

This is a compilation of Q&A from the trainings that have been held, questions that have come in from [COVID19questions@bop.gov](mailto:COVID19questions@bop.gov), and elsewhere. Questions that are new or updated from previous versions have been highlighted.

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## General:

**NEW - 12/3/2020** - Is there any potential liability issues with the BOP giving experimental vaccines? Liability will be the same as any other vaccine we administer. Medication authorized under an EUA may be used on the U.S. population under the guidance of the EUA. It is not considered experimental, does not require additional review, and does not require P&T reporting.

Will these slides be sent out to staff? If so, when? Slides from [November 12<sup>th</sup>](#) and [November 20<sup>th</sup>](#) have been posted to Sallyport. HSD will continue to post slides for future presentations as they become available.

## Staff Related:

**NEW - 12/3/2020** - Will this vaccine be mandatory for PHS officers? Guidance has not yet been provided from Commissioned Corps Headquarters, as soon as it is received, information will be provided to officers.

If staff are TDY, will they receive their dose at their TDY institution? Staff may receive their vaccine at any BOP facility where they are working.

Will the vaccine be offered to contractors who provide direct patient care? No. Contractors are accounted for within state/local health department for vaccination. However, it is recommended to offer the vaccine to a contractor if it would otherwise be wasted.

What guidelines should be used to administer to staff, especially if there's a limited supply e.g. staff with underlying conditions or a lottery system? [All staff were included and submitted to the CDC as high priority. 40,000 doses have been requested as priority 1 for staff. If the initial allocation request is not met, institutions will be given additional info.](#)

### Vaccine Specific:

**NEW - 12/3/2020** - Are there any long term safety concerns with the vaccine? [The long-term safety concerns are not known. However, most side effects from vaccines are observed in the first 8 weeks. Consequently, the FDA and ACIP required an 8 week observation period after the conclusion of the phase 3 trial to monitor for any additional side effects before they review the data for approval and use in the US.](#)

**NEW - 12/3/2020** - What guidance will be utilized for side effects and medication information? [The FDA and ACIP will release official vaccine guidance including side effects and contraindications upon approval of the vaccine.](#)

**NEW - 12/3/2020** - Are these vaccines contraindicated for pregnancy or any during breastfeeding? [The FDA and ACIP will release official vaccine guidance including side effects and contraindications upon approval of the vaccine.](#)

**NEW - 12/3/2020** - Is there any evidence that the vaccine could cause a positive COVID-19 test after vaccination without the person actually being infectious or symptomatic, creating a higher rate of false positives if a vaccinated person is tested? [Pfizer and Moderna vaccines do not contain any virus. It is not infectious and will not cause a positive COVID test.](#)

Is the vaccine live or inactive? [Both the Pfizer and Moderna vaccines do not contain any live or inactive virus and are non-infectious. As such, the vaccine will not result in a positive COVID-19 test.](#)

Do you shed virus after vaccination? [No, both the Pfizer and Moderna vaccines are not live viruses and will not cause viral shedding or result in a positive COVID test.](#)

**NEW - 12/3/2020** - What else is in the pipeline of other vaccines? [There are several other vaccines in the pipeline but they may not be available until next spring.](#)

**NEW - 12/3/2020** - Does the day of vaccination count for "Day 0" or "Day 1" of the series to receive vaccine two? Example: Vaccination December 1st with Pfizer product, return December 21st or 22nd for second dose? [In the example listed first dose on Tuesday December 1, the second dose would be Tuesday December 22. The amount of flexibility, if any, in this sequence has not been released yet and is expected to be contained in the EUA.](#)



If an inmate or staff member misses the second dose, what is the grace period? We likely won't get this information until after the FDA and ACIP review. All efforts should be made by all staff to make appropriate arrangements to ensure both doses are administered within the required time frame.

