Addressing the COVID-19 Crisis: An Open Forum Webinar Series for Pharmacy

January 14, 2020

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Host and Moderator

Today's Focus:

Discuss common myths about COVID-19 vaccines, including the implications on immunity, testing and treatment.

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Subject Matter Expert: Q&A

Disclosures

APhA staff declare no conflicts of interest or financial interests in any product or service mentioned in this activity, including grants, employment, gifts, stock holdings, and honoraria.

CPE Information

Target Audience: Pharmacists

ACPE#: 0202-0000-21-121-L01-P

Activity Type: Knowledge-based

Learning Objectives

1. Identify common myths about COVID-19 treatment and testing.
2. Discuss common myths about COVID-19 vaccination.
3. Describe the latest information about COVID-19 that pharmacists should know.

Format for Today's Webinar

1:00 pm: Introductions

1:05 pm: Presentation from Dan Zlott and Mitch Rothholz

1:30 pm: Open Forum: A Minute for Your Thoughts

1:50 pm: Wrap Up: Review of APhA's Ongoing Activities and Assessment Questions

Open Forum Ground Rules

- Use the **Questions** field on the GoToWebinar toolbar to submit comments and questions related to the topic discussion.
- We will try to get to as many comments and questions as possible.
- We have created a forum for COVID-19 discussions where further discussion post-webinar. Information on participating in this forum will be provided at the end of the open forum.

Assessment Question #1

True or False: If a person had COVID-19 infection, they do not need to be vaccinated against COVID-19.

a. True
b. False

FACT: People who have gotten sick with COVID-19 may still benefit from getting vaccinated

- Due to the severe health risks associated with COVID-19 and the fact that re-infection with COVID-19 is possible
  - **Get a COVID-19 vaccine even if you have been sick with COVID-19 before**
    - Experts do not know how long someone is protected from getting sick again after recovering from COVID-19.
    - Some early evidence suggests natural immunity may not last very long.
    - We won’t know how long immunity produced by vaccination lasts until we have a vaccine and more data on how well it works.

Vaccination of persons with SARS-CoV-2 infection or exposure

- Defer vaccination until the person has recovered from the acute illness (if the person had symptoms) and criteria have been met for them to discontinue isolation.
- No recommended minimal interval between infection and vaccination
  - Reinfection uncommon in the 90 days after initial infection
  - Can delay vaccination up to 90 days

Assessment Question #2

True or False: Ivermectin has been proven effective for treatment of COVID-19.

a. True
b. False

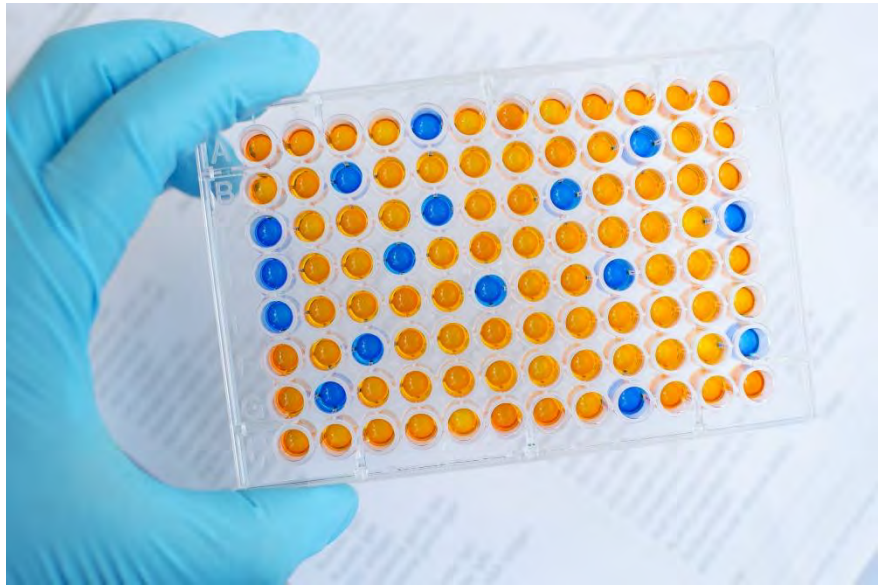
Myth: Ivermectin has been proven effective for treatment of COVID-19.

