



DEFENSE HEALTH AGENCY
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DHA-IPM 20.004
June 16, 2022

MEMORANDUM FOR DISTRIBUTION

SUBJECT: Defense Health Agency Implementation of Department of Defense (DoD)
Coronavirus Disease 2019 (COVID-19) Vaccination Program Implementation

References: See Attachment 1.

Purpose. This Defense Health Agency-Interim Procedures Memorandum (DHA-IPM), based on the authority of the References (a) through (c), and in accordance with the guidance of References (d) through (ad), establishes the Defense Health Agency's (DHA) procedures to implement instructions, assign responsibilities, and prescribe procedures for the DHA's implementation of the DoD's COVID-19 Vaccination Program.

Applicability. This DHA-IPM applies to DHA, DHA Activities (under the authority, direction, and control of the DHA), Military Departments, and the United States Coast Guard (USCG).

Cancellation. This DHA-IPM cancels and replaces DHA-IPM 20-004, "Department of Defense (DoD) Coronavirus Disease 2019 (COVID-19) Vaccination Program Implementation," May 6, 2021.

Releasability. **This DHA-IPM is cleared for public release** and is available on the Internet from the Health.mil site at: <https://health.mil/Reference-Center/Policies> and is also available to authorized users through the DHA SharePoint site at: <https://info.health.mil/cos/admin/pubs/SitePages/Home.aspx>.

Proponent and Waivers. The proponent of this publication is the Director, DHA Public Health. When Activities are unable to comply with this publication the activity may request a waiver that must include a justification, to include an analysis of the risk associated with not granting the waiver. The activity director or senior leader will submit the waiver request through their supervisory chain to the Director, DHA Public Health to determine if the waiver may be granted by the Director, DHA or their designee.

Forms. The following forms are available as indicated:

(a) U.S. Food and Drug Administration (FDA) Vaccine Adverse Events Reporting System (VAERS) Form 2.0, is available at: <https://vaers.hhs.gov/index.html>.

(b) DHA Form 177, Potentially Compromised Temperature Sensitive Medical Product Worksheet is available at:
https://info.health.mil/cos/admin/DHA_Forms_Management/Lists/DHA%20Forms%20Management/AllItems.aspx

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(c) DHA Form 207, COVID-19 Screening and Immunization Documentation is available at: <https://www.health.mil/Reference-Center/Forms/2021/03/25/DHA-Form-207-COVID-19-Vaccine-Screening-and-Immunization-Document>

(d) DHA Form 236, Pediatric (5-11 years) COVID-19 Vaccine Screening and Immunization Documentation is available at: <https://health.mil/Reference-Center/Forms/2022/01/07/DHA-Form-236-Pediatric-5-11-years-COVID19-Vaccine-Screening-and-Immunization-Documentation>

Effective Date. This DHA-IPM is effective upon signature. It will expire 1 year from the date of signature if it has not been reissued or cancelled before this date in accordance with Reference (c).

/S/
RONALD J. PLACE
LTG, MC, USA
Director

Attachments:

1. References
2. Procedures
3. COVID-19 Vaccine Adverse Events Reporting
4. DoD Reportable Event Timeline
5. Referenced Links
6. Glossary

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Surgeon General of the National Guard Bureau

ATTACHMENT 1

REFERENCES

- (a) DoD Directive 5136.01, “Assistant Secretary of Defense for Health Affairs (ASD(HA)),” September 30, 2013, as amended
- (b) DoD Directive 5136.13, “Defense Health Agency (DHA),” September 30, 2013, as amended
- (c) DHA-Procedural Instruction 5025.01, “Publication System,” August 24, 2018
- (d) United States Code, Title 10, Section 1073c, "Administration of Defense Health Agency and Military Treatment Facilities"
- (e) DoD Instruction 6205.02, “DoD Immunization Program,” July 23, 2019
- (f) DoD Instruction 6200.02, “Application of Food and Drug Administration (FDA) Rules to Department of Defense Force Health Protection Programs,” February 27, 2008
- (g) United States Code, Title 10, Section 1107a
- (h) U.S. Food and Drug Administration (FDA) Guidance, “Emergency Use Authorization of Medical Products and Related Authorities,” January 2017
- (i) Deputy Secretary of Defense Memorandum, “Coronavirus Disease 2019 Vaccine Guidance,” December 7, 2020
- (j) Under Secretary of Defense for Personnel and Readiness Memorandum, “Supplemental Guidance for Providing Coronavirus Disease 2019 Vaccines to DoD Contractor Employees and Select Foreign Nationals,” December 31, 2020
- (k) Defense Health Agency Memorandum, “Access to COVID-19 Vaccine for Members of the Selected Reserve (SELRES),” March 2, 2021
- (l) Secretary of Defense Memorandum, “Mandatory Coronavirus Disease 2019 Vaccination of Department of Defense Service Members,” August 24, 2021
- (m) Deputy Secretary of Defense Memorandum, “Available Authorities to Administer Coronavirus Disease 2019 Vaccines to Non-Department of Defense-Affiliated Personnel,” July 14, 2021¹
- (n) Under Secretary of Defense Memorandum, “Force Health Protection Guidance (Supplement 23) Revision 3- Department of Defense Guidance for Coronavirus Disease 2019 Vaccination Attestation, Screening Testing, and Vaccination Verification,” December 20, 2021, as amended
- (o) Assistant Secretary of Defense for Health Affairs Memorandum, “Mandatory Vaccination of Service Members using the Pfizer-BioNTech COVID-19 and Comirnaty COVID-19 Vaccines,” September 14, 2021²
- (p) United States Centers for Disease Control and Prevention Morbidity Mortality Weekly Report, “Use of Pfizer-BioNTech COVID-19 Vaccine in Persons Aged ≥ 16 Years:

¹ This reference can be found with CAC access at this link: <https://www.milsuite.mil/book/docs/DOC-1039885>

² This reference can be found with CAC access at this link: <https://go.usa.gov/xtYuZ>

Recommendations of the Advisory Committee on Immunization Practices — United States,” September 24, 2021

- (q) Congressional Research Service, “FDA Approval of the Pfizer-BioNTech COVID-19 Vaccine: Frequently Asked Questions,” September 29, 2021³
- (r) DHA-Procedural Instruction 6205.01, “Medical Logistics Guidance for the DoD Coronavirus Disease 2019 (COVID-19) Vaccination Program,” May 10, 2021
- (s) USD(P&R) Memorandum, “Coronavirus Disease 2019 Vaccination for Pregnant and Breastfeeding Service Members,” October 5, 2021⁴
- (t) Center for Disease Control and Prevention Guidance, “COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations,” October 29, 2020⁵
- (u) ASD(HA) Memorandum, “Updated Guidance on Co-Administration of Coronavirus Disease 2019 Vaccine with Other Vaccines,” October 7, 2021⁶
- (v) DHA-Procedural Instruction 3700.01, “Directors Critical Information Requirements (DCIR), Situation Report (SITREP),” October 4, 2019
- (w) DHA-Procedures Manual 6025.13, “Clinical Quality Management in the Military Health System, Volume 2: Patient Safety,” August 29, 2019
- (x) Army Regulation 40-562, Bureau of Medicine and Surgery Instruction 6230.15B, Air Force Instruction 48-110_IP, Coast Guard Commandants Instruction M6230.4G, “Immunizations and Chemoprophylaxis for the Prevention of Infectious Diseases,” October 7, 2013
- (y) DHA-Procedural Instruction 6025.17, “Healthcare Resolutions, Disclosure, Clinical Conflict Management and Healthcare Provider (HCP) Resiliency and Support in the Military Health System (MHS),” June 18, 2019
- (z) DoD Instruction 5400.11, “DoD Privacy and Civil Liberties Programs,” January 29, 2019, as amended
- (aa) DoD Manual 6025.18, “Implementation of the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule in DoD Health Care Programs,” March 13, 2019
- (ab) DoD Instruction 8580.02, “Security of Individually Identifiable Health Information in DoD Health Care Programs,” August 12, 2015
- (ac) DoD Instruction 6040.45, “DoD Health Record Life Cycle Management,” November 16, 2015, as amended
- (ad) DHA-Procedural Instruction 6010.01, “Health Benefit Eligibility Verification and Patient Registration Procedures,” January 14, 2020, as amended

