



COO: The Health Care Supply Chain

AHRMM Webinar

COVID-19 Vaccine Supply, Distribution and Handling Overview: An Operation Warp Speed Panel Discussion





Panelists







COL Victor Suarez, CMRP, Vaccine Program Manager, OWS



Mr. Darrell Rawlings, McKesson, VP, Enterprise Program Lead Covid-19 Vaccines



Mr. Geoffrey Glauser, BARDA Supply Chain SME / Consultant

Moderated by Mike Schiller, CMRP, Sr. Director, Supply Chain, AHRMM/AHA















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PHARMACOVIGILANCE (FDA & CDC) 24 month post trial monitoring for adverse effects/additional safety feature



OPERATION WARP SPEED VACCINE DELIVERY MILESTONES

AUTHORIZATION - APPROVAL



Phase 3 Trials

Randomized, double-blind, placebo-controlled studies with more than 30k participants each, including diverse populations, providing rapid data collection



Data Safety Monitoring Board

Independent board evaluates data from ongoing Phase 3 trial, advises manufacturer whether pre-specified success criteria is met

Emergency Use Authorization (EUA)

Granted by the FDA following a recommendation by the Vaccines and Related Biological Products Advisory Committee and an independent analysis of drug manufacturing facilities, processes and drug product data

Biologics Licensure Application (BLA)

Includes safety and efficacy data along with product, manufacturing and clinical studies information to consider full approval, potentially following six months of additional monitoring



National Academies of Science, Engineering and Medicine

Informs the CDC Advisory Committee on Immunization Practices (ACIP) on which populations receive priority for vaccines



Vaccine Priority

ACIP recommends vaccine priority to the CDC director. who reviews and recommends to the HHS Secretary

KITTING

packages in



HHS Secretary

Endorses recommendation and staffs policy for approval to National Security Council

PRIORITIZATION - ALLOCATION

Distribution based on census data for prioritized groups: drives the delivery of available doses to states. tribes, territories, localities and federal agencies

Allocation

Jurisdictions/Federal Agencies

Execute federal priority guidance to identify points for vaccine delivery and administration



Delivery

Begins 24 hours after EUA, first doses available within 96 hours

DISTRIBUTION - ADMINISTRATION

Initial dose administered at various locations:





Preassembles and ready-to-ship kits



Delivers vaccine and

Administration sites Pharmacy

- Public health clinic
- Long term care facility
- Hospital
- Federally gualified health center Healthcare provider (doctors' office)
- Mass vaccination site
- Indian Health Service
- Home health
- Mobile site
- Other federal sites



Data IT/Systems

Jurisdictions provide dosing information to CDC data clearing house through immunization information systems and partner systems; patient data is de-identified with no personal identifying or health information



Second Dose Tracking

As most vaccines require two doses - 21 to 28 days apart from the same manufacturer, second dose reminders will be generated through existing IT systems



Pharmacovigilance

Post-vaccination monitoring continues for 24 months to detect. assess, understand, and prevent adverse effects; coordinated with vaccine companies, the CDC and FDA through multiple vaccine safety systems and V-SAFE







OWS coordination cell





Storage & Handling of Pfizer Vaccine

- Transport from Pfizer locations direct to Administration sites
- -75°C vaccine temperature range +/- 15°C
- 23 Kg Dry Ice contained in the insulated shipper which will be recycled
- Contains temperature monitors, GPS
- Temperature monitor may be re-used for continuous monitoring upon arrival
- If not transferred to -80°C freezer, requires replenishment of Dry Ice upon arrival then every 5 days – pellets 9 mm – 16 mm
- Open the container 2x per day for 5 minutes each to withdraw vials
- 5 Days @ 2-8°C after removing from -80°C
- Once defrosted and diluted with 0.9% NaCl use within 6 hours stored at 2-8°C
- Do not re-freeze
- 2 Doses 21 days apart
- Provided in trays of 195 2mL vials x 5-doses per vial once diluted Up to 5x trays per shipment
- Further Pfizer guidance at: <u>https://www.pfizer-biontechcovid19logistics.com/home</u>
- CDC Guidance at: https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim Playbook.pdf#page=29
- FDA EUA Authorization at: <u>https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine</u>



