# DEPARTMENT OF THE ARMY UNITED STATES ARMY SPECIAL OPERATIONS COMMAND 2929 DESERT STORM DRIVE STOP A FORT BRAGG, NORTH CAROLINA 28310-9110

USASOC Supplement 1 to AR 40-562 Dated: 16 June 2022

# Medical Services Immunizations and Chemoprophylaxis for the Prevention of Infectious Diseases

**Summary.** This publication provides guidance for immunizations and chemoprophylaxis specific to Army Special Operations Forces (ARSOF) required for Soldier readiness in order to protect against infectious diseases in our operational environments worldwide. This supplement and Army regulation (AR) 40-562 dated 7 October 2013, provides guidance required for immunizations and chemoprophylaxis currently developed to prevent communicable infectious diseases and is not all inclusive of all prevention measures or for all infectious diseases. A supplement is an integral part of the regulation and must be filed with it. File supplements in front of the parent regulation.

**Applicability.** To all units and organizations of the United States Army Special Operations Command (USASOC); Active Component (AC) and Reserve Component (RC), inclusive of the National Guard; their assigned personnel and those attached for operational control (OPCON) to USASOC, or its subordinate units in support of operations. When used, ARSOF refers to all USASOC component subordinate commands and subordinate units, AC and RC.

**Purpose.** This supplement provides guidance, when used with AR 40-562, determined necessary to identify geographic requirements to protect Soldiers against endemic and epidemic disease threats encountered in operational environments worldwide. It delineates policy and procedure, establishes standards, and identifies responsibilities within USASOC to implement immunization and chemoprophylaxis programs to protect operating forces.

**Authority.** Authority for this supplement was reviewed and granted by the Office of the Surgeon General as the USA proponent for immunization and chemoprophylaxis required for the prevention of infectious diseases. Upon request of USASOC, the Defense Health Agency (DHA) Immunization Healthcare Branch consulted on review of this guidance.

**Proponent and exception authority.** The proponent for this supplement is the Headquarters, USASOC Deputy Chief of Staff (DCS), Surgeon (AOMD), 2929 Desert Storm Drive (Stop A), Fort Bragg, NC 28310-9110. The proponent has the authority to approve exceptions or waivers to this publication that are consistent with controlling law and regulations. Activities may request a waiver to this supplement by providing justification that includes a full analysis of the expected benefits and must include formal review by the activity's senior legal officer. All waiver requests will be endorsed by the commander or senior leader of the requesting activity and forwarded through their higher headquarters to the policy proponent.

**Supplementation.** Supplementation of this publication and establishment of command and local forms is prohibited without prior approval from Headquarters, USASOC DCS, Surgeon (AOMD).

Suggested Improvements. Users are invited to send comments and suggested improvements directly to the proponent.

**Distribution.** This publication is available in electronic media and is intended for A5 distribution. Paper copies will be provided for those not having access to e-media.

\*AR 40-562 dated 7 October 2013, is supplemented as follows, effective date signed and remains in effect until rescinded or superseded.

# Chapter 1. Introduction. Add the following:

- **1-4.***b.***(8).** USASOC commanders at all levels will ensure full compliance with immunization requirements. Unit immunization programs will be established to meet this standard.
- **1-4.***b***.(9).** Commanders will identify all personnel in their units who are not in compliance with immunization requirements. These personnel are to be considered non-deployable until a waiver is annotated in MEDPROS and supporting documentation for the waiver is recorded in the Service Electronic Health Record.
- (a) Personnel can have allergies to excipients in vaccines. Excipients are substances, other than the active ingredients, contained in very small amounts in the vaccines. Some excipients are added to a vaccine for a specific purpose. These include:
  - 1. Preservatives, to prevent contamination. For example, thimerosal.
  - 2. Adjuvants, to help stimulate a stronger immune response. For example, aluminum salts.
- 3. Stabilizers, to keep the vaccine potent during transportation and storage. For example, sugars or gelatin.
- (b) Others are residual trace amounts of materials that were used during the manufacturing process and removed. These can include:
- 1. Cell culture materials, used to grow the vaccine antigens. For example, egg protein, various culture media.
  - 2. Inactivating ingredients, used to kill viruses or inactivate toxins. For example, formaldehyde.
  - 3. Antibiotics, used to prevent contamination by bacteria. For example, neomycin.
- (c) Appendix B lists substances, other than active ingredients (antigens), shown in the manufacturers' package insert (PI) as being contained in the final formulation of each vaccine. Substances used in the manufacture of a vaccine but not listed as contained in the final product (culture media) can be found in each PI, but are not shown on this table. Each PI, which can be found on the Food and Drug Administration's (FDA's) website (see below) contains a description of that vaccine's manufacturing process, including the amount and purpose of each substance. In most PIs, this information is found in Section 11: "Description." Please refer to the PI for a complete list of ingredients or excipients. A table listing vaccine excipients and media by excipient is published by the Institute for Vaccine Safety at Johns Hopkins University and can be found at: <a href="http://www.vaccinesafety.edu/components-Excipients.htm">http://www.vaccinesafety.edu/components-Excipients.htm</a>.
- **1-4.b.(10).** Commanders at all levels will ensure that civilian employees under their authority who are traveling outside the continental United States (OCONUS) on official business under USASOC auspices receive appropriate immunizations to satisfy host nation requirements and to protect the health of the employees. This supplement, when used with AR 40-562, provides all known requirements for immunizations and chemoprophylaxis for USASOC military and civilian. Additional guidance is available in the Department of the Army (DA) Personnel Policy Guidance for Contingency Operations: https://home.army.mil/lewis-mcchord/application/files/4214/9063/4784/PPG 08-Aug-2013.pdf
- **1-4.b.(11).** Commanders will further ensure that the most current Geographic Combatant Command (GCC) guidance is followed for the administration of pre-deployment medical requirements. In cases where the PPG is not updated to reflect the most current requirements for a given area, the GCC guidance will prevail. In the event where guidance is unclear or contradictory, the DCS, Surgeon will review to reconcile to safeguard the health of the Force. https://www.health.mil/Military-Health-Topics/Health-Readiness/Immunization-Healthcare/Vaccine-Recommendations/Vaccine-Recommendations-by-AOR
- 1-4.c.(2)(e). Component subordinate commands and subordinate unit surgeons at all battalions and above will secure annually and retain a copy of the current edition of Health Information for International Travel, United States Public Health Service (USPHS). This publication is available at https://www.cdc.gov and https://health.mil/ vaccines.
- **1-4.c.(2)** (f). Component subordinate commands and subordinate unit surgeons at all battalions and above will secure annually and retain a copy of the current edition of General Best Practice Guidelines for

Immunization: Best Practice Guidance of the Advisory Committee on Immunization Practices (ACIP), U.S. Department of Health and Human Services, USPHS, United States Centers for Disease Control and Prevention (CDC). It is also available electronically from the web at https://www.cdc.gov or https:health.mil/vaccines. This publication is also published periodically as a "Recommendations and Reports" issue of Morbidity and Mortality Weekly Report, usually as number RR-1.

**1-4.c.(9).** The Office of the Deputy Chief of Staff (ODCS), Surgeon, USASOC will monitor immunization compliance throughout the Command via the Medical Protection System (MEDPROS) of the Medical Operational Data System (MODS).

# Chapter 2. Program Elements and Clinical Considerations. Add the following:

- **2-1.e(4).** *Immunization Intervals.* Under extreme circumstances when an impending deployment may present an obstacle to compliance with the approved dosing timetable, or when antibody levels are needed sooner than would normally be expected, consult with the DCS Surgeon, USASOC for an alternate dosing plan.
- **2-1.f(4).** Simultaneous immunizations. Most vaccines can be administered safely and effectively at different sites simultaneously. Those associated with more local or systemic reactions should be administered separately. Live injected vaccines that are not administered simultaneously should be separated by at least four weeks. Varicella and smallpox vaccine should never be administered on the same day and must be separated by four weeks. COVID-19 mRNA vaccines will be administered in accordance with the most current CDC COVID19 Immunization schedule (Attachment 1).
- **2-1.h(2).** Live virus vaccines can interfere with the immune response and cause a false-negative response to tuberculosis testing. Purified Protein Derivative skin test or Interferon-Gamma Release Assays (IGRAs), may be administered simultaneously with live virus vaccines but will be deferred for 28 days after any live virus vaccine. Immune globulin (IG) antibodies interfere with good live virus immune response, so live virus vaccines and IG shots should be separated by an interval. Because the interval varies based on different antibody-containing products and doses, refer to ACIP interval recommendations.
- **2-1.i.** All USASOC units will maintain year-round, ongoing immunization programs. Newly assigned USASOC personnel will be screened medically during unit in-processing to ensure compliance with AR 40-562 and this supplement. Personnel requiring immunizations will be identified via MEDPROS on a monthly basis to their commanders.
- **2-1.j.** The USASOC immunization compliance standard is not less than 90% for military personnel while in garrison and 100% for deployment. Minimum requirements for USASOC military personnel are listed in Appendix D, Table D-2 (added), provided at Attachment A of this supplement.
- **2-1.***j*(1). United States Army John F. Kennedy Special Warfare Center and School personnel have a generic ARSOF profile commensurate with their training mission. This profile, Attachment A, Appendix D, Table D-2 (added), is annotated as the "SWCS Profile".
- **2-1.***j*(**2**). All USASOC personnel, military or civilian, will have a current (within two years), documented negative HIV screening test prior to the administration of any live virus or bacterial vaccines. Females must be certain they are not pregnant (and willing to articulate it) or a pregnancy test will be done prior to administration of any live virus or bacterial vaccine. Personnel unable to meet these requirements will be considered ineligible for deployment until the requirement is met. Live virus vaccines include vaccinia (smallpox), yellow fever, intra-nasal influenza, Measles Mumps Rubella (MMR), and varicella (chickenpox). Oral typhoid vaccine is a live bacterial vaccine.

