COVID WAGGINE INFORMATION FOR LEADERSHIP

NOTE: This FAQ is current as of Jan 15, 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.

Questions about the Vaccine Itself

- Q. How would 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. 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. Can we eliminate COVID restrictions for those vaccinated (masks, social distancing, ROM, leave, etc.)? Why not?

- 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 is 3 months prior to deployment, is it good for entire deployment?
- Q. Is there herd immunity? When will we know?
- Q. Didn't the CDC say people who have COVID should wait 90 days before getting the vaccine?
- Q. Is the Navy looking at using the half-doses of the Moderna vaccine that was talked about in the news?
- Q. Can COVID-19 vaccines affect fertility?
- Q. Will the mRNA vaccine affect my DNA?

Questions about Vaccine Distribution

- Q. How will the vaccine be distributed and administered?
- Q. What are the initial sites?
- Q. Will vaccines be available at MTFs? When will they be available?
- Q. Why is the vaccine not available here?
- Q. Why is the plan phase driven and not population or hot spot focused?
- Q. Who will be the first to get the vaccine?
- Q. Who in the Navy and Marine Corps is determining which units are in which priority level?
- Q. How will the Navy 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. When will ships at sea get the vaccine?
- Q. What is DoD's supporting role in Operation Warp Speed?
- Q. Where can I learn more about Operation Warp Speed?
- Q. Is the DoD considering purchasing vaccine from foreign governments?
- Q. How are we doing on vaccination rates, compared to both other services and our internal expectations? If there are differences, any sense as to the why?

- Q. What should CNO or other senior leaders say when asked "why should I get the vaccine?"
- Q. What is the vaccination strategy for Navy Senior Leaders and their staffs. Do we know how other services are doing this? Are we all in-step.
- 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?

Questions about MY Vaccine

- 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. How will the Navy 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. For entities that are currently Tier 1 and required to be tested for COVID...why are these same entities not also Tier 1 for the vaccine?
- Q. If I am not medical personnel, should I be wearing an N95 mask?
- 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. 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?

Questions about who can get the Vaccine

- 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. Will the Navy or Marine Corps distribute the vaccine to the American public too?
- 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. 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. Tab C of the WARNORD (Memo): Is there a deadline for COs to complete this? When complete, where do they need to send it?
- Q. Are there outcome-based planning measures/milestones to allow transition from Operational Phase 2a to 2b?
- Q. Locations OCONUS that are receiving initial distributions, are they getting Pfizer or Moderna?
- 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. If the Moderna vaccine is leftover after vaccinating Phase 1, can the initial allocation be redistributed to another clinic?
- 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. Will the number of doses received cover all of Tier 1a personnel in all three subtiers?
- Q. The WARNORD says "begin within 24 hours of receipt of vaccine." While MTFS will start within 24 hours, they do not need to finish correct?
- 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. 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?

Additional Information

Questions about the Vaccine Itself

Q. How would 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. Vaccines for COVID-19 are only available after they are demonstrated to be safe and effective in large phase-three clinical trials, have been authorized by the U.S. Food and Drug Administration, and have been manufactured and distributed safely and securely.

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).¹

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. We understand that some people may be concerned about getting vaccinated once a COVID-19 vaccine is available in the United States. While these vaccines are being developed 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.² The vaccine

² https://www.cdc.gov/coronavirus/2019-ncov/vaccines/vaccine-benefits.html

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

manufacturers conducted very large studies which include an analysis of 18,801³ and 15,185⁴ participants (Pfizer and Moderna, respectively) who received the vaccine and were followed for a median of more than two months to evaluate safety.

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

A. Currently there is no data on transmission blocking for the Pfizer or Moderna vaccine. Both 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.

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

A. Both 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.⁵

Q. Are vaccines interchangeable?

A. Currently there are only two vaccine available. Vaccines should not be mixed. 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. If you happen to get two different manufacturers, the CDC states that individuals should NOT receive another dose. Furthermore if this happens, the command will complete a patient safety report.

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

³ https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19

⁴ https://www.fda.gov/news-events/press-announcements/fda-takes-additional-action-fight-against-covid-19issuing-emergency-use-authorization-second-covid

⁵ https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fpfizer%2Fclinical-considerations.html

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. Can we eliminate COVID restrictions for those vaccinated (masks, social distancing, ROM, leave, etc.)? Why not?

