COVID-19 VACCINATION TRAINING

DECEMBER 4, 2020

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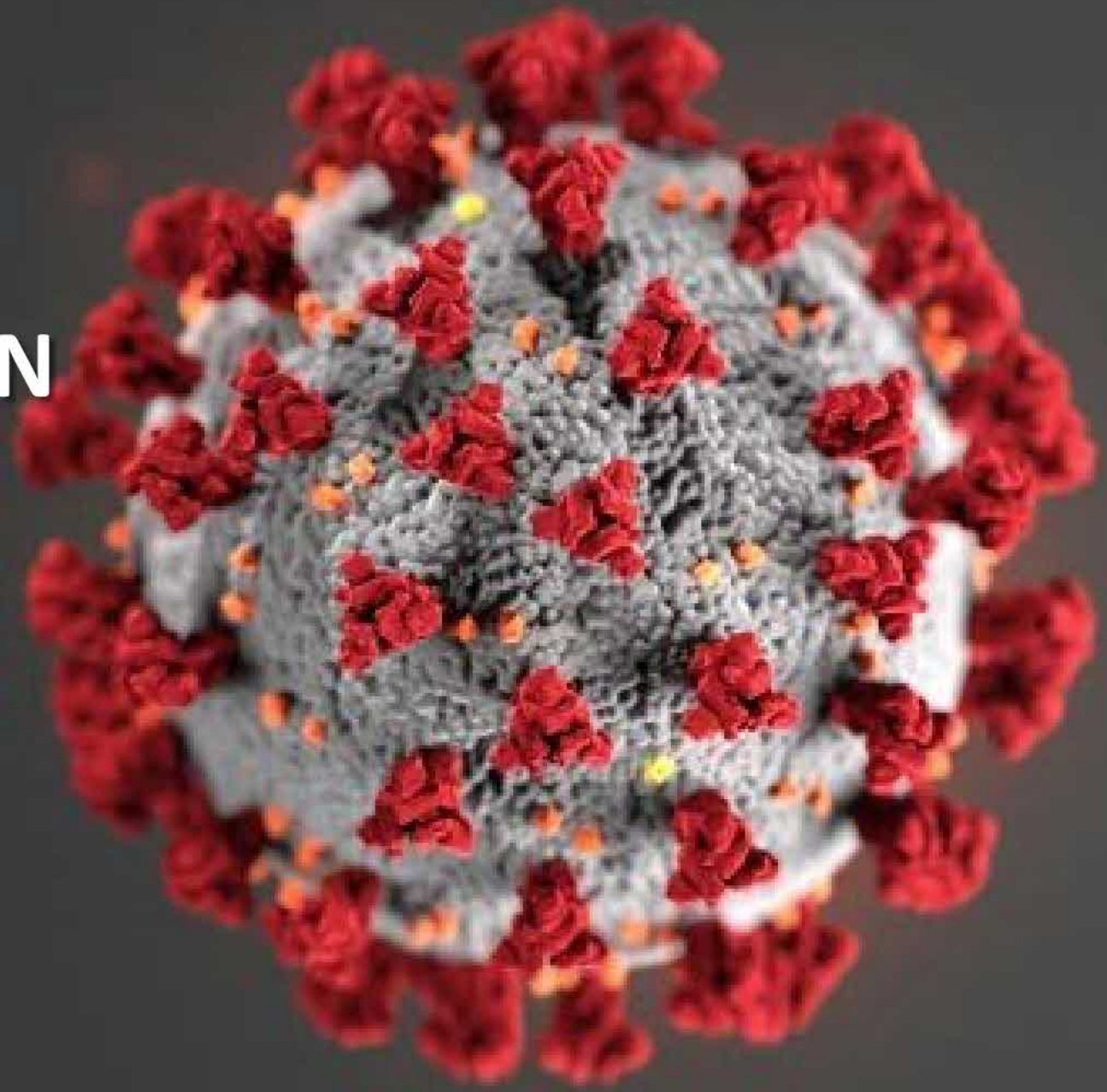
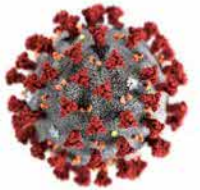