- **2-4.d.** Personnel with sensitivities or allergies preventing the administration of any required drugs (chemoprophylaxis) or vaccines will be evaluated by a medical officer (physician, physician assistant or nurse practitioner) for risk and deployability qualification prior to any departure and/or exposure to high-risk epidemic/endemic disease areas.
- **2-4.***d***(1).** Individuals identified with valid medical constraints against immunizations necessary for prevention of disease within their unit's geographical area of responsibility may be permanently ineligible for assignment/deployment to that area based on the discretion of the Component Subordinate Command or Component Subordinate Unit Commander and senior medical officer. Additional guidance is available in paragraph 2-10, Adverse Events and DHA-Immunization Healthcare Division can be consulted for questions or concerns on immunization allergies by calling 1-877-438-8222.
- **2-6.a(6).** *Medical exemptions.* USASOC personnel with temporary medical conditions (fever, pregnancy, others), in which vaccinations are contraindicated, may be granted temporary immunization exemptions by component subordinate commands and subordinate unit Surgeons. Such exemptions will be considered valid for either a maximum of 90 days, the duration of the exercise/deployment for which the vaccination was required or the duration of the temporary medical condition, whichever is longest. Temporary conditions with a known duration (such as, pregnancy) may be exempted for the length of the condition. Temporary exemptions from recurring requirements such as influenza vaccination are generally not appropriate. All Medical exemptions will be annotated with the appropriate code in MEDPROS.
- **2-6.***b***(4).** Administrative exemptions. Personnel requiring an administrative exemption are considered non-deployable until a waiver is annotated with the appropriate Administrative Exemption Code in MEDPROS.
- **2-6.c.** All USASOC personnel who receive permanent medical deferments or permanent waiver of any vaccination may be referred to the medical review board process based on the discretion of the component subordinate commands and subordinate unit Commander and medical officer.
- **2-7.4.** Certain countries in Africa require proof of yellow fever vaccine (stamp) on an International Certificate of Vaccination or prophylaxis (CDC 731 yellow shot card) for entry. The list of countries is available in the CDC yellow book: https://wwwnc.cdc.gov/travel/yellowbook/2020/travel-related-infectious-diseases/yellow-fever
- **2-10.** All adverse events following immunizations will be described in detail in the health record on a Standard Form (SF) 600 (Chronological Record of Medical Care) or SF 558 (Emergency Care and Treatment) and recorded in the individual's e-medical record (AHLTA or MHS GENESIS).
- **2-10.f(4).** Adverse reactions to vaccines (DHHS/ Vaccine Adverse Event Reporting (VAER) System) and chemoprophylaxis (FDA/MedWatch System) will also be reported to the Commander and Preventive Medicine Officer of the supporting installation Military Treatment Facility (MTF). A Serious Incident Report is required through the USASOC CCIR/SITREP system to the Chain of Command and the DCS Surgeon, USASOC to initiate follow-up. Anyone who experiences an adverse reaction to a vaccine should be referred to DHA-IHD for further evaluation and recommendations.

# Chapter 3. Personnel Subject to Immunizations. Add the following:

**3-2.a(1).** Specific requirements for USASOC personnel. Appendix D, Table D-3 (added), provided at Attachment B of this supplement, which lists the dosages and routes of administration for vaccines used by USASOC personnel. Vaccine doses and routes rarely change, and schedules may change occasionally, so it is the responsibility of the health care provider to ensure that immunizations and chemoprophylaxis are administered properly. USASOC personnel will not receive vaccines that are approved as Investigational New Drugs (IND) by the FDA, such as Rift Valley Fever vaccines, without prior coordination and approval by the DCS Surgeon, USASOC. Requests for use of IND vaccines must

be submitted in memorandum format and contain the quantity required and valid justification for approval. New FDA-approved vaccines that have potential benefit to USASOC personnel and are marketed after the release of this supplement are not to be used without approval by the DCS Surgeon, USASOC or by a Combatant Commander for use in that area.

- **3-2.a(2).** Appendix D, Table D-2 (added), (Attachment A) lists required vaccinations for USASOC military personnel.
- **3-2.e(6).** Geographic Immunization Requirements. The USASOC profile is the minimum requirement for deployment; if additional theater Combatant Commander requirements are stated for specific immunizations, that guidance must also be adhered to. The DCS Surgeon, USASOC may also determine additional area-specific immunization requirements for USASOC personnel, as needed due to disease threat conditions within an area of operations.
- **3-6.a(1)(a).** Family members. Family members of USASOC military personnel are not authorized and will not receive immunizations from USASOC medical assets outside the clinical environs of the local MTF. Family Members who are USASOC civilian employees may receive immunizations required by their duties as civilian employees, usually through authorized MTF clinics, or offered under community health promotion programs such as the annual influenza vaccine campaign, that are sanctioned by the serving regional medical command or MTF commander. This does not apply to contractor personnel, unless provided under their contract due to the nature of their duties, such as deployments.
- **3-3.c.** Other Federal civilian employees and their family members. Civilian employees deploying as members of Security Assistance Teams or Mobile Training Teams will receive immunizations required to satisfy host nation and theater requirements for Force Health protection from their local supporting MTF. Minimum vaccination requirements for these personnel may include those are listed in Appendix D, Table D-4 (Added), presented at Attachment C. Note: Additional requirements may be placed by the host nation, or the geographical theater Combatant Commander by their Surgeon, or the Army Surgeon General.

# Chapter 4. Specific Immunization Requirements for USASOC Personnel. Add the following:

- **4-5.e.** Hepatitis A. All USASOC personnel and select civilian employees will be immunized against Hepatitis A with Havrix ® or Vaqta ®. Two doses will be given intramuscularly (IM)at 0 and 6-12 months. Boosters are not required at this time. This vaccine takes approximately 15 days to provide protection. It is not intended for use immediately prior to departure to a risk area, but rather as a component vaccine in an ongoing immunization program. If the initial dose is given on deployment and immediate protection is desired, then IG or gamma globulin (GG) should be given concurrently.
- **4-5.f.** Twinrix ® (Hepatitis A Inactivated {Havrix ®} & Hepatitis B [Recombinant] vaccine {Energix B ®}). Primary immunization of adults consists of three doses, given on a 0, 1, and 6- month schedule. Each dose should be given IM in the deltoid region. Note that this is approved as a three-dose series. See package insert of this combination vaccine and/or www.health.mil/vaccines for detailed information on indications and usage, adverse reactions, etc.
- **4-5.***g.* Personnel documented to be immune to Hepatitis A should not be given IG or vaccine for protection from the disease. Sufficient documentation consists of one of the following:
- **4-5.***g***.**(1). Record of a series of two properly given doses of the licensed vaccine (after February 1995) on SF 601, PHS Form 731, Department of Defense Form 2766, MEDPROS or other official medical records.

- **4-5.***g***.**(2). Documentation in the medical record on an SF 600 overprint of Hepatitis A immune status provided by the investigator, the Walter Reed Institute of Research, for personnel who received the investigational vaccine (prior to March 1995) as part of the Hepatitis A vaccine trials.
- **4-5**.*g*.(3). Laboratory report of a hepatitis panel with immunity shown by presence of antibody to Hepatitis A
- **4-6.f.** Hepatitis B. All USASOC military personnel and select civilian employees (see Table D-3) will receive the Hepatitis B Vaccine (Energix B ®, Recombivax ®, or Heplisav-B ®). For, Energix B ® and Recombivax ®, three doses are required at 0, 1 and 6 months. Each dose should be given IM in the deltoid region Boosters are not required at this time. If an accelerated schedule is needed, the minimum interval between the first two doses is four weeks, and the minimum interval between the second and third doses is eight weeks. However, the first and third doses should be separated by no less than four months. Doses given at less than these minimum intervals should not be counted as part of the vaccination series. Personnel who previously received the 0.1 mL intradermal (ID) dosing regimen must receive a single 1.0 mL booster after three years. For Heplisav-B ®, two doses are required one month apart.
- **4-7.d.** *Influenza.* USASOC component subordinate commands and subordinate units will adhere and fully comply with the annual U.S. Army Medical Department Influenza Immunization Program guidance. All uniformed personnel will be immunized with the current seasonal influenza vaccine or pandemic vaccines as indicated. Immunizations will take place as soon as the vaccine becomes available each year. This applies to permanent party personnel, attachments, OPCON personnel, and students.
- **4-8.d.** Japanese Encephalitis (JE). Military personnel assigned, attached, or OPCON to USASOC units whose geographic area of responsibility includes a risk area for JE are required to be immunized against this disease. This is a standing readiness requirement. The primary immunization series for IXIARO® is two doses administered IM on Days 0 and 28. The immunization should be completed greater than 7 days before departure to ensure adequate immune response and access to medical care in the event of delayed adverse reactions. Affected units will immunize personnel on an ongoing basis. Other personnel traveling or deploying to risk areas are required to be immunized if they will be in a risk area for more than 29 days, or if they will spend any portion of time outside major urban areas. Risk areas are validated by the DCS, Surgeon, USASOC, and Combatant Commanders and updated as needed. They will include, at a minimum, areas determined by the CDC to be risk areas as published annually in Health Information for International Travel.
- **4-8.e.** A one-time booster dose is required if >11 months since series completion and if there is a continued risk for JE infection. No additional booster doses are required at this time.
- **4-8.f.** IXIARO® does contain protamine sulfate, a compound known to cause hypersensitivity reactions in some individuals. Individuals who show hypersensitivity reactions after receiving the first dose of the vaccine should not be given the second dose. IXIARO® should not be administered to individuals who have previously experienced a serious reaction to any JE vaccine.
- **4-9.c.(1).** Measles, Mumps and Rubella. IAW DOD policy persons born in 1957 or earlier are presumed to be immune through infection. Two lifetime doses of MMR vaccine are required for military personnel born after 1957; individuals should have positive serology or documentation of two doses as a record of vaccination. Vaccination or record of vaccination is required for civilian deployers.
- **4-10.f.** *Meningococcal Disease.* All USASOC military personnel are required to receive an initial dose of quadrivalent meningococcal A, C, Y, W-135 vaccine, and receive a booster dose every five years. Protective levels of antibody are usually achieved within 7-10 days of vaccination. Vaccination may be required for certain countries if the risk is assessed as being above the US baseline. Refer to GCC guidance for current geographic requirements or special circumstances.