³ This reference can be found at this link: <https://crsreports.congress.gov/product/pdf/R/R46913>

⁴ This reference can be found at: <https://go.usa.gov/xzXbs>

⁵ This reference can be found at: https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf

⁶ This reference can be found at: <https://go.usa.gov/xzXbP>

ATTACHMENT 2PROCEDURES1. COVID-19 VACCINE INFORMATION

a. Implementation of an FDA-approved, fully licensed, Biologics License Application (BLA) or Emergency Use Authorization (EUA) COVID-19 vaccine is a critical component of the United States' strategy and international efforts to reduce COVID-19-related illnesses, hospitalizations, and deaths.

b. DoD beneficiaries and other individuals eligible to receive vaccines from DoD will be offered COVID-19 immunization in accordance with recommendations from the U.S. Centers for Disease Control and Prevention (CDC), its Advisory Committee on Immunization Practices (ACIP), FDA, and DoD guidance.

(1) Deviation from FDA guidance or CDC recommendations will be published in policy.

(2) In accordance with current CDC recommendations, persons are considered fully vaccinated two weeks after completing the second dose of a two-dose COVID-19 vaccine or two weeks after receiving a single dose of a one-dose vaccine.

(3) Those with a medical history and/or serologic evidence of COVID-19 infection without also having received a complete primary series of COVID-19 vaccine are not considered fully vaccinated.

c. Personnel will comply with the terms of the FDA Fact Sheets and other regulatory requirements for licensed or EUA vaccines. All individuals seeking immunization will be provided the appropriate FDA Fact Sheet for vaccine recipients or Vaccine Information Statements (VIS), as applicable.

d. Use of vaccine products for force health protection under EUA will be executed in accordance with References (f) through (h). For EUA vaccines, per FDA guidance in Reference (h), vaccine recipients must be made aware of all of the following:

(1) FDA has authorized emergency use of the product.

(2) The significant known and potential benefits and risks associated with the emergency use of the product, and of the extent to which such benefits and risks are unknown.

(3) They have the option to accept or refuse the EUA product and are free from any consequences of refusing administration of the product.

(4) Any available alternatives to the product and of the risks and benefits of available alternatives, and of any other information or condition required by the EUA.

2. AUTHORIZATION FOR THE USE OF COVID-19 VACCINE. In accordance with References (i) through (m), a vaccine may be offered to, and administered at approved DoD vaccination sites for Uniformed Service members, both active and Selected Reserve personnel, including members of the National Guard and Officers of the United States Public Health Service Commissioned Corps, National Oceanic and Atmospheric Administration, DoD dependents, retirees, civilian employees, select DoD contractor personnel, and select foreign nationals. Additional individuals may be eligible for COVID-19 vaccine through the Secretarial Designee Program.

3. COVID-19 VACCINATION REQUIREMENTS

a. In accordance with Reference (l) and (n) all members of the Armed Forces under DoD authority on Active Duty or in the Ready Reserve, including National Guard are required to be fully vaccinated against COVID-19. Definition of fully vaccinated is as defined in section 1.b.(2) of this attachment.

(1) In accordance with Reference (l), mandatory vaccination against COVID-19 will only use COVID-19 vaccines that receive full licensure from the FDA in accordance with FDA-approved labeling and guidance. In accordance with Reference (o) through (q), and FDA guidance, phosphate buffered saline (PBS)-buffer Pfizer-BioNTech/COMIRNATY[®] has the same formulation and can be used interchangeably with the EUA PBS-buffer Pfizer-BioNTech COVID-19 vaccine without presenting any safety or effectiveness concerns. In accordance with Reference (o) providers will use the PBS-buffer Pfizer-BioNTech COVID-19 vaccine and the PBS-buffer Pfizer-BioNTech/COMIRNATY[®] COVID-19 vaccine interchangeably for the purpose of vaccinating Service members to meet DoD COVID-19 vaccination requirements. As additional vaccines receive FDA full licensure, locations must wait for DHA or Service notification before the vaccine may be used to meet the DoD COVID-19 vaccine vaccination requirement.

b. In accordance with CDC recommendations, personnel voluntarily immunized with a COVID-19 vaccine under FDA EUA or World Health Organization (WHO) Emergency Use Listing (EUL) in accordance with applicable dose requirements for the primary series are considered fully vaccinated.

c. Personnel, as noted in paragraph 3.a., who received the COVID-19 vaccine from a source outside of DoD, will provide official documentation of vaccine receipt for validation and documentation into a DoD electronic medical or readiness system.

(1) Acceptable proof of vaccination status is:

(a) the record of immunization from a health care provider or pharmacy,

(b) a copy of the U.S. CDC COVID-19 Vaccination Record Card (CDC Form MLS-319813_r), published on September 3, 2020,

- (c) a copy of medical records documenting the vaccination,
- (d) a copy of immunization records from a public health, state, or tribal immunization information system,
- (e) or a copy of any other official documentation that contains the type of vaccine administered, date(s) of administration, and the name of the health care professional(s) or clinic site(s) administering the vaccine(s).

(2) Personnel participating in COVID-19 vaccine clinical trials will provide a copy of their signed informed consent document or CDC COVID-19 vaccine card for validation and documentation into a DoD electronic health record or readiness system.

4. VACCINE DISTRIBUTION AND STORAGE AND HANDLING

a. All vaccination sites will comply with vaccine ordering, distribution, redistribution, and cold chain management procedures in accordance with Reference (r). All redistribution must be coordinated with United States Army Medical Materiel Agency-Distribution Operations Center (USAMMA-DOC) prior to the movement of any vaccine.

b. Each location receiving vaccines will have a named vaccine coordinator and a back-up coordinator who is the designated point of contact for receiving vaccine shipments, monitoring storage unit temperatures, and managing and reporting daily vaccine inventory. Any changes in vaccine coordinator must be communicated to USAMMA-DOC and the Defense Logistics Agency (DLA) through the appropriate Service Logisticians.

c. DoD vaccination sites will submit a Commander's Confirmation of Prepared to Receive COVID-19 Vaccines Memorandum and Checklist at: <https://surveys.max.gov/367286?lang=en> for review prior to vaccine shipment. Updates to vaccination site capabilities require resubmission of the checklist.

d. Vaccine coordinators, logistic, and immunization personnel will register to receive vaccine logistic and quality control updates from the Medical Materiel Quality Control (MMQC) messages at: <https://www.amlc.army.mil/USAMMA/Logistics/MMQCMIMsgMgmt/>.

e. All vaccine sites will establish and maintain standard operating procedures on the proper storage and handling of COVID-19 vaccines in accordance with Reference (r). Personnel must be present to receive and store vaccines upon arrival.

(1) Personnel who will be handling the thermal shipping containers and dry ice must be trained on the proper handling and disposal of dry ice. Due to hazards in handling of this product, appropriate competency for personnel should be annotated. An ultralow temperature vaccine handling competency document is available on the Defense Health Agency-Immunization Healthcare Division (DHA-IHD) website www.health.mil/vaccines.