**NEW - 12/3/2020** - Pfizer vaccine specific: Will there be 5 doses per vial ( $975/5 = 195$  vials (975 not divisible by 6))? Several staff at the meeting told me 6 was mentioned on one of the trainings. There are five doses per vial.

Will this vaccine be recommended for those who have already tested positive for COVID or just those with no exposure or a negative test result? It is expected the Advisory Committee for Immunization Practices (ACIP) will recommend the vaccine for all individuals who are eligible to receive the vaccine regardless of whether they tested positive or not in the past. However, until there is a vaccine available and the ACIP makes recommendations to CDC on how to best use COVID-19 vaccines, we cannot comment on whether people who had COVID-19 should get a COVID-19 vaccine.

Do you have to have the Influenza vaccine before you can get the COVID vaccine? No, although it is important to get a flu shot as soon as possible. It is expected the Advisory Committee for Immunization Practices (ACIP) will recommend to not administer any other vaccination (e.g., seasonal influenza vaccine) 14 days before or after administering either the first or second COVID-19 vaccine doses.

Do you have to use the same manufacturer for each dose? The same manufacturer must be used for both doses (i.e. you cannot use Pfizer then Moderna for the second dose on the same patient).

Is the vaccine SQ or IM? Intramuscular.

Are there any contraindications to vaccination? We likely won't get this information until after the FDA and ACIP review.

Will there be an observation time after receiving the vaccine? Not that we've heard. We likely won't get this information until after the FDA and ACIP review.

How many doses is the Pfizer vaccine? It is a 2 shot series separated by 21 days.

Once a person receives the series, how long does it take before they have immunity? Per the press release from Pfizer, there is 95% effectiveness 7 days after the second injection.

Do we have information about how long it takes for the Moderna Vaccine to achieve immunity? 14 days after the 2<sup>nd</sup> dose, which is the time set by the Moderna study protocol and different from the 7 days used by Pfizer.

How long does immunity last with the series? Will this be an annual vaccine? [We do not have this information yet.](#)

Are we doing antibody checks after vaccination? [No, that is not recommended at this time.](#)

### Administration:

**NEW - 12/3/2020** - If we have surplus vaccine on hand after first shipment can we give immediately to inmates or should we share our excess with other BOP facilities for staff? [You should immediately begin vaccinating inmates. Institutions should be focusing on messages promoting uptake and answering concerns from staff and inmates.](#)

**NEW - 12/3/2020** - Will administrative facilities be responsible for administering to inmates that are in other facilities (e.g. inmates held in county jails, etc.)? [No, inmates that are not in a BOP managed facility will fall under county or state allotments and will receive vaccine through those counties and states.](#)

Are MDC and MCCs expected to vaccinate USMS patients? A-PRE and A-HOLD USMS inmates? [Yes. However, if a USMS inmate is in a known short-term holdover status, a case could be made to wait to vaccinate them until they arrive at a more permanent destination.](#)

**NEW - 12/3/2020** - Will inmates in halfway houses be eligible to receive the vaccine as well? [All individuals in the US are eligible to receive the vaccine. Inmates that are not in a BOP managed facility will fall under county or state allotments.](#)

**NEW - 12/3/2020** - If an individual is in quarantine or isolation for COVID, can they receive the vaccine? [No. Individuals should not be vaccinated until they are released from quarantine or isolation.](#)

**NEW - 12/3/2020** - How should our inmates be prioritized? Similar to prioritizing for flu vaccine? [Inmates will be prioritized. Exact prioritization levels will not be finalized until release of ACIP guidelines. Upon finalization, inmate prioritization guidance will be provided and a dashboard is being developed to assist with identifying these priorities.](#)

**NEW - 12/3/2020** - Will there be a dashboard developed just like for flu vaccine administration? [Yes, it is in development.](#)

**NEW - 12/3/2020** - If an institution is having an active outbreak, will we still be receiving the COVID vaccine? [Yes](#)

**NEW - 12/3/2020** - Would Planning Sections Teams established at each institution be valuable for the vaccination process? [A multidisciplinary team approach is recommended and as many](#)



staff as able should be included in the planning process to ensure a successful vaccination campaign.