A. We do not yet know enough about the vaccines to make determinations about changing prevention measures. This is part of the reason we are asking people to get vaccinated as soon as possible, so that we can start making safe and evidence based assessments of these precautions in a post-vaccination environment. The current evidence used by the FDA in granting the EUA showed significant benefits to getting the vaccine. However, the available evidence did not completely describe those benefits or limitations and subsequently more evidence is needed before removing preventive precautions. If preventive precautions are removed prematurely, it introduces significant unknown risk to the individual, unit, and mission. Furthermore, preserving these precautions in the setting of vaccination immunity, will provide useful information to inform future decision making.

Q. When can we eliminate COVID restrictions? Can Senior leaders assist? 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 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 are making informed opinions and given the perspective that they are helping themselves and likely protecting others. Also, likely this will be a requirement sometime in the future, and getting a vaccine now would prevent any wait in the future, when incentives and penalties can be used.

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 is 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 herd immunity? When will we know?

A. We anticipate there will eventually be herd immunity but until we have more information we cannot draw conclusions. Furthermore it is unknown how long herd 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 herd 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. Is the Navy looking at using the half-doses of the Moderna vaccine that was talked about in the news?

A. No, the FDA rejected this proposal and included the following: "suggesting changes to the FDA-authorized dosing or schedules of these vaccines is premature and not rooted solidly in the available evidence."

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 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.

Questions about Vaccine Distribution

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. Full-scale, unrestricted vaccine availability to Naval personnel, similar to the annual influenza vaccine program, will be accomplished before or by mid-2021.

Q. What are the initial sites?

A. Initial distribution sites were selected by the DoD's COVID Task Force from sites recommended by the military services and U.S. Coast Guard. Navy and Marine Corps sites include:

- Navy Branch Health Clinic, Naval Air Station, Jacksonville, FL
- Naval Medical Center, San Diego, CA
- Naval Hospital, Camp Pendleton, CA (distribution from San Diego)
- Naval Hospital Pensacola, Pensacola, FL
- Walter Reed National Military Medical Center, Bethesda, MD
- Portsmouth Naval Medical Center, Portsmouth, VA
- Tripler Army Medical Center, Honolulu, HI

The number of sites has expanded from this initial list with the addition of the Moderna vaccine.

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

A. DoD initially expects limited quantity and a phased delivery of COVID-19 vaccine following FDA Emergency Use Authorization. Initial DoD distribution sites were selected by the DoD's COVID Task Force from sites recommended by the military services and U.S. Coast Guard to best support several criteria: anticipated supply chain requirements for initially approved vaccines (i.e. ultra-cold, bulk storage facility); sizeable local population to facilitate rapid vaccine administration to priority personnel across the military services; and sufficient necessary medical personnel to administer vaccines and actively monitor vaccine recipients after initial and second-dose administration. Initial vaccine doses will become available at select locations in late 2020 and early 2021, and at additional sites in spring 2021.

Q. Why is the vaccine not available here?

A. The distribution process is phase-driven to protect the DoD from COVID-19 as quickly as possible. In the initial phases, a limited number of sites were selected to receive vaccine. Initial sites also allow DoD to validate distribution and administration processes and structures and guide senior leader decisions to increase distribution and administration as vaccine manufacturing and CDC allocation permits. Initial site performance will guide follow-on site identification and the scaling of DoD distribution and administration processes.

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. In the initial phase, a limited number of sites were selected to receive vaccine. Initial sites also allow DoD to validate distribution and administration processes and structures and guide senior leader decisions to increase distribution as vaccine manufacturing and CDC allocation permits. Initial site performance will guide follow-on site identification and the scaling of DoD distribution and administration processes.

Q. Who will be the first to get the vaccine?

A. Vaccination distribution prioritization will focus on those providing direct medical care, maintaining essential national security and installation functions, deploying forces, and those at the highest risk for developing severe illness from COVID-19, before other members of the DoD population.

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 "Phase 1b Other Essential Workers." As vaccine becomes available, NAVMEDLOGCOM will follow the direction of the release authority and direct vaccines as instructed.

Q. How will the Navy 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 routinely imports 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 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. When will ships at sea get the vaccine?

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⁶ From CHINFO Briefing Card "COVID-19 Vaccine NAVADMIN" 22 Dec 2020.

A. Initially there are limited amounts of vaccine available and what is available will be sent to those at highest risk of infection or at highest risk of severe clinical courses. Ships, as a critical national asset, have a high priority but may not receive vaccine until the early 2021. Vaccines are expected to be distributed at military treatment facilities.

