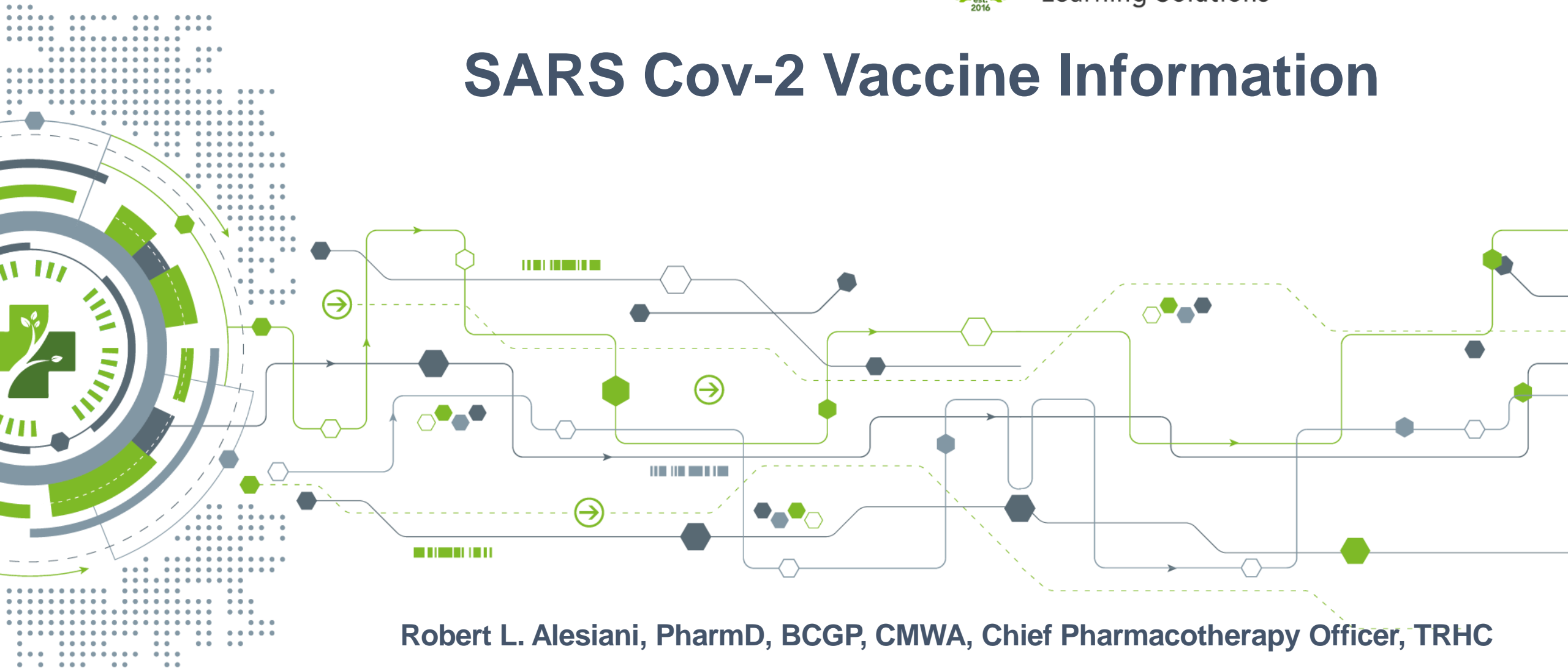


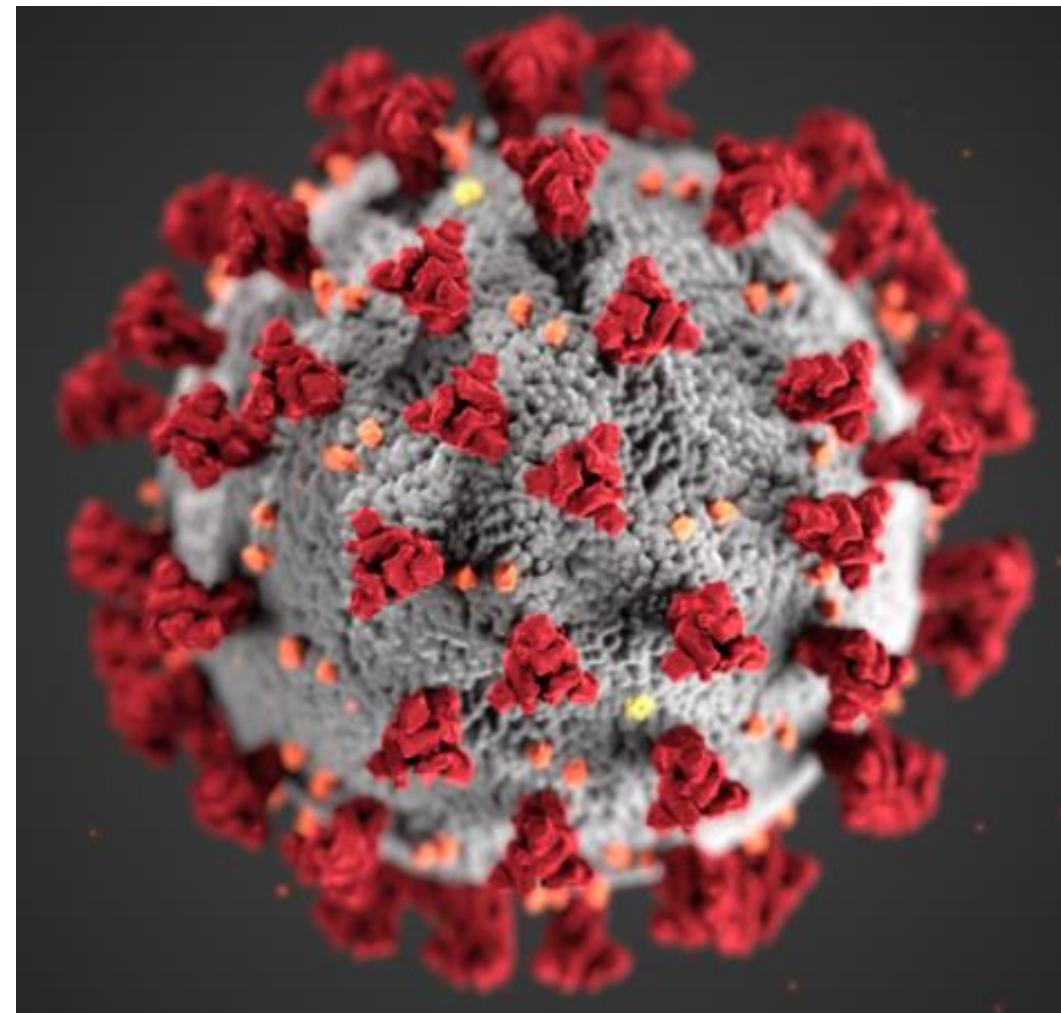
SARS Cov-2 Vaccine Information



Robert L. Alesiani, PharmD, BCGP, CMWA, Chief Pharmacotherapy Officer, TRHC

- ▶ I, Robert Alesiani, declare to not have any real or apparent conflicts of interest or financial interests with any pharmaceutical manufacturers, medical device company, or in any product or service, including grants, employment, gifts, stock holdings, and honoraria related to the content of this presentation.

- ▶ Explanation of history and goals of Operation WARP Speed
- ▶ Discussion of the vaccines that are pending release soon
 - Some Clinical Features
 - Injection Reactions
 - Unanswered Questions
 - Logistics Features
 - Financial Features
 - Documentation Requirements



► Goal:

- Produce and deliver 300 million doses of safe and effective vaccines with the initial doses available by January 2021
- Accelerate the development, manufacturing, and distribution of SARS CoV-2 vaccines, therapeutics, and diagnostics





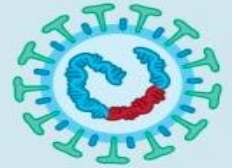
► Partnership:

- Department of Health and Human Services (HHS)
- Centers for Disease Control and Prevention (CDC)
- National Institute of Health (NIH)
- Biomedical Advanced Research and Development Authority (BARDA)
- Department of Defense (DoD)
- Private Firms/Pharma (Moderna, AstraZeneca, Johnson and Johnson, Eli Lilly, GSK, and others)

Vaccine Types

Types of coronavirus vaccine approaches

Scientists are casting a wide net to see what works best against the novel coronavirus.

