provides considerations for a <u>mixed series in exceptional circumstances</u>, this is still considered an administration error that requires VAERS reporting (as a mixed series is not authorized under the vaccine <u>Emergency Use Authorizations</u>.

If a site inadvertently administers a different vaccine for the 2<sup>nd</sup> dose, a patient safety report (PSR) should be submitted in addition to the VAERS report. The PSR is needed since the cross vaccination was a deviation from the proscribed process.

Any cross vaccinations, whether planned (e.g. person moves and original vaccine type is not available at new location) or by mistake, is a deviation from the DHA (DoD) policy and does not follow the CDC recommendations. The CDC recommendations provide guidance for situations when cross vaccination occurs, but does not recommend this as policy.

#### Q. Is the vaccine safe for pregnant or lactating women?

**A.** Currently, there are no data on the safety and efficacy of COVID-19 vaccines in these populations to inform vaccine recommendations. If you are pregnant or breastfeeding, discuss your options with your healthcare provider.

### Q. When can we eliminate COVID restrictions? Is there some level of risk we can/should assume?

**A.** This really depends on the availability of the vaccine. It is anticipated that there will likely be enough evidence by July to inform changes but this is an ever changing target based on many variables. Senior leaders can assist by ensuring that accurate information is being disseminated to Sailors and Marines and opportunities for vaccination are being emphasized. Commands should work to ensure good coordination with the MTF for receiving timely vaccinations. This includes appropriate planning for the second dose. Commands should plan on receiving the second dose on time. If delays occur in the second dose, this will lead to vaccine waiting on the shelf that could have been given to someone else.

Currently, Commanders should assume similar risks to the mission as if no vaccinations occurred – for the reasons previously discussed.

### Q. Are there any other incentives available for senior leaders to offer to encourage vaccination?

**A.** This is a voluntary vaccine and incentivizing it would also imply penalizing those who did not get it. Until it is made a requirement, commanders should focus on ensuring Sailors and Marines are making informed opinions and given the perspective that they are helping themselves and likely protecting others.

### Q. Latest on when the Emergency Use Authorization will be replaced by an approval which enables mandatory vaccination.

**A.** This is unknown. This is an unprecedented event. The only similar situation was the approval of Remdesivir, the only currently approved treatment for severe COVID infections: EUA granted 1MAY, approval granted 22OCT (174 days). It is likely that vaccines will require a longer period for licensure.

### Q. How long is vaccine good for? If you get it 3 months prior to deployment, is it good for entire deployment?

**A.** This is unknown and is precisely why we cannot make changes to current preventive measures. This question is being actively studied formally by the vaccine manufacturer and informally by sites across the country (including the DoD).

#### Q. Is there public immunity? When will we know?

**A.** We anticipate there will eventually be public immunity but until we have more information we cannot draw conclusions. Furthermore it is unknown how long public immunity will last – we don't know if this vaccine will be an annual requirement resulting in the need to vaccinate every year to maintain individual and public immunity.

### Q. Didn't the CDC say people who have COVID should wait 90 days before getting the vaccine?

**A.** The CDC did publish a 90-day delay recommendation after having an infection. Currently, this recommendation is based on vaccine scarcity and NOT concerns about safety. The CDC acknowledges that individuals may have some immunity up to 90 days after infection and subsequently, in the context of limited vaccine availability, planners may choose to vaccinate those who are either totally naïve to the virus (never been infected) or those who may have waning immunity (beyond 90 days).

### Q. Can COVID-19 vaccines affect fertility?

A. There is no evidence that the COVID-19 vaccines affect fertility.

#### Q. Will the mRNA vaccine affect my DNA?

**A.** There is no evidence that the COVID-19 vaccines affect your DNA. Based on current knowledge, experts believe that mRNA vaccines are unlikely to pose a risk to the pregnant person or the fetus because mRNA vaccines are not live vaccines. (https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html)

### Q. Can the vaccine cause problems if you have an auto immune disease like Lupus?

**A.** The Pfizer, Moderna and Jansen vaccines are NOT live virus vaccines, as such, they do not have any capacity to harm an immunocompromised person or an individual with an autoimmune disorder any more than someone who does not have these

conditions. For someone with auto-immune conditions, there is no contraindication or warning listed with either current vaccine.

### Q. Currently, there is no documentation of declination of 2nd dose. Is this something that needs to be tracked?

**A.** Formal declinations, after a vaccine is available and offered, must be logged in MRRS. If the DHA Form 207 is used to document a declination, it becomes a medical record and must be recorded in the electronic medical record. The DHA Form 207 is not required for declinations.

### Q. What do commands do with the vials of Pfizer vaccine that contain particulates?

**A.** 1.Do not administer and quarantine the vaccine, and 2.Contact the manufacturer (in this case Pfizer). 800-666-7248; <a href="mailto:cvgovernment@pfizer.com">cvgovernment@pfizer.com</a>

These vials are not lost and should be replaced by the manufacturer. Additionally, a SITREP should be submitted to note vaccine that cannot be used for DHA to aggregate for DoD totals.

### Q. Is there any plan to send Pfizer to Rota to immunize 16-17 year old's since Moderna is >18?

**A.** DLA has stated they cannot ship -80C OCONUS at this time.

### Q. Why is the Moderna vial a greenish or yellow tint?

**A.** Moderna has engaged multiple suppliers of vials for the Moderna COVID-19 Vaccine. Initially Moderna vials were all clear, however new vial suppliers use different processes/glass and a portion of the vials may appear thicker and display a slight green tint. Vial colors under various lighting conditions may be encountered in the field and over time, vial tinting may fade naturally, resulting in a faint yellow color. This tinting is strictly visual and has no impact on the vaccine.

#### Q. Will variants in the COVID virus change the need to get the vaccine?

**A.** No, from a science perspective, it is our expectation that the multiple strains of SARS-CoV-2, including variants, will be present within our populations. Also as expected, the SARS-CoV-2 variants may present asymptomatically within our active duty demographic. The continued presence of asymptomatic infection and the circulation of variants highlights the critical importance of vaccinations in order to prevent COVID-19 illness and reduce the prevalence of the virus. At the present time, BUMED continues to support public health measures as described in SOG 4.0.

#### Q. How do I know if the vaccine has expired?

**A.** The expiration date should be checked prior to preparing or administering vaccine. Expired vaccine or diluent should NEVER be used. As additional stability data become available, the expiration dates for some products may change.

For EUA COVID-19 vaccines that do not have a final expiration date, CDC has set up an expiration date of 12/31/2069 to serve as a placeholder date in VTrckS. Such vaccines have a dynamic expiration date, which can change over time as additional stability data become available. This placeholder date, which is far in the future, is intended to serve as a prompt for the provider to check the latest expiry information on the manufacturer's website.

Janssen COVID-19 vaccine: The expiration date is NOT printed on the vaccine vial or carton. To determine the expiration date:

- Scan the QR code located on the outer carton, or
- Call 1-800-565-4008, or
- Go to Caution-www.vaxcheck.jnj/

Moderna COVID-19 vaccine: The expiration date is NOT printed on the vaccine vial or carton. To determine the expiration date:

- Scan the QR code located on the outer carton, or
- Go to Caution-www.modernatx.com/covid19vaccine-eua/

Pfizer COVID-19 vaccine: This vaccine product has an expiration date located on the vaccine vial. CDC will be updating VTrckS effective immediately to replace the placeholder date in VTrckS with the actual expiration date.

CDC's COVID-19 Vaccine Expiration Date Tracking
Tool <a href="https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/expiration-tracker.pdf">https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/expiration-tracker.pdf</a> can help providers keep track of the expiration date by lot number.

### Q. If in the future there are issues with the vaccine, will volunteering, rather being mandated, change any potential claims with the VA?

**A.** Within certain limits, military members who incur or aggravate an injury, disease or illness in a qualifying duty status are covered for that episode of care under the Line of Duty authority. Determinations on any benefits from the Veterans Health Administration (VHA) will be made by the VHA. All individuals vaccinated with a Food and Drug Administration-authorized/approved COVID-19 vaccine may be eligible for compensation for adverse reactions under other programs, including: the Countermeasures Injury Compensation Program (CICP) program, National Vaccine Injury Compensation Program (VICP), applicable Workers Compensation authorities and other sources of care for which eligible (e.g., at Federally Qualified Health Centers in their community).