Storage & Handling of Moderna Vaccine

- -20°C vaccine, transport and storage temperature range -15°C to -25°C
- Transfer to -20°C freezer upon arrival
- Specialized coolant packs used during transit
- Transport with temperature monitors
- Critical to stop the monitor and read it immediately
- Once defrosted, 30 Days @ 2-8°C after removing from -20°C
- 12 hours at 25°C No return to 2-8°C
- Do not re-freeze
- Two doses, 28 days apart; .5ml per dose
- Further transport, post-arrival, recommended at -20°C*
- Provided in cartons of ten 10R vials x 10 Doses per vial
- Further Moderna guidance at: <u>http://www.modernatx.com/covid19vaccine-eua/</u>
- CDC Guidance at: <u>https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf#page=29</u>



Best Logistical Practices

Receipt -

- Immediate reporting of arrival
- Follow instructions on checking the temperature monitor
- Inspection, acceptance of vaccine
- Report any discrepancies quantities, temperature excursion, packing issues, etc.
- Storage Place into long term storage location (E.g. Freezer)
- Security Location, personnel access, notifications as necessary
- Site Prep- Plan space for distancing/flow, usage of markings & barriers when feasible
- Accountability by vial, by patient, by dose for inventory, pharmacovigilance, vaccine record card, links to electronic health records (EHRs).
- CDC System / tracking Success based upon reporting
- Temperature Monitoring / Reporting
 - Stop the temperature monitor upon arrival.
 - Access temperature data
 - Check out product websites for temp deviations/call center for companies
 - QR codes for lot and shelf-life updates
- Ancillary Kits Contains 105% of supplies for doses shipped
 - Kits take up significant storage space, plan
 - Dry ice safety practices
- Do not shake liquid vials. Mix as per Fact Sheets

Vaccine Record Card

COVID-19 Vaccination Record Card





Por favor, guarde esta tarjeta de registro, que incluye información médica sobre las vacunas que ha recibido.

| Last Name | | First Name | MI |
|----------------------------------|---|--------------------|---|
| Date of birth | | Patient number (me | edical record or IIS record number) |
| Vaccine | Product Name/Manufacturer Lot Number | Date | Healthcare Professional or Clinic Site |
| 1 st Dose COVID-19 | | // mmddyy | |
| 2 nd Dose COVID-19 | | // mmddyy | |
| Other | | // | |
| Other | | // mmddyy | |





YOU CALL_THE Vaccine Administration: SHOTS Needle Gauge and Length

Vaccines must reach the desired tissue to provide an optimal immune response and reduce the likelihood of injection-site reactions. Needle selection should be based on the: Route - Age - Gender and weight - Injection site for adults

(19 years and older)

The following table outlines recommended needle gauges and lengths. In addition, clinical judgment should be used when selecting needles to administer injectable vaccines.

| Route | Age | Needle gauge and length | Injection site |
|---------------------------|---|---|---|
| Subcutaneous injection | All ages | 23–25-gauge 5/8 inch (16 mm) | Thigh for infants younger than 12 months of age ¹ ; upper outer triceps area for persons 12 months of age and older |
| | Neonate, 28 days and younger | 22–25-gauge 5/8 inch (16 mm²) | Vastus lateralis muscle of anterolateral thigh |
| | Infants, 1–12 months | 22–25-gauge 1 inch (25 mm) | Vastus lateralis muscle of anterolateral thigh |
| | Toddlers, 1–2 years | 22–25-gauge 1–1.25 inches (25–32 mm) | Vastus lateralis muscle of anterolateral thigh ³ |
| | | 22–25-gauge 5/8 ² –1 inch (16–25 mm) | Deltoid muscle of arm |
| Intramuscular | Children, 3–10 years | 22–25-gauge 5/8 ² –1 inch (16–25 mm) | Deltoid muscle of arm ³ |
| injection | | 22–25-gauge 1–1.25 inches (25–32 mm) | Vastus lateralis muscle of anterolateral thigh |
| | Children, 11–18 years | 22–25-gauge 5/8 ² –1 inch (16–25 mm) | Deltoid muscle of arm ^{3,5} |
| | Adults, 19 years and older = 130 lbs (60 kg) or less = 130–152 lbs (60–70 kg) = Men, 152–260 lbs (70–118 kg) = Women, 152–200 lbs (70–90 kg) = Men, 260 lbs (118 kg) or more = Women, 200 lbs (90 kg) or more | 22–25-gauge 1 inch (25 mm ⁴) 1 inch (25 mm) 1–1.5 inches (25–38 mm) 1–1.5 inches (25–38 mm) 1.5 inches (38 mm) 1.5 inches (38 mm) | Deltoid muscle of arm ^{3,5} |

¹ May be administered into the upper outer triceps area if necessary

² If the skin is stretched tightly and subcutaneous tissues are not bunched

³Preferred site

⁴ Some experts recommend a 5/8-inch needle for men and women weighing less than 60 kg, if used, skin must be stretched tightly and subcutaneous tissues must not be bunched. ⁵The vastus lateralis muscle in the anterolateral thigh can also be used. Most adolescents and adults will require a 1- to 1.5-inch (25–38 mm) needle to ensure intramuscular administration.