Types of vaccines	DNA and RNA	Live attenuated	Inactivated	Subunit	Viral vector
How it works	 <p>This vaccine uses DNA or RNA molecules to teach the immune system to target key viral proteins.</p>	 <p>This is a weakened version of the actual virus.</p>	 <p>An inactivated vaccine uses the whole virus after it has been killed with heat or chemicals.</p>	 <p>This vaccine uses a piece of a virus' surface to focus your immune system on a single target.</p>	 <p>This approach takes a harmless virus and uses it to deliver viral genes to build immunity.</p>
Advantages	Easy and quick to design.	Stimulates a robust immune response without causing serious disease.	Safe because the virus is already dead and is easy to make.	Focuses the immune response on the most important part of the virus for protection and cannot cause infection.	Live viruses tend to elicit stronger immune responses than dead viruses or subunit vaccines.
Disadvantages	Never been done before. There are no licensed DNA or RNA vaccines currently in use.	May not be safe for those with compromised immune systems.	Not as effective as a live virus. Some previous inactivated vaccines have made the disease worse; safety for the novel coronavirus needs to be shown in clinical trials.	May not stimulate a strong response, other chemicals may need to be added to boost long-term immunity.	Important to pick a viral vector that is truly safe. An immune response to the viral vector could make the vaccine less effective.
Existing examples	<ul style="list-style-type: none"> • None 	<ul style="list-style-type: none"> • Measles, Mumps and Rubella • Chickenpox 	<ul style="list-style-type: none"> • Polio 	<ul style="list-style-type: none"> • Pertussis • Hepatitis B • Human papillomavirus (HPV) 	<ul style="list-style-type: none"> • Ebola • Veterinary medicine
Group testing this approach for COVID-19	<ul style="list-style-type: none"> • Moderna (RNA) • Inovio (DNA) 	<ul style="list-style-type: none"> • Codagenix • Indian Immunologicals Ltd. 	<ul style="list-style-type: none"> • Sinovac • Sinopharm 	<ul style="list-style-type: none"> • Novavax • AdaptVac 	<ul style="list-style-type: none"> • University of Oxford & AstraZeneca • CanSino Biologics • Johnson & Johnson






Sources: CDC; NIAID; FDA

MICHELLE GUERRERO and JONATHAN WOSEN U-T
The San Diego Union-Tribune, 6/6/2020

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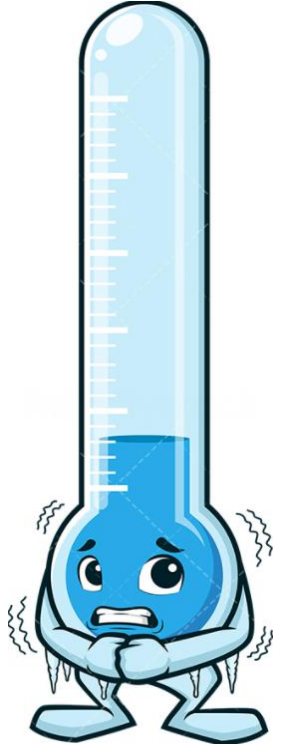
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MICHELLE GUERRERO and JONATHAN WOVEN U-T
The San Diego Union-Tribune, 6/6/2020