- **4-10.g.** All USASOC personnel with anatomic or functional asplenia must maintain a current Meningococcal vaccination (serogroup B meningococcal (MenB) vaccine and serogroups A,C,Y, and W meningococcal vaccine (MenACYW), as well as immunizations against pneumococcal (for example: Pneumovax 23 ® vaccine and pneumococcal conjugate vaccine (PVC13)) and Haemophilus influenza type B (HiB) (such as, ActHIB conjugate vaccine) infections.
- **4-13.d.** Polio. Vaccination or record of vaccination of one adult dose of vaccine is required for USASOC personnel and civilian deployers. Combatant Command Surgeons or the DCS, Surgeon, USASOC, may impose additional requirements for booster doses based on the medical threat, such as an epidemic or emergence of a new strain in a specific area.
- **4-14.** Rabies. Selected USASOC personnel are at increased risk for rabies and may not have access to rapid medical response to an exposure during operations. Pre-exposure prophylaxis against rabies will be given to select personnel, prior to deployment, in the following risk groups:
- **4-14.***b***.(1).** Army Medical Department personnel, Veterinarians; assigned, attached, or OPCON to a Special Forces Group or Group element who have the potential to come into contact with animals in rabies endemic areas during the course of their duties.
- 4-14.b.(1)(a). Serologic testing confirms a rabies titer below 1:5.
- **4-14.b.(1)**(*b*). Personnel are scheduled to deploy to areas where rabies is highly endemic/enzootic. Reference the current issue of CDC Health Information for International Travelers.
- **4-14.b.(1)(c).** Personnel may have potential for frequent exposure to indigenous wildlife and domestic livestock and animals. (Normally limited to Veterinary Corps officers, veterinary technicians, and personnel assigned to participate directly in veterinary duties.
- **4-14.***b***.(2).** Personnel assigned, attached, or OPCON to an Operational Detachment, Alpha or Bravo (ODA/ODB) are considered high-risk to come into contact with animals in rabies endemic areas during the course of their operational deployments and engagement activities, and may not be immediately supported by deployed healthcare delivery systems to administer post-exposure rabies treatment.
- **4-14.***b***.**(3). Personnel assigned or attached to deployed battalion-level SF Operational Base (SFOB), Rangers, Civil Affairs, Military Information Support (Psychological) Operations units, and Special Operations Aviation units are considered to be in a medium-to-high risk who will also be administered the vaccine routinely IAW the established schedules for high-risk exposure groups.
- **4-14.***b***.(4).** Request and justification for administration of rabies vaccine by exception must be submitted in memorandum format to the DCS, Surgeon, USASOC, for authorization.
- **4-14.c.** The currently available rabies vaccines are licensed for IM use only, with injections given for pre-exposure protection (PrEP) on days 0, 7 with a titer test 1-3 years after PrEP or patient may elect to receive a booster dose 3 weeks 3 years after PrEP in lieu of a one-time titer check. And one booster 3 weeks 3 years. Anyone involved in the administration of rabies vaccine should refer to the package insert (dosage and administration) prior to administering the vaccine. Routine serologic testing every two years is indicated for personnel authorized rabies prophylaxis as indicated in 4.14.b.(1) (3). Special Operations Forces Surgeons are authorized to provide IM booster doses on a limited basis within their commands at two-year intervals. The criteria for administering booster doses are as follows, if:
- **4-14.** If shortages of the vaccine occur, additional requirements for the administration of pre-exposure vaccination may be implemented by the Office of the DCS, Surgeon, USASOC.
- **4-14.e.** For post-exposure prophylaxis, persons who have received the pre-exposure vaccine series should receive two 1mL doses of any approved rabies vaccine IM, one each on Days 0 and 3. Any

person not having a documented history of pre-exposure vaccine will receive the full course of post-exposure treatment which includes a single 20 IU/Kg body weight dose of human rabies immune globulin (RIG), at least one half infiltrated at the bite site if anatomically feasible) and the remainder IM on Day 0; and four 1 mL IM doses of any approved rabies vaccine, one each on Days 0, 3, 7 and 14).

- **4-14.f.** All animal bite situations will be recorded on DD Form 2341, Report of Animal Bite Potential Rabies Exposure, reported to the higher headquarters and supporting MTF in garrison or thru medical channels via Veterinary and Preventive Medicine (PM) area support to the operational theater headquarters and command and control element, info copied (CCIR/SITREP) to USASOC, while deployed.
- **4-15.** Tetanus, Diphtheria, and Acellular Pertussis (Tdap/Td). All USASOC military personnel will be immunized against tetanus, diphtheria and acellular pertussis. Administer booster doses of Td to all personnel every 10 years. A one-time dose of Tdap in place of a Td booster during adulthood is required, regardless of interval. Once an individual has received one dose of Tdap, all future boosters will be with Td or Tdap. In the treatment of contaminated wounds, if more than 10 years have elapsed, administer a booster shot.
- **4-16.** *Tick-Borne Encephalitis (TBE)*. Military personnel assigned, attached, or OPCON to USASOC units whose geographic area of responsibility includes a risk area for TBE are strongly encouraged to be immunized against this disease. TICOVAC® is an inactivated vaccination with a schedule of 3 primary doses, and 1 booster dose administered at ≥3 years after the primary series if there is ongoing risk of exposure. The vaccination is administered IM on Day 0, 14 days-3 months after 1st dose, and at 5-12 months after 2nd dose. The immunization should be completed greater than 7 days before departure to ensure adequate immune response and access to medical care in the event of delayed adverse reactions. Affected units will immunize personnel on an ongoing basis. Other personnel traveling or deploying to risk areas are strongly encouraged to be immunized if they will be in a risk area for more than 29 days, or if they will spend any portion of time outside major urban areas. Risk areas are validated by the DCS, Surgeon, USASOC, and Combatant Commanders and updated as needed. They will include, at a minimum, areas determined by the CDC to be risk areas as published annually in Health Information for International Travel.
- **4-17.***b***.(1).** *Typhoid.* All USASOC military personnel will be immunized against typhoid, and will receive boosters on the appropriate schedule. Boosters are required on different schedules, based on the LAST type received. As such, use MEDPROS entry, the Health Record (using SF 601) and the yellow shot record (CDC 731) to indicate clearly which vaccine was used, by brand, route, and dose.
- **4-17.***b*.(2). Oral live-attenuated (Vivotif Berna ®, Berna) Ty21a vaccine maybe used. This vaccine requires four oral doses to be given on alternating days, given with a cool beverage, about one hour before a meal. All doses should be completed at least one week before potential exposure. Mefloquine and antibiotics interfere with the antibody response to oral live-attenuated typhoid vaccine. Therefore, at least 24 hours will be allowed between any dose of oral live typhoid vaccine and any dose of these drugs. This vaccine provides protection for five years.
- **4-17.***b***.**(3). Injectable Vi capsular polysaccharide vaccine (Typhim Vi ®, Pasteur-Merieux Connaught) may also be used. This vaccine is given in a single 0.5 mL IM dose and provides protection for two years. Personnel must then be re-vaccinated.
- **4-17.***b***.(4).** It is acceptable to use either oral Ty21a or injectable Typhim Vi ® to revaccinate persons previously immunized with the other type of typhoid vaccine, keeping in mind the required frequency of the last type given.
- **4-18.e.** Varicella. USASOC personnel who do not have serological confirmation of infection are required to be given 0.5 mL SC of varicella vaccine at 0 and 1-2 months. Serological testing has been validated

cost-effective for those who have no record, memory or reliable history (first order Family Members) of infection. One can assume immunity to varicella for those born before 1980, with the exception of healthcare workers.

- **4-19.** Yellow Fever. Vaccination for USASOC Personnel consists of one lifetime SC injection of 0.5 mL of reconstituted vaccine.
- **4-20.** Cholera. Use of the Cholera vaccine is not recommended. The vaccine has limited efficacy after 90 days and concomitant anti-malarials may further impact vaccine efficacy. Prior to a unit administering the Cholera vaccine, a request for use will be routed to the DCS, Surgeon, USASOC for review and approval. The request will be in memorandum format and contain the quantity required, duration of event, and justification for use.

## Chapter 5. Chemoprophylactic Requirements. Add the following:

- **5-1.d.** Personal Protective Measures. Chemoprophylactic agent use does not negate the need for other preventive medicine measures, to include education and training, use of insect repellents, bed netting in insect-borne disease endemic areas, and proper wearing of clothing. These other measures must receive continuous command emphasis.
- **5-6.c.** USASOC. Anti-malarial chemoprophylaxis will be provided to all at-risk USASOC personnel. Specific risk areas will be determined by consulting the area specific command guidance; current edition of Health Information for International Travel, USPHS, CDC; DA Personnel Policy Guidance for OCO and malaria risk assessment guidance from the National Center for Medical Intelligence. Guidance maybe supplemented by the Command Surgeon, USASOC. The decision to place individuals on chemoprophylaxis and the drug of choice should be based on: specific travel itinerary (towns/cities/countries visited) and most prevalent type of malaria; duration of stay in an endemic/epidemic area for malaria; intensity of mosquito exposure(especially evening/night exposure); individual medical contraindications or precautions (such as: sun sensitivity, gastrointestinal distress, medical history); and compliance, especially in the post- deployment phase. The ODCS, Surgeon, USASOC or local installation Preventive Medicine authority should be consulted if there is a question on need for or type of chemoprophylaxis. G6PD status is required for deployment to an endemic and epidemic malaria area IAW with standards for administration of post-deployment prophylaxis.
- **5-6.c.(1).** Four malaria chemoprophylaxis agents are available currently for use by USASOC personnel: atovaquone-proguanil (Malarone), doxycycline, chloroquine and primaquine. Approved regimens are listed below. Departures from these regimens will be made only for medical reasons, and then approved by a medical officer. Any other variations require approval of the DCS Surgeon, USASOC. Mefloquine is no longer approved for use by USASOC personnel. For additional information on side effects of mefloquine and recognition of mefloquine toxicity refer to paragraphs 5.6.e.(5) and (6).
- **5-6.c.(2).** Regimen M. Atovaquone-proguanil (Malarone) is the first line prophylaxis for USASOC personnel based on its residual effect, low side effect profile and widespread effectiveness. Atovaquone-proguanil is also an option in areas of confirmed resistance to alternate medications.
- **5-6.c.(2)(a).** Pre-deployment. Administer/take orally an initial loading dose of one (1) tablet (250mg/100mg) on Days 0 and 1 before entering an endemic and epidemic malaria area. This is followed by a regimen of one (1) tablet (250mg/100mg) daily.
- **5-6.c.(2)(b).** During and post-deployment. One tablet (250mg/100mg) every day continuing for seven days after leaving a known area of exposure for endemic or epidemic malaria.
- **5-6.c.(3).** Regimen D: Doxycycline, 100mg, one tablet EVERY DAY beginning TWO (2) days prior to entering the endemic or epidemic malaria area and continuing through FOUR weeks after leaving the

area. This is an effective choice of chemoprophylaxis in P. vivax, malariae and ovale endemic areas but based on the lack of any residual effect, it is the second line choice in P. falciparum endemic areas. This regimen can be used:

- **5-6.***c.***(3)**(*a*). By aviation crew members or other personnel needing fine motor control, or personnel who cannot take atovaquone-proguanil in areas of confirmed chloroquine resistance.
- **5-6.c.(3)(b).** In areas of confirmed chloroquine resistance.
- **5-6.c.(3)(c).** In areas of confirmed mefloquine resistance.
- **5-6.c.(4).** Regimen C: Chloroquine alone. This will be used in areas without confirmed chloroquine resistance, as follows: one tablet (300mg) per week, beginning TWO (2) weeks prior to deployment, and continuing through FOUR (4) weeks after leaving the endemic or epidemic malaria area.
- **5-6.d.** *Primaquine.* All USASOC travelers to P. vivax, P. knowlesi and P. ovale malarious areas will ALSO take Primaquine, one pill (15mg) EVERY DAY for 14 continuous days after leaving an area known for endemic or epidemic malaria. It can be initiated immediately or soon after personnel depart the area of exposure, or during the last two weeks using Regimen C or D.
- **5-6.e.** All personnel taking malaria chemoprophylaxis will be advised of potential adverse effects:
- **5-6.e.(1).** Doxycycline may cause photosensitivity (exaggerated sunburn reaction). Appropriate sunburn precautions should be followed, to include sunscreen use. Doxycycline may also cause mild gastrointestinal disturbances, which can be minimized by taking the medication with a meal. Vaginal yeast infections may also occur in women on long-term doxycycline so Diflucan should be made available during deployment. Doxycycline is contraindicated in pregnancy and in children less than 8 years of age.
- **5-6.e.(2).** Primaquine may cause hemolysis in G6PD-deficient persons. DODI 6465.1 mandates that all personnel entering or on active duty in the Military Services shall be tested for the presence of Hemoglobin S and Erythrocyte glucose-6-phosphate dehydrogenase (G6PD) deficiency. Those personnel who already have been tested need not be retested. Required testing of those on active duty should be completed within 2 years. Most individuals with mild G6PD deficiency (defined as 10-20 percent of enzyme activity) tolerate primaquine without difficulty. Terminal prophylaxis using 45mg of primaquine orally, once per week for eight weeks is recommended in these individuals. Persons with a history of hemolytic anemia or favism and individuals of Mediterranean extraction may be more likely to have severe G6PD deficiency with less than 10 percent enzyme activity. If individuals are identified as having a significant G6PD deficiency, they are still deployable, but should not be given routine terminal primaquine chemoprophylaxis. Health education counseling should be provided to these individuals, informing them of the possibility that they may develop vivax and/or ovale malaria long after returning from endemic or epidemic malaria areas.
- **5-6.e.(3).** In the rare occurrence when exposure to chloroquine-resistant P. falciparum is unavoidable for a pregnant Soldier she may take chloroquine. Doxycycline and atovaquone- proguanil are contraindicated for malaria prophylaxis during pregnancy and lactation. Anti-malarials, except as noted with doxycycline and atovaquone-proguanil, can be safely given to breastfeeding mothers. A very small amount of the drugs are excreted in the breast milk, but do not harm the baby. Consequently, if the baby needs malaria prophylaxis, he must be given his own dose.
- **5-6.e.(4).** All military personnel must be tested for G6PD before receiving Primaquine for post- exposure prophylaxis.
- **5-6.e.(5).** Mefloquine is no longer approved for use by personnel assigned to USASOC units. Acknowledged side effects can last for months to years or become permanent. Mefloquine has been associated with serious adverse reactions (for example, psychoses or seizures) at prophylactic doses;

these reactions are more frequent with the higher doses used in treatment. In addition, when used for prophylaxis, mefloquine may cause other psychiatric symptoms such as anxiety, paranoia, depression, and hallucinations. Rarely, these symptoms have been reported to continue after mefloquine has been stopped. Rare cases of suicidal ideation and suicide have been reported.

**5-6.e.(6).** Warnings regarding the potential side effects were recently strengthened. For personnel who have used mefloquine previously, be aware that neurologic and psychiatric side effects can occur at any time during drug use and can last for months to years after the drug is stopped or become permanent. Patients, caregivers, and health care professionals should watch for these side effects. Mefloquine may cause dizziness, balance problems, and ringing

in the ears. These symptoms can occur at any time during use and can last for months to years after the drug is stopped or can be permanent.

## Chapter 6. Biological Warfare Defense. Add the following:

- **6-2.f.** Anthrax. Deploying units will align with the requirements of the supported GCC regarding anthrax vaccination. Rapid response forces and units with a CBRN response mission will receive the anthrax vaccination. For this supplement, rapid response forces are defined as those with a predesignated deployment sequence too short to allow for vaccination, and CBRN response units are those with specified CBRN tasks, such as a Chemical Decontamination Detachment (CDD) or Chemical Reconnaissance Detachment (CRD).
- **6-2.g.** Smallpox. Deploying units will align with the requirements of the supported GCC regarding smallpox vaccination. Rapid response forces and units with a CBRN response mission will receive the smallpox vaccination IAW DOD Smallpox Vaccination Program (SVP) guidance. For this supplement, rapid response forces are defined as those with a predesignated deployment sequence too short to allow for vaccination, and CBRN response units are those with specified CBRN tasks, such as a CDD or CRD.

# Appendix A. Section II, Related Publications. Add the following:

AR 40-501, Standards of Medical Fitness.

Army Anthrax Vaccine Immunization Program Plan, ALARACT 024/2007.

Army Smallpox Preparedness and Vaccination Program Implementation Plan.

USASOC Regulation 40-7, Medical Readiness Standards and Reporting.

# Glossary. Section I, Abbreviations. Add the following:

#### **AVIP**

Anthrax Vaccine Immunization Program Plan

#### **MEDPROS**

Medical Protection System

#### **MODS**

Military Occupational Data System

#### **SVP**

Smallpox Vaccination Plan

### Attachment A

# Appendix D

# Table D-2 Vaccinations for USASOC Military Personnel. Add the following:

# D-2. Required Vaccinations for USASOC Military Personnel

Immunization requirements apply to all USASOC military personnel, active and reserve, assigned, attached, or OPCON to USASOC or any of its subordinate units. Modifications to the profile must be approved by the DCS, Surgeon, USASOC.

Table D-2.			
	r USASOC Military Personnel.		
Vaccine	Requirement	Comment	
Anthrax	IAW GCC guidance, required for rapid response and CBRN response units	see para 6-2f, this supplement	
Hepatitis A	Initial series, or serologic testing required		
Hepatitis B	Initial series, or serologic testing required		
Influenza	Annual		
Japanese Encephalitis	Determined by geographic area	see paragraph 4-8.d, this supplement	
MMR**	Two documented vaccinations or serologic titer testing required		
Meningococcus ACYW	Initial dose. Booster every 5 years.		
Polio	One adult dose required.		
Rabies	All ARSOF, less approved exceptions	see para 4-14, this supplement	
Smallpox**	IAW GCC guidance, required for rapid response and CBRN response units	see para 6-2g, this supplement	
Tdap/Td	One-time adulthood dose Tdap; 10 years boosters with Tdap or Td		
Tick-Borne Encephaliti s	IAW GCC guidance, required for rapid response and CRRN response units.	See para 4-16, this supplement	
Typhoid VI or Oral**	Initial shot/series. Revaccinate every two years if Soldier had injectable vaccine, or every five years if oral vaccine.		
Varicella**	Required if no documented serologic evidence of immunity or documented application 2 lifetime doses		
Yellow Fever**	One lifetime dose required		

vp - Vaccination Profile (requirements)

<sup>\*</sup>Oral form is a live vaccine

<sup>\*\*</sup>Live vaccine

# **Attachment B**

# **Appendix D**

# Table D-3 Vaccine Dosages and Routes. Add the following:

# D-3. Vaccine dosages and routes for USASOC personnel.

Vaccine	Initial Dosage/Route	Booster Dose
Anthrax	0.5 mL IM at 0 and 4 weeks, and at 6, 12, and 18 months	0.5 mL IM annually
Hepatitis A	1 mL IM at 0 and 6-12 months.	none currently required
Hepatitis B	1 mL IM at 0, 1 and 6 months.	none currently required
Influenza	One dose annually: ideally administered in months of October through December	annual re-immunization administered IAW influenza threat
Japanese Encephalitis	0.5 mL IM at 0 and 28 days.	one time booster if greater than 11 months since series complete
MMR	0.5 mL SC at 0 and 30 days or documentation of positive serology.	none currently required.
Meningococcus	0.5 mL IM single dose	0.5 mL IM every 5 yrs. minimum
Polio	0.5 mL IM, one time adult dose.	Determined and directed by the COCOM Surgeon, or the DCS, Surgeon, USASOC.
Rabies	1mL IM at 0, 7.	see para 4-14, this supplement
Smallpox	0.0025 mL administered as 15 percutaneous jabs. Administered only by trained qualified personnel.	every 10 years
Tetanus-Diptheria Toxoid or Tdap	If no prior immunization is documented - 0.5 mL IM at 0, 2, and 8-14 months. If documented, but there is no evidence of tetanus shot within 10 years, 0.5 mL IM.	0.5 mL IM Td every 10 years. Do not give more frequently except for prophylaxis after severe wounds.
Tick-Borne Encephalitis	Three shot series of 0.5mL IM at 0, (14 days-3 months) after first vaccination, (5-12 months) after 2 <sup>nd</sup> vaccination.	Single Booster dose (fourth dose) may be given ≥3 yrs after primary series if there is ongoing risk of exposure.
Typhoid (two types of typhoid vaccine are authorized)	0.5 mL IM (injectable vaccine) or one capsule taken on alternate days (day 0,2,4,6) (oral vaccine)	Injectable: 0.5 mL IM every 2 years, Oral: 4 capsules every 5 years
Varicella	0.5 mL SC at 0 and 1-2 months or documentation of positive serology.	none currently required
Yellow Fever	Fever 0.5 mL SC none currently require	