#### Q. Are the 95% efficacy numbers reflected with real data?

**A.** Pfizer: "Real life" vaccine effectiveness of 87-94% (depending on endpoint measured) is only slightly lower than clinical trial vaccine efficacy of 95%. Moderna / J&J: No "real life" vaccine efficacy data is currently available (only small immunologic

studies). The 94-95% COVID vaccine efficacy for Moderna and Pfizer was from clinical trials conducted in highly controlled settings with perfect adherence to vaccination and monitoring schedules among a healthier "subpopulation" due to certain exclusion criteria, such as chronic diseases.

### Q. Does age make a difference in vaccine efficacy—younger being less likely to get the disease after vaccinated?

**A.** Vaccine effectiveness has more to do with timing after dose one or two, than gender, age, or underlying medical conditions.

### Q. Are there any documented cases of an immunized person(s) spreading the virus?

**A.** Contact tracing is not an exact science. However, increasing amounts of evidence suggests that fully immunized individuals present a low risk of transmission to others<sup>2</sup>. There are a number of factors at play for viral transmission, but one that deals directly with dynamics of the virus is called viral shedding. Those who shed high levels of virus for longer periods of time will potentially transmit more virus to others. Viral shedding begins before symptoms and can occur even without symptoms.

A recent study from Israel showed that the Pfizer vaccine was 90% effective against asymptomatic infection, and the few immunized individuals who developed COVID-19 had a substantially lower viral load than the-non-immunized.<sup>3</sup>

There are several reasons why an immunized individual may test positive for COVID-19. There is a lag between immunization and the body's mounting of a protective response, which can take anywhere from a few days to a few weeks after receiving the vaccine series. Vaccines do not work retroactively; if there was asymptomatic infection prior to being immunized, individuals could still have a positive screening test, as reported in a number of healthcare workers who were vaccinated. A screening test also has the potential of detecting dead/residual virus after prior infection, as well as false positive based on the screening test.

A positive test following vaccine administration does not necessarily mean an individual has the ability to spread COVID-19 to others. The likelihood of this is low, based on experience with other vaccines. The emergence of viral variants will require vaccine makers to continue assessing vaccine effectiveness and processes. However, based on available evidence, existing FDA EUA vaccines are effective against the currently circulating vaccine variants.

### Q. Do we have the age/risk factor demographics for those who have had a severe reaction?

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<sup>&</sup>lt;sup>2</sup> Christie A, Mbaeyi SA, Walensky RP. CDC Interim Recommendations for Fully Vaccinated People: An Important First Step. JAMA. Published online March 10, 2021. doi:10.1001/jama.2021.4367

<sup>&</sup>lt;sup>3</sup> Centers for Disease Control and Prevention. Science Brief: background rationale and data for public health recommendations for fully vaccinated people. March 8, 2021. https://www.cdc.gov/coronavirus/2019-ncov/more/fully-vaccinated-people.html

**A.** Severe reactions to vaccines or "anaphylaxis" may include itching, swelling, hives, respiratory distress, a drop in blood pressure, and loss of consciousness. Anaphylaxis is a very rare allergic reaction, unexpected, usually occurs within 5 to 30 minutes of vaccination, and can be fatal if not dealt with adequately. Anaphylaxis to the mRNA COVID-19 vaccines is currently estimated to occur in 2.5 to 11.1 cases per million doses, largely in individuals with a history of allergy.

#### Q. What is the efficacy of vaccines after 90 days?

A. There is no published data on the duration of vaccine efficacy yet.

### Q. What is the level of immunity in people who have had the disease after 90/120/150/180 days?

**A.** There have been re-infections of COVID reported in the medical literature from 48 days (US) to 7 months (India) after the initial episode. Overall reinfection with COVID-19 based on the current literature is rare. Scientists are assessing how long immunity from natural infection or vaccination lasts. Research is also being done as to how well the vaccines protect against SARS-CoV-2 variants.

Additionally, immunity isn't and on/off switch. We know that vaccines reduce the severity of illness, so even if the degree of immunity diminished over time, there is likely a degree of reduction of severity of illness that will last for quite some time.

### Q. What is the guidance from FDA regarding the Moderna vaccine for storage/handling and vials?

**A.** The FDA released revised guidance for Moderna vaccine storage/handling and vials.

- 1. Unpunctured Moderna vaccine can be held up to 24 hours at room temperature (increase from 12 hours)
- 2. Punctured Moderna vaccine vials can be held up to 12 hours (increase from 6 hours)
- 3. Labels for 10-dose Moderna vials will be revised to allow up to 11 doses
- 4. A new 15-dose vial has been approved and will be available in the near future; there will be two Moderna vial types (11 and 15 dose)

### Q. How many doses are there in the Moderna vaccine vials?

**A.** On 31 Mar 21 the FDA drafted revised EUA for the Moderna vaccine describing two vial types: 11 and 15 dose vials.

The 11-dose vials are authorized for up to 11 doses, however if 10 doses are drawn the 11th dose is not a counted as a loss.

15 dose vials are not available at this time, specific guidance on use, account and reporting losses will be provided at a later time.

### Questions about Vaccine Distribution

### Q. How old do you have to be to receive a vaccine?

A. The U.S. Food and Drug Administration expanded the emergency use authorization

(EUA) of the Pfizer-BioNTech COVID-19 vaccine for adolescents between the ages of 12 and 15. Once the Advisory Committee for Immunization Practices (ACIP) issues guidance on the vaccine's recommended use, the Department of Defense will issue guidance for DoD beneficiaries 12 to 15 years of age. Parents and guardians that have questions regarding vaccinations are encouraged to discuss their concerns with a medical provider.

#### Q. How will the vaccine be distributed and administered?

**A.** Distribution will be conducted in phases. Due to limited availability of initial vaccine doses, the first phase will distribute and administer vaccines at select locations. Then, as manufacturing rates and CDC allocation permits, DoD will increase distribution and administration to additional selected sites and then to broader, Navy and Marine Corpsbased locations. This process can be expected to take several months.

#### Q. Where can you sign up to get the COVID-19 vaccine?

**A.** Each military hospital or clinic may have a different process in place for signing up to get the vaccine. We encourage you to check with your local military hospital or clinic.

#### Q. Will vaccines be available at MTFs? When will they be available?

**A.** Each military hospital or clinic may be in different phases of the DoD Population Schema based on local availability. Please check with your local facility to find when you can get it.

The DoD vaccination efforts are data-driven and informed by the Centers for Disease Control and Prevention (CDC). Vulnerable beneficiaries, including retirees, will be offered the vaccine in accordance with the highest phase for which he or she qualifies within the DoD priorities and CDC guidance.

Each military hospital and clinic is vaccinating according to the CDC's priorities and DoD's population schema. Each location may be at different phases of the DoD Population Schema based on availability of the vaccine and the total population they serve. You should contact your local military hospital or clinic, visit their website or follow them on social media to see when they are ready for you to be vaccinated. Also, you can check with your local pharmacy. You can get the COVID-19 vaccine at any pharmacy, network or non-network, at no cost to you. Keep in mind TRICARE does NOT cover access to other vaccines (e.g. Flu, Shingles, etc.) at non-network pharmacies.

#### Q. Why is the plan phase driven and not population or hot spot focused?

**A.** The distribution process is phase driven to safely protect the DoD from COVID-19 as quickly as possible. The DoD vaccination efforts are data-driven and informed by the Centers for Disease Control and Prevention. Vulnerable beneficiaries, including retirees, will be offered the vaccine in accordance with the highest phase for which he or she qualifies within the DoD priorities and CDC guidance.

### Q. Who in the Navy and Marine Corps is determining which units are in which priority level?

**A.** Designated representatives from the Navy and Marine Corps have formed a "Release Authority" working group. This group is responsible for identifying and assigning vaccine to specific units within the schema group. As vaccine becomes available, NAVMEDLOGCOM will follow the direction of the release authority and direct vaccines as instructed.

# Q. How will the Navy and Marine Corps work with host nations, who may have not approved COVID 19 vaccines for their national populations, to distribute and administer vaccines to Naval personnel stationed in overseas locations?

**A.** The Navy and Marine Corps routinely import medicines for its personnel, some of which may not be something that can be prescribed in the host country. EUAs have previously been used in foreign nations without significant issues. There are unlikely to be any international or Status of Forces Agreement (SOFA) issues with the Navy or Marine Corps distributing the vaccine to U.S. Service Members or SOFA-status DoD personnel (military dependents, civilian employees and their dependents, and contract personnel) as doing so would be deemed an internal matter and host nations would not intervene.