Q. What is DoD's supporting role in Operation Warp Speed?

A. DoD's is in support of the Department of Health and Human Services and is harnessing vast DoD logistical expertise to provide the vision and intent for the distribution strategy, while working hand in hand with the CDC to leverage their planning efforts. To that end, Gen. Gustave F. Perna is the OWS chief operating officer responsible for coordination of planning, logistics, security and assurance, supply chain development, and manufacturing in support of OWS. Our unique capabilities will enable faster distribution and administration across the United States than would have otherwise been possible.

Q. Where can I learn more about Operation Warp Speed?

A. The DOD page for Operation Warp Speed is here: https://www.defense.gov/Explore/Spotlight/Coronavirus/Operation-Warp-Speed/
The Department of Health and Human Services page is here: https://www.hhs.gov/coronavirus/explaining-operation-warp-speed/index.html

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 are we doing on vaccination rates, compared to both other services and our internal expectations? If there are differences, any sense as to the why?

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 that both moderna and Pfizer provide an average of 95% efficacy in preventing symptomatic infections and moderna has evidence of reducing severity of infections. The full benefits arent 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 herd 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. What is the vaccination strategy for Navy Senior Leaders and their staffs. Do we know how other services are doing this? Are we all in-step.

A. All Services are following the SECDEF approved prioritization schema.

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.

We may be looking at this becoming an annual event, the evidence suggests that SARS-CoV-2 is similar to influenza. In the future or at some interval, the virus may also mutate to the point where the vaccine needs modification. Current mutations of SARS-CoV-2 do not appear to impact vaccine efficacy. Both Pfizer and Moderna are conducting studies to verify this.

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. We will share the NMCPHC's models in the next 2-3 weeks, once they have completed their work.

Questions about MY Vaccine

Q. Are individuals required to get the vaccine?

A. Under the current Pfizer-BioNTech and Moderna 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 Pfizer-BioNTech vaccine 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.⁷

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. TRICARE beneficiaries who receive care at DoD MTFs on a space-available basis can alternately receive vaccine through the local civilian jurisdiction.

Q. How will the Navy track personnel who receive a COVID vaccine?

A. The Navy 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?

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⁷ From CHINFO Briefing Card "COVID-19 Vaccine NAVADMIN" 22 Dec 2020.

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. Yes. Both vaccines work to protect individuals from disease symptoms, but it is unknown at this time whether vaccinated people will still be able to 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. Additionally, we will not have enough vaccine initially to vaccinate everyone who wants the vaccine and COVID-19 pandemic risks will continue. We will continue to recommend wearing masks and practicing physical distancing, for everyone, until pandemic risk of COVID-19 is substantially reduced.

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

A: The data from a New England Journal of Medicine paper on the development of SARS-CoV-2 antibodies following administration of the Pfizer vaccine (https://www.nejm.org/doi/full/10.1056/NEJMoa2034577) indicates a linear increase in neutralization of SARS-CoV-2 over time with a peak at 43 days after the first shot if one completed the vaccination series and received the second shot. Increasing immunity should correlate with reduced risk of developing COVID-19, but as the vaccine is 95% effective, approximately 5% of those who receive both doses of the vaccine may still get COVID-19. The data also suggests a similar pattern for the Moderna vaccine (https://www.nejm.org/doi/full/10.1056/NEJMc2032195).

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. Initial reports were that the influenza vaccine and COVID vaccine could be given at the same time. However, a recent report from the CDC directed individuals to have a 14-day buffer around the COVID vaccine during which no other vaccines can be given. This is subject to change.

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. You need to continue all protective measures until specific guidance is provided from DoD and DoN leadership. The vaccine is still under investigation to determine how much protection it provides. Relaxing protective measures may put you, your family, coworkers, and friends at risk of infection.

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. There are many vaccines currently in development, the leading vaccines are intramuscular injections, similar to the flu vaccine. The currently available COVID vaccines are authorized under an EUA are a two-dose series separated by 21 or 28 days depending on the product. Vaccines from different manufacturers will NOT be interchangeable. The vaccine must receive the same vaccine for the entire dose series (e.g., 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 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. For entities that are currently Tier 1 and required to be tested for COVID...why are these same entities not also Tier 1 for the vaccine?

A. The vaccine schema was developed by the CDC's Advisory Committee of Immunizations Practices based on risk of exposure (medical personnel), impact (critical infrastructure) and at risk. This is the same criteria States used and is required by the MOA between the CDC and DoD.