Will a medical hold be placed on the inmates once they receive first dose? Yes. A medical hold will be placed on inmates following the first dose of the vaccine. The medical hold should remain in place after the first dose until the second dose is given, even if the inmate says they refuse the second dose. In other words, they would need to refuse on the day the second dose is due so they have every opportunity to receive it. If an inmate is released, they should be provided the vaccination administration card in order to obtain the second dose in the community.

Along with that, what about inmates releasing before the 21 or 28 days? Halfway house? Transfer/writ? A medical hold is placed on inmates after their first dose of COVID vaccine and they should not be transferred until they receive their second dose. However, in some situations (e.g. immediate releases, GCT/FT releases, and court-mandated moves) the inmate can no longer be held at that facility and must be released. If an inmate is released or sent to RRC, institutions will have to provide the vaccination administration card with the exit summary. If an inmate wishes to refuse the 2<sup>nd</sup> dose they should still be under the medical hold until after the 2<sup>nd</sup> dose is due.

## Supplies:

**NEW - 12/3/2020** - Where should the ice packs be stored? To maintain required temperatures, the ice packs are to be used in the provided cold shipper when transporting the vaccine from the hub to spoke site and from the refrigerator to vaccine administration sites. Ice packs should be stored in a freezer until transferred to the cold shipper for vaccine transport.

**NEW - 12/3/2020** - What is included in the ancillary kits? Syringes, needles for reconstitution and administration, diluent, vaccine administration cards, and a limited amount of PPE (face shields and gowns) will be included in the kits. Not included are gloves (the CDC does not recommend gloves when administering vaccinations) and sharps containers.

**NEW - 12/3/2020** - Will the Moderna vaccine include ancillary kits or will syringes and needles need to be procured separately? The Moderna vaccine will include ancillary kits.

**NEW - 12/3/2020** - What are the specifics of the ancillary kits with regard to syringe and needle sizes? We do not have this information at this time.

**NEW - 12/3/2020** - Please provide additional information about travel boxes and ice packs, as well as anticipated use. Will hubs be given all materials needed for breakdown and transport of vaccine and ancillary kits to spokes? All BOP institutions will receive cold shippers, ice packs,



payload boxes for the vials, and data temperature loggers to transport the vaccine. These will be shipped prior to shipment of the vaccine.

Will the syringes ship with the vaccine at the same time? Ancillary kits, including syringes, will arrive before or on the same day as the vaccine.

### Logistics:

**NEW - 12/3/2020** - Will we have to open/inspect the shipping container the Pfizer day it arrives? Yes. The vaccine should be inspected immediately upon arrival to the hub site. Once the box is opened, it must be transferred to refrigeration.

**NEW - 12/3/2020** - How long can the dry ice be maintained before the vaccine needs to be refrigerated? Upon opening the box for initial inspection, the vaccine must be refrigerated. The dry ice should not be used unless specifically directed by the Central Office, Health Services Division.

**NEW - 12/3/2020** - How long after you remove the Pfizer vaccine from the refrigerator can it be left out prior to administration? Upon removal from refrigeration, the Pfizer vaccine can be left at room temperature for up to 2 hours before reconstitution. Once reconstituted the vaccine can be left at room temperature for up to 6 hours (for a max total of 8 hours out of refrigeration). The vaccine should not be returned to refrigeration once removed.

**NEW - 12/3/2020** - What is the Ultra-Low Temperature (ULT) range? It is -70 °C, with an acceptable range of -60 to -80 °C.