### Q. For Foreign Nationals who qualify for COVID vaccine, does it matter if their HN did or did not approve the vaccine?

**A.** From the DoD's perspective, it does not matter if their host nation did or did not approve the vaccine. The vaccine is voluntary in this country at this time; eligible foreign nationals are responsible for coordinating with their home country/headquarters to understand what vaccine they can and cannot accept per their home country's policy (and opting out if required/appropriate).

#### Q. When will ships at sea get the vaccine?

**A.** Vaccines were initially sent to medical facilities and dedicated vaccination sites, however as more vaccines became available plans were developed to provide vaccines to ships. Vaccination of ships is coordinated with OPNAV to meet operational requirements and conform to medical guidelines.

### Q. Is the DoD considering purchasing vaccine from foreign governments?

**A.** No, not at this time. Any vaccine considered for use would need to be evaluated by the FDA and CDC for safety and efficacy before it could be used by the DOD.

#### Q. How much does the COVID-19 vaccine cost?

**A.** TRICARE will cover the cost of the vaccine from any location, but if you go to a civilian provider, there may be a cost for an office visit based on your plan. Those who receive their vaccine through a civilian pharmacy should not be billed. Active duty service members will require a referral from their primary care manager to get the vaccine from a TRICARE-authorized civilian provider, but a referral is not required to get the vaccine from a civilian pharmacy. To learn more, visit:

https://tricare.mil/HealthWellness/HealthyLiving/Coronavirus/COVID-Vaccine

### Q. How are we doing on vaccination rates?

**A.** Vaccinations are proceeding in an efficient and safe manner. Safety to staff and patients is paramount and initially, while implementing the new protocols, vaccinations occurred at a measured rate that was less than currently being done. It is anticipated that as staff becomes more familiar with the process and commands begin engaging in vaccination events as discrete units, vaccinations will occur notably faster.

### Q. What should CNO or other senior leaders say when asked "why should I get the vaccine?"

**A.** Vaccinations are crucial to the prevention of disease and the preservation of health and readiness. While there is still much we don't know about the full benefits of the vaccines, what we do know is very good. Specifically all three vaccines we are currently using are highly effective in preventing symptomatic infections. The full benefits aren't known but it is expected that as more people become vaccinated, we will learn more about how it prevents transmission, prevents asymptomatic infections, how long it lasts, and implications on public immunity. So not only will you be benefiting yourself and those you interact with but also contributing to future understanding about the vaccine and how it protects everyone else.

### Q. Anything else the team recommends for leaders to know/understand.

**A.** Dispelling misinformation and preventing premature relaxation of preventive precautions will be a major effort as the vaccination year progresses. It is likely we will see increasing cases among those who are partially or even fully immunized as they begin re-engaging in risk taking behavior.

# Q. If we were to vaccinate 70% of a crew, then ROM-S the other 30% and combine to form a bubble, can we say the risk is driven low enough? Can we use rapid testing and vaccine to get rid of ROM while keeping risk low?

**A.** The NMCPHC is developing mathematical models to provide an indication of the risk assumed by the Commander if he or she decides to adopt a combined ROM-vaccine policy. However models are only as good as the information and assumptions that are put into them. We will not know how these combinations will work until we observe vaccinated individuals for the next few months.

#### Q. Can ROTC personnel get DoD vaccine?

A. Yes, if they are empaneled at a DoD MTF and/or are a Tricare beneficiary (e.g. dependent, have a Service contract). Note as well that ROTC members fall in a low category on the current approved DoD prioritization schema.

### Q. Any prohibition on dependents getting vaccine from host nation if outside the US?

A. For family members/dependents, the Department of Defense cannot restrict them from going off-post to get another vaccine. In the event of any adverse events, MHS facilities should still give care as they are beneficiaries.

Service members should wait for DoD deployment of the vaccine if they are near a MTF. As a second (and less preferred option), if vaccines that have US FDA EUAs are offered for Service members in host nations, it is ok for them to get it. However, vaccination must be documented in their record. If this happens, recommend the Navy and Marine Corps ensure that the vaccine that is being offered has the equivalent dose/schedule as the US product (assume they are exactly the same since it is the same manufacturer).

### Q. How will you know when a command is in need of an allotment to cover 2nd doses from week to week?

**A.** Navy Medical Logistics Command will initiate orders for 2<sup>nd</sup> doses.

### Q. Who sets priority for DoN Personnel to receive the vaccine? And are recruiters 1b personnel?

**A.** OPNAV sets the priority for Navy personnel. Recruiters have been prioritized as Tier/Phase 1b.4 in the OPNAV schema

https://portal.secnav.navy.mil/cop/crc/COVID/Vaccine%20Info/Forms?ALLItems.aspx) . This corresponds to Tier/Phase 1b in the DoD schema which does not include sub-tiers.

#### Q. Is there any guidance on transporting the vaccine?

**A.** The Moderna vaccine cannot be transported at 2-8C without risk of the vaccine being damaged. .

Moderna can be transported at -25C to -15C without concern for damage from rough handling. The Defense Logistics Agency can help with transport materials.

Pfizer is not being considered for shipboard use at this time per discussions with OPNAV. However, redistribution at 2-8C by car was authorized during the pilot phase in Dec 2020.

The Johnson & Johnson COVID-19 single-dose vaccine is compatible with standard vaccine storage and distribution channels with ease of delivery to remote areas. The vaccine is estimated to remain stable for two years at -4°F (-20°C), and a maximum of three months at routine refrigeration at temperatures of 36-46°F (2 to 8°C). The Company will ship the vaccine using the same cold chain technologies it uses today to transport treatments for cancer, immunological disorders and other medicines. The COVID-19 vaccine should not be re-frozen if distributed at temperatures of 36°F–46°F (2°-8°C).<sup>4</sup>

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<sup>&</sup>lt;sup>4</sup> https://www.jnj.com/johnson-johnson-covid-19-vaccine-authorized-by-u-s-fda-for-emergency-usefirst-single-shot-vaccine-in-fight-against-global-pandemic

#### Q. Should a ship vaccinate if they are currently having an outbreak?

**A.** Yes, ships should proceed with immunizations for all those who are not Covid-19 positive.

### Q. Is there any guidance on vaccinating American citizens living abroad if they are not otherwise eligible for care at our overseas MTFs?

**A.** Per our current policy, these individuals are not eligible. Individuals may want to ask for Secretarial Designee (SECDES) status to receive this particular medical service.

### **Questions about MY Vaccine**

### Q. Am I at risk for serious adverse events if I receive the Janssen COVID-19 vaccine?

**A.** At this time, the available data suggest that the chance of these adverse events occurring is remote, but investigation into the level of potential excess risk due to vaccination is ongoing. We are also continuing to closely monitor the safety of the vaccine, as we are doing with all COVID-19 vaccines.

In people who have developed blood clots with low levels of platelets following the Janssen COVID-19 Vaccine, symptoms began approximately 1 to 2 weeks following vaccination

You should contact your health care provider immediately if you are experiencing any of the following symptoms:

- shortness of breath
- chest pain
- leg swelling
- persistent abdominal pain
- neurological symptoms (including severe or persistent headaches or blurred vision)
- easy bruising
- tiny blood spots under the skin beyond the site of injection of the vaccine

These symptoms are distinct from the commonly reported side effects that people may experience in the first few days following vaccination, which can include headache, fatigue, muscle aches and nausea. Most of these side effects are mild to moderate in severity and last 1 to 2 days.

### Q. What activities can I participate in if I have been fully vaccinated?

**A.** If you've been fully vaccinated:

 You can gather indoors with fully vaccinated people without wearing a mask or staying 6 feet apart.

- You can gather indoors with unvaccinated people of any age from one other household (for example, visiting with relatives who all live together) without masks or staying 6 feet apart, unless any of those people or anyone they live with has an increased risk for severe illness from COVID-19.
- You can gather or conduct activities outdoors without wearing a mask except in certain crowded settings and venues.
- If you <u>travel in the United States</u>, you do not need to get tested before or after travel or self-quarantine after travel.
- You need to pay close attention to the situation at your international destination before traveling outside the United States.
  - You do NOT need to get tested **before** leaving the United States unless your destination requires it.
  - You still need to <u>show a negative test result</u> or documentation of recovery from COVID-19 **before** boarding an international flight to the United States.
  - You should still get tested 3-5 days after international travel.
  - You do NOT need to self-quarantine after arriving in the United States.
- If you've been around someone who has COVID-19, you do not need to stay away from others or get tested unless you have symptoms.
  - However, if you live in a group setting (like a correctional or detention facility or group home) and are around someone who has COVID-19, you should still stay away from others for 14 days and get tested, even if you don't have symptoms.