Q. If I am not medical personnel, should I be wearing an N95 mask?

A. N95 are best suited for healthcare staff because they are at high risk due to patient care that includes exposure to potential viruses. Face coverings, minimum of two layers (over ear or neck gaiter), are sufficient to protect yourself from COVID while practicing social distancing of 6' or greater. N95 masks are required to be fitted by professionals for optimum use and protect. Buying an off the shelf N95 mask and wearing it without professional fitting only provides a marginal increase in protection and is not required to provide safety compared to a two-layer face covering in a non-hospital setting.

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 nor Moderna 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: Neither the recently authorized and recommended vaccines nor the other COVID-19 vaccines currently in clinical trials in the United States 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, which is 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.⁸

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 Pfizer and Moderna vaccines have evidence of very high efficacy. The recommendation to continue prevention measures for the near future is not likely to change based on the availability of new 'better' vaccines. Instead, it 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 changes to preventive measures.

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

⁸ https://www.cdc.gov/coronavirus/2019-ncov/vaccines/vaccine-benefits/facts.html

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.

Questions about who can get the Vaccine

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. Will the Navy or Marine Corps distribute the vaccine to the American public too?

A. Operation Warp Speed is facilitating vaccine distribution to the American public. HHS and CDC lead planning and implementation, with DoD augmenting the deliberate, comprehensive micro-planning efforts down to the state/territory (jurisdiction) level. At this time, we do not anticipate a large commitment of Navy or Marine Corps units or personnel to support the nationwide distribution of vaccines to the US civilian population.

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 the Pfizer-BioNTech 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. 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. See below for excess instructions.

Q: Can remainder doses of 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. Tab C of the WARNORD (Memo): Is there a deadline for COs to complete this? When complete, where do they need to send it?

A. We are working up a DoN Tracker to collect this for Navy reporting. In the interim please submit to dha.ncr.dha-ops.mbx.cov-19-vaccine-distro-opt@mail.mil and copy Mr. Oliveria, Dr. Tela, LCDR Hall and me. The OPT email and those copied will assure DHA receives the documents.

Q. Are there outcome-based planning measures/milestones to allow transition from Operational Phase 2a to 2b?

A. The draft base plan (with OSD OGC for review) includes the criteria. Ultimately it will up to LTG Place who was granted authority to oversee vaccine distribution in the

EXORD from the DEPSECDEF. The intent is to demonstrate safe administration and efficient distribution/reporting.

Transition Criteria

Benchmark	Criteria
	Loss of Vaccine (incidents)
Less is better	0
	1
	3
	Distribution Beyond Initial Receiving Site (# events w/out loss)
More is better	3
	1
	0
	2nd Order Submitted to USAMMA-DOC/DLA within 7-14 days prior to next dose
YES/NO	YES
	N/A
	NO
	Reporting in Accordance with Defined Requirements (submission to CDC every 24hrs)
Higher % is better	90-100%
	80-89%
	<79% 16

Q. Locations OCONUS that are receiving initial distributions, are they getting Pfizer or Moderna?

A. All foreign OCONUS are receiving Moderna vaccine. Some US OCONUS (Hawaii, Alaska, Puerto Rico) will receive Pfizer.

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. If the Moderna vaccine is leftover after vaccinating Phase 1, can the initial allocation be redistributed to another clinic?

A. During Op Phase 2a redistribution must be approved by LTG Place as an exception to policy. After Op Phase 2a this can be done after notifying USAMMA DOC for accountability. The DoD plan allows the use of vaccine on lower priority personnel to avoid loss after a vial is 'opened' and vaccine can be stored up to 6 months if there is a larger amount of vaccine and wide scale vaccination of Phase 1b personnel has not be authorized.

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. Will the number of doses received cover all of Tier 1a personnel in all three sub-tiers?

A. Not all sites will have 100% tier 1a personnel covered in the first shipment. This data is being tracked closely by the NMLC, BUMED, and the OPT.

Q. The WARNORD says "begin within 24 hours of receipt of vaccine." While MTFS will start within 24 hours, they do not need to finish correct?

A. The current understanding is that all of it does not need to be given within 24 hours of receipt, only that vaccinations must start within that period and vaccinations should progress as expeditiously as possible.

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

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: https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/downloads/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 vaccine candidates such as the Moderna vaccine are expected to be available for ships and 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.

Additional Information

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

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

CDC - https://www.cdc.gov/coronavirus/2019-ncov/index.html

DHA – www.health.mil/COVIDVaccine

FDA COVID Vaccines – https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines

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