

A microscopic image of a virus particle, likely a coronavirus, showing its characteristic spherical shape and surface spikes. The image is rendered in shades of teal and blue, with a dark blue diagonal line separating it from the white text area on the right.

COVID-19 Vaccine Pre-positioning: Issues & Challenges

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IDAHO DEPARTMENT OF
HEALTH & WELFARE



- Vaccine Pre-positioning
- Challenges
- Questions for CVAC



- Vaccine A (the ultra cold vaccine) manufacturer anticipates applying for Emergency Use Authorization as early as third week of November
 - FDA's Vaccines & Related Biological Products Advisory Committee (VRBPAC) is committed to reviewing any EUA request to make a recommendation to the FDA.
 - Estimated timeline – at least two weeks from EUA filing
 - Advisory Committee on Immunization Practices (ACIP) will hold emergency meeting to consider recommendations for use of a vaccine candidate
 - Estimated timeline - within 24-hours of FDA authorization or approval



- Single tray holds 195 vials
- 975 doses per tray

- Store as frozen liquid at $-75^{\circ}\text{C} \pm 15^{\circ}\text{C}$ for long term storage.
 - Emergency Use vials are labeled as $-70^{\circ}\text{C} \pm 10^{\circ}\text{C}$, however they can be safely stored in a freezer set to $-75^{\circ}\text{C} \pm 15^{\circ}\text{C}$
- Different size of ULT freezers are available in the market.

A small size (under or over the countertop ULT Freezers can store as much as 30K doses)



- Can be stored at 2 to 8°C up to 5 days
- Room temperature hold time is no more than 2 hours.
- Thawing: 3 hours at 2 to 8°C or 30 min at room temperature.
- Post-dilution in use period is 6 hours.



11/16/2020 - EAU Request from manufacturer to FDA

11/30/2020 - VRBPAC recommends authorization of Vaccine A

12/1/2020 – ACIP reviews & recommends use of Vaccine A

Shortest Timeline – If All Processes Go Smoothly and As Planned



- CDC/OWS Request: Name sites with ultra-cold freezer capacity to pre-position Vaccine in the interim between FDA authorization and ACIP recommendations & specify number of doses
 - Timeline of storage could be 24-hours or longer awaiting ACIP recommendations, after which jurisdictions would begin allocating and redistributing to enrolled providers for vaccine administration



- Advantages

- Vaccine is in custody of provider as soon as ACIP recommendation is made; saving time as vaccination distribution begins
- Allows for redistribution across state in very small amounts as we determine vaccine uptake
- Reduces chance for vaccine wastage

- Challenges

- Will save 24-48 hours of providers having vaccine before it will be shipped via normal distribution routes after ACIP recommendation
- Currently only two ultra-cold freezers available among Phase 1A vaccinators in state with storage
 - Intent of early distribution is for EACH Phase 1A vaccination site to have some doses
- Could potentially be storing vaccine for an undetermined time, if there is a lag between EUA and ACIP recommendation
- Early distribution to two urban hospitals is not an equitable scenario for Idahoans



- CDC – not requiring a decision by 11/6
- Washington is considering not accepting early distribution
 - Idaho and Washington Immunization Programs will meet early next week to discuss



Question 1

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- Do you recommend that Idaho accept Vaccine A (ultra-cold vaccine) after a FDA Emergency Use Authorization, but prior to Advisory Committee on Immunization Practices?