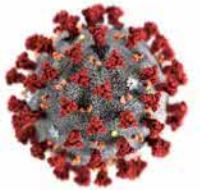
Housekeeping

- Please utilize the Chat function to ask questions during the presentation.
- We will have ample time for questions at the end of the presentation.
- There have been five presentations thus far to various staff in the field on specific details of this plan with additional presentations scheduled in the future.
- Previous presentation slides and FAQs are available on Sallyport



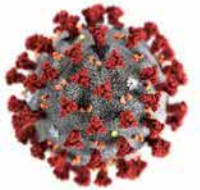
Objectives

- Review key points of the BOP COVID-19 vaccination plan
- Review safety and efficacy of the vaccines expected in the BOP
- Answer submitted questions



Agenda

- Opening Remarks
- Safety and Effectiveness of the vaccine
- Basic timeline
- Hub and Spoke
- Employee Vaccinations
- Inmate Vaccinations
- Recommendations for Institutions on what preparations they should be taking
- Update on available and forthcoming information
- Questions and Answers



Remarks from HSD Leadership

MICHAEL SMITH, ASSISTANT DIRECTOR

(b)(6); (b)(7)(C), PHARMD, SR. DEPUTY ASSISTANT DIRECTOR

Vaccine Safety & Efficacy

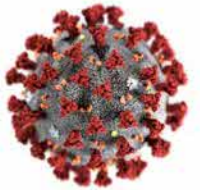
DR. JEFFERY ALLEN, MD, MEDICAL DIRECTOR

CAPT (b)(6); (b)(7)(C) MD, ACTING CHIEF, QUALITY MANAGEMENT

INFECTION PREVENTION & CONTROL OFFICER

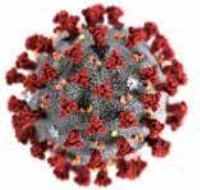
Vaccine Efficacy, Safety & Quality - FDA

- FDA authorization / approval requires demonstration of vaccine efficacy, safety, and quality/consistency.
  - No shortcuts being taken.
  - Vaccine production allowed to be concurrent with trials, which is not the norm.



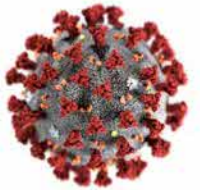
Vaccine Efficacy, Safety & Quality

- 7 vaccines currently being tracked by OWS
  - 2 in phase 3 trials, 2 completed trials.
  - Pfizer and Moderna have completed their trials and submitted application for approval.
  - Neither Pfizer nor Moderna vaccines contain the SARS-CoV-2 virus (causes COVID-19) and cannot give a person COVID-19.
    - Both cause the immune system to produce protective antibodies.



Vaccine Efficacy, Safety & Quality - Trials

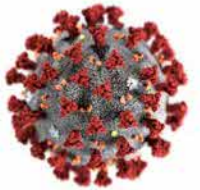
- Human clinical trials
  - Phase 1: Small-scale safety trials – dose and safety
  - Phase 2: Expanded safety trials – safety and efficacy
  - Phase 3: Large-scale trials – safety and confirm efficacy
  - Phase 4: Post-marketing surveillance



Vaccine Efficacy, Safety & Quality - Pfizer

- **Pfizer/BioNTECH vaccine phase 3 study**
  - 43,661 participants enrolled worldwide since July 27, 2020
  - 95% effective in preventing COVID-19 (disease)
    - 162 COVID-19 cases in placebo group; 8 in vaccine group
    - 9 severe cases in placebo group; 1 in vaccine group.
  - Results consistent across all age, gender, and racial / ethnic groups
  - No serious safety concerns reported. Adverse events reported were fatigue (3.8%) and headache (2%).