Reference: Advisory Committee on Immunization Practices General Best Practice Guidelines for Immunization. www.cdc.gov/vaccines/hcp/acip-recs/general-recs/administration.html



CDC – Needle Gauge & Length

moderna[®] Ancillary supplies - Moderna

- All components 105% of 100-doses per case
- Alcohol prep pads (1 for vial top wipe, 1 for administration)
- 10 x 1 ml or 3ml syringes for each vaccine vial, 1 syringe for each dose per patient in a 10-dose vial
- Either a 23 or 25 gauge needle of different lengths 5/8", 1", 1 ¹/₂" based on the person's body size (heavier person needs a longer needle)
- Enough PPE to support 2 vaccinators (limited to 2 face shields and 4 surgical masks).
- Administration site provides protective nitrile gloves, hand sanitizer, other common protective measures
- Vaccination shot cards: Shot card to facilitate second dose reminder
- 2 pads/vaccine dose = 200 alcohol pads

*Sites need to plan to acquire enough gloves, hand sanitizer, sharps containers as required





BIONTECH *CH* Ancillary Supplies - Pfizer

- Alcohol prep pads 1 per vaccine vial, 1 per diluent vial
- 1 x Diluent for withdrawing & mixing, 0.9% NaCl Injection USP for each vial of Pfizer/BNT162b2
- 1 x 3 ml (mixing) syringe (optimal size) or 5 ml syringe (also acceptable) to pull up 1.8mL of 0.9% NaCl
- 1 x 21 gauge needle (mixing syringe) or narrower should be used to withdraw the diluent for vaccine administration (I.M. injection)
- 5 x 1 ml luer lock syringes for each vaccine vial, 1 syringe for each dose per patient Pfizer/BNT162b2 in a 5-dose vial
- Either a 23 or 25 gauge needle of different lengths 5/8", 1", 1 ½" based on the person's body size (heavier person needs a longer needle)
- Pfizer vaccine: 5-dose vials + diluent vial. 1:1 ratio vaccine to diluent. 1 mixing syringe per vaccine vial. 1 alcohol pad per vial
- PPE to support 2 vaccinators
- Administration site provides protective nitrile gloves, hand sanitizer, other common protective measures
- Vaccination shot cards: Shot card, 1 x dose, to facilitate second dose reminder

*Sites need to plan to acquire enough gloves, hand sanitizer, sharps containers as required





Ancillary Supplies Kit Label - Pfizer







Ancillary Supply Case

- Note size of ancillary kit (~2'x2'x'2).
- Plan for storage and availability.







Ancillary Supplies







Ms. Marion Whicker, SES, Deputy Chief, Supply Production Distribution, OWS

Ms. Marion G. Whicker was selected to the Senior Executive Service in June 2018, and is currently serving as the Executive Director of the Integrated Logistics Support Center (ILSC), U.S. Army Tank-automotive and Armaments Command. In this position, Ms. Whicker oversees the readiness of the majority of Army maintenance, fielding, new equipment training, supply chain management and system readiness. Ms. Whicker has direct oversight for a major Integrated Materiel Management Center with over 3,200 combined military and civilians. She provides the senior leader logistical support to almost 500 (63% of the Army's) new acquisition programs, as well as the sustainment support for over 10,000 major end items, ensuring operational readiness and support to the majority of the Army's major weapon systems. She provides leadership of a major logistics organization to include Weapon Systems Program Management, Materiel Management, Maintenance, Customer Support/Readiness, Integrated Logistic Support, and logistics support to five Program Executive Offices and associated Program/Project/Product Manager Offices.