\*\*NOTE: Active duty personnel must abide by their location's HPCON provisions whether they are fully vaccinated or not.

#### Q. Are individuals required to get the vaccine?

**A.** Under the current EUAs, the vaccine is voluntary. It is expected that EUAs for other vaccines will have a similar provision, permitting a patient to refuse the vaccine.

There are three different methods that could trigger a mandatory vaccine requirement: (1) if an EUA is issued or amended so that it no longer contains the option to refuse vaccination; (2) if the President of the United States grants a waiver, finding voluntary vaccination is not in the interest of national security and SECDEF makes it mandatory for members of the armed forces; or (3) once the vaccine receives full approval from the FDA. The FDA has found the vaccines granted an EUA to be safe and effective and it is anticipated that it will eventually receive full approval later in 2021, at which time the military may require personnel to be vaccinated (similar to other existing vaccination requirements).

### Q. Why should I get the vaccine?

**A.** Getting vaccinated can help prevent getting sick with COVID-19. While many people with COVID-19 have only a mild illness, others may can have serious, life-threatening complications get a severe illness or they may even die. There is no way to know how COVID-19 will affect you, even if you are not at increased risk of severe complications,

we don't fully understand the long term consequences of infection. COVID-19 vaccination may help protect you by creating an antibody response without having to experience the infection.

COVID-19 vaccination will likely be a safer way to help build protection COVID-19 can have serious, life-threatening complications, and there is no way to know how COVID-19 will affect you, or the long term consequences of infection. There is mounting evidence that infections result in at least some duration of protection against reinfection or severe symptoms for approximately 3 months after infection.

However, gaining that type of natural protection comes with risks of serious complications and potentially death. Vaccinations offer a controlled and largely very safe way to prepare your immune system to protect you from future infections. COVID-19 vaccination will be an important tool to help stop the pandemic.<sup>5</sup>

#### Q. How will I know when I am eligible to get the vaccine?

**A.** Your unit will be notified when portions or all of your unit are eligible to get the vaccine.

#### Q. Which iteration of the vaccine will I get?

**A.** As COVID-19 vaccine becomes available, vaccines will continue to be distributed based on availability and the DOD prioritization. You will likely only have the option to receive whichever vaccine is available at the MTF you are visiting. While there is limited vaccine availability, vaccination distribution prioritization will focus on those providing direct medical care, maintaining essential national security and installation functions, deploying forces, and those beneficiaries at the highest risk for developing severe illness from COVID-19.

#### Q. Where should I be vaccinated?

**A.** To the greatest extent possible, beneficiaries in priority groups who are enrolled at Military Treatment Facilities (MTF) should come to the MTF to be vaccinated. This will ensure the maximum number of vaccine opportunities allocated to jurisdictions other than DoD are available for the non-DoD population.

#### Q. Where can I get the COVID-19 vaccine?

**A.** The availability of the vaccine may vary by location. Eventually, you'll be able to get the vaccine at:

- Your local military hospital or clinic.
- Your civilian provider.
- TRICARE network pharmacies.
- TRICARE non-network providers or TRICARE non-network pharmacies.

If you visit a non-network provider or pharmacy, you may need to pay a cost-share based on your plan, and file a claim for reimbursement. The vaccine itself is offered at no cost, but there may be a cost based on your plan for an office visit or if you require

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<sup>&</sup>lt;sup>5</sup> From CHINFO Briefing Card "COVID-19 Vaccine NAVADMIN" 22 Dec 2020.

follow-on care. Wherever you eventually receive your vaccination, please remember you need to check availability before showing up.

### Q. How will the Navy and Marine Corps track personnel who receive a COVID vaccine?

**A**. The Navy, Marine Corps and all of DOD will track COVID vaccine administration through existing medical record reporting systems.

### Q. If I already had COVID-19, should I still get a vaccine?

**A.** Yes, because duration of immunity following COVID-19 infection is unknown, and the vaccine may be effective in protecting previously infected people.

### Q. Will I still need to wear masks and practice physical distancing once a vaccine is available?

**A.** Based on the CDC's latest science, fully vaccinated people can safely participate in most activities, indoor or outdoor, without wearing a mask or social distancing. It is recommended by both the CDC and the DOD to continue to practice public health protective measures like washing your hands and frequently cleaning common areas. There may be some places where you are still asked to wear a mask, based on the rules in local communities or businesses.

#### Q. How soon does the vaccine take effect after getting the first shot?

**A.** COVID-19 vaccines teach our immune systems how to recognize and fight the virus that causes COVID-19. It typically takes two weeks after vaccination for the body to build protection (immunity) against the virus that causes COVID-19. For the 2-dose vaccines this would be 14 days after the second dose and for 1-dose vaccines this would 14 days after vaccination.

#### Q. Can I still get COVID once I have been vaccinated?

**A.** Yes, the protection provided by the vaccine is not immediate, it takes time for a person's body to respond to the vaccine and produce antibodies. The vaccine reaches full effect of approximately 95% at least 7 days after the second dose. At the 95% effective rate, approximately 5% of those who receive both doses of the vaccine may still get COVID-19.

### Q: How long will protection last following vaccination?

**A.** We do not know how long protection will last following vaccination but it will be critically important to measure long-term protection (at least two years) in the phase 3 trials and in other groups prioritized for early vaccination. We are still learning about the duration of protection following infection with COVID-19 and it is too early to tell how long protection will last.

#### Q. Should I get the vaccine for influenza (flu shot)?

**A.** Yes, it is very important to get the influenza vaccine, particularly this season when both influenza viruses and COVID-19 will infect people.

#### Q. Can I get the flu vaccine and the COVID vaccine at the same time?

**A.** COVID-19 vaccine series should be administered alone, with a minimum of 14 days before or after receiving other vaccines. The exception would be situations where the benefits of vaccination are deemed to outweigh the potential unknown risks of vaccination co-administration. For example, needing a tetanus, measles or hepatitis A shot during an outbreak.

### Q. Should I get the flu vaccine or the Pfizer vaccine? Alternately, should I hold off on required vaccines so that I can get the Pfizer vaccine?

**A.** The Pfizer vaccine is voluntary and subsequently not required and does not impact readiness. Because of this, you should get the flu shot and complete any other required vaccination before getting a COVID-19 vaccination if given the opportunity.

### Q. If I get the vaccine do I still need to ROM, quarantine, or wear a mask?

**A.** Based on the CDC's latest science, fully vaccinated people can safely participate in most activities, indoor or outdoor, without wearing a mask or social distancing. • There may be some places where you are still asked to wear a mask, based on the rules in local communities or businesses.

#### Q. Will DoD require all service members to receive the vaccine?

**A.** The currently available COVID vaccines are authorized under an EUA and are voluntary. All populations for which the vaccine is authorized are highly encouraged to get the vaccine, but service members may not be compelled to receive the vaccine. When formally approved by the FDA, the DoD may require a COVID-19 vaccine for military personnel or civilians in specific fields, as is the case for the annual influenza vaccine.

### Q. Why should we receive the first-available vaccine when there are several other vaccines still in trials?

**A**. People who are offered the first-available vaccine are considered to be in groups that are most in need of COVID-19 protection. Vaccinated people will be protecting themselves, as well as their families and all people with whom they interact. Evaluation of the first-available vaccine will continue, even after its pre-licensure release. The release of other vaccines cannot be fully predicted, so people who are offered the first-available vaccine will be encouraged to receive this vaccine.

#### Q. How will the vaccine be administered?

**A.** The vaccines currently available are intramuscular injections, similar to the flu vaccine. The Pfizer and Moderna COVID-19 vaccines are administered in a two-dose series separated by 21 or 28 days depending on the product. The newly authorized Janssen (Johnson and Johnson) vaccine is a single dose to complete the immunization. Vaccines from different manufacturers will NOT be interchangeable. If the vaccine requires two doses, individuals must receive the same vaccine for both doses.

### Q. If the vaccine is voluntary does it change the guidance for masks and social distancing?

**A.** No. There is no data on transmission blocking for the Pfizer or Moderna vaccine. Additionally, the vaccine will not be required so vaccine coverage will be variable.

## Q. Would a command need to put out guidance for work? Such as 'if you do not get the vaccine you continue to telework, if you do get the vaccine you must return to normal work schedules'.