Clinical studies evaluating the use of ivermectin for the treatment or prevention of COVID-19 are ongoing – to date no results have been published

Additionally, the currently FDA warns against taking ivermectin for COVID-19[1]

1. U.S. Food and Drug Administration. "FAQ: COVID-19 and Ivermectin Intended for Animals". December 16th, 2020. https://www.fda.gov/news-events/press-announcements/fda-issues-alert-regarding-sars-cov-2-viral-mutation-health-care-providers-and-clinical-laboratory. Accessed 1/13/2021

Myth: Ivermectin has been proven effective for treatment of COVID-19.



Why all the excitement about ivermectin?

An article in Antiviral Research published in June demonstrated that ivermectin inhibited COVID-19 viral replication in vero-hSLAM cells in cell culture (*in vitro*)[1]

1. Caly, et al. Antiviral Research, 2020. doi: https://doi.org/10.1016/j.antiviral.2020.104787

Assessment Question #3

True or False: COVID-19 viral tests can detect the new COVID-19 variant.

a. True
b. False

True or False: COVID-19 tests are able to detect the new COVID-19 Variant

Answer: It depends! There isn't a 100% clear-cut answer.

Whether or not test will recognize a mutated variant of COVID-19 depends on:

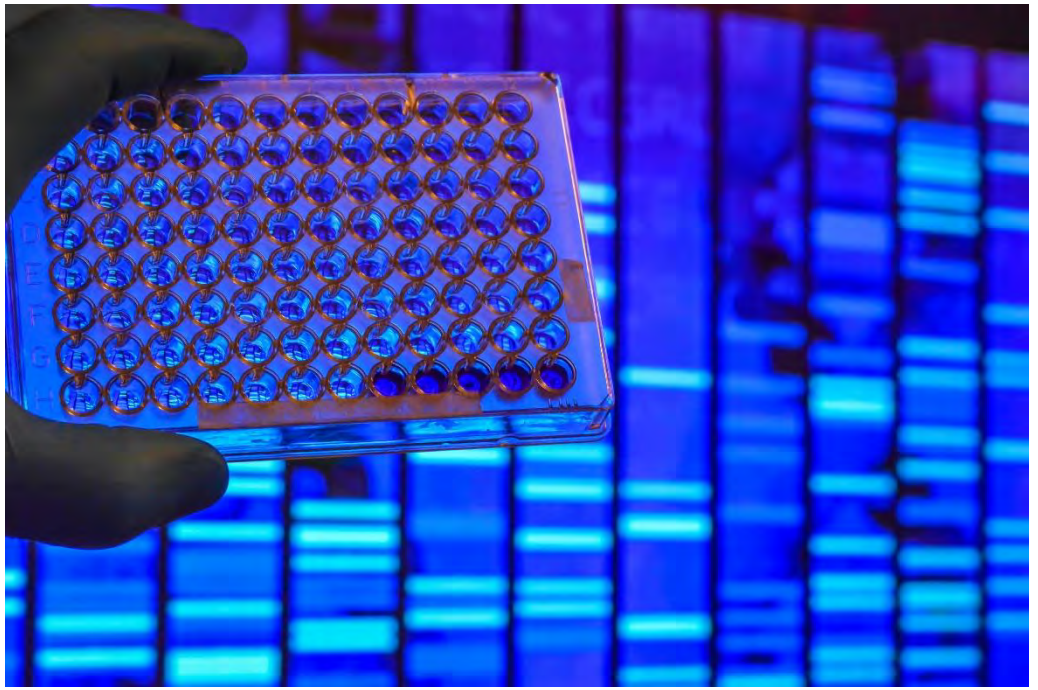
1) The nature of the variant mutation
2) The mechanism of the test