(2) All personnel handling dry ice must ensure they have appropriate thermal protection equipment to safely handle the products.

f. Always transport and store COVID-19 vaccines within the temperature parameters specified for each product. If the vaccines are not stored within the correct temperature parameters, they may lose potency. It is anticipated storage and handling procedures for individual products may change over time. Current information may be found at: <https://www.cdc.gov/vaccines/hcp/admin/storage-handling.html>.

g. If at any time a temperature compromise is suspected after the vaccine has been delivered to the facility, locations will follow procedures in accordance with Reference (r). Immediately notify your DHA-IHD Immunization Healthcare Specialist (IHS) and prepare a DHA Form 177, Potentially Compromised Temperature Sensitive Medical Product Worksheet. Submit the completed worksheet to your IHS and the e-mail noted in the worksheet. To find your location's IHS go to: www.health.mil/ContactYourIHS.

h. Vaccines that have expired or are deemed temperature compromised by Defense Logistics Agency-Troop Support Medical or USAMMA-DOC will be disposed in accordance with Reference (r).

i. Vaccine sites will comply with all vaccine storage and handling procedures noted in the Fact Sheet for Healthcare Providers found at: <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines>.

(1) When approved by the FDA, or published in manufacturer guidance, additional doses may be obtained in properly prepared COVID-19 vaccine vials and may be administered; however, any remaining product that does not constitute a full dose will not be pooled from multiple vials to create a single dose.

(2) Vaccination sites will follow the licensed vaccine package inserts or the fact sheets for the specified vaccine beyond use dates of the product after reconstitution and vial puncture. To help vaccination providers determine vaccine expiration dates, register for access to the CDC COVID-19 Vaccine Lot Number and Expiration date files at: <https://vaccinecodeset.cdc.gov/LotNumber>. Files are updated on a daily basis Monday through Friday as new lots are released by each manufacturer, or as updates are made to the lot expiration dates. As manufacturers confirm their product stability data, some expiration dates may be updated.

(a) The expiration date must be checked prior to preparing or administering vaccine. Expired vaccine or diluent should **never** be used.

(b) The Pfizer-BioNTech product expiration dates on the vial may not be accurate due to FDA-approved shelf life extensions. Current expiry guidance may be found on the FDA Fact Sheet for Healthcare Providers at: <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/comirnaty-and-pfizer-biontech-covid-19-vaccine>

(c) The Moderna product expiration date may be found by entering the lot number at: <https://www.modernatx.com/covid19vaccine-eua/providers/vial-lookup> or by scanning the Quick Response (QR) code located on the vial or carton.

(d) The Janssen product expiration date may be found by scanning the QR code on the outer carton or entering the lot number at: <https://vaxcheck.jnj>.

j. Vaccine vials suspected to be contaminated (e.g., discoloration) or that have other product deficiencies must be quarantined from the active supply and maintained at appropriate temperature, labeled “Do Not Use”, and reported to DoD. Submit a Director’s Critical Information Report (DCIR), a Product Quality Deficiency Report (PQDR), and contact the vaccine manufacturer. The PQDR is accessed at: <https://www.medical.dla.mil/Portal/Customer/ProductQualityDeficiency.aspx>.

k. Ancillary supplies will be shipped separately from the vaccine, in amounts to match the vaccine order. Supplies include: diluent (when required); needles and syringes for both administration and reconstitution; alcohol preparation pads; vaccination record cards; and limited surgical masks and face shields. Locations should plan to purchase additional supplies to include sharps containers, gloves, bandages, and other personal protective equipment as needed. If a Military Medical Treatment Facility (MTF) is redistributing the vaccine to outlying locations, the MTF must also send the appropriate number of ancillary supplies to the receiving location. Discrepancies or concerns with the ancillary kits must be directed to USAMMA DOC at: usarmy.detrick.usamma.mbx.vaccines@mail.mil for Continental United States sites and U.S. territories. Outside Continental United States and Fleet customers should contact DLA at dla.trpsptccc@dla.mil directly. Complete a PQDR for non-vaccines discrepancies and route to normal processing channels prior to or after contacting the appropriate point of contact.

5. VACCINATION SITE PERSONNEL REQUIREMENTS

a. Only appropriately trained and qualified medical personnel in accordance with Military Department policies will administer the COVID-19 vaccine to adults (those 18 years of age or older) and/or pediatric patients (those less than 18 years of age).

(1) COVID-19 vaccinators are limited to: Doctors of Medicine (MD)/Doctors of Osteopathic Medicine (DO), Registered Nurses (RN), Nurse Practitioners (NP), Physician Assistants (PA), Licensed Practical Nurses (LPN)/Licensed Vocational Nurses, Pharmacists (PharmD), Dentists (DDS), Veterinarians (DMV), and all other licensed medical professionals and enlisted personnel in a medical field that involves patient care, including but not limited to Army Medics, Air Force Medical Technicians, Navy Corpsmen, Coast Guard Corpsmen, and Pharmacy, Veterinary, and Dental Technicians.

(2) COVID-19 vaccination staff will complete, at a minimum, the training requirements as noted in Appendix 1. Additional adult and/or pediatric training materials from the manufacturer, CDC, or DoD, as applicable, will be made available as each vaccine product is authorized or licensed by the FDA.

(3) Personnel will demonstrate the tasks required to perform their appropriate role within the vaccination program and will have their competencies verified and documented on a COVID-19 vaccination competency document. Sample competency documents are available at https://health.mil/COVID19vaccineresources_HCP#Competency.

(4) Vaccination sites will locally track and maintain training and competency certification documents for all employees participating in the management or administration of the vaccine.

6. VACCINE SCREENING AND PATIENT EDUCATION

a. At a minimum, screen all potential vaccine recipients prior to vaccination with the age-appropriate standardized screening questions noted in DHA Form 207, COVID-19 Screening and Immunization Documentation, for vaccine recipients 12 years and older, or DHA Form 236, Pediatric (5-11 years) COVID-19 Vaccine Screening and Immunization Documentation, for vaccine recipients less than 12 years. Screening questions are subject to change at any time.

(1) Indications for, and contraindications and/or precautions to COVID-19 vaccines will be updated by the FDA and CDC as additional data becomes available. The most current FDA Fact Sheets and/or CDC's recommendations will be found at: <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines> and <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html>.

(a) As of 22 February 2022, the CDC considers a history of the following to be a contraindication to vaccination with COVID-19 vaccines: severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine; known (diagnosed) allergy to a component of the COVID-19 vaccine; and for the Janssen COVID-19 vaccine, Thrombosis with Thrombocytopenia Syndrome (TTS) following receipt of a previous Janssen COVID-19 vaccine (or other COVID-19 vaccines not currently authorized in the United States that are based on adenovirus vectors).

(b) COVID-19 vaccine components may be found in the appropriate Package Insert, Fact Sheet, or at CDC's Interim Clinical Considerations Appendix C, found at: <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html>.

(c) At minimum, individuals who report severe allergic reactions to a previous dose of COVID-19 vaccine or have a history of allergy to a component of the vaccine should be referred to an allergist/immunologist for further evaluation. Vaccine recipients or clinical personnel may also contact the 24 hour a day, 7 day a week (24/7) DHA-IHD Immunization Healthcare Support Center at: 1-877-GET-VACC (1-877-438-8222) option 1, or Defense Switch Network (DSN) 761-4245, option 1.

b. Pregnant people with COVID-19 are at increased risk for severe illness when compared with non-pregnant people. COVID-19 vaccination is recommended for those who are pregnant, lactating, trying to get pregnant now, or might become pregnant in the future. In accordance

with Reference (s) and Service specific guidance, pregnant Service members are highly encouraged to receive the vaccine or may request a temporary medical exemption.

(1) Individuals who receive an EUA vaccine in the periconception period or during pregnancy are encouraged to participate in the voluntary V-SAFE COVID-19 Vaccine Pregnancy Registry: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafepregnancyregistry.html>.

