

### Announcements



• Registration is required:



- Register at: <u>https://tiny.army.mil/r/Qdo4/EpiTechFY21</u>
- Log in with CAC, or follow prompts to Request access/Logon ID
- Contact your service surveillance hub to receive monthly updates and reminders
- Attendance:
  - Please enter your full name/email/location into the DCS chat box to the left, or email your service hub
  - An attendance confirmation will be sent to your email; if you do not receive this message within 3 days, please contact your service hub
- Reminder:
  - Mute your phones by pressing the mute button or 0
  - DO NOT press the "hold" button as the rest of the conference will hear the hold music





### FY21 Epi-Tech Surveillance Training

Thursday, October 1, 2020 - Thursday, September 30, 2021 DCS, Aberdeen Proving Ground, MD

*Provided By* U.S. Army Medical Command

Activity ID	<b>Course Director</b>	CME Planner
2020-0845	John Ambrose	Mimi C. Eng

#### **Accreditation Statement**

The U.S. Army Medical Command is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

#### **Credit Designation**

The U.S. Army Medical Command designates this Live Activity for a maximum of 5 AMA PRA Category 1 Credit(s)TM. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

This is a required handout. It must be disseminated to each learner prior to the start of the activity.





#### Statement of Need/Gap Analysis

### The purpose of this CME activity is to address the identified gap(s):

1. Disease identification - Verification of disease by established case definitions have been utilized by the local health departments, Centers for Disease Control and Prevention, World Health Organization, and the Department of Defense. With the every changing list of reportable medical events and new emerging infections, case definitions change rapidly. Army epidemiologist conduct verification studies that monitor the efficiency of reporting by local public health experts and have concluded that completeness percentages for reportable medical events range as low as 35% for select diseases.

2. Outbreak reporting - Recent evidence have demonstrated that outbreak reporting and communication between public health agencies is poor. In fact, the Army failed to report six outbreaks in the DRSi between June 2016 and September 2016.

3. Surveillance techniques - Surveillance of common communicable diseases continues to be a problem among local MTFs. In fact, cases of campylobacter were not investigated in 2015 for PACOM MTFS, while 2016 cases of salmonella were not investigated. Civilian public health agencies are required to conduct investigations into all reportable medical events. However, DoD facilities often do not take initiative to conduct this investigation.

### **Learning Objectives**

1. Based on case presentation, enhance your ability to improve case finding and surveillance practices within your local MTF.

#### **Target Audience / Scope of Practice**

Target Audience: The intended audience for this educational activity includes preventive medicine physicians, community health nurses, public health nurses, and epidemiology technicians.

Scope of Practice: This activity will improve the performance of preventive medicine personnel who conduct surveillance activities in inpatient and outpatient settings.





#### **Disclosure of Faculty/Committee Member Relationships**

It is the policy of the U.S. Army Medical Command that all CME planning committee/faculty/authors disclose relationships with commercial entities upon invitation of participation. Disclosure documents are reviewed for potential conflicts of interest and, if identified, they are resolved prior to confirmation of participation.

#### **Faculty Members**

Bylsma, Victoria Gillooly, Paul Montgomery, Jay

#### **Committee Members**

Ambrose, John Bowman, Wendi Bylsma, Victoria Constantino, Joycelyn Diaz, Rolando Eng, Mimi Kebisek, Julianna Riegodedios, Asha

- No information to disclose.

#### Acknowledgement of Commercial Support

There is no commercial support associated with this educational activity.



### DHA Immunization Healthcare Division

# **COVID-19 Vaccine Program Update**

### Tri-Service PrevMed Webinar

30 March 2021



"Medically Ready Force...Ready Medical Force"



- The presenter has no relevant financial or non-financial relationships to disclose relating to the content of this activity; or the presenter must disclose the type of affiliation/financial interest (e.g. employee, speaker, consultant, principal investigator, grant recipient) with company name(s) included.
- The views expressed in this presentation are those of the author and do not necessarily reflect the official policy or position of the Department of Defense (DoD), nor the U.S. Government.
- Commercial support was not received for this activity.



- Describe current and potential SARS-CoV-2 vaccines to be used in the military population
- Outline strength and limitations of each vaccine
- Describe steps of the military roll out

# **COVID-19 Vaccine Efforts**





\* Other efforts include testing whether existing vaccines against poliovirus or tuberculosis could help to fight SARS-CoV-2 by eliciting a general immune response (rather than specific adaptive immunity), or whether certain immune cells could be genetically modified to target the virus.