Fact: COVID-19 Variants May Affect the Ability of COVID-19 tests to detect COVID-19 (but this is rare)

For example, if there is a mutation in the COVID-19 virus RNA that affects the sequence that a PCR-based test uses to detect the COVID-19 virus, it is possible that the test may not be able to detect that particular variant

According to the FDA, the impact of COVID-19 variants on COVID-19 tests remains low[1]

To date, the FDA has identified 3 PCR-based assays that may be impacted by COVID-19 variants[1]



1. U.S. Food and Drug Administration. "FDA Issues Alert Regarding SARS-CoV-2 Viral Mutation to Health Care Providers and Clinical Laboratory Staff". January 8th, 2020. https://www.fda.gov/news-events/press-announcements/fda-issues-alert-regarding-sars-cov-2-viral-mutation-health-care-providers-and-clinical-laboratory. Accessed 1/11/2021

Assessment Question #4

True or False: Individuals who are pregnant, breastfeeding or immunocompromised should wait to get vaccinated until more data is available.

a. True
b. False

FACT: COVID-19 vaccine can be administered to pregnant or breastfeeding women

- Pregnant people with COVID-19 have an increased risk of severe illness and might be at increased risk of adverse pregnancy outcomes, such as preterm birth.
- Animal studies – showed no safety concerns. Ongoing evaluation in humans.
- Based on current knowledge, experts believe that mRNA vaccines are unlikely to pose a risk to the pregnant person or fetus because mRNA vaccines are not live vaccines.
- Conversation between patient and their clinical team suggested but not required – Decision is patient-choice, considering Benefit vs Risk.
- No evidence that the vaccine causes infertility in women or sterility in males

Immunocompromised Individuals

- May receive COVID-19 vaccination if they have no contraindications to vaccination.
  - Should be counseled about the unknown vaccine safety profile and effectiveness in immunocompromised populations, as well as the potential for reduced immune responses
  - Need to continue to follow all current guidance to protect themselves against COVID-19
  - Antibody testing is not recommended to assess for immunity to COVID-19 following mRNA COVID-19 vaccination.
- At this time, re-vaccination is not recommended after immune competence is regained
- Recommendations on re-vaccination or additional doses of mRNA COVID-19 vaccines may be updated as additional information is available.

Assessment Question #5

True or False: A patient who received the Pfizer-BioNTech vaccine for their first dose can receive the Moderna vaccine for their second dose if that's the only vaccine the pharmacy has available.

a. True
b. False

FACT: You should not mix COVID-19 vaccines

- Currently authorized vaccines require 2 doses
- Each dose needs to be from the same manufacturer
  - Both mRNA vaccines
  - Patients do not need to get each dose from the same provider
  - Note differences in vaccine doses and dose spacing
- If 2 doses of different mRNA COVID-19 vaccine products are inadvertently administered, no additional doses of either product are recommended at this time.

ADDITIONAL FACT: You should not restart vaccine series if administered beyond 21 or 28 day vaccine spacing for dose 2

- Never restart regimen
- Prefer to give 2nd dose within 1 week of recommended time –
  - Administer vaccine when you can
  - DON'T schedule too early
    - 4 day grace period only applies if inadvertently administered early
    - Starting point for 2nd dose is 21 or 28 day, depending on vaccine