14

### **Attachment C**

# Appendix D

Table D-4 Required Vaccinations for USASOC Civilian Federal Employees Traveling OCONUS. Add the following:

# D-4. Required Vaccinations.

Required vaccinations for civilian federal employees traveling outside the U.S. under the auspices or authority of USASOC. Geographic risk areas are defined by Combatant Commanders or the ODCS, Surgeon, USASOC.

tions for USASOC Civilian Federal			
Requirement	Comment		
Specific logistics workers, and as determined, high-risk groups	check with current guidance		
Initial series, or serologic testing required.			
Initial series, or serologic testing required.			
Annually			
Determined by geographic area.	See paragraph 4-8. <i>d</i> . of this supplement		
One dose as an adult required, if born after 1956.			
By geographic area. Booster every 5 years if returning to endemic area.	Booster at 5-year mark when going to highly endemic area Serologiv testing required		
One dose as an adult required.			
Determined by geographic location and administered only by trained qualified personnel.  See paragraph 4-15 of AF 562.			
One time adulthood dose Tdap; Td every 10 years.			
Determined by geographic location			
Initial series. Revaccinate every two years if individual had injectable vaccine, or every five years if had oral vaccine.			
0.5 mL SC at 0 and 1-2 months or documentation of positive serology.			
By geographic area.  One-lifetime dose			
	Requirement  Specific logistics workers, and as determined, high-risk groups  Initial series, or serologic testing required.  Initial series, or serologic testing required.  Annually  Determined by geographic area.  One dose as an adult required, if born after 1956.  By geographic area. Booster every 5 years if returning to endemic area.  One dose as an adult required.  Determined by geographic location and administered only by trained qualified personnel.  One time adulthood dose Tdap; Td every 10 years.  Determined by geographic location  Initial series. Revaccinate every two years if individual had injectable vaccine, or every five years if had oral vaccine.  0.5 mL SC at 0 and 1-2 months or documentation of positive serology.		

#### Attachment D

## Appendix E

#### Rabies Information Paper. Add the following:

#### E-1. Rabies Information Paper

Document from Military Health System Website--- Rabies Information Paper: <a href="https://www.health.mil/Military-Health-Topics/Health-Readiness/Immunization-Healthcare/Vaccine-Preventable-Diseases/Rabies">https://www.health.mil/Military-Health-Topics/Health-Readiness/Immunization-Healthcare/Vaccine-Preventable-Diseases/Rabies</a>

#### INFORMATION PAPER

DHA-IHD 18 May 2022

SUBJECT: Rabies Disease and Rabies Vaccines

- Purpose. To describe rabies disease and the vaccines that prevent it.
- Facts.
  - Microbiology. Rabies is a zoonotic disease (transmitted from animals to humans) caused by viruses in the family Rhabdoviridae, genus Lyssavirus.
  - b. Epidemiology. Lyssaviruses have been found on all continents except Antarctica. Rabies is the most common lyssavirus infection in humans. Transmission of rabies virus occurs when saliva or nerve tissue from an infected mammal is introduced into a person or another animal, generally through a bite or contact with mucous membranes. Rabies virus variants exist in dogs and wildlife, such as bats, foxes, jackals, mongooses, raccoons, and skunks. Dogs are the main reservoir in developing countries, and canine rabies virus variant (CRVV) remains enzootic (endemic in certain animals) in many areas of the world, including Africa, Asia, and Central and South America. Bat bites anywhere in the world are a cause of concern and an indication to consider prophylaxis. Accurate information about global rabies occurrence is difficult to find. It is estimated that the rabies exposure rate is 16-200 of every 100,000 travelers, with 59,000 human deaths each year.
  - c. Disease. After infection, the incubation period is variable, but is often several weeks to several months. Early symptoms of rabies in people are similar to that of many other illnesses: pain and numbness at the bite site, fever, headache, and general weakness or discomfort. As the disease progresses, more specific neurologic symptoms appear, such as anxiety, difficulty swallowing, fear of water (hydrophobia), paralysis, delirium, and convulsions, followed rapidly by coma and death. Once symptoms of rabies appear, the disease is nearly always fatal.
  - d. Vaccines. Imovax® (Sanofi Pasteur) and RabAvert® (GlaxoSmithKline) are the only two rabies vaccines currently FDA-licensed for use in the United States. Both vaccines can be used for pre-exposure (PrEP) or post-exposure (PEP) prophylaxis.

Figure E-1. Rabies Information Paper.

- Imovax® is a human diploid cell vaccine (HDCV) derived from a human cell line, and contains human albumin, neomycin, phenol, and trace amounts of beta-propiolactone.
- (2) RabAvert® is a purified chick embryo cell (PCEC) vaccine derived from chicken fibroblasts, and contains bovine gelatin, human albumin, potassium glutamate, sodium EDTA, chicken protein (ovalbumin), neomycin, chlortetracycline, and amphotericin B.

#### e. Contraindications.

- PrEP: contraindicated in people with a history of a serious reaction (e.g., anaphylaxis) after vaccination or to any vaccine component, to include neomycin.
- (2) PEP: as rabies is virtually 100% fatal once symptoms appear, there is no contraindication to PEP. Patients with a history of hypersensitivity who require PEP may be given antihistamines and vaccinated under observation by an Allergist. Equipment and medications to manage a medical emergency should be readily available.
- (3) For information on vaccine components, refer to the <u>manufacturer's package insert or http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/b/excipient-table-2.pdf.</u>

#### Precautions.

- Moderate or severe acute illness with or without fever.
- (2) Syncope (fainting) can occur in association with administration of injectable vaccines. Have procedures in place to avoid a falling injury (e.g. observation after administration) and to restore cerebral perfusion following syncope.
- g. Special Populations: These individuals should discuss vaccine receipt timing and medication management with their primary or specialty healthcare provider(s).
  - (1) Pregnancy: There is no evidence of adverse fetal effects from vaccinating pregnant women with inactivated virus, bacterial vaccines, or toxoids, and a growing body of data demonstrate the safety of such use.

Figure E-1. Rabies Information Paper (continued).

- (2) Lactation: Inactivated vaccines have not been shown to affect the safety of breastfeeding for women or their infants.
- (3) Infants and children: although limited safety data are available, PrEP and PEP may be administered if patients meet current clinical criteria. Administer indicated product(s) using the same dosing and timing as for other high-risk groups.
- (4) Immunocompromised: In persons with <u>primary or secondary immunodeficiencies</u>, delay PrEP vaccination (when possible) until a temporary immunocompromising condition has resolved or immunosuppressive medications can be withheld. Do not delay PEP treatment for these patients.

#### Immunization.

- (1) PrEP vaccination with Imovax® or RabAvert® for persons in certain risk categories consists of a 2-dose primary series given intramuscularly (IM) at 0 and 7 days. (See Table 1). Both vaccines are supplied by the manufacturer in a pre-packaged single-dose (1mL) kit. Booster doses are indicated based on risk category and titer level. For Risk Category 3, patients may elect to receive a booster dose between 21 days and 3 years after the primary series in lieu of a one-time titer check.
- (2) PEP vaccination with Imovax® or RabAvert® consists of a multipledose series with the addition of rabies immune globulin (RIG) for patients who did not receive PrEP. (See Table 2.)
- (3) Do not start PrEP if the series cannot be completed before travel: limited data exists to guide PEP after a partial immunization series.
- i. Adverse Events. The most common adverse reactions after any vaccination are fever and injection site complaints such as soreness, warmth, redness, swelling, or induration. Mild systemic reactions such as headache, nausea, muscle aches, or dizziness may also occur. Serious reactions are very rare. Approximately 6% of people who receive HDCV booster vaccinations may experience systemic reactions characterized by urticaria (rash), pruritus (itching), and malaise. The likelihood of these reactions may be less with PCEC. Do not interrupt or discontinue PEP because of local or mild systemic reactions: consider switching to the alternative vaccine for the remainder of the series. Clinically-significant adverse events following vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS), even if a causal relation to vaccine is not certain. Reports can be submitted to VAERS online at

Figure E-1. Rabies Information Paper (continued).

https://vaers.hhs.gov. Information about VAERS is also available by telephone at (800) 822-7967.

 DOD Policy. Administer rabies vaccines to DOD beneficiaries who are in a high-risk category per current ACIP recommendations, local Public Health guidance for disease outbreak prevention, or IAW Service-specific guidelines.

#### References.

- Centers for Disease Control and Prevention. (2020). CDC Yellow Book 2020: Health Information for International Travel. Oxford University Press. https://wwwnc.cdc.gov/travel/page/yellowbook-home-2020.
- b. Centers for Disease Control and Prevention. (2021). Epidemiology and Prevention of Vaccine-Preventable Diseases (14th ed.). Public Health Foundation. <a href="https://www.cdc.gov/vaccines/pubs/pinkbook/index.html">https://www.cdc.gov/vaccines/pubs/pinkbook/index.html</a>.
- c. Rao, A. K., Briggs, D., Moore, S. M., Whitehill, F., Campos-Outcalt, D., Morgan, R. L., Wallace, R. M., Romero, J. R., Bahta, L., Frey, S. E., & Blanton, J. D. (2022). Use of a Modified Preexposure Prophylaxis Vaccination Schedule to Prevent Human Rabies: Recommendations of the Advisory Committee on Immunization Practices - United States, 2022. MMWR. Morbidity and Mortality Weekly Report, 71(18), 619–627. https://doi.org/10.15585/mmwr.mm7118a2.