Nature 580, 576-577 (2020)

### **SARS-CoV-2** Nucleic-Acid Vaccines





### **SARS-CoV-2** Viral Vector Vaccines





# **COVID-19 Vaccine Candidates**



Vaccine manufacturer	Vaccine Platform	Vaccine category	Description	Doses (timing)	Dose Route	Storage Temp
<b>Pfizer</b> BioNTech	mRNA	non-live	Lipid nanoparticle-encapsulated mRNA encoding spike protein, 3LNP-mRNAs	2 doses (0, 21d)	0.3mL IM	Ultra-low freezer (-80C) 2 weeks at (-20C) 5 days unopened at (2-8C)
Moderna	mRNA	non-live	Lipid nanoparticle-encapsulated mRNA encoding spike protein, mRNA-1273	2 doses (0, 28d)	0.5mL IM	Freezer (-20C) 30 days unopened at (2-8C)
<b>Janssen</b> Johnson & Johnson	Non- replicating viral vector	live*	Replication-defective human adenovirus 26, Ad26.COV2-S	1 dose	0.5mL IM	Freezer (-20C) Until expiration date at (2-8C)
AstraZeneca Univ Oxford	Non- replicating viral vector	live*	Replication-defective simian adenovirus, ChAdOx1 nCoV-19, now AZD1222	2 doses (0, 28d)	IM	Refrigerator (2-8C)
Novavax	Protein subunit	non-live	Recombinant glycoprotein nanoparticle with Matrix M1 adjuvant	2 doses (0, 21d)	IM	Refrigerator (2-8C)
<b>Sanofi</b> GSK	Protein subunit	non-live	Recombinant surface protein (Flublok technology) with GSK's ASO3 adjuvant	2 doses (0. 21d)	IM	Refrigerator (2-8C)
Inovio	InovioDNAnon-liveNovel DNA product delivered by intradermal (ID) route with electroporation (EP)		2 dose (0, 28d)	ID/EP	Refrigerator (2-8C)	
Merck IAVI	Live replicating viral vector	live	Live Vesicular Stomatitis Virus (VSV∆G, Ervebo technology) delivering spike protein	1 dose?	oral	TBD



### BIONTECH Prizer / PFR

- 2-dose, mRNA vaccine, 0.3 mL/dose 21 day interval
- To exp date @ -80°C, 2 wks @ -25° to -15°C, 5 days @ 2°-8°C,
  6 hrs diluted/2 hrs undiluted @ room temp
- Dilute with 1.8mL of NS (Do not use bacteriostatic 0.9% NaCl)
- 6 doses per vial
- ≥16 years of age
- **~95%** vaccine efficacy
- CVX Code: 208
- CPT Code: 91300
- Administration Code: Dose #1 0001A, Dose #2 0002A
- OK to transport refrigerated vaccine via helicopter (for 12 hrs)



# moderna" / MOD

messenger therapeutic

- 2-dose, mRNA vaccine, 0.5mL/dose, 28 day interval
- To exp date -20°C storage, 30 days @ 2°-8°C, 12 hrs unpunctured @ room temp, 6 hrs punctured
- 10-11 doses per vial
- ≥18 years of age
- **94%** vaccine efficacy
- CVX Code: 207
- CPT Code: 91301
- Administration Code: Dose #1 0011A, Dose #2 0012A
- Probably OK to transport refrigerated vaccine via helicopter



# Johnson Johnson / Janssen / JSN

- 1-dose, viral vector vaccine (human adenovirus), 0.5mL/dose
- To exp date unopened/6 hrs punctured @ **2°-8°C**, DO NOT FREEZE, 12 hrs unpunctured/2 hrs punctured @ room temp
- 5 doses per vial
- ≥18 years of age
- **~74%** vaccine efficacy in US.
- CVX Code: 212
- CPT Code: 91303
- Administration Code: 0031A
- No expiration dates on vials. To find, enter the lot number found on the via at the website www.vaxcheck.jnj



### Interchangeability of COVID-19 vaccines

- The safety & efficacy of a mixed-product series have not been evaluated. Both doses of the series should be completed with the same product.
  - Provide vaccination card, use v-Safe, VaxText (reminder), record in EHR.
- If brand of first dose cannot be determined or is no longer available, any available mRNA COVID-19 or the Janssen vaccine may be administered at a minimum interval of 28 days between doses to complete the series.
- In situations where the same mRNA vaccine is temporarily unavailable, it is preferable to delay the 2nd dose (up to 6 weeks) to receive the same product.
- If two doses of different mRNA COVID-19 vaccine products are administered in these situations (or inadvertently), no additional doses of either product are recommended.