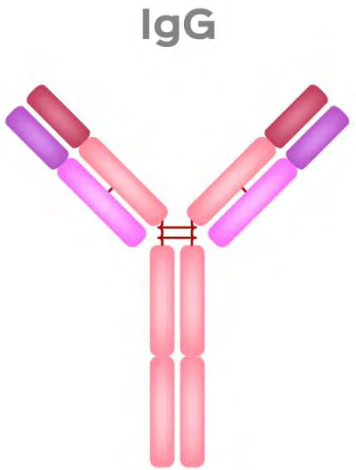
Assessment Question #6

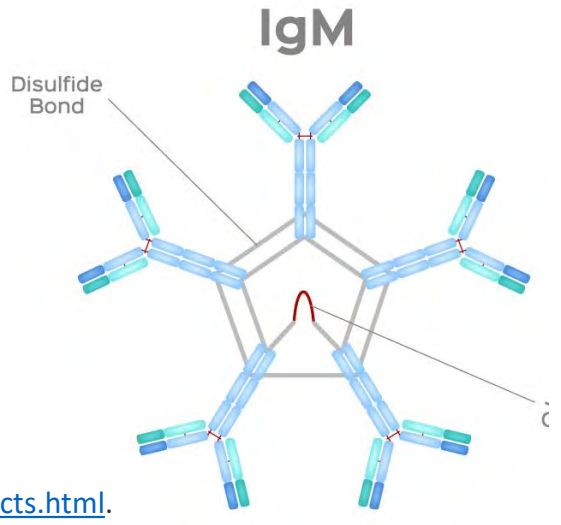
True or False: COVID-19 vaccines can result in false-positives on COVID-19 viral tests.

a. True
b. False

FACT: COVID-19 vaccines will not cause false positives on COVID-19 viral tests

- Neither recently authorized or under clinical trial in US cause you to test positive on viral tests used to see if you have a **current infection**.[1]
- Antibody tests: If your body develops an immune response, which is the goal of vaccination, there is a possibility you may test positive on some antibody tests.[1]
  - These tests indicate you had a **previous infection** and that you may have some level of protection against the virus.
    - ❑ Experts are currently looking at how COVID-19 vaccination may affect antibody testing results.





1. U.S. Centers for Disease Control. "Facts About COVID-19 Vaccines". January 4th, 2021. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/facts.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fvaccines%2Fvaccine-benefits%2Ffacts.html. Accessed 1/13/21

Open Forum Discussion: A Minute for Your Thoughts *Comments, Questions, Feedback*

Review of APhA's Ongoing Activities and What's Coming

Update from FDA on Variability in the Number of Doses per Vial

- After dilution, vials of Pfizer-BioNTech COVID-19 Vaccine contain **six doses** of 0.3 mL of vaccine.
- **Use low dead-volume syringes and/or needles to extract six doses from a single vial.**
- Each dose must contain 0.3 mL of vaccine.
- Do not pool excess vaccine from multiple vials."

[Pfizer-BioNTech Fact Sheet for Healthcare Providers]

CDC Pharmacy Partnership Programs for COVID-19 Vaccination

	Federal LTCF Program	Leveraging Pharmacy Partners in Phase 1 (Jurisdiction Transfers)	Federal Retail Pharmacy Program Phase 2
How is it activated?	• Jurisdiction requests activation, two-week notice	• Jurisdiction requests transfer	• OWS activates based on vaccine supply
When can it be activated?	• Jurisdiction chooses first clinic date	• Jurisdiction chooses timing	• OWS chooses time, incremental roll out nation-wide
How many doses are required to activate?	• 25% of doses needed for LTC population before first clinic; remainder within next three weeks	• N/A - jurisdiction chooses amount to transfer to the pharmacy partner	• OWS chooses threshold to activate broader site footprint
Where does allocation come from?	• Transferred from jurisdiction allocations to pharmacy	• Transferred from jurisdiction allocation to pharmacy	• Direct Federal allocation to pharmacy partner
Who enrolls providers?	• USG; no effort required on behalf of the jurisdiction	• USG; no effort required on behalf of the jurisdiction	• USG; no effort required on behalf of the jurisdiction
Which populations will be vaccinated?	• LTCF residents and staff	• Jurisdiction chooses; likely essential workers or individuals ≥75 years, could include HCP not previously vaccinated	• General /broader population (general, elderly)
Which sites will vaccinate?	• Pharmacy partners hold clinics at all enrolled and eligible LTCFs	• Select retail pharmacy sites chosen by jurisdiction in coordination with partners	• Initial rollout: coordinated by CDC with jurisdiction input • Later expansion: pharmacies choose expansion of sites based on uptake; CDC provides oversight
Who will carry out vaccination?	• Pharmacy partner staff	• Pharmacy partner staff	• Pharmacy partner staff