South Atlantic Region Vaccine Safety Hub Approved: Deputy Chief, Immunization Healthcare Division (877) 438-8222 (DSN 761-4245), option 1

Figure E-1. Rabies Information Paper (continued).

Table 1. Ra	Table 1. Rabies Pre-Exposure Prophylaxis (PrEP) Recommendations				
Risk Category	Typical population*	Primary Series (2 doses)	Titer / Booster (1 dose)		
Elevated risk for unrecognized† or recognized†† exposures, including unusual or high- risk exposures	Work with live rabies virus in research or vaccine production facilities; perform rabies testing in diagnostic laboratories	Vaccine on days 0 and 7	Titer: every 6 months  Booster: if titer < 0.5 IU/mL <sup>§</sup> I		
2. Elevated risk for unrecognized† or recognized†† exposures	Frequently handle or have contact with bats; enter high-density bat environments; perform animal necropsies (e.g., biologists who frequently enter bat roosts or who collect suspected rabies samples)	Vaccine on days 0 and 7	Titer: every 2 years  Booster: if titer < 0.5 IU/mL <sup>§ </sup>		
3. Elevated risk for recognized†† exposures, sustained risk¶	Interact with animals that could be rabid* (e.g., veterinarians, vet techs, animal control officers; wildlife biologists, rehabilitators, and trappers); spelunkers Travelers with increased risk for exposure to potentially rabid animals (particularly dogs) who might not have prompt access to safe PEP (e.g., rural area, far from closest PEP clinic)	Vaccine on days 0 and 7	Titer: once, 1–3 years after PrEP  Booster: if titer < 0.5 IU/mL <sup>§I</sup> OR  These patients may elect to receive a booster dose 3 weeks-3 years after PrEP in lieu of a one-time titer check. I		
4. Elevated risk for recognized <sup>††</sup> exposures, risk not sustained <sup>¶</sup>	Same as Risk Category 3, but risk duration ≤ 3 years (e.g., short-term animal care, no expected high-risk travel > 3 years after PrEP)	Vaccine on days 0 and 7	None		
5. Low risk for exposure	Typical person living in the United States	None	None		

Adapted from CDC MMWR 71(18), 619-627 (08 May 2022): https://www.cdc.gov/mmwr/volumes/71/wr/mm7118a2.htm.

Abbreviations: IU = international units; PEP = post-exposure prophylaxis

Figure E-1. Rabies Information Paper (continued).

<sup>\*</sup> Nature of exposure is the most important variable to consider when determining risk category. Examples provided are only a guide; categorizations should be done on a case-by-case basis. If an individual falls into more than one category, follow guidance for the highest-risk category. Risk categories may change over an individual's lifetime. † Example: a small scratch during an inconspicuous personal protective equipment breach while testing neural tissue from a rabid animal or conducting studies on bats in the field, etc.

<sup>††</sup> Noticed because the exposure is unusual (e.g., contact with a bat, splash with contaminated fluids) or painful (e.g., bite or scratch from a raccoon).

<sup>§</sup> Give a booster when rabies antibody titers are < 0.5 IU/mL. For immunocompetent patients, titers to verify booster response are not needed. For immunocompromised patients, verify response with a titer ≥ 1 week (ideally, 2–4 weeks) after every booster dose.

DHA-IHB Information Paper Subject: Rabies Disease and Rabies Vaccines

¶ Elevated risk for rabies > 3 years after the completion of the primary rabies PrEP series.

Table 2. Rabies Post-Exposure Prophylaxis (PEP) Recommendations*					
Status	Product	Dose	# of Doses	Schedule (Days)†	Route
Not previously vaccinated			1	0	Infiltrated at bite site (if possible); remainder IM
	HDCV or PCEC	1.0 mL	4 or 5‡	0, 3, 7, 14 (and 28) <sup>‡</sup>	IM
Previously vaccinated <sup>§, ¶</sup>	HDCV or PCEC	1.0 mL	2	0, 3	IM

Adapted from CDC Yellow Book (2020): <a href="https://wwwnc.cdc.gov/travel/yellowbook/2020/travel-related-infectious-diseases/rabies">https://wwwnc.cdc.gov/travel/yellowbook/2020/travel-related-infectious-diseases/rabies</a>.

Abbreviations: RIG: rabies immune globulin; IM: intramuscular; HDCV: human diploid cell vaccine; PCEC: purified chick embryo cell.

Figure E-1. Rabies Information Paper (continued).

<sup>#</sup> Rabies virus is unlikely to persist outside a deceased animal's body for an extended time. Risk of transmission to persons handling animal products (e.g., hunters or taxidermists) is unknown but presumed to be low (risk category 5); direct skin contact with saliva or neural tissue of mammals should be avoided regardless of profession or activity.

| Titer after recommended booster dose(s) not indicated unless patient has altered immunity.

<sup>\*</sup> All PEP should begin with immediate, thorough wound cleansing with soap and water, povidone iodine, or other substances with virucidal activity.

<sup>†</sup> For most minor schedule deviations (delays of a few days), resume vaccination as though the traveler were on schedule. If substantial deviations occur, assess immune response with a titer 7–14 days after the final dose is administered.

<sup>‡</sup> Five vaccine doses for the immunocompromised patient. The first 4 vaccine doses are given on the same schedule as for an immunocompetent patient, and the fifth dose is given on day 28. Verify immune response with a titer ≥ 1 week (ideally, 2–4 weeks) after the final dose is administered. For more information, see <a href="https://www.cdc.gov/mmwr/preview/mmwr/tml/rr5902a1.htm">www.cdc.gov/mmwr/preview/mmwr/tml/rr5902a1.htm</a>.

<sup>§</sup> Prior PrEP or PEP immunization with HDCV or PCEC, or previously received any other type of rabies vaccine and have a subsequent documented protective titer response (> 0.5 IU/mL).

<sup>¶</sup> RIG not recommended.

#### Attachment E

# Appendix F

CDC COVID-19 Vaccine Interim COVID-19 Immunization Schedule for Ages 5 Years and Older. Add the following:

#### F-1. CDC COVID-19 Vaccine Interim COVID-19 Immunization Schedule for Ages 5 Years and Older

Document from CDC website---Vaccine Excipient Summary:

https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/b/excipient-table-2.pdf



COVID-19 vaccines are recommended for persons 5 years of age and older within the scope of the Emergency Use Authorization or Biologics License Application for the vaccine. The table below provides guidance for COVID-19 vaccination schedules based on age and medical condition. Considerations when scheduling vaccine doses include:

- Administer the appropriate vaccine product based on the recipient's age and the vaccine product's age indications.
- COVID-19 vaccines may be administered on the same day as other vaccines.
- Doses administered up to 4 days before the minimum interval (4-day grace period) are considered valid. Doses administered at any time after the recommended interval are valid.

Detailed information can be found in CDC's Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States (link provided).

Table 1. Immunization schedule for persons 5 years of age and older

Туре	Recipient	Product		ARE NOT Moderately or imunocompromised	Persons Who ARE Moderately or Severely Immunocompromised	
	Age		Primary Series*	Booster Dose†‡	Primary Series*	Booster Dose†‡
	5–11 years	Pfizer-BioNTech Ages: 5–11 years Orange cap	2 doses. Separate: Dose 1 and 2 by at least 3 weeks.	Booster dose 1: At least 5 months after Dose 2 Booster dose 2: N/A	3 doses. Separate: Dose 1 and 2 by at least 3 weeks. Dose 2 and 3 by at least 4 weeks.	Booster dose 1: At least 3 months after Dose 2 Booster dose 2: N/A
	12–17 years	Pfizer-BioNTech Ages: 12 years and older Gray cap or Purple cap	2 doses. Separate: Dose 1 and 2 by at least 3 - 8 weeks. <sup>5</sup>	Booster dose 1: At least 5 months after Dose 2 Booster dose 2: N/A	3 doses. Separate: Dose 1 and 2 by at least 3 weeks. Dose 2 and 3 by at least 4 weeks.	Booster dose 1: At least 3 months after the previous dose Booster dose 2: At least 4 months after booster dose 1
mKNA vaccine	nRNA accine 18 years and older	Pfizer-BioNTech Ages: 12 years and older Gray cap or Purple cap	2 doses. Separate: Dose 1 and 2 by at least 3 - 8 weeks. <sup>5</sup>	Booster dose 1: At least 5 months after Dose 2 Booster dose 2: At least 4 months after booster dose 1 for persons ages 50 years and older	3 doses. Separate: Dose 1 and 2 by at least 3 weeks. Dose 2 and 3 by at least 4 weeks.	Booster dose 1: At least 3 months after the previous dose Booster dose 2: At least 4 months after booster dose 1
		and older  2 doses. Separate: Dose 1 and 2 by at least 4 - 8 weeks.	Booster dose 1: At least 5 months after Dose 2 Booster dose 2: At least 4 months after booster dose 1 for persons ages 50 years and older	3 doses. Separate: Dose 1 and 2 by at least 4 weeks. Dose 2 and 3 by at least 4 weeks.	Booster dose 1: At least 3 months after the previous dose Booster dose 2: At least 4 months after booster dose 1	
Viral vector vaccine	18 years and older	Janssen <sup>¶</sup>	1 dose	Booster dose 1: At least 2 months after the primary series dose Booster dose 2**: At least 4 months after previous dose for persons 50 years of age and older. (mRNA vaccine only)	2 doses. Separate: Dose 1 and 2 <sup>††</sup> by at least 28 days	Booster dose 1: At least 2 months after the previous dose Booster dose 2: At least 4 months after the previous dose (mRNA vaccine only)

05/26/2022 CS321629.AV

Figure F-1. CDC COVID-19 Vaccine Interim COVID-19 Immunization Schedule for Ages 5 Years and Older.