A. No, while the vaccine is voluntary, there are no restrictions on individuals with regard to what they can or cannot do at work. All preventive measures should be continued.

Q. If someone declines to receive the vaccine, how is it noted in their record?

A. The current goal is to offer the vaccine to all military personnel. Documentation of the vaccination will be recorded as receiving vaccine, exempted, or declining the vaccine in the Medical Readiness Reporting System (MRRS). So long as vaccination is taking place under the EUA, MRRS will record all individuals who have been contacted (i.e., vaccinated, exempted or declined vaccination) as having met the vaccination requirement. This report will be updated in the event receiving the vaccine is made a readiness requirement.

#### Q. What are the consequences of declining vaccination?

A. So long as vaccination is taking place under a voluntary Emergency Use Authorization (EUA), the Medical Readiness Reporting System will record all individuals who have been contacted (i.e., vaccinated, exempted or declined vaccination) as having met the vaccination requirement. Under a voluntary EUA, personnel may not be compelled to accept the vaccine and commands cannot impose punitive or administrative measures against individuals who exercise the right to decline the vaccine.

**Q.** What can I do to encourage vaccination by members of my command? **A.** The current goal is to offer the vaccine to all personnel. So long as vaccination is taking place under a voluntary Emergency Use Authorization (EUA), the Medical Readiness Reporting System will record all military individuals who have been contacted (i.e., vaccinated, exempted or declined vaccination) as having met the vaccination requirement. Because of the health benefits conferred by the vaccine, it is natural to want to maximize the number of people vaccinated, but under a voluntary EUA personnel may not be compelled to accept the vaccine and commands cannot impose punitive or administrative measures against individuals who exercise the right to decline the vaccine. Commands must avoid any policy, such as imposing different standards or benefits for vaccinated personnel, which could be perceived as unlawfully coercing acceptance of the vaccine. Following collection of evidence from vaccinated populations and as informed by the advice of medical experts, Navy and Marine Corps leadership may issue guidance in the future on exempting vaccinated personnel from certain health protective measures.

Q. Under what circumstances could the vaccine become mandatory?

A. There are three different methods that could trigger a mandatory vaccine requirement: (1) if an Emergency Use Authorization (EUA) is issued or amended so that

it no longer contains the option to refuse vaccination; (2) if the President of the United States grants a waiver, finding voluntary vaccination is not in the interest of national security and SECDEF makes it mandatory for members of the armed forces; or (3) once the vaccine receives full approval from the FDA. Currently available vaccines are voluntary. All populations for which the vaccine is authorized are highly encouraged to get the vaccine, but service members may not currently be compelled to receive the vaccine. Following full FDA approval, the DoD may require a COVID-19 vaccine for military personnel or civilians in specific fields, as is the case for the annual influenza vaccine.

#### Q. How would a command know who got the vaccine and who did not?

A. While under EUA the vaccine will not be a readiness requirement. MRRS will log members as complete if they were offered the vaccine and note if they took the vaccine, but not count that as a readiness metric.

### Q. For platforms such as ships and submarines would there still be an opt out for the vaccine?

A. While released under an EUA, the vaccine is voluntary and therefore there are no restrictions regarding service members serving afloat or ashore.

#### Q. What exemptions will be made when the vaccine is required?

**A.** At this time, the vaccine is voluntary, further guidance will be provided if/when the FDA approves full licensure of a vaccine. Contraindications for the vaccine are anticipated to be released by the CDC's ACIP.

### Q. Will the manufacture of the vaccine be disclosed to the patient prior to immunization?

**A.** Yes, that is part of the informed consent of receiving an EUA vaccine.

#### Q. Will a prescription be necessary for a vaccine under an EUA?

**A.** Neither the Pfizer-BioNTech, Moderna or Jansen EUA require an individual prescription from a provider. It is expected that other vaccines authorized in the future may also be administered without the requirement for an individual prescription for each vaccine recipient from an authorized healthcare provider.

#### Q. Can I pick which vaccine to get?

**A.** At this point in time, most locations will only receive one version of the vaccine. We are encouraging all to get the vaccine when it becomes available regardless of the type of vaccine.

#### Q. Can I test positive due to the COVID-19 Vaccine?

**A**. None of the FDA-approved vaccines contain the live virus (SARS-CoV-2) that causes COVID-19. This means that they cannot make you sick with COVID-19 or transmit it to others. This includes the Janssen vaccine.

### Q. After getting a COVID-19 vaccine, will I test positive for COVID-19 on a viral test?

**A.** No. Neither the recently authorized and recommended vaccines nor the other COVID-19 vaccines currently in clinical trials in the United States can cause you to test positive on viral tests, which are used to see if you have a current infection. If your body develops an immune response—the goal of vaccination—there is a possibility you may test positive on some antibody tests. Antibody tests indicate you had a previous infection and that you may have some level of protection against the virus. Experts are currently looking at how COVID-19 vaccination may affect antibody testing results.

### Q. What changes for me when I get inoculated?

**A.** Getting the complete vaccination series will likely protect you from symptomatic COVID-19 infection.

### Q. Why should I get vaccinated if it doesn't change the rules for what I can and cannot do?

**A.** The vaccine is an additional public health measure to augment current measures to get us through this pandemic as soon as possible. This is a global pandemic, and will take time to extinguish. We have done well so far, and in order to complete the job, we will have to maintain this posture for a while longer. The more people that get vaccinated, the faster we can assess the evidence and make safe and informed changes to prevention measures and begin to relax additional public health measures. The vaccines are very effective. The recommendation to continue prevention measures will be based on evidence gathered from those who have already received the vaccinations and the evidence of their protection from infection.

#### Q. Can a vaccinated individual transmit to a non-vaccinated individual?

**A.** This is also unknown. The studies that are currently published and used to grant the EUAs focused on preventing symptomatic laboratory confirmed infections. Again, this is why we cannot currently make significant changes to preventive measures yet.

#### Q. Can I get the COVID vaccine if I recently had COVID?

A. Yes. Data from clinical trials indicate that mRNA COVID-19 vaccines are safe in persons with evidence of a prior SARS-CoV-2 infection. Vaccination should be offered to persons regardless of history of prior symptomatic or asymptomatic SARS-CoV-2 infection.

#### Q. Can I get the COVID vaccine if I currently have COVID?

**A.** Individuals who are actively infected and infectious should not be given the vaccine. Vaccination should be deferred until the person has completed the required isolation time period.

### Q. Is there any evidence of passing the virus or the immunity from mother to child in a pregnant woman?

**A.** Currently there are only case studies examining these issues (meaning a few individual cases, not larger observational studies). Early data suggests that approximately 5% of pregnant women with COVID-19 in the third trimester do give birth to babies with COVID-19. Most cases have been very mild in the newborns. Lower than expected SARS CoV 2 antibodies were found in newborns whose mothers had COVID-19 during pregnancy than antibodies for other diseases such as the flu.

### Q. Are there any issues with persons receiving chemotherapy and the effectiveness of the vaccine?

**A.** For someone who is receiving chemotherapy and may be immunocompromised, there is increased risk that the vaccine will not illicit the proper immune response, and thus be less protective against COVID-19 in that person. While the COVID-19 vaccines currently authorized (Pfizer, Moderna and Jansen) are NOT live virus vaccinescancer patients or cancer survivors should discuss with their oncologist whether they should get the COVID-19 vaccine.

**Q.** I received my first dose of the vaccine. Will I be notified for the 2nd dose? **A.** Yes, you will be informed about when your next dose is due when you get the first dose. You will also be notified about when and where to receive your 2nd dose. Each military treatment facility (MTF) has a 2nd dose notification plan and will work with commands to inform them and their personnel. If you received the Janssen (Johnson & Johnson) vaccine, only one dose is required.

### Q. Do I go back to the where I received my first dose on the day highlighted on my vaccination card, or will I be sent to an alternate location?

**A.** Your 2nd dose may or may not be given at the same location of your first dose. The location where you will receive the second dose will be provided upon notification. If you have questions or are not contacted, reach out to the MTF where you received the first dose and clarify.

### Q. Do I need to receive my second dose from the same entity (i.e. DoD, VA, private healthcare provider) that provided my first dose?

**A.** We highly recommend that you receive your 2nd dose from the same organization you received your first dose however, that is not mandatory. The priority is to get personnel vaccinated. It is of vital importance that you have your CDC COVID-19 vaccination card with you when you present for your 2nd dose to ensure accuracy and timeliness.