APhA COVID-19 Resources: Know the Facts

Practical Information for Pharmacists to Know Now

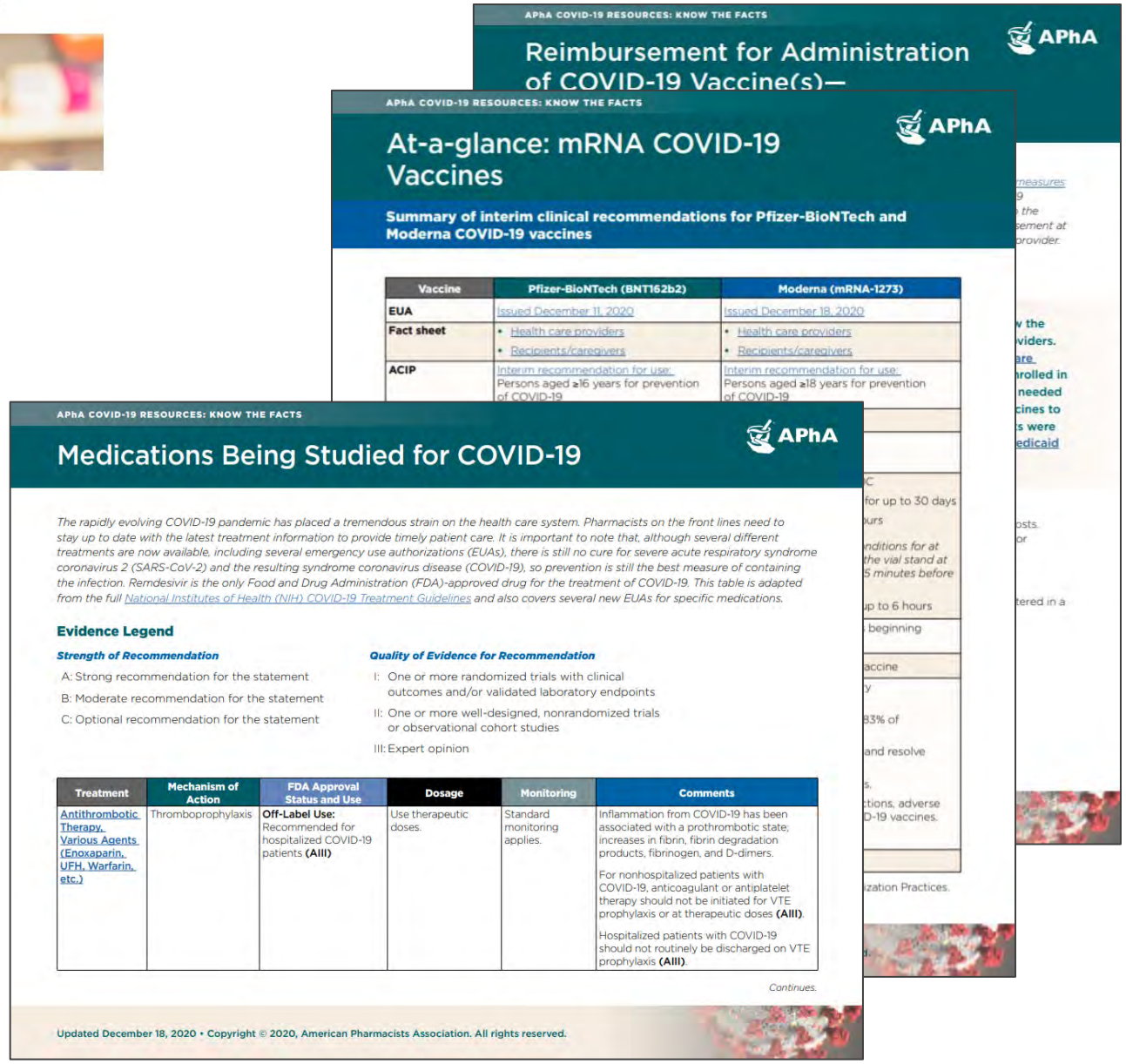
New Resource:

