

Distribution Office Hours

January 18, 2021

UNOFFICIAL NOTES [these notes have not been reviewed by CDC]

Pfizer Under 5 Vaccine

- Pfizer is saying that they can complete trials and have the data by **Q1 2022** after previously saying the vaccine wouldn't come until Q2
- Details on the Pfizer under 5 vaccine:
 - 6 months - 4 years of age; unsure on how many doses in the series; could be 3 doses instead of 2 but unsure at this time
 - Same vaccine, different presentation - will be a **MAROON CAP** with **diluent required**
 - 9 months frozen ULT
 - 10 weeks in fridge
 - Dispose 12 hours post reconstitution
 - Pfizer's under 5 vaccine candidate will need FDA authorization and consideration/recommendation by ACIP/CDC, but that could happen as soon as February 2022
 - 10 dose vial; **100 minimum order right off the bat** (no 300 dose push at rollout)
 - Different configuration; clinicians will draw same as orange cap but a different amount of diluent to mix it correctly
 - Tedious to ensure the correct prep for correct age and use of the correct product
- Allocations are unknown at this time; vaccine is not yet manufactured so should have 9 month shelf life at roll out.
- AIM is holding listening sessions to hear about challenges/recommendations for roll out.
- Maroon, orange, gray for each of the various ages - providers may need to carry all three

Thresholds

- Next threshold top off will be the **January 20th → cadence still every two weeks**
- If you've requested permanent increases, be sure to check when replenishments happen and if you have not received/don't see the higher amount requested, reach out to PO
- ***Process for permanent thresholds:** CDC is saying that that decision was that states that continue to request higher threshold amounts would have a permanent increase. If this is not the case, reach out to POs and POB staff.

Moderna Label Update

- Moderna reprinted their label to say it can be a primary and a booster
- Moderna label now says that it can be for either or but it is still ½ dose for the booster (.25mL) and full for primary (.5mL).
- No changes to vaccine formulation; CDC is letting people know in case there are questions.
- No changes to NDC codes, just wording on vial label.
- No updates from CDC on Moderna < 18-year-old

Pfizer Gray Cap

- Pfizer Gray cap is the only available presentation for 12+; purple is no longer available for ordering. CDC wants jurisdictions to limit providers with both purple and gray cap vials, and are urging the depletion of purple cap inventory before sending/ordering gray cap.

- There is currently no way of distinguishing between purple versus gray cap other than the NDC code - i.e. lot numbers won't tell you which is which - CDC is encouraging providers and jurisdictions to look carefully at NDC codes.
- Unsure when 100 dose min orders will be available for Pfizer adult Tris → Pfizer Tris is currently packaged in **5 packs of 60 doses**. Configuration of vials and ancillary kits would need to be completely reworked when moving to 100 dose min orders; this would be detrimental for waste and other logistics

J&J

- J&J is undergoing studies for a shelf-life extension request but have not submitted data yet. Current inventory is due to expire in April 2022.
- J&J is available in the warehouse so if you cannot physically transfer it, put in the request to CDC team for doses

Waste

- Waste rates are currently at ~ 7.5%. Pfizer is starting to gain on Moderna in terms of waste when they released the 10 dose vials for peds.
- Reported waste is helpful to change manufacturing to lower dose amounts.

New COVID Vaccine - Novavax

- Novavax will be filing for EUA with the FDA in the near future. [AIM will be reaching out to Novavax to have an informational webinar on the Novavax COVID vaccine.]