

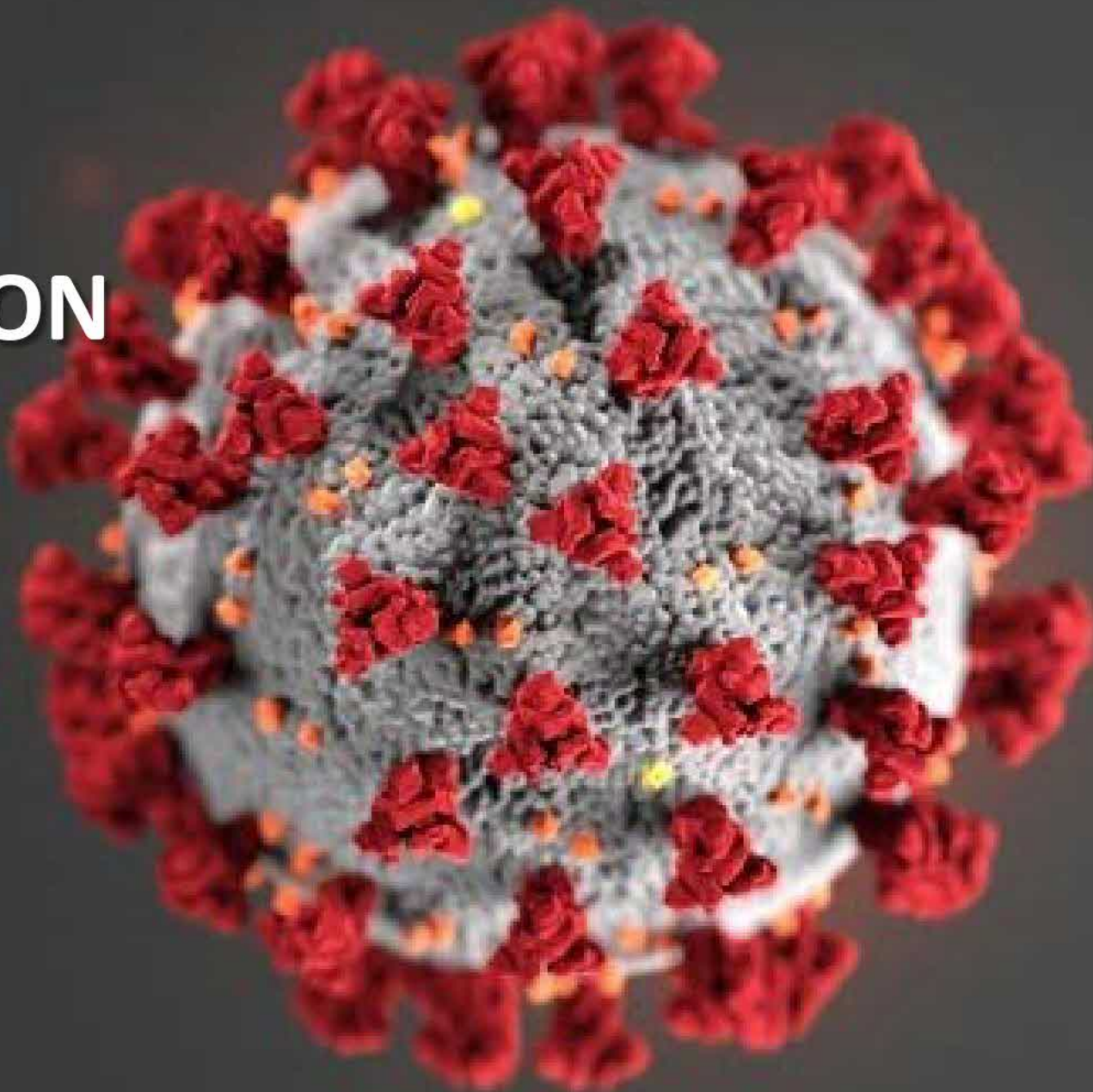
COVID-19 VACCINATION TRAINING

NOVEMBER 20, 2020

(b)(6); (b)(7)(C)

DR. JEFFREY ALLEN

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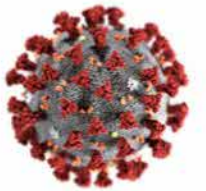
Housekeeping

- Please utilize the Chat function to ask questions
- Today's presentation is a follow-up to last week's and will provide updates and answers to questions received by HSD.
 - Slides from the prior presentation are posted on the Sallyport COVID-19 Guidance page
- There will be additional presentations with more detail on specific parts of this plan in the near future.