### Q. Do my first and second doses need to be the same vaccine (i.e. Pfizer or Moderna)?

**A.** Yes, both doses should be from the same vaccine manufacturer; i.e., if you received the Pfizer vaccine for your first dose you must receive the Pfizer vaccine for your second dose. If you received the Janssen (Johnson & Johnson) vaccine, only one dose is required.

**Q.** What should you do if you get COVID between the two doses of the vaccine? **A.** It is possible to contract COVID-19 after receiving the 1st dose. The body requires time to build the antibodies necessary to prevent COVID. Additionally, the vaccine can only reach its full 95% effectiveness mark approximately 7 days after receiving both doses.

If you are diagnosed with COVID-19 in between receiving your 1st and 2nd doses, follow the established protocols already in place regarding strict isolation and symptom monitoring for the recommended period of time. When you are notified about receiving your 2nd dose, do not leave your isolation to get it. Once your isolation is complete and symptoms have improved, you may then proceed to receive your second dose.

### Q. Can you provide more information / clarification on the mutations of the virus and if the vaccine will protect against the new forms/variants?

**A.** It is not known for certain at this time if any new variants or mutations of the virus are resistant to the current vaccines. Research is ongoing, but preliminary results indicate the vaccines are likely to offer protection against the UK and South Africa variants.

### Q. What if I can't get the 2nd dose of my vaccine exactly 21 or 28 days after my first dose?

If it is not possible to get the second dose on that exact schedule, the CDC recommends you get the vaccine no earlier than 4 days before it is due to allow your body to develop an immune response after the 1st dose. It is recommended you receive the 2nd dose within 7 days after your due date to allow medical facilities to plan and schedule COIVD vaccinations. If individuals cannot complete this window, it is recommended to get the second dose as soon as possible after the window has expired.

### Q. Do we have guidance on acceptability of giving the 1st dose to deployers without a guarantee of getting the 2nd dose?

Service members can wait until they return to their parent MTF to get the second dose. The EUA for Pfizer and Moderna do not have a date by which the second shot must be administered, though the CDC recommends that every person receiving the vaccine get the second dose within the timeframe indicated in the EUA.

### Q. Can people finish vaccine series with DoD if started at civilian location (or the reverse)?

A. Yes, eligible personnel can finish the vaccine series at DoD if started at civilian location (or vice versa). However, it is ill-advised for them to do so because 1) current guidance recommends all eligible personnel, particularly Service members, receive their vaccination at a MTF and return to that same site for the second dose, and 2) not returning to the same site skews the supply/demand numbers for DoD and states in which vaccine is received through the Civilian sector because these locations are currently holding and/or accounting for a second dose). Service members must ensure the vaccine is documented in their medical record.

### Q. Will the Navy and Marine Corps follow the same recommendation from the CDC about the need to quarantine if exposed after vaccination?

**A.** Public health recommendations for vaccinated persons: While mRNA COVID-19 vaccines have demonstrated high efficacy at preventing severe and symptomatic COVID-19, there is currently limited information on how much the vaccines might reduce transmission and how long protection lasts. In addition, the efficacy of the vaccines against emerging SARS-CoV-2 variants is not known. At this time, vaccinated persons should continue to follow current guidance to protect themselves and others, including wearing a mask, staying at least 6 feet away from others, avoiding crowds, avoiding poorly ventilated spaces, covering coughs and sneezes, washing hands often, following CDC travel guidance, and following any applicable workplace or school guidance, including guidance related to personal protective equipment use or SARS-CoV-2 testing. However, vaccinated persons with an exposure to someone with suspected or confirmed COVID-19 are not required to quarantine if they meet all of the following criteria†:

Are fully vaccinated (i.e., ≥2 weeks following receipt of the second dose in a 2-dose series, or ≥2 weeks following receipt of one dose of a single-dose vaccine)

Are >2 weeks past full vaccination

Have remained asymptomatic since the current COVID-19 exposure

Persons who do not meet all 3 of the above criteria should continue to follow current quarantine guidance after exposure to someone with suspected or confirmed COVID-19.

### Q. Can I take Tylenol, Motrin or antihistamines after I get my vaccine?

**A.** Treatment with Tylenol or Motrin post-vaccination for local or systemic symptoms is okay (with medical provider consent) but routine preventative use is not recommended – due in part because they haven't been studied in relation to mRNA vaccination efficacy. Giving antihistamines (such as Benadryl) to COVID-19 vaccine recipients prior to vaccination to prevent allergic reactions is not recommended. Antihistamines do not prevent anaphylaxis (allergic reactions), and their use might mask skin-related symptoms, which could lead to a delay in the diagnosis and management of anaphylaxis or any allergic reaction.

### Q. Are there any documented cases of immunized personnel (14 days following both doses) getting COVID 19?

**A.** Documented COVID-19 cases of immunized personnel are very infrequent, and of these in the Navy or Marine Corps as of 17 March 2021, all cases have been mild to moderate in severity (e.g.: no cases of hospitalization or death) following completion of vaccine series (defined as 14 days after final dose). The number of Sailors and Marines who have contracted COVID-19 after completing their vaccination series is far less than the number of Sailors and Marines who have contracted COVID-19 prior to receiving

their vaccination series. Furthermore, there were only two severe cases among partially immunized individuals. These facts reinforce the point that the COVID-19 FDA EUA vaccines are highly effective, and begin to have a protective effect even before completion of the full series.

### Questions about who can get the Vaccine

### Q. I previously declined to take a vaccine, but now I would like to get vaccinated. Is a vaccine still available to me?

**A.** Personnel who previously declined vaccination, are still eligible and able to receive a vaccine, even if the vaccination site has moved on to vaccinating personnel in subsequent population tiers.

### Q. Will TRICARE beneficiaries including military retirees have access to the vaccine?

A. Yes, based on DoD prioritization. While there is limited vaccine availability, vaccination distribution prioritization will focus on those providing direct medical care, maintaining essential national security and installation functions, deploying forces, and those beneficiaries at the highest risk for developing severe illness from COVID-19. TRICARE beneficiaries empaneled at a DoD Military Treatment Facility (MTF) are eligible to receive the vaccine at a DoD MTF. TRICARE beneficiaries who receive care at DoD MTFs on a space-available basis can alternately receive vaccine through the local civilian jurisdiction.

Q. Which Select Reserve and National Guard personnel will receive the vaccine?

A. Selected Reserve personnel include drilling members of the Federal Reserve and National Guard. Selected Reserve personnel on orders for more than 30 days are included in the active component.

Q. I don't live near a military treatment facility or DoD vaccination site. Can I get the COVID-19 through my county health department or civilian employer?

A. Yes. Reserve Component service members can utilize local civil vaccination programs. The goal is to rapidly and safely vaccinate as many service members in order to build COVID-19 immunity across the force. Reserve Component service members should not wait for DoD vaccination opportunities if they have earlier access to civil vaccination programs. Reserve Component service members must report their vaccination status to their chain of command.

## Q. I am a NAF employee (or DoD Contractor) but can't be treated by a military treatment facility normally. Can I still get my COVID-19 vaccine at my installation MTF or site?

**A.** DoD civilian employees, who are not otherwise eligible DoD beneficiaries, are eligible to receive the vaccine, and select contractor personnel who usually receive influenza vaccines as part of a DoD occupational safety and health program (e.g., health care workers, maintenance depot workers), and who are not otherwise eligible DoD beneficiaries, may be offered COVID-19 vaccines at DoD vaccination sites. Follow-on

care (other than the administration of a second vaccine dose) will be provided through such individuals' existing health care plans or personal health care providers.

### Q. I am an employee of a DoD contractor supporting DoD efforts. Can I get the vaccine from the DoD?

**A.** DoD's allocation may be offered, and administered at DoD vaccination sites to employees of DoD contractors directly supporting the DoD on DoD installations or in an operational environment, in accordance with the attached DoD COVID-19 vaccine population schema (e.g. health care providers/support personnel, personnel preparing to deploy), and the terms of applicable contracts.

### Q. Can OCONUS DoD Contractor dependents receive their COVID vaccine from military treatment facilities?

**A.** In certain situations, DoD contractors who are stationed or employed outside the United States and their accompanying dependents, when residing in the same household, are authorized on a space-available basis to be vaccinated in accordance with the DoD prioritization schema. To qualify as "accompanying dependents," there must be authorization from the sponsoring DoD entity that authorizes the accompaniment of dependents. This authorization may be pursuant to the contract or other written documentation

#### Q. Is the vaccine safe for pregnant or lactating women?

**A.** Currently, there are no data on the safety and efficacy of COVID-19 vaccines in these populations to inform vaccine recommendations. If you are pregnant or breastfeeding, discuss your options with your healthcare provider.