(2) Pregnant people who receive the Pfizer BioNTech or COMIRNATY[®] product should be advised there is a Pfizer pregnancy exposure registry that monitors pregnancy outcomes in people who received the vaccine during pregnancy, and they are encouraged to also enroll in the Pfizer pregnancy registry by visiting: <https://mothertobaby.org/ongoing-study/covid19-vaccines/>.

c. In accordance with Reference (t), individuals receiving COVID-19 vaccines will be provided a product-specific FDA Fact Sheet for vaccine recipients prior to vaccination. Per FDA guidance, vaccine recipients of EUA vaccines must be made aware of each item noted in paragraph 1.d.(1) through 1.d.(4) of this attachment. Fact Sheets are available at: <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines>.

(1) Per Reference (h), the fact sheet may be provided to recipients in a variety of ways to include hard copy, poster format, online, video, or other electronic means of dissemination.

(2) Locations will ensure immunizers have read the fact sheets, understand them, and are clear on the requirement to provide the fact sheet or VIS, once available, to each vaccine recipient prior to administering the vaccine. Vaccine recipients will be provided an opportunity to ask questions prior to vaccine administration.

7. VACCINE ADMINISTRATION

a. COVID-19 vaccines will be administered in accordance with CDC recommendations and the FDA product-specific package inserts or Fact Sheets.

b. Prior to immunization, verify the person's previous COVID-19 vaccination history by reviewing the CDC vaccination record card and electronic medical records to include the Joint Legacy Viewer and the Service Readiness Systems. If a person provides documentation of previous vaccination that is not visible in the immunization record, validate and transcribe all available elements (date of vaccination, product name, manufacturer, dose, lot number) into the immunization module of the electronic health record (EHR) before proceeding with vaccine administration.

c. Standing orders for FDA BLA and/or EUA COVID-19 vaccine products and are required at every immunization site. Standing Orders for each COVID-19 vaccine may be found at: <https://www.health.mil/standingorders>. Military Health System (MHS) clinicians may use

standing orders, competency documents, and other DHA products to guide administration of COVID-19 vaccines. DHA products are in compliance with all federal regulations and represent best practices for immunization in the MHS.

d. COVID-19 vaccine clinical updates will no longer be released solely through MMQCs. Updates may be communicated to activities through DHA and/or Service published guidance. Ahead of this communication, and to expedite implementation of CDC's recommendations, vaccination sites and administrators may execute updates posted on CDC's Interim Clinical Considerations for Use of COVID-19 Vaccines website at: <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html>, or on the Health.mil Chief Medical Officer website at: <https://info.health.mil/sites/DADMA/Pages/Home.aspx>.

e. In accordance with CDC recommendations, viral testing to assess for acute Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) infection or serologic testing to assess for prior infection is not recommended for the purposes of COVID-19 vaccine decision-making. Individuals should be offered vaccination regardless of their history of symptomatic or asymptomatic SARS-CoV-2 infection; these individuals include people with prolonged post-COVID-19 symptoms.

(1) In accordance with References (l) and (n) those with a medical history and/or serologic evidence of COVID-19 infection without also having received a complete primary series of COVID-19 vaccine are not considered fully vaccinated.

(2) Vaccination of people with known current SARS-CoV-2 infection should be deferred until the person has recovered from the acute illness (if the person had symptoms) and they have met criteria to discontinue isolation. This recommendation applies to people who experience SARS-CoV-2 infection before receiving any vaccine dose and those who experience SARS-CoV-2 infection after the first dose of a Messenger Ribonucleic Acid (mRNA) vaccine but before receipt of the second dose.

f. In accordance with CDC recommendations and Reference (u), COVID-19 vaccines may be administered without regard to timing of other vaccines. This includes simultaneous administration of COVID-19 vaccine and other vaccines on the same day, as well as co-administration within 14 days. The only exception to this rule is the co-administration with the live smallpox vaccine that should be separated by at least 28 days from the mRNA vaccines.

g. Several of the COVID-19 vaccines have a multi-dose primary series. Immunizers must ensure adherence to FDA guidance and CDC recommendations for each COVID-19 vaccine product, additional primary doses ((i.e., in those moderately/severely immunocompromised), and booster doses). A CDC quick reference chart may be found at: <https://www.cdc.gov/vaccines/covid-19/downloads/covid19-vaccine-quick-reference-guide-2pages.pdf>

(1) All doses of the primary series and the additional primary dose (for moderately or severely immunocompromised people) if indicated, should be completed with the same mRNA vaccine product (i.e., the same manufacturer). 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.

(a) In certain situations, in which the COVID-19 vaccine product given as 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 primary mRNA COVID-19 vaccination series.

(b) In situations where the same mRNA vaccine product is temporarily unavailable, it is preferable to delay the second dose to receive the same product than to receive a mixed series using a different product.

(c) If two doses of different mRNA COVID-19 vaccine products are administered in these situations (or inadvertently) but at the appropriate interval, no additional doses of either product are recommended at this time.

(2) On 25 October 2021, CDC updated the acceptable minimal dosing intervals for the mRNA primary series on its Interim Clinical Considerations webpage. These updated minimal dosing interval recommendations align with ACIP's General Best Practice Guidelines for Immunization.

(a) As of 25 October 2021, individuals who receive dose 2 of an mRNA COVID-19 primary series no earlier than 4 days before (referred to as the "grace period") or any time after the recommended interval [21 days (Pfizer-BioNTech) or 28 days (Moderna)] are considered to have completed the primary series.

(b) Individuals who received dose 2 of an mRNA COVID-19 primary series on or after 25 October 2021 and received the second dose earlier than the 4-day "grace period" are recommended to repeat the dose. The repeat dose should be given no earlier than the minimum interval noted above.

(c) Individuals who received dose 2 of an mRNA COVID-19 primary series prior to 25 October 2021 and received the second dose earlier than the 4-day "grace period" are recommended to consult with their healthcare provider to discuss whether repeating the dose is recommended.

h. On 17 December 2021, CDC preferentially recommended mRNA COVID-19 vaccines over the Janssen COVID-19 vaccine for the prevention of COVID-19 in those ≥ 18 years of age.

(1) Activities should no longer offer Janssen COVID-19 vaccine as an option for either primary series or as an option for a booster dose.

(2) Any request for an exception to this guidance, for individuals who are unable or unwilling to receive an mRNA vaccine, will be captured by a credentialed provider in a face-to-face medical encounter, or telehealth visit, in the EHR, documenting the risks and benefits of receiving Janssen over an mRNA vaccine.

(3) Education about the risk and symptoms of TTS associated with Janssen COVID-19 vaccine, the need to seek immediate medical care should symptoms develop, and availability of alternative COVID-19 vaccines is required to guide vaccine decision-making.

(4) Due to potential cross-reactive hypersensitivity between vaccine components in mRNA and Janssen vaccines, consultation with an Allergist-Immunologist or DHA-IHD Clinical Consultation at <https://www.health.mil/vaccineconsult> should be considered to determine if a patient with a contraindication to mRNA vaccine can safely receive Janssen vaccine.

(5) Standing orders for the Janssen product have been discontinued. This change is implemented to reduce the risk of inadvertent routine administration of the Janssen product.

i. Heterologous (i.e., mix and match) booster doses are authorized though as described above, mRNA COVID-19 vaccines are preferentially recommended over the Janssen COVID-19 vaccine.

j. There are two formulations of Pfizer-BioNTech that are FDA-approved for use in persons aged 16 years and older and FDA-authorized for use in persons aged 12–15 years:

(1) A formulation supplied in a multiple dose vial with a purple cap and label with a purple border, and that must be diluted prior to use. It uses PBS as a buffer. Each diluted 0.3 mL dose contains 30 µg of modified mRNA.

(2) A formulation supplied in a multiple dose vial with a gray cap and label with a gray border, and does not require dilution prior to use. It uses tromethamine (Tris) buffer. Each 0.3 mL dose contains 30 µg of modified mRNA.