Objectives

- Briefly review key points of the BOP COVID-19 vaccination plan
- Review updates since the last presentation
- Answer submitted questions



Comments from HSD Leadership

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PHARMD, SR. DEPUTY ASSISTANT DIRECTOR

Vaccine Safety & Efficacy

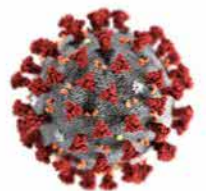
DR. JEFFREY ALLEN, MD, MEDICAL DIRECTOR

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MD, ACTING CHIEF, QUALITY
MANAGEMENT INFECTION PREVENTION & CONTROL OFFICER

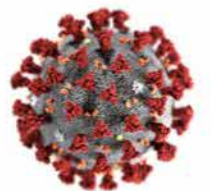
Vaccine Efficacy, Safety & Quality

- FDA authorization / approval requires demonstration of vaccine efficacy, safety, and quality/consistency.
 - No shortcuts being taken.
 - Vaccine production allowed to be concurrent with trials.
- 8 vaccines currently undergoing clinical trials, 4 in phase 3 trials.
 - Pfizer has concluded their phase 3 trial
 - Moderna issued an interim analysis of their phase 3 trial.
 - Both Pfizer and Moderna vaccines are mRNA vaccines which code for human cell production of the immunogenic SARS-CoV-2 spike protein. Both cause the immune system to produce protective antibodies.



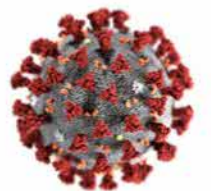
Vaccine Efficacy, Safety & Quality – Human Clinical Trials

- 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



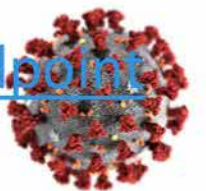
Vaccine Efficacy, Safety & Quality – Pfizer/BioNTech Vaccine Phase 3 Study

- 43,661 participants enrolled worldwide since July 27, 2020
- 95% effective in preventing COVID-19 (disease) after 2nd dose in patients with and without prior COVID-19 infection.
- 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%).



Vaccine Efficacy, Safety & Quality – Moderna Vaccine Phase 3 Study (COVE Study)

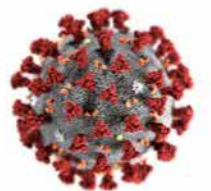
- **Moderna vaccine phase 3 study (COVE study)**
 - 30,000+ U.S. participants since July 27, 2020
 - Interim analysis - 94.5% effective in preventing COVID-19 (disease) 14 days after 2nd dose in patients with and without prior COVID-19 infection.
 - 90 COVID-19 cases in placebo group; 5 in vaccine group
 - 11 severe cases in placebo group; 0 in vaccine group.
 - No serious safety concerns reported. Adverse events reported included injection site pain (2.7%), fatigue (9.7%), muscle pain (8.9%), joint pain (5.2%), headache (4.5%), pain (4.1%) and erythema/redness at the injection site (2.0%).
 - [Moderna's COVID-19 Vaccine Candidate Meets its Primary Efficacy Endpoint in the First Interim Analysis of the Phase 3 COVE Study](#)
 - [Moderna Clinical Study Protocol 20 Aug 2020](#)



Vaccine Efficacy, Safety & Quality – FDA Application vs Authorization

FDA Biologic License Application (BLA) vs. Emergency Use Authorization (EUA)

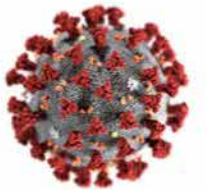
- Two main criteria: safety and efficacy
- COVID-19 vaccines to be issued under an EUA
 - Held to a higher standard than typical EUA – standard closer to a BLA
 - Must be safe with clinical evidence and of vaccine efficacy in protecting humans from SARS-CoV-2



Vaccine Efficacy, Safety & Quality – Advisory Committee

Advisory Committee on Immunization Practices (ACIP): rigorous and robust review

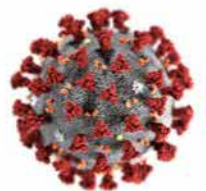
- Independent advisory committee provides advice/guidance to the CDC director
- Independent review of all available vaccine data including Phase 3 clinical trial data



Vaccine Efficacy, Safety & Quality Q&A

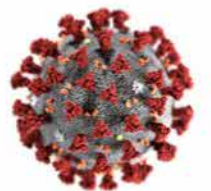
Does an EUA constitute "experimental" medication status for the BOP Pharmacy & Therapeutics (P&T) requirements for reporting?