### **Concomitant vaccination**

- ACIP Best Practices states non-live vaccines (such as mRNA vaccine), can safely and effectively be given any time before, during, or after any other vaccines.
- However, out of an abundance of caution, CDC/ACIP recommended that Pfizer and Moderna COVID-19 vaccines be spaced 14 days from other vaccines. Buts also says COVID-19 and other vaccines may be administered within a shorter period in situations where the benefits of vaccination are deemed to outweigh the potential unknown risks of vaccine co-administration.
- DHA207 screening form respects CDC/ACIP guidance, but added clinical decision-making option to administer concomitant vaccines.
- 03MAR2021 ASDHA Memo supported CDC guidance but added: "a HCP may, based on their best medical judgment and following review of an individual's health information, recommend co-administration of a COVID-19 vaccine with other vaccines to a Service member."



### Allergic reaction to first dose

- CDC/ACIP recommends "If you had an immediate allergic reaction after a COVID-19 vaccine, you should not get a second shot of that vaccine, even if reaction was not severe enough to require emergency care."
  - Issue is "which acute reactions are allergic and which are not?"
  - Issue is "what are the risks of not completing the series?"
  - IHD recommends whenever possible that the patient be referred to an Allergist to determine the nature of the reaction.
  - Consideration may now be given to vaccination with Janssen COVID-19 vaccine under the supervision of an Allergist. A 28-day interval between the two vaccines is recommended.



- Ensure vaccination providers have appropriate training
- Establish well supported venue(s) for SHOTEX
- Apply appropriate pandemic precautions for patient care
- Conscientiously screen potential vaccine recipients (DHA-207)
- Provide EUA 'Fact Sheet for Recipients and Caregivers" (in lieu of VIS)
- Enforce vaccine recipients to remain in clinical area at least 15 minutes for observation after vaccination
- Document vaccination on individual COVID-19 shot card, in medical record (AHLTA or GENESIS), and in military readiness system (MRRS, MEDROS, ASIMS) as applicable

Please keep about the va	this record card, which includes n recines you have received.	nedical informatio	- Jr
Poi favor, gu médica sobr	urde esta tarjeta de registra, que) re las vacunas que ha recibido.	induye informació	a
Las, Naine		Firs, Name	м
Date of birth		Patient number (m	calical record or 15 record numbers
Vaccine	Product Name/Manufacturer Lot Number	Date	Healthcare Professional or Clinic Site
1 <sup>4</sup> Dese COVID-19		inter da yy	
2 <sup>NI</sup> Dose COVID 19		me'da <sup>7</sup> yy	
Same and the State		ona da 1	
Other			

 Guidance for managing vaccines from multiple manufacturers - see 22MAR IHD Info Paper at https://go.usa.gov/xsejk

### **Special situations: Pregnancy**

• CDC/ACIP language is permissive, to remove barriers from COVID-19 vaccination during pandemic, stating pregnant people may choose to receive a COVID-19 vaccine. [CDC Interim Guidance 5MAR2021]



- Despite very limited data on vaccination in pregnancy, "pregnant people may chose to be vaccinated"
- FDA and CDC intend to evaluate the post-EUA pregnancy experiences of vaccinated women and their children
- Moderna has established a pregnancy registry; Pfizer has not
- Breastfeeding should not affect vaccination decisions. The CDC states "lactating people may choose to be vaccinated."



### **Special situations: Underlying Medical Conditions**

- Immunocompromise or immune-modulating medications may reduce effectiveness of vaccination; nonetheless, these conditions are not contraindications and should not prompt changes in vaccine dosing or schedules
- Individuals with a history of an autoimmune condition may receive any authorized COVID-19 vaccine.
- History of **Guillain-Barre Syndrome or Bell's Palsy** does not currently change clinical counseling on COVID-19 vaccination
- History of receipt of **cosmetic dermal fillers** may prompt advice that swelling may occur around filler sites ((usually face or lips) after mRNA COVID-19 vaccination. Janssen vaccine may be an option



### **Special situations: Allergic Reactions**

- Contraindications: Severe allergic reaction [e.g., anaphylaxis or hives, hypotension, respiratory distress within 4 hours of exposure] to prior COVID-19 vaccine, polyethylene glycol, or polysorbate
- **Precautions**: History of allergic reaction of any severity to a vaccine or injectable medication; history of anaphylaxis for any reason; those with 'precautions' should be observed in clinic for at least 30 minutes after vaccination
- Early reports suggest anaphylaxis, while rare, may occur at rates 10fold higher after mRNA vaccines than after other vaccines (incidence approximately 10 per million doses)
- All vaccine clinics need to be prepared for anaphylaxis