<sup>\*</sup>Complete the primary series using the same product. Every effort should be made to determine which vaccine product was received as the first dose. If the vaccine product previously administered cannot be determined or is no longer available, any age-appropriate mRNA COVID-19 vaccine product may be administered at least 28 days after the first dose. If A different age-appropriate COVID-19 vaccine product than the primary series may be administered for the booster dose. An mRNA COVID-19 vaccine is preferred. Persons with a recent SARS-CoV2 infection may consider delaying a primary series or booster dose by 3 months from symptom onset or positive test iff infection was asymptomatic). If A 8-week interval may be optimal for some people, including makes 12-29 years of age because of the small risk of myocardistic associated with mRNA COVID-19 vaccines as generally as interval longer than 3 or at weeks (depending on the product).

I mRNA COVID-19 vaccines are preferred over the Janssen COVID-19 Vaccine for all vaccine-eligible people. However, the Janssen COVID-19 Vaccine may be offered in some situations. "People ages 18-49 years: Those who received Janssen COVID-19 Vaccine as both their primary series dose and booster dose may receive a second booster dose using an mRNA COVID-19 Vaccine or 19. Vaccine or 19.





Table 2. COVID-19 Vaccine Products Summary

Tuble 2: COVID-191	able 2. COVID-19 vaccine Products Summary					
Product	Age Indications	Diluent	Dosage (amount injected)			
Type: mRNA vaccine	Type: mRNA vaccine					
Pfizer-BioNTech		1.3 mL	Primary doses 1, 2 and 3*	0.2 mL		
Orange cap and bordered label	5 - 11 years	(normal saline, preservative-free)	Booster dose	0.2 mL		
Pfizer-BioNTech		NONE	Primary doses 1, 2 and 3*	0.3 mL		
Gray cap and bordered label	12 years and older		Booster dose	0.3 mL		
Pfizer-BioNTech	12 years and older	1.8 mL 0.9% sodium chloride	Primary doses 1, 2 and 3*	0.3 mL		
Purple cap	12 years and older	(normal saline, preservative-free)	Booster dose	0.3 mL		
Moderna 18 years and older	19 years and older	NONE	Primary doses 1, 2 and 3*	0.5 mL		
	NONE	Booster dose	0.25 mL			

Product	Age Indications	Diluent	Dosage (amo	ount injected)	
Type:Viral Vector Vaccine					
Janssen <sup>†</sup> Blue Cap			Dose 1	0.5 mL	
	18 years and older	NONE	Dose 2*	Dose 2 Administer mRNA vaccine only ‡	
			Booster dose <sup>†</sup>	0.5 mL	

#### **CDC Resources**

CDC COVID-19 Vaccine clinical training and materials at: <a href="www.cdc.gov/vaccines/covid-19/info-by-product/index.html">www.cdc.gov/vaccines/covid-19/info-by-product/index.html</a> CDC Interim clinical considerations for the Use of COVID-19 Vaccines Currently Approved or Authorized in the United States at www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#primary-series

05/26/2022 CS321629.AV 2

Figure F-1. CDC COVID-19 Vaccine Interim COVID-19 Immunization Schedule for Ages 5 Years and Older (continued).

<sup>\*</sup> For most people COVID-19 vaccination is a 2-dose primary series. A 3rd primary series dose is recommended for moderately or severely immunocompromised persons only.
† mRNA vaccines are preferred.
† Additional dose for moderate or severely immunocompromised persons only. Administer Moderna or Pfizer-BioNTech COVID-19 Vaccine ONLY. Administer the correct product based on the recipient's age. If administering Moderna COVID-19 Vaccine, administer 0.5 mL.

#### Attachment F

# Appendix G Vaccine Excipient

#### G-1. Vaccine Excipient

From Johns Hopkins Institute for Health Safety's complete listing of Excipients: https://www.vaccinesafety.edu/components-Excipients.htm

#### Vaccine Excipient Summary

Excipients Included in U.S. Vaccines, by Vaccine

In addition to weakened or killed disease antigens (such as weakened, killed, or parts of viruses or bacteria), vaccines contain very small amounts of other ingredients – excipients.

Some excipients are added to a vaccine for a specific purpose. These include:

- · Preservatives, to prevent contamination. For example, thimerosal.
- · Adjuvants, to help stimulate a stronger immune response. For example, aluminum salts.
- . Stabilizers, to keep the vaccine potent during transportation and storage. For example, sugars or gelatin.

Others are residual trace amounts of materials that were used during the manufacturing process and removed. These can include:

- · Cell culture materials, used to grow the vaccine antigens. For example, egg protein, various culture media.
- Inactivating Ingredients, used to kill viruses or inactivate toxins. For example, formaldehyde.
- . Antibiotics, used to prevent contamination by bacteria. For example, neomycin.

The following table lists substances, other than active ingredients (i.e., antigens), shown in the manufacturers' package insert (PI) as being contained in the final formulation of each vaccine. Substances used in the manufacture of a vaccine but not listed as contained in the final product (e.g., culture media) can be found in each PI, but are not shown on this table. Each PI, which can be found on the FDA's website (see below) contains a description of that vaccine's manufacturing process, including the amount and purpose of each substance. In most PIs, this information is found in Section 11: "Description." Please refer to the PI for a complete list of ingredients or excipients. A table listing vaccine excipients and media by excipient is published by the Institute for Vaccine Safety at Johns Hopkins University, and can be found at <a href="http://www.vaccinesafety.edu/components-Excipients.htm">http://www.vaccinesafety.edu/components-Excipients.htm</a>.

Figure G-1. Vaccine Excipient.

# Vaccine Excipient Table

Vaccine (Trade Name)	Package Insert Date	Contains <sup>(a)</sup>	
Adenovirus	10/2019	monosodium glutamate, sucrose, D-mannose, D-fructose, dextrose, human se albumin, potassium phosphate, plasdone C, anhydrous lactose, microcrystallin cellulose, polacrilin potassium, magnesium stearate, cellulose acetate phthalat alcohol, acetone, castor oil, FD&C Yellow #6 aluminum lake dye	
Anthrax (Blothrax)	11/2015	aluminum hydroxide, sodium chloride, benzethonium chloride, formaldehyde	
BCG (Tice)	02/2009	glycerin, asparagine, citric acid, potassium phosphate, magnesium sulfate, Iron ammonium citrate, lactose	
Cholera (Vaxchora)	06/2016	ascorbic acid, hydrolyzed casein, sodium chloride, sucrose, dried lactose, sodium bicarbonate, sodium carbonate	
Dengue (Dengvaxla)	06/2019	sodium chloride, essential amino acids (including L-phenylalanine), non-essential amino acids, L-arginine hydrochloride, sucrose, D-trehalose dihydrate, D-sorbitol, trometamol, urea	
DT (Sanofi)	06/2018	aluminum phosphate, isotonic sodium chloride, formaldehyde	
DTaP (Daptacel)	01/2021 <sup>(b)</sup>	aluminum phosphate, formaldehyde, glutaraldehyde, 2-phenoxyethanol	
DTaP (Infanrix)	01/2021 <sup>(b)</sup>	formaldehyde, aluminum hydroxide, sodium chloride, polysorbate 80 (Tween 80)	
DTaP-IPV (Kinrix)	01/2021 <sup>(b)</sup>	formaldehyde, aluminum hydroxide, sodium chloride, polysorbate 80 (Tween 80), neomycin sulfate, polymyxin B	
DTaP-IPV (Quadracel)	02/2021	formaldehyde, aluminum phosphate, 2-phenoxyethanol, polysorbate 80, glutaraldehyde, neomycin, polymyxin B sulfate, bovine serum albumin	
DTaP-HepB-IPV (Pediarix)	01/2021 <sup>[b]</sup>	formaldehyde, aluminum hydroxide, aluminum phosphate, sodium chloride, polysorbate 80 (Tween 80), neomycin sulfate, polymyxin B, yeast protein	
DTaP-IPV/HIb (Pentacel)	12/2019	aluminum phosphate, polysorbate 80, sucrose, formaldehyde, glutaraldehyde, bovine serum albumin, 2-phenoxyethanol, neomycin, polymyxin B sulfate	
DTaP-IPV-HIb-HepB (Vaxelis)	10/2020	polysorbate 80, formaldehyde, glutaraldehyde, bovine serum albumin, neomycin, streptomycin sulfate, polymyxin B sulfate, ammonium thiocyanate, yeast protein, aluminum	
Ebola Zaire (ERVEBO)	01/2021 <sup>(b)</sup>	Tromethamine, rice-derived recombinant human serum albumin, host cell DNA, benzonase, rice protein	
HIb (ActHIB)	05/2019	sodium chloride, formaldehyde, sucrose	
Hib (Hiberix)	04/2018	formaldehyde, sodium chloride, lactose	
HIb (PedvaxHIB)	01/2021 <sup>(b)</sup>	amorphous aluminum hydroxyphosphate sulfate, sodium chloride	
Hep A (Havrix)	01/2021 <sup>(b)</sup>	MRC-5 cellular proteins, formalin, aluminum hydroxide, amino acid supplement, phosphate-buffered saline solution, polysorbate 20, neomycin sulfate, aminoglycoside antibiotic	
Hep A (Vaqta)	01/2021 <sup>(b)</sup>	amorphous aluminum hydroxyphosphate sulfate, non-viral protein, DNA, bovine albumin, formaldehyde, neomycin, sodium borate, sodium chloride, other process chemical residuals	
Hep B (Engertx-B)	01/2021 <sup>(b)</sup>	aluminum hydroxide, yeast protein, sodium chloride, disodium phosphate dihydrate, sodium dihydrogen phosphate dihydrate	
Hep B (Recombivax)	12/2018	formaldehyde, potassium aluminum sulfate, amorphous aluminum hydroxyphosphate sulfate, yeast protein	
Hep B (Heplisav-B)	05/2020	yeast protein, yeast DNA, deoxycholate, phosphorothioate linked oligodeoxynucleotide, sodium phosphate, dibasic dodecahydrate, sodium chloride, monobasic dehydrate, polysorbate 80	
Hep A/Hep B (Twinrix)	01/2021 <sup>(b)</sup>	MRC-5 cellular proteins, formalin, aluminum phosphate, aluminum hydroxide amino acids, sodium chloride, phosphate buffer, polysorbate 20, neomycin sulfate, yeast protein	
HPV (Gardasil 9)	08/2020	amorphous aluminum hydroxyphosphate sulfate, sodium chloride, L-histidine, polysorbate 80, sodium borate, yeast protein	

Figure G-1. Vaccine Excipient (continued).