- No, medication authorized by the FDA under an EUA may be used in the US Population under the guidance in the EUA. It is not considered experimental, does not require additional review, and does not require P&T reporting.



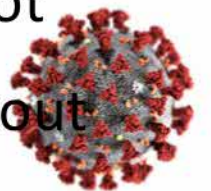
Vaccine Safety Monitoring

- 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



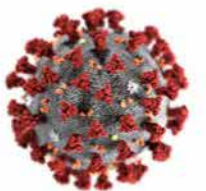
Vaccine Administration (1 of 2)

- **What if a staff tests positive between the 1st and 2nd vaccine? Will the process start over?** Per guidance from the CDC, staff should proceed with getting the second dose as scheduled.
- **Is there a +/- on the number of days to receive the second dose of Pfizer Vaccine?** At this time, the vaccine must be given at day 21. However, there may be more flexibility upon release of EUA or ACIP guidelines.
- **What allergies, if any, would prevent someone receiving the COVID vaccine?** Preliminary data reports no drug-allergy interactions. Final information regarding allergies will come out with the EUA.
- **Pregnancy or other contraindications?** Pregnant patients were not included in clinical trials and there is no guidance at this time. Final information regarding pregnancy and other contraindications will come out with the EUA.



Vaccine Administration (2 of 2)

- **If someone has tested positive for COVID-19 in the past, should they still get the vaccine?** Persons with a history of COVID-19 should still get the vaccine
- **If someone gets the COVID-19 vaccination, does the same time period of 14 days apply for influenza vaccination after the second dose if someone chooses to do this?** Yes. All staff and inmates are strongly encouraged to get the influenza vaccine prior to availability of COVID vaccine.
- [COVID-19 Clinical Training and Resources for Health Care Professionals posted to Sallyport](#)



VAMS

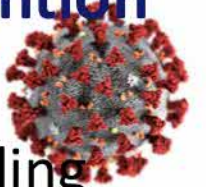
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MEDICAL RECORDS ADMINISTRATOR

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Staff Vaccine Administration

- The following information is an update to prior messaging posted on Sallyport
 - CDC will receive de-identified information for all staff and inmates receiving the vaccine
 - The CDC system Vaccine Administration Management System (VAMS) will be utilized to report vaccine administration for BOP employees to the CDC.
 - Staff will not be required to register with the VAMS as previously reported.
 - Institution health services will coordinate dates and times for staff wishing to receive the vaccine.
 - HSD is coordinating vaccine administration for BOP employees not located at an institution. This will include staff at central and regional offices, Glynco, Grand Prairie, MSTC and RRM.
- **While it was not recommended to pre-survey staff regarding intention to be immunized, would it be acceptable to set up appointments for staff in advance?** More information will be given to VAMS site administrators regarding staff administration however advanced scheduling will likely be an option.



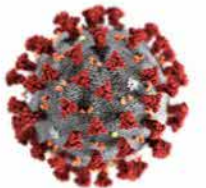
Logistics

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RPH, CHIEF PHARMACY LOGISTICS

Vaccine Logistics Overview


- **Pfizer Vaccine**
 - Request for EUA submitted November 20, 2020
 - Ordered through VPOC and Central office - Hub and spoke model for delivery
 - Ultra-low temperature storage, stable refrigerated for 5 days
 - 21 days between doses
- **Moderna Vaccine**
 - Expected approval shortly after Pfizer vaccine
 - Ordered through VPOC and Central office - Delivered directly to institutions
 - Vaccine freezer storage, stable refrigerated for 30 days
 - 28 days between doses
- Vaccines **ARE NOT** interchangeable



Storage & Timing

Timing requirements for Pfizer vaccine:

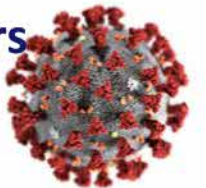
- Upon opening box, vaccine should be refrigerated or dry ice recharged within 24 hours
- After removal from dry ice storage: 5 days in the refrigerator and/or cold ship package (with appropriate temperature monitoring)
- After removal from refrigeration: max 2 hours at room temp
- After room temp: max 6 hours until vaccination