(3) In accordance with CDC Interim Clinical Considerations and Reference (o), the FDA-approved COMIRNATY® and the EUA authorized formulation of Pfizer-BioNTech COVID-19 Vaccine for people 12 years of age and older (purple cap and label with purple border), when prepared according to their respective instructions for use, can be used interchangeably.

k. For children age 5-11 years, the Pfizer-BioNTech 10 µg, Tris buffer formulation is FDA-authorized for primary vaccination. It is supplied in a multi-dose vial with an orange cap, label, and border, and must be diluted before use. Each diluted 0.2 mL dose contains 10 µg of modified mRNA.

l. Individuals vaccinated outside of the United States with a WHO EUL COVID-19 vaccine and received all recommended primary series doses are authorized to receive a booster dose in accordance with the current CDC Interim Clinical Considerations. Individuals who have not received all the recommended doses of a WHO EUL vaccine will be offered a complete, FDA-approved, or authorized COVID-19 vaccine series. WHO EUL approved vaccines may be found at: <https://covid19.trackvaccines.org/agency/who/>.

m. All vaccine recipients will be observed for at least 15 minutes after receipt of a COVID-19 vaccine. Recipients who report a previous anaphylaxis history due to any cause, a history of an immediate allergic reaction of any severity to other vaccines or injectable therapies or people with a contraindication to a different type of COVID-19 vaccine will be observed for 30 minutes post vaccination. CDC recommendations for wait periods may be found at:

<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#Appendix-B>.

n. All vaccine recipients should be provided CDC Vaccine Safety (V-SAFE) information, a smartphone based, voluntary program, offering text-message-based health check-ins for vaccine recipients. All vaccine recipients should be instructed to call their healthcare provider if they experience any adverse events after vaccination. The V-SAFE flyer and poster are available at: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe/printresources.html>.

o. Activities may review COVID-19 vaccine coverage of their enrolled population and identify populations for targeted communication (e.g., select age groups, immunocompromised) via the Carepoint Population Health Portal, Population Risk Assessment Tool.

p. Vaccination sites will institute a plan for vaccine recipients to receive a reminder for follow-up doses. Reminders are critical to ensure the compliance with vaccine dosing intervals and to achieve optimal vaccine effectiveness. Locations may leverage Secure Messaging and AudioCARE (or Televox at MHS GENESIS capable sites) to maximize beneficiary awareness of COVID-19 vaccination information and reminders for vaccine appointments.

q. Vaccination sites are only authorized to use the following DoD-approved online and web-based appointment scheduling tools: the DHA Appointing Portal, Composite Health Care System, TRICARE Online, MHS GENESIS, and the MHS GENESIS Patient Portal. Vaccination sites will post vaccine appointment availability and procedures for appointments on MTF websites and social media site and ensure the correct information is reflected on the DHA TRICARE COVID-19 appointment page.

8. PATIENT SAFETY REPORTING

a. MTF Joint Patient Safety Reporting (JPSR) event reporting is required for vaccine administration errors and events associated with COVID-19 vaccines, including near miss, no harm, and all patient harms, to ensure near real-time reporting and response by DoD. All HCP involved in the COVID-19 vaccination program must understand when and how to report patient safety events through JPSR and VAERS. Anyone with a valid common access card and internet access can report an event into JPSR reporter using this link: <https://patientsafety.csd.disa.mil>. Vaccine specific information, to include lot and expiration, must be included in JPSR documentation.

(1) Start the JPSR event description section with the key term “COVID-19 Vaccine-Vaccine Manufacturer Name (i.e., Pfizer-BioNTech, Moderna, and Janssen)”.

(2) A VAERS report is also required for vaccine administration errors per the CDC, and the corresponding VAERS report number if available, must be included in the associated JPSR report in the event description field. The JPSR may be updated as additional VAERS information becomes available.

(3) Patient safety professionals managing JPSRs at the MTF, select from the JPSR medication dropdown menu the correct vaccine. The pick list will be updated with new vaccines as First Databank releases the updates.

b. Patient Safety Managers will monitor JPSR weekly for COVID-19 vaccine associated events. The DHA patient safety team will be monitoring the JPSR system to export data on real time events and trends that may drive additional reporting via DoD Reportable Events (RE) process and DCIR activity in accordance with Reference (w).

(1) If a COVID-19 vaccine associated event meets the DoD RE criteria in accordance with Reference (w) and timeline in Appendix 4, MTFs must follow existing processes for reporting DoD REs to Intermediate Headquarters Market, and applicable DHA entities. These types of events are associated with severe temporary harm, permanent harm, or death. MTFs will submit a DoD RE Notification letter. DHA Patient Safety Analysis Center will monitor all DoD RE activity to provide DHA leadership data visibility.

(2) The timeline for reporting vaccination administration errors or events is 24 hours from the time of discovery of the event. This timeline is an exception to the policy under Reference (w), which allows MTF Directors 5 calendar days to determine if an event must be reported as a DoD RE. If the adverse event related to a vaccine meets criteria for DoD RE it has to be reported to their respective Market Director with DoD RE process in accordance with Reference (w).

(3) If a vaccination site is not accessing the DoD JPSR system for routine patient safety event reporting, they will report the vaccine safety events via VAERS and inform their normal Patient Safety reporting channels.

9. ADVERSE EVENTS

a. All vaccination sites will be prepared to respond to an adverse event following immunization, in accordance with Reference (x). Staff will be trained on the equipment and proper response to a COVID-19 vaccine reaction. A written plan and appropriate medical supplies for emergency response and standing order for the management of anaphylaxis and fainting is required.

(1) Minimum emergency supplies for adult and pediatric vaccine recipients may be found at: <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html>.

(2). Adverse event management standing orders may be found at: <https://www.health.mil/standingorders>.

(3) DoD Clinical Guidelines for Post-Vaccination Associated Myopericarditis may be found at: https://health.mil/COVID19vaccineresources_HCP#AE

(4) The DoD COVID-19 practice management guide may be found at: <https://info.health.mil/Pages/covid-19.aspx>.

(5) Additional staff education on adverse events on selected adverse events reported after COVID-19 vaccination is available at: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html>.

b. Refer persons reporting an allergic reaction to a component of the COVID-19 vaccines to a primary care provider, with consultation to allergy/immunology, if indicated, for further evaluation prior to vaccination. If immediate clinical consultation is needed, contact the 24/7 DHA-IHD Immunization Healthcare Support Center at: 1-877-GET-VACC (1-877-438-8222) option 1 or Defense Switch Network (DSN) 761-4245, option 1 for immunization clinical consultation. Enter the “medical, temporary” exemption code into the Service-specific Immunization Tracking System when vaccination is deferred pending specialist evaluation.

c. In accordance with FDA guidance, CDC recommendations, and Reference (t), adverse events that occur in a recipient following COVID-19 vaccination will be reported to CDC’s VAERS as well as via the local patient safety reporting system, as appropriate.

(1) FDA requires vaccination providers to report certain adverse events that occur after COVID-19 vaccination. These events include, but are not limited to, those listed in Appendix 3.

(2) Sites will report any additional safety reporting requirements in accordance with the FDA’s conditions of authorized administration through the duration of the EUA.