- **Medications Being Studied**

COVID-19 Vaccine Resources:

- **At-a-glance: mRNA COVID-19 Vaccines**
- **Reimbursement for Administration of COVID-19 Vaccine(s) – What We Know**

Check out the library of practice resources here



Post on ENGAGE

Pharmacy's Response to COVID-19

POST your questions

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SUPPORT your colleagues

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Weekly Open Forum Webinars

Join Us!

Thursday, January 21, 1-2pm ET

Today's webinar recording and slides will be available within 24hrs

https://www.pharmacist.com/coronavirus/weekly-webinars

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- Be prepared to record the code when it appears
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  1. After the webinar ends, return to the “My Training” page on pharmacist.com (http://elearning.pharmacist.com/my-training)
  2. Log in using your pharmacist.com username and password
  3. Click on the “COVID-19 Vaccines: Myth vs. Fact” session listed in your enrollments
  4. Click on “COVID-19 Vaccines: Myth vs. Fact” under the “Activities” heading
  5. Enter the attendance code
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FACT: COVID-19 vaccines will not give you COVID-19

- None of the currently authorized or in development COVID-19 vaccines in the US contain the live virus that causes COVID-19.
  - Goal for each of them is to teach our immune systems how to recognize and fight the virus that causes COVID-19.
  - Sometimes this process can cause symptoms, such as fever. These symptoms are normal and are a sign that the body is building immunity.
  - Typically takes a few weeks for the body to build immunity after vaccination.
    - That means it's possible a person could be infected with the virus that causes COVID-19 just before or just after vaccination and get sick. This is because the vaccine has not had enough time to provide protection.

FACT: Receiving an mRNA vaccine will not alter your DNA

- mRNA provides instructions for how to make a protein or even just a piece of a protein.
- mRNA is not able to alter or modify a person's genetic makeup (DNA).
- The mRNA from a COVID-19 vaccine never enter the nucleus of the cell, which is where our DNA are kept.
  - This means the mRNA does not affect or interact with our DNA in any way.
  - Instead, COVID-19 vaccines that use mRNA work with the body's natural defenses to safely develop protection (immunity) to disease.

FACT: There is no tracking microchip in the COVID-19 vaccine

- Online discussions alleging that that the COVID-19 vaccine contains a tracking microchip are **completely false.**
- The only tracking is on the shipment box (Pfizer-BioNTech)

FACT: Continue to wear a face mask and social distance after completing the COVID-19 vaccine series

- Continue to wear face masks and follow other recommended protection procedures even after completing the vaccination series.
  - Need 70+% of communities vaccinated

FACT: The COVID-19 Vaccine is safe

- Multiple phases of the process were conducted simultaneously based on existing knowledge of studied platforms and approaches.
- Unprecedented financial resources allocated to support product production (at financial risk).
- Companies followed safety protocols, performed appropriate testing, and had independent body oversight.
- The number of individuals in the clinical trials for authorized vaccines were equivalent to or exceeded those in previously approved vaccines.
- To receive EUA, the manufacturer must have followed at least half of the study participants for at least two months after completing the vaccination series, and the vaccine must be proven safe and effective in that population.
- The FDA and the CDC Advisory Committee on Immunization Practices convened panels of experts to independently evaluate the safety data from the clinical trials.
    - The EUAs and CDC Clinical Guidance provide information to support provider administration and management of COVID-19 vaccination programs.

FACT: You should not draw COVID-19 vaccine doses from different vials

- FDA acknowledges ability to attain 6 doses from Pfizer-BioNTech vials (possibly 7 doses) – awaiting information related to Moderna vaccine
- All doses need to come from same vial
  - Both mRNA vaccines