### Q. Should children get the vaccine?

**A.** The current vaccine trials have not studied the safety and efficacy for children and manufactures are not currently asking the FDA for authorization to vaccinate children.

#### Q. Are our contractor HCWs eligible to receive the vaccine?

**A.** Per Coronavirus Disease 2019 Vaccine Guidance issued by the Deputy Secretary of Defense on 7 Dec 2020, select contractor personnel who usually receive influenza vaccines as part of a DoD occupational safety and health program (e.g., health care workers, maintenance depot workers), and who are not otherwise eligible DoD beneficiaries, may be offered COVID-19 vaccines at DoD vaccination sites.

### Q. I've heard people with allergies should not get the vaccine, is that accurate?

**A.** You should not get a COVID-19 Vaccine if you:

- had a severe allergic reaction after a previous dose of this vaccine
- had a severe allergic reaction to any ingredient of this vaccine

### Q. Should aviators or other personnel in a special medical status (i.e. flight status) get the vaccine?

**A.** The vaccine is available to anyone in a flight duty status, but individual units may have operational requirements that require vaccine administration to occur in a

staggered fashion. Personnel in a flight status of any class will have a grounding period after each dose of the vaccine. This is the same for any vaccine in those who are in a flight duty status. Aviators who have questions should see their flight surgeon.

### Q. If aviators or other personnel do get the vaccine, are they medically down for a period of time?

**A.** Personnel in a flight status of any class will have a grounding period after each dose of the vaccine. This is the same for any vaccine in those who are in a flight duty status. Aviators who have questions should see their flight surgeon.

### Q. Can Allied and Partner personnel stationed on DOD installations get the vaccine?

**A.** Per the Supplemental Guidance for Providing DOD Coronavirus Disease 2019 Vaccines issued Dec 31, 2020 the following are eligible for DOD vaccine (provided it is in accordance with applicable contracts and agreements):

- 1) Employees of DoD contractors directly supporting the DOD on DOD installations or in an operational environment;
- 2) Members of allied, coalition, or partner forces stationed on DOD installations on a reimbursable basis; and
- 3) Embedded non-US national personnel providing direct support to US military forces on a reimbursable basis.

# **Q. What about individuals not covered in the list of eligible foreign nationals? A.** Beyond those identified in the 31 Dec 2020 memo, any additional requests for vaccination of other than US Forces personnel should be routed to the Office of the Assistant Secretary of Defense for Health Affairs (ASD(HA)) for consideration.

### Q. Will foreign nationals then be eligible for follow-on care?

**A.** Per the Supplemental Guidance for Providing DOD Coronavirus Disease 2019 Vaccines issued Dec 31, 2020, individuals not otherwise eligible to receive healthcare from the DOD will pursue any follow-on care (other than the second vaccine dose) through their existing healthcare plans or personal healthcare providers.

### Provider/CO Questions on Vaccine

### Q. What should health care providers look for in evaluating Janssen COVID-19 vaccine recipients for these serious adverse events?

**A.** Healthcare providers should be alert to the signs and symptoms of thrombosis with thrombocytopenia syndrome in individuals vaccinated with Janssen COVID-19 Vaccine. In individuals with suspected thrombosis with thrombocytopenia and who were vaccinated with Janssen COVID-19 Vaccine, heparin may be harmful and alternative treatments may be needed. Consultation with hematology specialists is strongly recommended.

- Additional information for clinicians is available from CDC in its Health Alert Network notice, "Cases of Cerebral Venous Sinus Thrombosis with Thrombocytopenia after Receipt of the Johnson & Johnson COVID-19 Vaccine."
- In addition, The American Society of Hematology has information on its website
   External Link Disclaimer relevant to the diagnosis and treatment of thrombosis
   with thrombocytopenia following the Janssen COVID-19 Vaccine.

### Q. What information can be released if a state official requests information on COVID-19 vaccination at a MTF or vaccination site?

**A.** Per CHINFO guidance, we can release at the MTF level the number of vaccines administered at the MTF level. There should not be a break down by tier or demographic or vaccines lost/wasted. An example response: "Naval Health Clinic New England has administered a total of XXX vaccines. This number reflects XXXX individuals who have completed the full course for immunization (one shot for J&J and two for Moderna and Pfizer) and XXXX who have received the first of two doses".

## Q. What information can be released if a US Senator or Member of the House of Representative requests information on COVID-19 vaccination at a MTF or vaccination site?

**A.** Refer these requests Legislative Affairs.

#### Q. How many doses are there in each vial of vaccine?

**A.** Pfizer is at least 5 does per vial and Moderna is at least 10 doses per vial. The Janssen (Johnson & Johnson) vaccine has 5 doses per vial.

### Q: Can remainder doses of Pfizer vaccine in vials, after the prescribed 5 doses, be used by providers?

**A.** Per the DHA IHD, Medical Treatment facilities and Immunization sites that administer the Pfizer COVID-19 vaccine may use the additional volume of vaccine in the vial after the prescribed 5 doses has been drawn. Ancillary kits shipped for use with the Pfizer COVID-19 vaccine will not have enough supplies to cover these additional doses. Clinics may use existing assemblages/supplies for use with this vaccine. Copies of the second dose vaccination cards may be made as an interim solution. Additional information on right-size of the ancillary kits will be shared as soon as it is available.

Additional instructions and authorizations for DOD providers available here: MMQC-20-1259

(https://www.usamma.amedd.army.mil/sitepages/mmqcmsgsearch.aspx?qsMsgNum=M MQC-20-1259)

### Q: How should we manage anaphylaxis if something happens as a result of giving the vaccine?

**A:** Additional guidance on management of anaphylaxis following vaccination with the Pfizer product is available on the CDC website here:

https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html

### Q. Is there a safety mechanism in place to ensure the same vaccine is used for the second dose once vaccine distribution expands and there could potentially be more than vaccine at a location?

**A.** There is a layered approach with training, public affairs, policy and technology. The need to use the same vaccine for both doses will be highlighted in public affairs guidance/talking point as well as training for providers and patients. Additionally, policies were included the DoD plan that limit only 1 vaccine type shipped to a location and the screening form in the IPM asks about staying at the same MTF for both doses to minimize risk of mixing vaccine types due to moving between doses. Lastly, the electronic health record will record the vaccine type follow administration which should be checked prior to administering the second dose.

# Q. Do all MTFS and tracking authorities need ADVANA? It says DHA will be required to use ADVANA, but will the MTFS need to use to report up to DHA? A. They do not need ADVANA (a dashboard for leadership), MTFs will use MRSS, VIALS and DMLSS. However, ADVANA will have all of the information consolidated for shipment, administration, and inventory and it will be used by senior leaders so I would highly recommend getting it.

### Q. When it lists "1000 doses," in a shipment, is that all for immediate use or should we save half for the second dose?

**A.** All first doses. No doses should be held for the second round. Allocation of the first dose is made with arrangements for a follow on shipment for the second round.

#### Q. Does an EUA have any impact on standing orders?

**A.** Standing orders are a type of medical order authorized or allowed under state laws. They permit the delegation and delivery of healthcare services through standardized criteria and procedures. Standing orders are one mechanism to enable non-physician healthcare providers (e.g., nurses, pharmacists) to assess and vaccinate persons who meet the criteria for vaccination without requiring a direct, individual order each time. The Pfizer-BioNTech EUA includes such a provision and it is anticipated that future EUAs for COVID-19 vaccines will also allow flexibility so that states could use their own mechanisms, like standing orders, to authorize appropriate healthcare providers to administer COVID-19 vaccine(s).

### Q. Can a COVID-19 vaccine be administered to populations not included in the authorized use of the vaccine under its EUA?

**A.** No. Use of any vaccine in populations outside the scope of its EUA would be an unauthorized use of the vaccine. Each EUA issued by FDA will describe the scope of the vaccine's authorized use, including populations (e.g., age groups) to which the vaccine may be administered. The scope of what is authorized under each EUA will be based on the available safety and efficacy data from populations studied in clinical trials.

#### Q. Is there a standing order for the Pfizer vaccine?

A. Yes, the standing order for the Pfizer product here: https://www.health.mil/Military-

<u>Health-Topics/Health-Readiness/Immunization-Healthcare/IHD-COVID-19-Vaccine-Resource-Center-for-Health-Care-Personnel#Forms</u>

#### Q. Is there a standing order for the Moderna vaccine?

**A.** Yes, the standing order for the Moderna product can be found on the CDC website: <a href="https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/downloads/standing-orders.pdf">https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/downloads/standing-orders.pdf</a>.