(3) When completing a VAERS report, include all available information on the vaccine and the adverse event. The first line of Section 18, Description of Events, must start with the following line “Manufacturer (Pfizer-BioNTech, Moderna, etc.) COVID-19 Vaccine EUA.” Section 27 and 28 of Form FDA VAERS 2.0 (09/21) must be completed for any individual who received a COVID-19 vaccine from the DoD or USCG. This information is required for DoD to monitor VAERS reports generated by DoD locations and the potential follow-up with patients or managing providers as needed.

d. CDC routinely updates selected adverse events reported after COVID-19 vaccination at <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html>. Current topics described include: anaphylaxis, thrombosis with thrombocytopenia syndrome, myocarditis and pericarditis, and death. Selected adverse events may be expanded as indicated.

e. In accordance with Reference (i), individuals not otherwise eligible to receive healthcare from the DoD must pursue any follow-on care (other than on-site emergency care immediately

post-vaccination and the administration of a second dose for the COVID-19 vaccine) through their existing healthcare plans or personal healthcare providers. The authority to administer the COVID-19 vaccine to personnel not otherwise eligible to receive healthcare from the DoD does not otherwise grant additional DoD healthcare eligibility benefits to those individuals.

f. MTF and Immunization sites should coordinate with Healthcare Resolutions and/or Customer Service for assistance in notifying affected patients of issues related to management and disclosure of adverse, unexpected, or unanticipated events, or clinical conflict in the administration of the vaccines in accordance with Reference (y).

g. The Public Readiness and Emergency Preparedness Act provides immunity from liability for those involved in the manufacture, distribution, and dispensing of a COVID-19 vaccine, except for willful misconduct. In conjunction with this declaration, the U.S. Department of Health and Human Services Countermeasures Injury Compensation Program (CICP) provides a compensation mechanism for individuals who are seriously injured by a COVID-19 countermeasure approved under EUA or other emergency authorities under the Federal Food, Drug, and Cosmetic Act. Affected individuals, or their beneficiaries, must submit a Request for Benefits Package to CICP within 1 year of receiving the vaccine. For more information on the program and CICP benefits package application see: www.hrsa.gov/cicp.

10. DOCUMENTATION

a. Sites will utilize EHR COVID-19 vaccine screening templates or hard copy of DHA Forms 207 and 236 for screening each vaccine recipient. In accordance with Reference (y), DHA Forms 207 and 236 are considered medical documents. All personally identifiable information and protected health information must be stored in accordance with References (aa, ab, and ac).

(1) If the patient response to the vaccine screening question is captured in the EHR template, scanning of Form 207 or Form 236 into the EHR is not required.

(2) If the patient response to the vaccine screening is only captured on the hard copy of Form 207 or Form 236, in accordance with Reference (ac), it is required to be scanned into the EHR or placed in a paper medical record. Once digitized and verified, the original document may be destroyed in accordance with National Archives and Records Administration disposition schedules.

b. Document vaccinations in the immunization module of the EHRs to ensure accurate and automated reporting process, with exceptions as follows:

(1) Army National Guard will continue to use Medical Protection System but must place unit Defense Medical Information System Identifier in the “Admin Provider Location” field.

(2) USCG will continue to utilize Medical Readiness Reporting System.

(3) Department of Air Force may utilize Aeromedical Services Information Management System when direct access to Armed Forces Health Longitudinal Technology Application or MHS GENESIS is unavailable or significantly impedes expedient vaccination throughput.

(4) Deployed and shipboard locations will use Theater Medical Information Program-Joint (TMIP-J). If using Armed Forces Health Longitudinal Technology Application – Theater component of TMIP-J, document using the appropriate current procedure code. Ship report will be made as operationally feasible; operations will not be modified for the sole purpose of vaccine reporting.

(5) Documentation of immunization administration for DoD civilian employees will occur in the EHR by an MTF or DoD covered entity only after advising the individual that such documentation will occur.

(6) DoD civilian employees and non-beneficiaries receiving vaccine at DoD vaccination sites who are not currently enrolled in the EHRs will be registered in accordance with Reference (ad) and the DHA Patient Category Table at: <https://www.health.mil/Military-Health-Topics/Business-Support/Uniform-Business-Office/Online-Training-Courses>.

c. All vaccine recipients will be provided a copy of the CDC COVID-19 Vaccination Record Card after receipt of the vaccine. The cards will be provided to locations as part of the ancillary kits shipped with the vaccine. After verifying that the vaccine recipient's personal information is accurately documented on the CDC COVID-19 Vaccination Record Card, vaccination site staff will document all necessary COVID-19 vaccine information (i.e., vaccine manufacturer, lot number, date of first dose administered, and date of second-dose due date) on the card.

d. In accordance with Reference (x), proper documentation of the COVID-19 vaccines into the medical record includes vaccine recipient identification, date vaccine was administered, vaccine name or vaccine administered code (CVX), manufacturer and lot number, dose administered, route and anatomic site of vaccination, and name of HCP administering the vaccine.

(1) Vaccinations will be documented in the EHR immunization module at the time of administration. If access is unavailable at the time of administration, documentation in the immunization module will be entered no later than close of business (1700 local). Subject to deployed limitations and as a last resort, if there is no access to one of the EHRs the service individual medical readiness systems can be used to document the vaccination. Locations should provide enough staff, computers, and have adequate connectivity to support real-time documentation at immunization sites. A continuity of operations plan will be developed to document vaccine administration in real time for locations with degraded or intermittent connectivity, such as in an operational care setting.

(2) When transcribing a vaccine from a paper record, all available vaccine information will be transcribed into the electronic immunization record. Beneficiaries who receive COVID-19 vaccinations from network or other sites are encouraged to provide immunization data (a copy of the CDC COVID-19 Vaccination Record Card) for transcription into their immunization

record. Locations may be able to verify immunizations administered outside of the DoD by accessing the state Immunization Information System where the immunization was administered. The by state Immunization Information System list is located at:
<https://www.cdc.gov/vaccines/programs/iis/contacts-locate-records.html>.

e. Staff will verify all product names and CVX codes before documentation. It is critical that all vaccine information is accurately transcribed to allow for matching the second dose to the first dose of a primary series. Staff should be educated on the correct product naming in each documentation system they are utilizing. Validate the CVX codes for the COVID-19 vaccines against the CDC Health Level 7 Standard Code Set mapping product names to CVX and manufacturer codes at <https://www2a.cdc.gov/vaccines/iis/iisstandards/vaccines.asp?rpt=cvx>.

f. Document medical exemptions in accordance with Reference (y) and Service specific policies. The only authorized medical exemption code to temporarily defer the COVID-19 vaccine is “Medical Temporary”. In accordance with select Service policies “Medical, Permanent” may also be used for those with a valid medical contraindication. Do not use exemption codes “Medical, Immune”, “Medical, Assumed”, “Medical, Declined”, “Not required”, or “Medical, Reactive” to defer a vaccination for military personnel. Due to the anticipation of multiple COVID-19 vaccines obtaining full FDA BLA approval in the future, individuals identified as having a current contraindication should continue to be evaluated for COVID-19 vaccination with alternate vaccines on an annual basis by a treating provider. Healthcare providers who have clinical questions about whether or when to authorize medical exemptions from vaccination may consult directly with specialists, including the DHA Immunization Healthcare Support Center clinical team at:
<https://www.health.mil/vaccineconsult>.

11. **RESOURCES.** The COVID-19 Resource Center located on the DHA-IHD website at: www.health.mil/vaccines. See Appendix 5 for additional resource website links noted in the document.

12. **QUESTIONS.** For any clinical COVID-19 Vaccine Program questions, please contact the DHA-IHD 24/7 at: 1-877-GET-VACC (1-877-438-8222), DSN: 761-4245 or via e-mail at DoDvaccines@mail.mil.