# **Adverse Events Following Immunization (AEFIs)**

Most frequently reported symptoms through the CDC's v-Safe surveillance process

#### Dose 2 Dose 1 100 100 Participants (%) 90 90 Injection site pain 80 80 Fatigue Headache 70 70 Mvalgia 60 60 Chills 50 50 ď 40 40 Percentage 30 30 20 20 10 10 0 0 Day 0 Day 0 Day 1 Day 2 Day 3 Day 4 Day 5 Day 6 Day 7 Day 1 Day 2

#### A. Persons ages less than 65 years

B. Persons ages 65 years or older



Immunization Healthcare

Injection site pain

Fatigue Headache

Myalgia

Day 5

Day 6

Day 7

Chills

Day 3

Day 4





- Phase I [June 2020]
  - □ Pre-vaccination phase
  - Policy development
  - □ Site preparation
  - USAMMA-DOC/DLA preparation





- Phase 2a [14 DEC 2020]
  - Controlled Pilot
  - Small quantities of vaccine to test distribution and execution policies and structures at a few MEDCENS in CONUS
  - DoD demonstrated the receipt, storage and handling of -80°C vaccine directly from Pfizer and the execution of vaccination within the selected MTF catchment areas.





### ■ Phase 2a [27 DEC 2020]

- Increased distribution of -80°C Pfizer vaccine to further test logistics flow to thirteen CONUS locations and three OCONUS locations.
- Customs agreements and SOFAs reviewed.





### Phase 2b [27 DEC/02MAR]

- Expanded Distribution
- Vaccine supplies increase and logistics & vaccination processes mature.
- Moderna's -20°C vaccine facilitates DLA ordering and distribution via vTrcks per Service prioritization.
- Janssen's 2°-8°C vaccine projected to be first distributed to austere/ shipboard sites. Eventually Services will decide their distribution.





### Phase 2c [TBD]

- Saturation
- COVID-19 Vaccine Program
  resembles other DOD
  Vaccine Programs
- More supply than demand, allows for less vaccine allocation management
- Multiple vaccine manufacturers, vaccine specificity
- Services submit order request using normal systems through their Service Logisticians to USAMMA-DOC

# **COVID-19 Vaccination Plan, MODs of Note**



- COVID-19 Vaccination Base Plan (12DEC20) serves as the Department of Defense's (DoD) integrated global response to distribute and administer COVID-19 vaccinations.
  - MOD3 = updates the "Commander's Confirmation of Prepared to Receive COVID-19 Vaccines, Memorandum and Checklist" and provide task for ensuring vaccination sites are ready; provides updated DHA-IPM
  - □ MOD4 = provides USAMMA-DOC CONUS Ordering and Distribution Process, and the DLA OCONUS Ordering and Distribution Process
  - MOD6 = provides consolidated list of reports (Annex R); update Vaccination Daily Roll-Up spreadsheet; and provide further guidance for vaccination sites to complete the Commander's Confirmation of Prepared to Receive COVID-19 Vaccines, Memorandum and Checklist.
  - □ MOD7 = provides guidance to Combatant Commands regarding vaccine allocation coordination; defines what is to be reported as vaccine loss

# **COVID-19 Vaccination Plan, MODs of Note**



- MOD8 = provides instructions for documenting vaccinations in the immunization modules of the EHR and AHLTA Rapid Entry Immunization Guide; instructions for COVID-19 vaccine accounting for sites without DMLSS; updated DHA MEDLOG Procedural Instruction; and COVID-19 Response Program Standard Assemblage Management Quick Reference
- MOD9 = defines DoD vaccinator and training requirements; provides COVID-19 Vaccination Program Director's Critical Information Report (DCIRs) and DHA DCIR Form; provides guidance for registering patients.
- MOD10 = provides guidance related to the Janssen COVID-19 vaccine EUA; provides updated instructions for utilizing the AHLTA Immunization Module; provides DoD-approved, online tools for COVID-19 vaccination scheduling; provides updated FAQs; and provides updates to clarify the OCONUS ordering and distribution process
- MOD11 = provides updated & J&J-specific training, and "Ready to Receive Vaccine Checklist" guidance and COVAXX Appointing Tool User's Guide