COL Victor Suarez, CMRP, Vaccine Program Manager, OWS

COL Victor A. Suarez joined Operation Warp Speed (OWS) as a Vaccine Program Manager supporting the Moderna PCT on 17 June 2020. During the past year, he served as Assistant Chief of Staff for Logistics/G-4 for the US Army Regional Health Command-Atlantic (RHC-A), Fort Belvoir, VA. In this role, he managed the healthcare, PPE, lab diagnostics and medical maintenance supply chain for 14 direct reporting medical treatment facilities (medical centers, hospitals, clinics), including oversight of all RHC-A COVID-19 MEDLOG response. Prior to this assignment, COL Suarez was the Chief of Staff of the Walter Reed Army Institute of Research (WRAIR), DOD's largest biomedical research laboratory headquartered in Silver Spring, MD and was the Joint Product Manager of the Joint Vaccine Acquisition Program, a biodefense advanced development vaccine program. COL Suarez attended UCLA and earned a Bachelor of Science in Anthropology. Upon graduation, he was commissioned as a 2nd Lieutenant in the US Army Medical Service Corps and served in a broad range of tactical, operational and strategic assignments and has commanded twice during combat in the CENTCOM area of responsibility. He completed his Master of Science in Health Services Administration from Central Michigan University and graduated from the Defense Acquisition University's Program Managers Course, and holds Defense Acquisition Workforce certifications in Science and Technology Management (Level III), Life Cycle Logistics (Level III), and Program Management (Level III). He's also a graduate of the Tufts CSDD Postgraduate Course in Clinical Pharmacology, Drug Development and Regulation and the Cornell University Pharmaceutical Management Program. He is a Certified Resource & Materials Professional (CMRP®) via the American Hospital Association and was awarded the 9A designator for Acquisition and Medical Logistics by the Army Surgeon General. COL Suarez will be taking brigade level command upon completing his time with OWS in Summer 2021. Check out his AHRMM PODCAST on forming a MEDLOG Crisis Action Team (MEDLOG CAT) https://www.ahrmm.org/forming-medical-logistics-crisis-action-team-medlog-cat





CQO: The Health Care Supply Chain



Mr. Darrell Rawlings, McKesson, VP, Enterprise Program Lead Covid-19 Vaccines

Darrell Rawlings, Vice President, Enterprise Program Lead Covid-19 Vaccines – Darrell is serving as McKesson's Enterprise Wide COVID-19 Vaccine Program Lead – Darrell is responsible for the overall programmatic execution and success of COVID-19 vaccine distribution and related supplies. Darrell has over 25 years of distribution and logistics experience including UPS, Apria Healthcare and 20 years at McKesson. Mr. Rawlings has been responsible for numerous product categories including laboratory supplies, medical surgical supplies, and private label. Most recently he has been responsible for the pharmaceutical business, which includes core and flu vaccines, within McKesson's Med Surg business unit. Darrell holds a BA in liberal arts degree with emphasis on Business from Western Illinois University, and a Master of Science in Logistics Management from Florida Institute of Technology.





Geoffrey Glauser, BARDA Supply Chain SME / Consultant

Geoffrey Glauser is currently subject matter expert and contractor in support of the Biomedical Advancement Research Development Authority (BARDA) in the Office of the Assistant for Preparedness and Response (ASPR) within Health and Human Services (HHS), assigned full-time to COVID19 supply chain issues. Interactions with the FDA, CDC, and international regulatory agencies have supported his experience in contracting, product development, manufacturing, supply of vaccines, antivirals, diagnostics, therapeutics and ancillary products for both commercial and government products including pediatric and adult vaccines, sterile pharmaceuticals, Pandemic Influenza, and numerous research and development programs leading to regulatory approval. He has lead the on-the-ground physical handling of a, now approved, -80C Ebola vaccine clinical trial in Sierra Leonne for 8400 healthcare practioners without the loss of any doses. He is a contributing technical author to the Parenteral Drug Association publications and the International Society for Pharmaceutical Engineering (ISPE). Mr. Glauser has held senior supply chain line and staff positions including heading the global vaccine & sterile products planning group with Merck - 25 years, Pfizer (Wyeth), and Fisher Clinical Services in biological, sterile and chemical manufacturing activities. A former US Navy officer and engineer, Mr. Glauser degrees from Indiana University and Philadelphia's CHS.





Vaccines are being developed by multiple companies.

Are the Operation Warp Speed (OWS) vaccine distribution partnerships different and how are the shipments being allocated and prioritized, e.g., centralized, regionally, by state, other?



Who are the primary OWS distributors involved in delivery and further dispersal of the vaccines and what is the extent of their roles?



What recommendations/contingency plans do you have/should the health care organization have for vaccine storage, handling and distribution?



It is understood that the vaccines and supplies to support vaccination (i.e., needles, syringes, etc.) will follow separate logistics channels and converge at some point in the delivery chain.

Where does this convergence occur, at the distributor, hospital location, immunization clinic or healthcare provider?





What are the perceived delivery/distribution challenges for Urban vs. Rural destinations?





Where can we find more detailed information on specific vaccine storage and handling?