APPENDIX 1

EDUCATION AND TRAINING REQUIREMENTS

Table 1. Current Immunizers

1. Has administered a vaccine to a human w/in last year AND 2. Had a current vaccine competency assessment checklist on file										
	CPR cert	CDC Training- You Call the Shots: Vaccine Administration*	CDC Training- You Call the Shots: Vaccine Storage and Handling*	CDC Training- Pfizer-BioNTech COVID-19 Vaccine: What Healthcare Professionals Need to Know	CDC Training- Moderna COVID-19 Vaccine: What Healthcare Professionals Need to Know	CDC Training- Janssen COVID-19 Vaccine (Johnson & Johnson): What Healthcare Professionals Need to Know ³	CDC Training- COVID-19 Vaccine Training: General Overview of Immunization Best Practices for Healthcare Providers* **	DoD Immunization Augmentee Didactic Training	DoD Immunization Augmentee Hands-on Skills Practice/ Demonstration	COVID-19 Competency Assessment Under Direct Observation
MD/DO	x	x	x	x	x	x	x	o	o	N/A
NP/PA	x	x	x	x	x	x	x	o	o	N/A
RN	x	x	x	x	x	x	x	o	o	N/A
LPN	x	x	x	x	x	x	x	o	o	N/A
PharmD	x	x	x	x	x	x	x	o	o	N/A
DDS	x	x	x	x	x	x	x	o	o	N/A
DMV	x	x	x	x	x	x	x	o	o	N/A
All other licensed medical professionals and enlisted personnel with a medical military occupational specialty (MOS)	x	x	x	x	x	x	x	o	o	N/A
*Required by PREP Act Amendment	x = Required									
	o = Optional									
** Required by DHA-IPM 20-004	x/o = Required if individual has never received human immunization training / certification; optional for others									

Note: CDC regularly updates training modules with changes to the interim clinical considerations. Locations should ensure vaccination staff are trained on the updates.

Table 2. New Immunizers

1. Not currently licensed, certified, or trained to administer vaccines to humans OR 2. Has not administered a vaccine to a human w/in last year OR 3. Does not have current vaccine competency assessment checklist on file										
	CPR cert	CDC Training- You Call the Shots: Vaccine Administration*	CDC Training- You Call the Shots: Vaccine Storage and Handling*	CDC Training- Pfizer-BioNTech COVID-19 Vaccine: What Healthcare Professionals Need to Know*	CDC Training- Moderna COVID-19 Vaccine: What Healthcare Professionals Need to Know**4	CDC Training- Janssen COVID-19 Vaccine (Johnson & Johnson): What Healthcare Professionals Need to Know*	CDC Training- COVID-19 Vaccine Training: General Overview of Immunization Best Practices for Healthcare	DoD Immunization Augmentee Didactic Training	DoD Immunization Augmentee Hands-on Skills Practice/ Demonstration	COVID-19 Competency Assessment Under Direct Observation*
MD/DO	x	x	x	x	x	x	x	x/o	o	x
NP/PA	x	x	x	x	x	x	x	x/o	o	x
RN	x	x	x	x	x	x	x	x/o	o	x
LPN	x	x	x	x	x	x	x	x/o	o	x
PharmD	x	x	x	x	x	x	x	x/o	o	x
DDS	x	x	x	x	x	x	x	x/o	o	x
DMV	x	x	x	x	x	x	x	x/o	o	x
All other licensed medical professionals and enlisted personnel with a medical MOS	x	x	x	x	x	x	x	x/o	o	x
*Required by PREP Act Amendment	x = Required									
**Required by DHA-IPM 20-004	o = Optional									
	x/o = Required if individual has never received human immunization training / certification; optional for others									

NOTE: CDC regularly updates training modules with changes to the interim clinical considerations. Locations should ensure vaccination staff are trained on the updates.

Table 3. Links to Trainings

TABLE 3. LINKS TO TRAININGS (For best results, copy full link address into browser)	
CDC Training You Call the Shots: Vaccine Administration*	Alt Link: https://www.cdc.gov/vaccines/ed/youcalltheshots.html
CDC Training- You Call the Shots: Vaccine Storage and Handling*	Alt Link: https://www.cdc.gov/vaccines/ed/youcalltheshots.html
CDC Training Pfizer-BioNTech COVID-19 Vaccine: What Healthcare Professionals Need to Know*	Alt Link: https://www2.cdc.gov/vaccines/ed/covid19/
CDC Training Moderna COVID-19 Vaccine: What Healthcare Professionals Need to Know*	Alt link: https://www2.cdc.gov/vaccines/ed/covid19/
CDC Training Janssen COVID-19 Vaccine (Johnson& Johnson): What Healthcare Professionals Need to Know*	Alt link: https://www2.cdc.gov/vaccines/ed/covid19/
CDC Training COVID-19 Vaccine Training: General Overview of Immunization Best Practices for Healthcare Providers**	Alt link: https://www2.cdc.gov/vaccines/ed/covid19/SHVA/00005.asp
COVID-19 Competency Assessment Under DirectObservation*	http://health.mil/COVID19vaccinecompetency
DoD Immunization Augmentee Didactic Training	Alt link: https://www.dhaj7-cepo.com/content/dod-covid-19-immunization-augmentee-didactic-training#group-tabs-node-course-default1
DoD COVID-19 ImmunizationAugmentee Facilitator Training	Relias link: https://www.dhaj7-cepo.com/content/dod-covid-19-immunization-augmentee-training

APPENDIX 2

SERVICE SPECIFIC DOCUMENT LINKS AND COMPLIANCE DATES
APPENDIX 3

Table 4. Links to Service Specific Policy Documents

	DOCUMENT REFERENCE LINK
Army	https://phc.amedd.army.mil/topics/campaigns/covid19/Pages/vaccine.aspx
Navy	NAVADMINS https://www.mynavyhr.navy.mil/References/Messages/NAVADMIN-2021/ BUMEDNOTES https://www.med.navy.mil/Directives/
Air Force	https://usaf.dps.mil/teams/COVID-19/SitePages/Home.aspx
Marine Corps	https://www.marines.mil/News/Messages/Messages-Display/Article/2761259/mandatory-covid-19-vaccination-of-marine-corps-active-and-reserve-components/
Coast Guard	https://cg.portal.uscg.mil/units/cgcpce2/Pages/HomeCOP.aspx?View=%7B4724ff56-43ee-4941-beaf-5af3500e88f4%7D

APPENDIX 3

COVID-19 VACCINE ADVERSE EVENTS REPORTING

1. COVID-19 VACCINE VAERS REPORTING REQUIREMENTS. Healthcare providers are required, by law, to report the following COVID-19 Vaccine adverse events to VAERS.

- a. Vaccine administration errors (whether associated with an adverse event or not).
- b. Multisystem inflammatory syndrome in adults and children (if vaccine is authorized for use in children).
- c. Cases of COVID-19 that result in hospitalization or death after the recipient has received a COVID-19 vaccine.
- d. Serious adverse events (irrespective of attribution to vaccination), including:
 - (1) Death. Report if you suspect that the death was an outcome of the adverse event, include the date if known.
 - (2) Life-threatening events. Report if suspected that the patient was at substantial risk of dying at the time of the adverse event or use or continued use of the device or other medical product might have resulted in the death of the patient.
 - (3) Hospitalization (initial or prolonged). Report if admission to the hospital or prolongation of hospitalization was a result of the adverse event. Emergency room visits that do not result in admission to the hospital should be evaluated for one of the other serious outcomes (e.g., life threatening; required intervention to prevent permanent impairment or damage; other serious medically important event).
 - (4) Disability or Permanent Damage. Report if the adverse event resulted in a substantial disruption of a person's ability to conduct normal life functions, i.e., the adverse event resulted in a significant, persistent, or permanent change, impairment, damage or disruption in the patient's body function/structure, physical activities and/or quality of life.
 - (5) Congenital Anomaly/Birth Defect. Report if you suspect that exposure to a medical product prior to conception or during pregnancy may have resulted in an adverse outcome in the child.
 - (6) Required Intervention to Prevent Permanent Impairment or Damage (Devices). Report if you believe that medical or surgical intervention was necessary to preclude permanent impairment of a body function, or prevent permanent damage to a body structure, either situation suspected to be due to the use of a medical product.

(7) Other Serious (Important Medical Events). Report when the event does not fit the other outcomes, but the event may jeopardize the patient and may require medical or surgical intervention (treatment) to prevent one of the other outcomes.

e. Healthcare providers are also encouraged to report any clinically significant adverse events that occur after vaccine administration. Adverse events should be reported even if the cause of the adverse events is uncertain. Healthcare providers should report any additional adverse events and adhere to any revised safety reporting requirements per the FDA conditions of authorized vaccine use posted on FDA's website at: <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines>, throughout the duration of the EUA.

APPENDIX 4

DoD REPORTABLE EVENT TIMELINE

5 Activity 5: Report a DoD Reportable Event

OVERVIEW

Once a DoD RE has been identified, there are specific requirements for reporting to the Market/Intermediate HQ and DHA/HA. These reporting requirements have specific time frames. This implementation guidance includes 1) Completing the DoD RE Notification Form, 2) Submitting the form to the Market/Intermediate HQ, 3) Submitting the notification to DHA/HA, 4) DHA receipt of DoD REs, and 5) Submitting additional information or retracting a DoD RE.

DHA-PM 6025.13

- Clarifies that all DoD REs must be reported to the Market/Intermediate HQ within 24 hours of determining an event met DoD RE criteria.
- Outlines that the Market/Intermediate HQ has 24 hours to report the DoD RE to DHA/HA once received.
- Explains that a notification of a DoD RE must include the MTF/organization's name, the event type, date of occurrence, date of discovery, patient demographics (i.e., gender, age, beneficiary category, current clinical status of patient), and a brief event-facts synopsis.

IMPLEMENTATION GUIDANCE

The MTF is responsible for reporting all DoD REs to the Market/Intermediate HQ within 24 hours of determining an event met DoD RE criteria. All DoD REs also need to be reported into JPSR. The notification process consists of five steps, as shown in Figure 8.

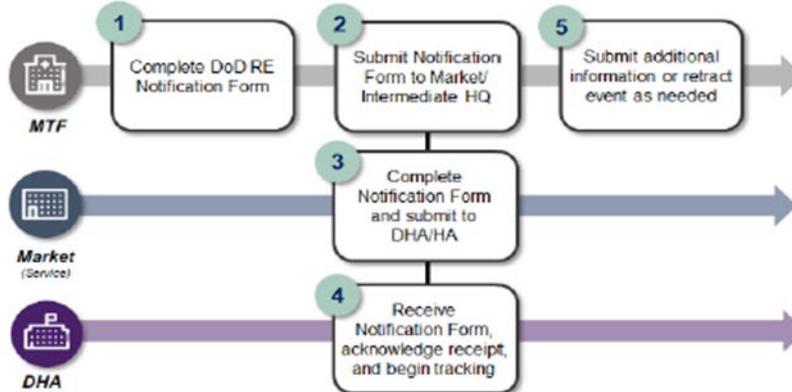


Figure 8. DoD RE Notification Process

APPENDIX 5

REFERENCED LINKS

- (1) DHA-Immunization Healthcare Division: www.health.mil/vaccines
- (2) DHA Immunization Healthcare Specialist: www.health.mil/ContactYourIHS
- (3) DoD Prepared to Receive COVID-19 Vaccines Memorandum and Checklist: <https://surveys.max.gov/367286?lang=en>
- (4) DoD sample COVID-19 vaccine competency documents: https://health.mil/COVID19vaccineresources_HCP#Competency
- (5) DoD conducting mass immunizations during pandemic conditions resource: https://health.mil/COVID19vaccineresources_HCP
- (6) DoD Standing Orders for each COVID-19 vaccine: <https://www.health.mil/standingorders>
- (7) DoD Clinical Guidelines for Post-Vaccination Associated Myopericarditis: https://health.mil/COVID19vaccineresources_HCP#AE
- (8) DoD COVID-19 practice management guide: <https://info.health.mil/Pages/covid-19.aspx>
- (9) US Army Medical Material Agency – Distribution Operations Center’s Medical Materiel Quality Control messages: <https://www.amlc.army.mil/USAMMA/Logistics/MMQCMIMsgMgmt/>
- (10) Defense Logistics Agency Product Quality Deficiency Report (PQDR): <https://www.medical.dla.mil/Portal/Customer/ProductQualityDeficiency.aspx>
- (11) DHA Joint Patient Safety Reporting: <https://patientsafety.csd.disa.mil>
- (12) State Immunization Information System: <https://www.cdc.gov/vaccines/programs/iis/contacts-locate-records.html>
- (13) CDC Quick Reference Guide for Healthcare Professionals: <https://www.cdc.gov/vaccines/covid-19/downloads/covid19-vaccine-quick-reference-guide-2pages.pdf>
- (14) CDC Interim Clinical Considerations: <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html>
- (15) CDC adverse event minimum supplies <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html>,

- (16) CDC's selected adverse events reported after COVID-19 vaccination: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html>
- (17) CDC wait period recommendations (Appendix B): <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#Appendix-B>
- (18) CDC's COVID-19 vaccine components (Appendix C): <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html>
- (19) CDC COVID-19 vaccine storage and handling: <https://www.cdc.gov/vaccines/hcp/admin/storage-handling.html>
- (20) CDC COVID-19 Vaccine Lot Number and Expiration date files: <https://vaccinecodeset.cdc.gov/LotNumber>
- (21) Pfizer expiration dates: <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/comirnaty-and-pfizer-biontech-covid-19-vaccine>
- (22) Moderna expiration dates: <https://www.modernatx.com/covid19vaccine-eua/providers/vial-lookup>
- (23) Janssen expiration dates: <https://vaxcheck.jnj>
- (24) CDC's V-SAFE: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe/printresources.html>
- (25) V-SAFE COVID-19 Vaccine Pregnancy Registry: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafepregnancyregistry.html>
- (26) Pfizer pregnancy registry: <https://mothertobaby.org/ongoing-study/covid19-vaccines/>
- (27) Countermeasures Injury Compensation Program: www.hrsa.gov/cicp
- (28) WHO Emergency Use List approved vaccines: <https://covid19.trackvaccines.org/agency/who/>.
- (29) FDA COVID-19 vaccine Fact Sheets: <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines>

GLOSSARY

ABBREVIATIONS AND ACRONYMS

24/7	24 hours a day, 7 days a week
ACIP	Advisory Committee on Immunization Practices
AD	Active Duty
BLA	Biologics License Application
CDC	U.S. Centers for Disease Control and Prevention
CICP	Countermeasures Injury Compensation Program
COVID-19	Coronavirus Disease 2019
CVX	vaccine administered code
DAD-CS	Deputy Assistant Director, Combat Support
DCIR	Director's Critical Information Report
DDS	Dentists
DHA	Defense Health Agency
DHA-IHD	Defense Health Agency-Immunization Healthcare Division
DHA-IPM	Defense Health Agency-Interim Procedures Memorandum
DLA	Defense Logistics Agency
DMV	Veterinarian
DO	Doctors of Osteopathic Medicine
DSN	Defense Switch Network
EHR	electronic health record
EUA	Emergency Use Authorization
EUL	Emergency Use Listing
FDA	U.S. Food and Drug Administration
HCP	healthcare personnel
IHS	Immunization Healthcare Specialist
JPSR	Joint Patient Safety Reporting
LPN	Licensed Practical Nurse
MD	Doctors of Medicine
MHS	Military Health System
MMQC	Medical Material Quality Control
MOS	military occupational specialty

mRNA	Messenger Ribonucleic Acid
MTF	Military Medical Treatment Facility
NP	Nurse Practitioner
PA	Physician Assistant
PharmD	Pharmacists
PQDR	Product Quality Deficiency Report
QR	Quick Response
RE	reportable events
RN	Registered Nurse
SARS-CoV-2	Severe Acute Respiratory Syndrome Coronavirus 2
TMIP-J	Theater Medical Information Program- Joint
Tris	tromethamine
USAMMA-DOC	United States Army Medical Materiel Agency-Distribution Operations Center
USCG	United States Coast Guard
V-SAFE	Vaccine Safety
VAERS	Vaccine Adverse Events Reporting System
VIS	Vaccine Information Statement
WHO	World Health Organization