Max 8 hours once removed from refrigeration

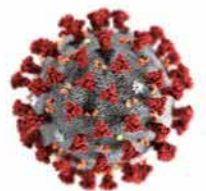
Hub and Spoke

- **Is the hub responsible for repackaging into smaller allotments than the 975 doses they will receive?** The hubs will break down the shipment immediately prior to pick up by the spoke site.
- **Can we have a list of hub sites?** The list of hub and spoke sites is being finalized and institutions will be notified shortly.
- **What, if any, documentation will be required for institutions to indicate receipt of vaccine and ancillary kits? How will this differ from hub-sites and non-hub sites?** The data logger included in the box sent to hub sites allows tracking of the shipment until delivery to the institution. No additional paperwork is required to document receipt at hub or spoke sites. Ancillary kits will need to be entered into sharps inventories.
- **If the vaccine is approved and ready to ship the week of Christmas through New Years day, any thought being given to the decreased staffing typically during those two weeks?** The hope is that this will not occur but, if this happens, we will consider and adjust as able.



Storage

- **Remind me about the ice packs that need to be frozen flat... do they go in the fridge with the vaccine?** The ice packs will be provided to put in the transportation boxes in order to keep the vaccine at the appropriate temperature during transport to administration sites. When not being actively used, they should be kept in a refrigerator.
- **What are the actual dimensions required for storage of the vaccine and ancillary kits?** The shipper sent to hub sites is 16"x16"x22". Spoke shippers will likely be smaller. The mega ancillary kit (1000 dose) is 24"x 20.5"x 20.5". The smaller kit (100 doses) is 14.5"x 13.5"x 9.5"
- **Will the diluent of the Pfizer product need to be refrigerated?** No
- **How should wasted vaccine be handled?** We are awaiting additional instructions from the CDC on the handling of waste. Pending further guidance, all wasted vaccine should be stored in one location within pharmacy.



General Q&A

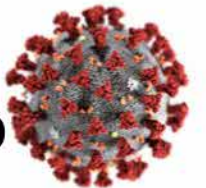
CAPT (b)(6); (b)(7)(C), RPH, MID-ATLANTIC CHIEF PHARMACIST

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Prioritization

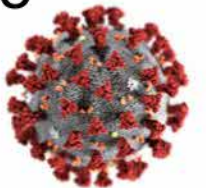
As a reminder: BOP will prioritize vaccine administration based on number of vaccines allocated

- BOP has advocated to the CDC that all staff should be in the highest priority grouping and staff should be offered the vaccine first.
- Upon completion of staff, institutions should then immediately begin vaccinating the inmate population, based on the priority levels, until all vaccine is gone. ***Wasted vaccine should be avoided at all costs.***
- Eventually there will be plenty of vaccine for all who wish to receive the vaccine.



Vaccine Allocations (1 of 2)

- **How are you determining how many doses of the vaccine will be allocated for each institution? Is that something we will be involved with directly at the institution?** The CDC is using total staff and inmate numbers to determine allocations for the BOP. Central office will subdivide this total number to individual institutions based on staffing numbers.
- **BOP has requested enough vaccine for all staff, but we won't know what our allotment is until after the EUA is approved?** We do not yet know when the allocations will be released. Once known, allocation information will be shared with institutions immediately in order to develop specific plans.



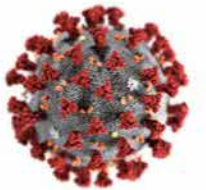
Vaccine Allocations (2 of 2)

- **Will standard language be available to educate stakeholders regarding the prioritization of BOP populations ahead of others in the community?** BOP allocations are being determined *concurrently* with allocations to all other federal, state and territorial jurisdictions. As correctional workers, all BOP staff are critical infrastructure workers.
- **When will institution know the prioritization levels for inmates?** The Immunization Clinical Guidance will be updated to include priority levels for COVID vaccination
- **Will our contractors be able to receive the vaccine?** Not through the BOP allocations. Contractors are accounted for within state/local health department for vaccination.



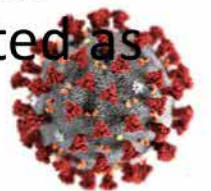
Consents and Refusals

- **Will staff or inmates have to sign a refusal for the vaccine similar to influenza?** HSD is currently reviewing and will come out with additional guidance in the near future.



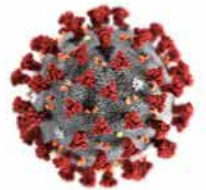
Communications

- **Will standard language be available to educate staff about the immunization?** Educational links and information will continue to be added to the BOP COVID-19 Sallyport page. Continue to check back regularly.
- **Do we have any preemptive education plans for staff and inmate in regards to taking the COVID vaccine?** The CDC has developed and released communications this week and the BOP has posted these to Sallyport. Additional information is forthcoming. BOP Leadership continues to explore ways to encourage staff and inmate uptake.
- **Are institutions responsible for deciding when to start notifying staff about the vaccine?** The first communications to staff and inmates were released November 16th. Additional information will continue to be sent and posted as it becomes available.



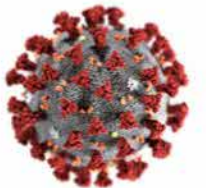
Training

- **How early will vaccine administration procedures be made available to institutions?** HSD is developing guidance which will be released prior to vaccine shipment.
- **Will there be funding available for training of staff to have more vaccinating staff available?** Nurses, APPs, physicians, dentists and pharmacists are able to administer vaccines. Other staff, such as medication and pharmacy technicians, may also be authorized to administer vaccines with appropriate documentation of training and competencies.



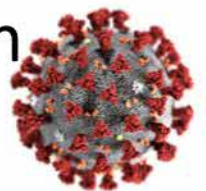
Key positions at institutions

- **VPOC**
 - Primary point of contact between institution and Central Office regarding **LOGISTICS**: Inventory, Handling, Waste of vaccine
 - VPOCs will be granted access to a Vaccine Provider Order Portal (VPOP) for order entry, inventory reporting, and waste
 - Site level orders will be processed by Central Office and then transmitted to CDC
- **VAMS Site Administrator**
 - Manages local VAMS to support vaccination operations, data collection and tracking to meet COVID-19 vaccination requirements.
 - VAMS will be utilized **ONLY** for BOP employees.
- Immunizers
- Support staff



Institution Planning - Tabletop Exercise

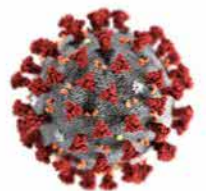
- The CDC is planning a logistics test of the shipment and receiving process at select institutions within the next week.
- **NOW** is the time to prepare – The vaccine will be shipped within 24 hours of release of ACIP guidelines. When the vaccine is shipped, the clock starts
- ***HSD highly recommends that all institutions perform a tabletop exercise from point of vaccine delivery to shots in arms***
- Consider incorporating institution leadership, planning section teams and non-medical staff in the exercise.



Institution Planning - Tabletop Exercise

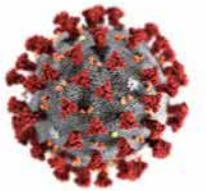
Points to Consider

- Transportation plan to pick up vaccine from hub sites
- Handling of initial vaccine delivery (special handling – i.e. dry ice used in shipping)
- Identification of Vaccine Administration Sites for both staff and inmates
 - Vaccine storage at site of administration
 - Are there computers accessible to record vaccine administration?
- Location for overnight vaccine storage (vaccine refrigerators)
- Familiarization with dashboards for rosters
 - Central office is developing additional dashboards to track vaccine progress
- Familiarization with new BOP Medication Error/Adverse Reaction Reporting System
- *Contingencies:* lock downs, short staffing (illness, weather events, etc.), power outages



Future Education

- VPOCs
- VAMS Coordinators
- Executive Staff



Questions?

General Questions – COVID19Questions@bop.gov

VPOCS – COVID19Questions@bop.gov

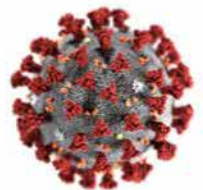
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VAMS – bop-hsd-healthinformatics@bop.gov

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 Chief of HIM
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 HIM Informaticist



References

- [COVID-19 Clinical Training and Resources for Health Care Professionals posted to Sallyport](#)
- [Moderna's COVID-19 Vaccine Candidate Meets its Primary Efficacy Endpoint in the First Interim Analysis of the Phase 3 COVE Study](#)
- [Moderna Clinical Study Protocol 20 Aug 2020](#)
- [Pfizer/BioNTECH Vaccine Phase 3 Study](#)