Vaccine (Trade Name)	Package Insert Date	Contains <sup>(n)</sup>
Influenza (Afluria) Quadrivalent <sup>ici</sup>	03/2021	sodium chloride, monobasic sodium phosphate, dibasic sodium phosphate, monobasic potassium phosphate, potassium chloride, calcium chloride, sodium taurodeoxycholate, ovalbumin, sucrose, neomycin sulfate, polymyxin B, beta- propiolactone, hydrocortisone, thimerosal (multi-dose vials)
Influenza (Fluad) Quadrivalent <sup>(c)</sup>	03/2021	squalene, polysorbate 80, sorbitan trioleate, sodium citrate dihydrate, citric acid monohydrate, neomycin, kanamycin, hydrocortisone, egg protein, formaldehyde
Influenza (Fluarix) Quadrivalent <sup>(c)</sup>	2021	octoxynol-10 (TRITON X-100), α-tocopheryl hydrogen succinate, polysorbate 80 (Tween 80), hydrocortisone, gentamicin sulfate, ovalbumin, formaldehyde, sodium deoxycholate, sodium phosphate-buffered isotonic sodium chloride
Influenza (Flublok) Quadrivalent <sup>ici</sup>	03/2021	sodium chloride, monobasic sodium phosphate, dibasic sodium phosphate, polysorbate 20 (Tween 20), baculovirus and Spodoptera frugiperda cell proteins, baculovirus and cellular DNA, Triton X-100
Influenza (Flucelvax) Quadrivalent <sup>ici</sup>	10/2021 <sup>(b)</sup>	Madin Darby Canine Kidney (MDCK) cell protein, phosphate buffered saline, protein other than HA, MDCK cell DNA, polysorbate 80, cetyltrimethlyammonium bromide, and $\beta$ -propiolactone, thimerosal (multi-dose vials)
Influenza (Flulaval) Quadrivalent <sup>(c)</sup>	2021	ovalbumin, formaldehyde, sodium deoxycholate, α-tocopheryl hydrogen succinate, polysorbate 80, phosphate-buffered saline solution
Influenza (Fluzone) Quadrivalent <sup>(c)</sup>	2021	formaldehyde, egg protein, octylphenol ethoxylate (Triton X-100), sodium phosphate-buffered isotonic sodium chloride solution, thimerosal (multi-dose vials)
Influenza (Fluzone) High Dose <sup>(c)</sup>	07/2021	egg protein, octylphenol ethoxylate (Triton X-100), sodium phosphate-buffered isotonic sodium chloride solution, formaldehyde
Influenza (FluMist) Quadrivalent <sup>(c)</sup>	08/2021	monosodium glutamate, hydrolyzed porcine gelatin, arginine, sucrose, dibasic potassium phosphate, monobasic potassium phosphate, ovalbumin, gentamicin sulfate, ethylenediaminetetraacetic acid (EDTA)
IPV (Ipol)	01/2021 <sup>(b)</sup>	calf bovine serum albumin, 2-phenoxyethanol, formaldehyde, neomycin, streptomycin, polymyxin B, M-199 medium
Japanese Encephalitis (Ixlaro)	09/2018	aluminum hydroxide, protamine sulfate, formaldehyde, bovine serum albumin, host cell DNA, sodium metabisulphite, host cell protein
MenACWY (Menactra)	04/2018	sodium phosphate buffered isotonic sodium chloride solution, formaldehyde, diphtheria toxoid protein carrier
MenACWY (MenQuadfl)	01/2021(b)	sodium chloride, sodium acetate, formaldehyde
MenACWY (Menveo)	07/2020	formaldehyde, CRM <sub>107</sub> protein
MenB (Bexsero)	01/2021(b)	aluminum hydroxide, sodium chloride, histidine, sucrose, kanamycin
MenB (Trumenba)	2018	polysorbate 80, aluminum phosphate, histidine buffered saline
MMR (MMR-II)	12/2020	sorbitol, sucrose, hydrolyzed gelatin, recombinant human albumin, neomycin, fetal bovine serum, WI-38 human diploid lung fibroblasts
MMRV (ProQuad) (Frozen: Recombinant Albumin)	01/2021™	MRC-5 cells including DNA and protein, sucrose, hydrolyzed gelatin, sodium chloride, sorbitol, monosodium L-glutamate, sodium phosphate dibasic, recombinant human albumin, sodium bicarbonate, potassium phosphate monobasic, potassium chloride, potassium phosphate dibasic, neomycin, bovine calf serum, other buffer and media ingredients
PCV13 (Prevnar 13)	08/2017	CRM <sub>107</sub> carrier protein, polysorbate 80, succinate buffer, aluminum phosphate
PPSV-23 (Pneumovax)	09/2020	Isotonic saline solution, phenol
Rables (Imovax)	10/2019	human albumin, neomycin sulfate, phenol red, beta-propiolactone
Rables (RabAvert)	2018	chicken protein, polygeline (processed bovine gelatin), human serum albumin, potassium glutamate, sodium EDTA, ovalbumin, neomycin, chlortetracycline, amphotericin B
Rotavirus (RotaTeq)	01/2021 <sup>(b)</sup>	sucrose, sodium citrate, sodium phosphate monobasic monohydrate, sodium hydroxide, polysorbate 80, cell culture media, fetal bovine serum

Figure G-1. Vaccine Excipient (continued).

Vaccine (Trade Name)	Package Insert Date	Contains <sup>(a)</sup>
Rotavirus (Rotarix)	01/2021 <sup>tol</sup>	dextran, Dulbecco's Modified Eagle Medium (sodium chloride, potassium chloride, magnesium sulfate, ferric (III) nitrate, sodium phosphate, sodium pyruvate, D-glucose, concentrated vitamin solution, L-cystine, L-tyrosine, amino acids, L-glutamine, calcium chloride, sodium hydrogenocarbonate, and phenol red), sorbitol, sucrose, calcium carbonate, sterile water, xanthan [Porcine circovirus type 1 (PCV1) is present in Rotarix. PCV-1 is not known to cause disease in humans.]
Smallpox (Vaccinia) (ACAM2000)	03/2018	HEPES, 2% human serum albumin, 0.5 - 0.7% sodium chloride USP, 5% Mannitol USP, neomycin, polymyxin B, 50% Glycerin USP, 0.25% phenol USP
Td (Tenivac)	11/2019	aluminum phosphate, formaldehyde, sodium chloride
Td (TDVAX)	09/2018	aluminum phosphate, formaldehyde, thimerosal
Tdap (Adacel)	12/2020	aluminum phosphate, formaldehyde, 2-phenoxyethanol, glutaraldehyde
Tdap (Boostrix)	09/2020	formaldehyde, aluminum hydroxide, sodium chloride, polysorbate 80
Typhoid (Typhim Vi)	03/2020	formaldehyde, phenol, polydimethylsiloxane, disodium phosphate, monosodium phosphate, sodium chloride
Typhoid (Vivotif Ty21a)	9/2013	sucrose, ascorbic acid, amino acids, lactose, magnesium stearate, gelatin
Varicella (Varivax) Frozen	01/2021 <sup>tol</sup>	sucrose, hydrolyzed gelatin, sodium chloride, monosodium L-glutamate, sodium phosphate dibasic, potassium phosphate monobasic, potassium chloride, MRC-5 human diploid cells including DNA & protein, sodium phosphate monobasic, EDTA, neomycin, fetal bovine serum
Yellow Fever (YF-Vax)	2/2019	sorbitol, gelatin, sodium chloride
Zoster (Shingles) (Shingrix)	01/2021 <sup>tol</sup>	sucrose, sodium chloride, dioleoyl phosphatidylcholine (DOPC), 3-O-desacl- 4'monophosphoryl lipid A (MPL), QS-21 (a saponin purified from plant extract Quillaja saponaria Molina), potassium dihydrogen phosphate, cholesterol, sodium dihydrogen phosphate dihydrate, disodium phosphate anhydrous, dipotassium phosphate, polysorbate 80, host cell protein and DNA

Abbreviations: DT — diphtheria and tetanus toxoids; DTaP — diphtheria and tetanus toxoids and acellular pertussis; Hep A — Hepatitis A; Hep B — Hepatitis B; Hib — Haemophilus Influenzae type b; HPV — human papillomavirus; IPV — inactivated politovirus; LAIV — live, attenuated influenza vaccine; MenACWY — quadrivalent meningococcal conjugate vaccine; MenB — serogroup B meningococcal vaccine; MMR — measles, mumps, and rubella; MMRV — measles, mumps, rubella, varicella; PCV13 — pneumococcal conjugate vaccine; PPSV23— pneumococcal polysaccharide vaccine; Td — tetanus and diphtheria toxoids; Tdap — tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis.

http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093833.htm

November 2021

Figure G-1. Vaccine Excipient (continued).

RAII information was extracted from manufacturers' package inserts. The date shown in the Date column of the table is the edition date of the PI in use in January 2021 by month and year. In some cases, only a year was printed on the PI. If in doubt about whether a PI has been updated since this table was prepared, check the FDA's website at:

FiThe PI was not dated and this is the date the PI was reviewed for this table.

FIAII influenza vaccine in this table are 2021-22 northern hemisphere formulation.

USASOC Supplement 1 to AR 40-562

FOR THE COMMANDER:

OFFICIAL:

<sup>\*</sup> AR 40-562 dated 7 October 2013, is supplemented as written, effective date signed and remains in effect until rescinded or superseded.