#### Q. Is there a standing order for the Janssen (Johnson & Johnson) vaccine?

**A.** Yes, the standing order for the Janssen product can be found on the CDC website https://www.cdc.gov/vaccines/covid-19/info-by-product/janssen/downloads/Janssen-Standing-Orders.pdf.

#### Q. Will NMRTUs receive their own shipment or will it go through the NMRTCs?

**A.** Direct shipment is the preferred approach to limit logistic complexity. There is no restriction on the number of direct ship sites allowed, the only constraint will be if the is no storage capacity at a site or a site cannot justify delivery of the minimum order.

### Q. What system should be used for submitting adverse events as noted in the DHA-IPM?

**A.** 1) JPSR - submitted for all administration errors and any VAERS reported events.

- 2) VAERS submitted for those items in Appendix 8, and
- 3) RE form for those events that fall within DoD reportable event parameters (not all events will be RE), form and guide attached.

#### Q. How will my command order vaccines?

**A.** If your command has a vaccine POC they should order the vaccine as instructed through VIALS and communicate with their supporting MTF. If your command does not have a vaccine POC and receives their vaccine from the MTF, they should contact the MTF vaccine POC and provide unit counts and contact information. MTF vaccine POCs can be found at VIALS (navy.mil) located in the yellow box on the right side of the page.

#### Q. How will my command receive vaccines?

**A.** This depends on the vaccine that is available for your command and the requirements for storage and administration. The Pfizer vaccine is stored at ultra-low temperatures that make it infeasible for administration outside of the hospital environment. Therefore if commands are notified that they will be receiving the Pfizer vaccine, it will come through and likely be delivered by the MTF. Other vaccines such as the Moderna vaccine are expected to be available for ships and Marine Corps units at OCONUS locations. If your command is notified that it will be receiving Moderna or one of the other vaccines, then it may be shipped either directly to the command or to the MTF or delivery location for pick up – similar to the influenza vaccine.

### Q. Does COVID-19 impact readiness?

**A.** No. The vaccine will show up in readiness reports as required but it will not impact unit readiness. The required component of the report is enable to ensure that all Service

members are offered an opportunity to accept or decline the vaccine while it is under an EUA.

### Q. Who is eligible to decline a vaccine? Alternately, can I defer/decline my entire command to get rid of the requirement?

**A.** As per NAVADMIN 237/20, only when a person is offered the vaccine and a vaccine is available to be given can they chose to decline it. If MRRS is coded as all declined, then it will not only incorrectly skew the acceptance information about the vaccine in the DoN but also it will inappropriately be taking away the opportunity for a Service member to make an informed decision about their own care.

### Q. What is the process/documentation needed to be able to certify a ship to directly receive and administer the vaccine?

**A.** An update to this question is forthcoming.

### Q. If there is a full 0.5 mL 6th (extra) dose from a Janssen (Johnson & Johnson) vial can I use it?

**A.** There is a slight overfill in each vial to accommodate for dead volume in the needle/syringe during administration. Discard any remaining vaccine in the vial after 5 doses have been extracted. Janssen does not recommend drawing up leftover volume from multiple vials to obtain a full additional dose for patient administration.

### Addressing Counter Narratives

### 1. It's voluntary, I don't need to get it.

**A:** It is voluntary, but in order to stop this pandemic and return things to normal, we need everyone who is able to get vaccinated. Vaccinations offer a controlled and a safe way to prepare your immune system to protect you from future infections.

#### 2. Concern about fertility if I get the immunization

**A:** People who want to get pregnant in the future may receive the COVID-19 vaccine.

Based on current knowledge, experts believe that COVID-19 vaccines are unlikely to pose a risk to a person trying to become pregnant in the short or long term. Scientists study every vaccine carefully for side effects immediately and for years afterward. The COVID-19 vaccines are being studied carefully now and will continue to be studied for many years, similar to other vaccines.

The COVID-19 vaccine, like other vaccines, works by training our bodies to develop antibodies to fight against the virus that causes COVID-19, to prevent future illness. There is currently no evidence that antibodies formed from COVID-19 vaccination cause any problems with pregnancy, including the development of the placenta. In addition, there is no evidence suggesting that fertility problems are a side effect of ANY vaccine. People who are trying to become pregnant now or who plan to try in the future may receive the COVID-19 vaccine when it becomes available to them. (From CDC - <a href="https://www.cdc.gov/coronavirus/2019-ncov/vaccines/facts.html">https://www.cdc.gov/coronavirus/2019-ncov/vaccines/facts.html</a>)

On 10 Feb Dr. Fauci reported ~20k pregnant women have been vaccinated with "no red flags" following vaccination.

#### 3. The mission doesn't require that I get it.

**A:** Staying healthy by protecting yourself with the vaccine is one less person we need to worry about possibly being pulled away due to COVID. If you get COVID, you might be alright, or you might not, we don't know, but we do know that getting the vaccine means that there is a 95% chance you will be alright and we can focus on the mission.

#### 4. I shouldn't get it before older people, so I'll wait.

**A:** This is an incredible effort to get all of America vaccinated. We need your help by getting vaccinated to help protect those in the community by getting as many people vaccinated as we can.

#### 5. This vaccine was not designed taking minorities into account.

**A:** We understand that there may be some distrust in the system based on previous experience and historical cases.

For the Pfizer trials: total participants who received either Pfizer-BioNTech COVID-19 Vaccine or placebo, 9.1 percent were Black or African American, 28.0 percent were Hispanic/Latino, 4.3 percent were Asian, and 0.5 percent were American Indian/Alaska native.

For the Moderna trials: Overall, 20.5% of participants identified themselves as Hispanic or Latino, 10.2% as African American or Black, 4.6% as Asian, 0.8% as American Indian or Alaska Native, 0.2% as Native Hawaiian or other Pacific Islander, 2.1% identified their race as other, and 2.1% as multiracial. The demographic characteristics were similar among participants who received Moderna COVID-19 Vaccine and those who received placebo.

- The National Medical Association, a leading voice for quality healthcare and elimination of health disparities found, after an independent review, that both the percentage and number of Black people enrolled are sufficient to have confidence in health outcomes of the clinical trials.

  <a href="https://www.nmanet.org/news/544970/NMA-COVID-19-Task-Force-on-Vaccines-and-Therapeutics.htm">https://www.nmanet.org/news/544970/NMA-COVID-19-Task-Force-on-Vaccines-and-Therapeutics.htm</a>
- According to the US Census Bureau 18.5% of participants identified themselves as Hispanic or Latino, 13.4% as African American or Black, 5.9% as Asian, 1.3% as American Indian or Alaska Native, 0.2% as Native Hawaiian or other Pacific Islander, and 2.8% as multiracial in a July 2019 report.

### 6. I've had COVID so I'm immune already.

**A:** There is mounting evidence that infections result in at least some duration of protection against reinfection or severe symptoms for approximately 3 months after infection, the vaccine is a safer way to build on that protection. Due to the severe health risks associated with COVID-19 and the fact that re-infection with COVID-19 is possible,

the vaccine should be given regardless of whether you already had COVID-19 infection. (from CDC - <a href="https://www.cdc.gov/coronavirus/2019-ncov/vaccines/facts.html">https://www.cdc.gov/coronavirus/2019-ncov/vaccines/facts.html</a>)

#### **Additional Information**

**DOD –** https://www.defense.gov/Explore/Spotlight/Coronavirus/

**HHS –** https://www.hhs.gov/coronavirus/explaining-operation-warp-speed/index.html

**CDC** – <a href="https://www.cdc.gov/coronavirus/2019-ncov/index.html">https://www.cdc.gov/coronavirus/2019-ncov/index.html</a>

**DHA -** www.health.mil/COVIDVaccine

**FDA COVID Vaccines** – <a href="https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines">https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines</a>

#### Resources:

**CDC: 8 Things to Know about Vaccine Planning** 

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/8-things.html

**CDC: Understanding How COVID-19 Vaccines Work** 

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/how-theywork.html

CDC: Ensuring the Safety of COVID-19 Vaccines in the United States

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html

**CDC: Frequently Asked Questions about COVID-19 Vaccination** 

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html

FDA: Emergency Use Authorization for Vaccines Explained

https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained