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DHA-IPM 20-002 March 20, 2020

MEMORANDUM FOR DISTRIBUTION

SUBJECT: 2020 Southern Hemisphere Influenza Vaccination Program

References: See Attachment 1.

This Defense Health Agency-Interim Procedures Memorandum (DHA-IPM), based on the authority of References (a) and (b), and in accordance with the guidance of References (c) through (i), establishes the Defense Health Agency's (DHA) procedures to implement instructions, assign responsibilities, and prescribe procedures for the Southern Hemisphere Influenza Vaccination Program.

It is DHA's guidance, pursuant to Reference (g), that All Active Duty, Selected Reserve, and National Guard members receive an annual influenza vaccination. Personnel who are traveling to, conducting a permanent change of station to, or are located in the Southern Hemisphere will receive the Southern Hemisphere influenza vaccine or obtain an exemption (e.g., medical or administrative) in accordance with guidance in paragraph 6.a. of Attachment 2. Military personnel residing in the Southern Hemisphere who have received the Southern Hemisphere influenza vaccine in accordance with Appendix 1 meet the annual influenza immunization requirement in accordance with Reference (g).

This DHA-IPM is cleared for public release and is available on the Internet from the Health.mil site at: www.health.mil/DHAPublications and is also available to authorized users from the DHA SharePoint site on the SECURE Internet Protocol Router Network at: https://info.health.mil/cos/admin/pubs/SitePages/Home.aspx.

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). The point of contact for this DHA-IPM is Mr. William Watson who may be reached at (703) 681-5690 or william.c.watson.civ@mail.mil.

RONALD J. PLACE LTG, MC, USA

Director

Attachments:

As stated

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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
- (c) DHA-Procedural Instruction 5025.01, "Publication System," August 24, 2018
- (d) United States Code, Title 42, Sections 300aa-1–300aa-34
- (e) Centers for Disease Control and Prevention Vaccine Information Statement, "Influenza (Flu) Vaccine (Inactivated or Recombinant): What You Need to Know," August 15, 2019¹
- (f) Army Regulation 40-562/BUMEDINST 6230.15B, 48-110_IP/CG COMDTINST M6230.4G, "Immunizations and Chemoprophylaxis for the Prevention of Infectious Diseases," October 7, 2013
- (g) DoD Instruction 6205.02, "DoD Immunization Program," July 23, 2019
- (h) Medical Material Quality Control Message MMQC-19-1105, "MMQC Migration to ECRI Institute as the primary source for Hazard Alerts and Recalls (HAR)/Updated," January 15, 2019
- (i) World Health Organization Table of Influenza Vaccine Formulation, "Which Formulation," November 21, 2016²

https://www.who.int/influenza/vaccines/tropics/Recommendedvaccineformulationv2.pdf

¹ This reference can be found at: https://www.cdc.gov/vaccines/hcp/vis/vis-statements/flu.html

² This reference can be found at:

ATTACHMENT 2

PROCEDURES

1. 2020 SOUTHERN HEMISPHERE SEASONAL INFLUENZA INFORMATION

- a. Influenza or "flu" has the potential to adversely impact force readiness and mission execution. Influenza is caused by a virus that changes (mutates) frequently over the course of the influenza season. Seasonal influenza disease occurs mainly during October through March in the Northern Hemisphere and April through September in the Southern Hemisphere. It is not uncommon to have the predominant viral strains change between hemispheres during a single year warranting hemisphere-specific vaccines. Until 2018, the U.S. Food and Drug Administration (FDA) had only licensed a Northern Hemisphere-specific vaccine. In December of 2018, the FDA licensed a Southern Hemisphere influenza vaccine, but it was not made available for United States distribution by the manufacturer. Beginning in 2020, the manufacturer made this vaccine available for use within the DoD for personnel stationed in or traveling to the Southern Hemisphere.
- b. In accordance with Reference (g), the DoD Components will make preferential use of immunizations approved by the FDA. The DOD also, when applicable, follows the recommendations of the Advisory Committee on Immunization Practices while considering the unique needs of military populations. Information on the Southern Hemisphere influenza vaccine may be found on the DHA Immunization Healthcare Division (IHD) website at: https://www.health.mil/SHflu.
- c. The influenza vaccine formulated for the Southern Hemisphere differs in composition from the Northern Hemisphere vaccine. For persons traveling to the Southern Hemisphere during the Southern Hemisphere influenza season, receipt of the United States licensed Southern Hemisphere formulation influenza vaccine before departure should be considered. Countries designated by the World Health Organization (WHO) for vaccination with the Southern Hemisphere influenza vaccine are noted in Appendix 1. The 2020 Southern Hemisphere influenza quadrivalent vaccine will contain A/Brisbane/02/2018 (H1N1)-like virus, A/South Australia/34/2019 (H3N2)-like virus, a B/ Washington/02/2019-like virus (Victoria lineage), and B/Phuket/3073/2013-like virus (Yamagata lineage).

2. <u>INFLUENZA VACCINATION REQUIREMENTS AND RECOMMENDATIONS</u>

a. Southern Hemisphere influenza vaccination is required for all Active Duty, Reserve Component, National Guard members (and recommended for all other beneficiaries), permanently or temporarily assigned for at least 14 contiguous days between 1st of April through the 30th of September to an area designated as a Southern Hemisphere influenza zone by the WHO in accordance with Reference (i). U.S. Government civilian employees and family members of personnel who are living in or conducting a permanent change of station to the Southern Hemisphere are authorized to receive the Southern Hemisphere vaccine.

- b. Exemptions to the requirement in paragraph 6.a. of this Attachment may be granted on a case-by-case basis for medical or administrative reasons in accordance with Reference (f).
- c. Personnel traveling to the Southern Hemisphere between April and September should be vaccinated at least 2 weeks prior to entry into the region if possible.
- d. Personnel traveling/residing in the Northern Hemisphere for at least 14 days contiguous between October to March and who have not received the current seasonal Northern Hemisphere influenza vaccine are required to receive a Northern Hemisphere vaccine in accordance with most current DHA-IPM for Northern Hemisphere seasonal influenza vaccination program.

3. ORDERING, DISTRIBUTION, AND COLD CHAIN MANAGEMENT

- a. Sanofi Pasteur manufacturers the only United States licensed Southern Hemisphere influenza vaccine, Fluzone® Quadrivalent Southern Hemisphere, which received FDA licensure in 2018. DoD has purchased the vaccine to support the anticipated troop movement into the Southern Hemisphere. Vaccine will be located at forward locations and a limited supply will be available at Continental United States (CONUS) MTFs to support deployments to the Southern Hemisphere. CONUS MTFs requesting vaccine must submit orders to their respective medical logistic Seasonal Influenza Program Managers.
- b. ECRI is the primary source for Hazard Alerts and Recalls notifications, formerly known as Medical Material Quality Control Message. Logistics and immunization personnel must validate or register for a current subscription for Hazard Alerts and Recalls notifications in accordance with Reference (h). Personnel can register at: https://www.usamma.army.mil/Pages/MMQCMMIMsgMgmt.aspx.
- c. Activities administering influenza vaccine will establish procedures requiring the proper storage and handling of influenza vaccines. Personnel will be present to receive and store vaccines upon arrival. These vaccines will be promptly posted in the facilities' requisition processing system.
- d. To ensure proper receipt, Defense Logistics Agency-Troop Support Medical (DLA-TSM) will ship vaccine to Outside Continental United States locations on Mondays and Fridays, and to CONUS locations on Mondays, Tuesdays, and Wednesdays. DLA-TSM does not ship on holidays or weekends and will only ship on Thursdays on a case-by-case basis.
- e. All vaccine shipments include the same temperature monitoring devices. Immunizing activities will send temperature data to DLA-TSM as soon as possible after receipt of the vaccine per the instructions included in each shipment. Activities that use the pre-paid/pre-addressed Federal Express materials provided with shipping containers will physically return the actual temperature monitors to DLA-TSM. Activities that use the temperature monitor hardware and software package will electronically transmit the data to DLA-TSM and are not required to ship the device back.

- (1) No-Alarm temperature monitors: The material is released for immediate use. Disposition is not needed from DLA-TSM, but the temperature monitor must be returned for audit purposes.
- (2) Alarmed temperature monitors: Activity will segregate the vaccine in the refrigerator by temperature monitor serial number with a sign saying, "DO NOT USE," return temperature monitor to DLA-TSM, and await disposition instructions.
- (3) Un-started, malfunctioning, or absent temperature monitors: Activity will treat the shipment as alarmed.
- (4) If you do have the temperature monitor hardware and software, all temperature monitor data should be sent into DLA-TSM via email at: Dana.Dallas@dla.mil or nancy.collins@dla.mil. Un-started, malfunctioning, or damaged temperature monitors should be physically returned to DLA-TSM.
- f. Influenza vaccines will be stored and transported correctly within the temperature parameters of 2° to 8°C (36° to 46°F), at all times. If the vaccine is not stored correctly within the correct temperature parameters, it may lose potency. Any time a temperature compromise is suspected post receipt:
- (1) The vaccine will be placed immediately in a refrigerator approved for vaccine storage and marked "DO NOT USE."
- (2) Notify your DHA-IHD Immunization Healthcare Specialist and complete the Potentially Compromised Vaccine/Temperature Sensitive Medical Products response worksheet, located on the DHA-IHD website at: https://health.mil/Military-Health-Topics/Health-Readiness/Immunization-Healthcare. The worksheet must be submitted online to DLA-TSM, United States Army Medical Materiel Agency-Distribution Operations Center, and to your local medical logistics directorate.
- (3) Do not assume the vaccine is unusable, and do not discard potentially compromised vaccine(s) until directed by DLA-TSM and/or United States Army Medical Materiel Agency-Distribution Operations Center.

4. VACCINE ADMINISTRATION

- a. In accordance with Reference (f), only appropriately trained and qualified medical personnel working within their scope of practice, upon the order (including standing orders) of an appropriately privileged healthcare provider, will administer the influenza vaccine.
- b. Prior to vaccination, all potential vaccine recipients will be screened utilizing locally approved or current standardized screening questions available via DHA-IHD website (DHA Form 116).

- c. In accordance with Reference (e), individuals receiving a vaccine will be provided the current influenza Vaccine Information Statement (VIS) for inactivated influenza vaccines.
- d. Administration of the Southern Hemisphere influenza vaccine should be separated by at least 30 days from the previous dose of the Northern Hemisphere vaccine. Receipt of the Northern Hemisphere influenza vaccine should be separated by at least 30 days from previous dose of the Southern Hemisphere vaccine.

5. DOCUMENTATION

- a. In accordance with Reference (f), documentation of immunization is required in the appropriate Service-specific Immunization Tracking System: Appropriate systems include the Medical Protection System for Army, Medical Readiness Reporting System for Navy, Marine Corps, Coast Guard, and Aeromedical Services Information Management System for the Air Force. The DoD electronic health records (Armed Forces Health Longitudinal Technology Application and Military Health System GENESIS) send data to the above readiness system daily. Documentation of immunizations in either electronic health record system will fulfill the requirement for documentation in a readiness system.
- b. In accordance with Reference (d), proper documentation of an immunization includes patient identification, date vaccine was administered, vaccine name or CVX code, manufacturer and lot number, dose administered, route of administration, anatomic site of vaccination, date the VIS was provided, and VIS version date.
- c. CVX Code 194 will be used to document Fluzone® Quad Southern Hemisphere pre-filled syringes or until an additional Southern Hemisphere influenza CVX code is released by the Centers for Disease Control and Prevention.

6. ADVERSE EVENTS

- a. Minor adverse events can occur with influenza vaccination. Possible adverse events include local swelling, soreness at the injection site, and headache and are common side effects that are self-limiting, resolve quickly, and do not constitute an allergic reaction. Soreness at the immunization site lasting up to 2 days, fever, malaise, myalgia, and other systemic symptoms may occur. These begin 6 12 hours after immunization and can persist for 1 2 days. Immediate allergic reactions that include hives, angioedema, allergic asthma, and systemic anaphylaxis are rare.
- b. All suspected serious or unexpected vaccine-related adverse events (e.g., events resulting in hospitalization, life-threatening events, one or more duty shifts lost due to illness, or an event related to suspected contamination of a vaccine vial) must be reported through the Vaccine Adverse Event Reporting System at: https://vaers.hhs.gov/reportevent.html. The 24/7, 365

DHA-IHD Immunization Healthcare Support Center is available at: 1-877-GET-VACC (1-877-438-8222) option 1 (Defense Switched Network 761-4245) to answer questions regarding vaccine screening and potential vaccine-related adverse events.

- 7. <u>RESOURCES</u>. The Southern Hemisphere Influenza Resource Center located on the DHA-IHD website at: http://www.health.mil/SHflu.
- 8. <u>QUESTIONS</u>. For questions, please contact the DHA-IHD at: 1-877-GET-VACC (1-877-438-8222) or <u>DoDVaccines@mail.mil</u>.

APPENDIX

TABLE OF SOUTHERN HEMISPHERE INFLUENZA ZONE COUNTRIES AND TERRITORIES

Vaccination Zone	Countries, areas or territories
Southern Hemisphere - South America	Anguilla, Antigua and Barbuda, Argentina,
(including part of Central America and parts of	Bahamas, Barbados, Belize, Bolivia
the Caribbean) *	(Plurinational State of Bolivia), Brazil,
	Cayman Islands, Chile, Colombia, Costa
	Rica, Dominica, Dominican Republic,
	Ecuador, El Salvador, French Guiana,
	Grenada, Guyana, Haiti, Honduras,
	Montserrat, Netherlands Antilles, Nicaragua,
	Panama, Paraguay, Peru, Saint Kitts and
	Nevis, Saint Lucia, Saint Vincent and the
	Grenadines, Suriname, Trinidad and Tobago,
	Turks and Caicos Islands, Uruguay,
	Venezuela (Bolivarian Republic of
	Venezuela)
Southern Hemisphere - Southern and Western	Benin, Cabo Verde, Cameroon, Central
Africa	African Republic, Côte d'Ivoire, Gambia,
	Ghana, Guinea, Guinea-Bissau, Liberia,
	Nigeria, Senegal, Sierra Leone, Togo,
	Uganda, Angola, Botswana, Mozambique,
	Namibia, South Africa, Zambia, Zimbabwe
Southern Hemisphere - Tropical Asia	Bangladesh, Bhutan, Cambodia, India, Laos,
	Maldives, Myanmar, Nepal, Philippines,
	Thailand, Timor-Leste, Viet Nam
Southern Hemisphere - Oceania	Australia, New Zealand

^{*} Cuba has been removed from the WHO country list for Southern Hemisphere vaccines. Due to the restricted access of personnel at Guantanamo Bay Cuba, they will not be required to receive the Southern Hemisphere vaccine but will be required to remain current for the Northern Hemisphere vaccine.

9 APPENDIX

GLOSSARY

ABBREVIATIONS AND ACRONYMS

DHA Defense Health Agency

DHA-IPM Defense Health Agency-Interim Procedures Memorandum

DLA-TSM Defense Logistics Agency-Troop Support Medical

CONUS Continental United States

FDA U.S. Food and Drug Administration

IHD Immunization Healthcare Division

MTF Military Medical Treatment Facility

VIS Vaccine Information Statement

WHO World Health Organization

10 GLOSSARY