Pfizer Press Release

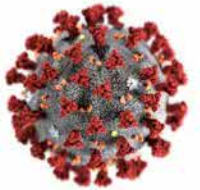


Vaccine Efficacy, Safety & Quality - Moderna

- **Moderna vaccine phase 3 study (COVE study)**
  - 30,000+ U.S. participants since July 27, 2020
  - 94.1% effective in preventing COVID-19 (disease) 14 days after 2nd dose in patients with and without prior COVID-19 infection.
    - 185 COVID-19 cases in placebo group; 11 in vaccine group
    - 30 severe cases in placebo group; 0 in vaccine group.
  - No serious safety concerns reported.
  - Adverse events reported included injection site pain, fatigue, muscle pain, pain, and erythema/redness at the injection site.

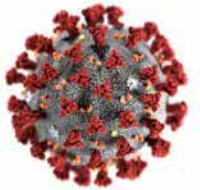
https://investors.modernatx.com/news-releases/news-release-details/moderna-announces-primary-efficacy-analysis-phase-3-cove-study

https://www.modernatx.com/sites/default/files/mRNA-1273-P301-Protocol.pdf



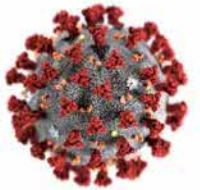
Vaccine Efficacy, Safety & Quality - EUA

- FDA Biologic Licensure Application (BLA) vs. Emergency Use Authorization (EUA)
  - Two main criteria: safety and efficacy
  - COVID-19 vaccines to be issued under an EUA
    - Held to a higher standard than typical EUA – standard closer to a BLA
    - Must be safe with clinical evidence an a of vaccine efficacy in protecting humans from COVID-19
    - Vaccines approved under EUA are not experimental vaccines



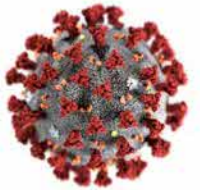
Vaccine Efficacy, Safety & Quality - ACIP

- Advisory Committee on Immunization Practices (ACIP): rigorous and robust review
  - Independent advisory committee provides advice/guidance to the CDC director
  - Independent review of all available vaccine data including Phase 3 clinical trial data



Vaccine safety monitoring

- Vaccination providers are required to report adverse events, etc., through VAERS
- V-safe
  - Smartphone-based tool uses text messages and web surveys for to check in with vaccine recipients and reminders to get second dose.
  - Staff will have access to V-safe
- BOP Medication Adverse Event reporting required through dashboard
- Numerous other vaccine safety surveillance procedures in effect at large health care systems



Timeline

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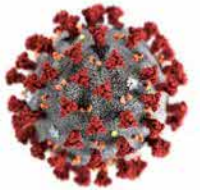
BOP OPERATION WARP SPEED LIAISON

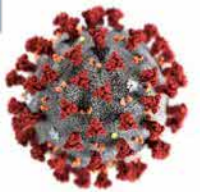
General timeline

- 11/23/2020 - Pfizer submitted EUA application
- 11/30/2020 - Moderna submitted EUA application
- 12/3/2020 – Cold shippers sent to institutions from CFAD (includes box, ice packs, temperature monitors)
- 12/4/2020 – BOP instructed by CDC to place first order
- 12/10/2020 – FDA Meeting on Pfizer application
  - Day 0 : FDA approval projected within 24 hours of meeting
  - Day 1 - 3: ACIP recommendations 24 -72 hours after FDA approval
  - Day 2 - 4: Institutions will receive shipment 1 day after ACIP approval
- 12/17/2020 – FDA Meeting for Moderna Vaccine (timeline same as Pfizer)



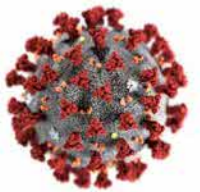
Pfizer Vaccine

- Shipped at -70°C in dry ice (much colder than regular freezer)
- 975 dose lots (195 vials of 5 doses each)
  - Will use Hub and Spoke Distribution System
- 2 doses per person (day 1 and then 21 days later)
- Shipper is 50+ pounds
- Vaccine to be removed at receiving location and immediately placed in refrigerator
- **Once removed from dry ice and placed in refrigeration: 5 days of viability**
  - **Vaccine must be used within these 5 days, anything left will need to be wasted**
- Facilities should not purchase dry ice or ultra cold freezers