**NEW - 12/3/2020** - In response to the fact that vaccine must be used within 5 days for removal from ULT storage: How is this being tracked? The institution Vaccine Point of Contacts (VPOC) are responsible for vaccine storage and ensuring appropriate storage and tracking. The temperature data log files created by the data loggers will serve as record, particularly for spoke institutions, as they move product from the dry ice container, transport it to the spoke institution, and then place into storage at the institution. The data logger should be started and the vaccine immediately placed in the provided cold shipper.

**NEW - 12/3/2020** - Is the transportation to/from HUB site solely resting on site vaccine point of contacts? The VPOC will need to coordinate this at the site level. It is recommended institution administration be involved with planning and deciding who will actually transport the product.

**NEW - 12/3/2020** - If the freezer is available instead of a refrigerator logistically, will that make any different if we store it in the regular freezer vs a refrigerator? Pfizer vaccine cannot be stored in a standard freezer. ULT temperature exceeds the requirements of a standard freezer.



**NEW - 12/3/2020** - Will the supply for the second dose be sent in a specific schedule after the first allotment? Or will it all be sent in the same batch? [The first and second doses will be shipped separately. If an institution gets 500 doses on day 0, they will get an additional 500 doses prior to the 21 days due date for the second dose.](#)

**NEW - 12/3/2020** - We are hoping that we will have a large percentage of staff and inmates who would like to receive the vaccine. But if we do not, do we know yet how we will proceed if we have remaining vaccine even after offering to all staff and inmates? [VPOCs will be responsible for consistently updating \(up to daily updates\) vaccine inventories for the Central Office to review. If it looks like there will be vaccine remaining Central Office will send instructions on how to handle the remaining vaccine.](#)

**NEW - 12/3/2020** - Do the regional offices and central office have refrigerators that are big enough to store the vaccines? [We are working with regional and central offices to provide capabilities to store the vaccine.](#)

**NEW - 12/3/2020** - Once the shipment is received at the hubs, should the terminal institutions begin movement to the hub to retrieve allotment? Or maybe even sooner? Maybe be there within an hour of arrival of the vaccine at the hub? [For Pfizer vaccine shipments under the hub and spoke model, there will be direct communication to the involved sites included exactly when movements should be made. There are a number of variables which could impact this and it will need to be determined on a case by case basis. Communications will flow through the VPOCs.](#)

**NEW - 12/3/2020** - How will notifications about vaccine delivery work? How much advanced notice is anticipated? Will hubs have contact information for the driver of the vaccine delivery? [VPOCs will have access to the VPOP system where they will enter order requests. Shipping information including tracking numbers will be uploaded back to VPOP daily for sites to review.](#)

**NEW - 12/3/2020** - What is the process for communication between hubs and spokes? [VPOCs should communicate with one another to establish plans for vaccine movement. A list of VPOCs for each institution will be provided.](#)

**NEW - 12/3/2020** - How much control does BOP have over the timing of the first vaccine delivery? Would it be possible to postpone initial delivery to January 4? [No. Vaccine delivery has been determined by the US Government and Operation Warp Speed and cannot be amended by the BOP.](#)

**NEW - 12/3/2020** - How many vaccine deliveries are expected and how often? [While exact allocation numbers and dates cannot be provided, after the initial shipment of Pfizer vaccine, institutions will continue to receive vaccine as often as weekly as requested by their VPOC.](#)



**NEW - 12/3/2020** - For the Pfizer product projected hub and spoke transportation, must a Health Services staff member be present for the transportation of the vaccine from the Hub to the final destination site? **No**, any BOP staff person can transport the vaccine however the VPOC should be closely involved to ensure proper handling of the vaccine throughout the transfer process.

**NEW - 12/3/2020** - Is there a plan for FDC Honolulu? Due to temperature requirements, OCONUS institutions will not receive an initial allocation of the Pfizer vaccine. They will be receiving the Moderna product (consistent with other US OCONUS territories).

Is there any reason why we can't get a head count of who wants it first before we get our order? **We don't recommend obtaining a head count in advance.** Due to the quickly changing vaccine availability and public perceptions of vaccination, projected acceptance rates are not dependable and will not change pre-determined allocations. However, it is OK to ask staff to proactively email a designated person regarding their interest if it would help organize local efforts so that vaccines can be administered in a timely manner upon receipt.

How will each institution determine how many vaccines to order (for staff and for inmates)? Initial allocations are determined by HSD based on the number of full time staff at each institution. Once the initial allocation has been administered, institution VPOCs will request additional vaccine as needed.

Will there be protocols for waste if we have to? **The primary objective is to not have waste.** Doing so would not only limit the number of people being protected, but the institution would need to be able to explain the reason for the waste to subsequent auditors. We are awaiting additional instructions from the CDC on the handling of waste. Pending further guidance, all wasted vaccine should be stored in a separate location within the pharmacy.

Is the VAMS POC different from the vaccine POC? **Yes.** In most cases, it is recommended that the VAMS site administrator should not be the same person as the VPOC.

Where are the regional hubs? **The list of hub and spoke sites has been sent to institution executive staff and posted on [Sallyport](#).** Please note that the regional hubs are for the Pfizer (ultra cold) vaccine only. All other vaccine will be shipped directly to the institution.

Will hubs receive the vaccines in increments of 975, which need to be used in the 5 days to ensure no waste? **For the Pfizer (ultra-cold vaccine), the 975 doses will be broken down into smaller amounts for pick up by spoke sites.** The vaccine, once removed from the shipping container at the hub, must be refrigerated and administered within 5 days to ensure no waste.



## Reporting:

**NEW - 12/3/2020** - Do staff reporting adverse reactions need to be reported thru the P&T adverse reaction system? [Staff adverse events must be reported through employee health and the VAERs. Only inmate adverse drug reactions are required to be reported through the BOP Events dashboard and P&T.](#)

**NEW - 12/3/2020** - Will there be a VIS (vaccine information statement) form? [Yes. When the EUA is approved by the FDA, there will be a VIS \(or equivalent\).](#)

**NEW - 12/3/2020** - A previous slide said that VAMS will be used to track inmates and staff. Is this correct? [VAMS is only used for staff vaccine documentation. Inmate vaccinations will be documented in BEMR. The CDC will receive de-identified information for both staff and inmate vaccinations.](#)

**NEW - 12/3/2020** - Who is registering the inmate in the VAMS? [VAMS is not used for inmates. Inmate documentation will take place in BEMR.](#)

**NEW - 12/3/2020** - Will the Immunization Information Systems (IIS) off-line vaccine administration documentation tool from the CDC be available in advance of vaccine distribution? [The BOP is not using the CDC IIS immunization tool for COVID-19 vaccine. We are using VAMS from the CDC for staff documentation, and BEMR for inmate documentation.](#)

**NEW - 12/3/2020** - Will the VAMS administrator be able to access information in advance about BOP staff who have registered? For example, to plan for initial appointment capacity? [Staff pre-registration will not be used in the BOP.](#)

**NEW - 12/3/2020** - What is the limit on VAMS administrators per institution? How many people from one institution can assist in administering VAMS? [One person will initially be assigned the VAMS administrator role and, if necessary, can reassign a new or additional VAMS Administrator to assist. We recommend 1-2 Administrators for a site at any given time. If a new VAMS Administrator will replace the initial VAMS Administrator, the newly assigned Administrator will need to remove the initially assigned Administrator from that role.](#)

If the CDC is monitoring the VAMS system for staff, will they be monitoring BEMR for the inmates? [The BOP will provide the CDC with data for both staff and inmates that has had all personally identifiable information removed.](#)

Will inmate refusals be considered differently than "regular" vaccine refusals? [HSD is currently reviewing and will come out with additional guidance in the near future.](#)

What will the inventory process be for the kits? [All sharps received in kits must be inventoried and accounted for per BOP policy.](#)