# **COVID-19 Vaccine Operations Update (15MAR2021)**



### **Controlled Unclassified Information**

Immunization Healthcare

### **COVID-19 Vaccine Phased Distribution (25FEB21)**



	DoD Tier Level (NOTE: The final tier is defined as the highest tier for which a person qualifies.)		Population Group <sup>2</sup>
	Tier 1a All healthcare providers, healthcare support personnel, and emergency services and public safety personnel	Sub-tier 1*	Intensive Care Unit personnel, Emergency Room/Urgent Care Center personnel, First Responders (e.g., Emergency Medical Services personnel, police, and Search and Rescue personnel, and fi re personnel (as identified by their DoD Component) and Armed Forces Retirement Home residents
	Healthcare and support personnel at Military Medical Treatment Facility (MTF) outpatient clinics and ambulatory care facilities (including but not limited to dental clinics, medical homes, blood donation facilities, and counseling centers) *May include military, civilian, and contractor personnel, students, and other hospital non- clinical staff authorized to receive vaccinations from DoO and who support patient care and are at heightened risk of exposure to individuals who have contracted COVID-19. Sub-tier 3*		Other inpatient healthcare and support personnel as identified by their DoD Component
			Outpatient healthcare and support personnel. This includes Active Duty or National Guard and Reserve personnel supporting U.S. Government COVID-19 response efforts in a Title 10 or Title 32 duty status up to 90 days before deploying to provide such support (e.g., personnel providing patient care, administering vaccines, conducting testing, and assisting in vaccine distribution).
			Strategic and nuclear deterrence forces, homeland defense forces, and national leadership (senior staff), as identified in writing by their DoD or OSD Component heads, U.S. Special Operations Command national mission force personnel, and U.S. Cyber Command National mission force personnel.
	YOU ARE    Tier 1b (all qualifying personnel have equal priority)      Critical National Capabilities      Personnel forward deployed to austere environments      Personnel preparing to deploy to locations outside the United States      Authorized <sup>4</sup> persons aged ≥ 75 years      Frontline essential workers		Personnel forward deployed to austere environments (i.e., conditions where no non-DoD advanced medical providers are available); Forward Deployed Naval Forces (FDNF) in accordance with JP- 3-32.
YOU			Personnel preparing to deploy outside the U.S. within the next 90 days and individuals on dedicated stand-by for missions outside the US and its territories (e.g., IRF, PTDO). This includes military, civilian, and contractor personnel authorized to receive vaccines from DoD.
HE			Authorized <sup>2</sup> persons aged ≥ 75 years
			Front Line Essential Workers: Education sector personnel (e.g., teachers, support staff, and child and youth services staff), eligible defense manufacturing personnel (e.g., those operating in depots and shipyards <sup>1</sup> ), DoD corrections staff, DoD postal service staff, DoD public transit workers, Military Service exchange workers <sup>2</sup> , and commissary and other installation food service or aericultural workers.
			Authorized <sup>2</sup> persons ared ≥ 65-74 years
	Tier 1c (all qualifying personnel have equal priority) Authori	zed <sup>2</sup>	Authorized <sup>2</sup> persons aged ≥ 16-64 with increased risk for severe illness <sup>1</sup> as defined by CDC
	persons aged ≥ 65-74 years		Personnel deployed/TDY for over 30 days outside of the US This group does not include members on orders to locations that retain personnel on a permanent basis (PCS, etc.).
Authorized <sup>a</sup> persons aged ≥ 16-64 with increased risk for severe illness <sup>1</sup> as defined by CDC Personnel deployed/TDY for over 30 days outside of the U.S. Essential workers not previously included in Tier 1a or 1b		ined by CDC Personnel usly included in Tier 1a	DoD and OSD Component personnel designated as Key, Essential (EE/NCE), or mission-essential <sup>2</sup> , as identified by their DoD or OSD Component in writing, not otherwise identified above.
			DoD prisoners
	Tier 2 Persons aged ≥ 16 years not previously identified for vaccination *As of February 24 2020, only the Pfizer-BioNTech COVID-19 vaccine is authorized for individuals ≥ 16 years and < 18 years of age		Healthy uniformed personnel (including authorized <sup>3</sup> new accessions and service academy cadets), and others authorized and those eligible to receive vaccines from DoD not otherwise mentioned above
<sup>1</sup> Please visit the following CDC link for the most recent list of conditions: <u>https://www.cdc.gov/coronavirus/2019-ncov/need-extra</u> <sup>2</sup> Individuals authorized to be offered the COVID-19 vaccine in accordance with Deputy Secretary of Defense Memorandum, "Coro Coronavirus Disease 2019 Vaccines to DoD Contractor Employees and Select Foreign Nationals," December 31, 2020, or otherwise applicable guidance.			eed-extra-precautions/people-with-medical-conditions.html m, "Coronavirus Disease 2019 Vaccine Guidance," December 7, 2020 and "Supplemental Guidance for Providing DoD otherwise applicable law includes Service Members, DoD civilian employees, and DoD Contractor employees as set forth in

<sup>3</sup>As defined in 10 USC 1580, DoD Directive 1200.17, and DoD Instruction 3020.42.

# **Reference Material**





# Questions