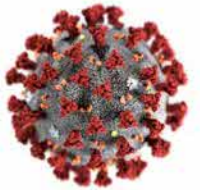
Moderna Vaccine

- Shipped at -20°C in (colder than regular freezer)
- 100 dose lots shipped direct to each institution
- 2 Doses per person (day 1 and 28 days later)
- Vaccine to be removed at receiving location and placed in refrigerator
- Once placed in refrigeration: 30 days of viability
  - Vaccine must be used within these 30 days, anything left will need to be wasted
- **No facilities are to purchase freezers – best place for storage is injected into a person**



Hub and Spoke

- Memo with list of Hubs and Spokes has been sent
  - Several factors involved in identifying institutions
    - Mileage, Numbers of staff, Numbers of Inmates
    - Group decision
- Plan includes all locations with BOP FTEs
  - MSTC, Glynco, Grand Prairie, Regional Offices, RRMS, Central Office
- Pick up by the spokes will be coordinated by institution Vaccine Point of Contact (VPOC)



At the Institution

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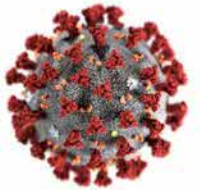
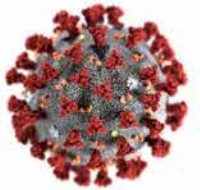
Employee Vaccinations

- All employees will be offered
  - Will need declination or consent for all BOP staff
  - BOP staff that decline initially may consent later
- Employees will be top priority for BOP
  - Protection for the employee
    - Based on front line law enforcement in consultation with CDC and OWS
  - Umbrella of protection for inmate population



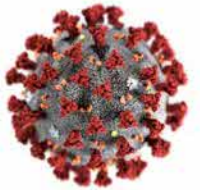
Employee Vaccinations (con't)

- Information will be entered into a CDC system called Vaccine Administration Management System (VAMS)
  - De-identified data will be sent to CDC daily
  - Will be coordinated by VAMS Coordinator at each institution
- Employees may download a cell phone app (V-Safe), if they choose, to have follow-up with CDC post vaccination
  - Information on V-Safe is on Sallyport



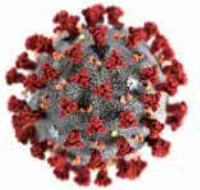
Inmate Vaccinations

- Offered after staff at that institution are vaccinated
- All inmates will be offered the vaccine
  - Prioritization based on CDC risk factors (dashboard in development)
  - Will need declination or consent for all inmates
  - Inmates that decline initially may consent later
- Administration documented in BEMR
- De-identified administration data uploaded to CDC daily



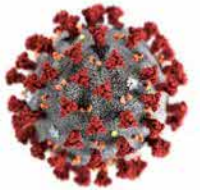
Institution Planning

- Recommend Table Top exercise
  - Who, Where, When, How
- VAMS Coordinators (completed)
- VPOCs (completed)
- Vaccinators
- Support staff
  - Collect consents and prepare vaccine
  - Direct staff or inmates at vaccination location



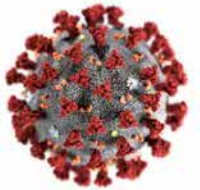
Upcoming information

- Promotional materials to encourage vaccine acceptance
- FAQs will continue to be updated as new questions are received
- Initial allocation numbers for each institution
- All information will be added to Sallyport and forwarded via email



Institution Surveys

- HSD is not recommending surveys
- Numbers are expected to be fluid as staff learn more about the vaccine and become more comfortable
- Initial allocations will be determined by CO based on staffing numbers and cannot be changed
- **Anything left over after staff vaccinations should be given to inmates – goal is not to waste.**
- Consents/Declination forms cannot be finalized until EUA information is received.



Questions