Pfizer Vaccine

- ▶ Type: mRNA - 95% effective
- ▶ Ordering nuances: Minimum: 1000 doses, maximum: 5000 doses
- ▶ Shipment:
 - Vaccine (from Pfizer) Shipped on Dry Ice*
 - Diluent (from USG supply) Shipped at Ambient Temperature
 - Ancillary Supply Kits (from USG supply) Shipped at Ambient Temperature
- ▶ Multi-dose vials only (five doses/vial)
- ▶ Expected to be first to market distribution
- ▶ On-Site Storage
 - “Ultra-Cold” (-70° to -100° C)
 - May stay in shipping cooler: “Re-charge” with dry ice pellets, day 0, 5, 10
 - * Discard after day 15
 - Thawed, refrigerated but NOT reconstituted: Use within 24-48 hours
 - Reconstituted @ room temperature: Use within 6 hours
- ▶ Administration:
 - Two dose series, 21 days between doses
 - On-site mixing recommended, just prior to administration. Best if five PPTs are queued
 - Deltoid IM injection



* Ultra cold storage requirements hinders mass vaccination outside of facilities/clinics. May not be ideal in PACE settings

Moderna Vaccine

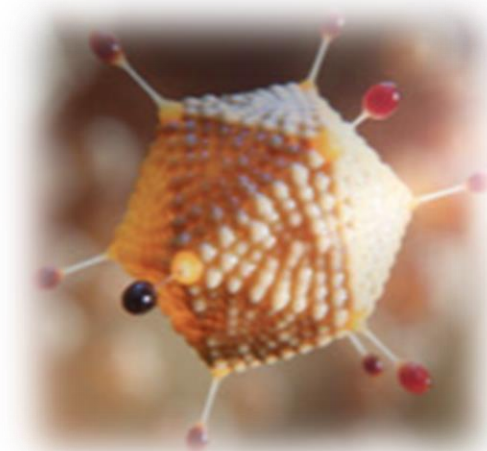
- ▶ Type: mRNA - 94.6% effective *100% against severe disease
- ▶ Ordering nuances: Minimum: 100 doses (10 x 10 dose sleeve of MDV)
- ▶ Shipment:
 - Vaccine (through wholesalers) Shipped under normal frozen temps (e.g. “Shingrix” Shingles vaccine)
 - Ancillary Supply Kits (from USG supply) Shipped at Ambient Temperature
- ▶ Ready to use, multi-dose vials only (10 doses/vial) (reconstitution not needed)
- ▶ Expected to be second to market distribution
- ▶ On-Site Storage (-20° C) normal freezer temperatures
 - Thawed, refrigerated: Use within 7-14 days
 - @ room temperature: Use within 6 hours
- ▶ Administration: Two dose series, 28 days between doses
Deltoid IM injection



Astra-Zeneca/Oxford Vaccine

- ▶ Type: Viral Vector (Coronavirus “spike” protein material linked to modified adeno-virus) 70 – 90+ % effective*
- ▶ Shipment:
 - Vaccine (through wholesalers) Shipped under normal “cool” refrigerated temps e.g., annual flu vaccine
 - Ancillary Supply Kits (from USG supply) Shipped at Ambient Temperature
- ▶ Ready to use, multi-dose vials only (10 doses/vial) (reconstitution not needed)
- ▶ Expected to market distribution possibly 2nd quarter 2021
- ▶ Ordering restrictions: Minimum: 100 doses (10 x 10 dose sleeve of MDV)
- ▶ On-Site Storage (2° - 8° C) normal refrigerator temperatures
Stable at least six months in refrigerator
- ▶ Administration: Two dose series, 28 days between doses

Administered deltoid IM injection
- ▶ Initial Study Flaw: During the initial phase, several patient volunteers received ½ dose with the initial series. Those that received the lower initial dose showed higher efficacy. A/Z has agreed to further study using two test groups (Note: all volunteers that received the lower dose were also < 55 years old, which can also contribute to the more robust response).
- Least expensive to produce, maybe a viable alternative not only for US distribution, but impoverished nations worldwide.



Adenovirus vector

<https://www.astrazeneca.com/media-centre/press-releases/2020/azd1222h1r.html>

Vaccine Injection Reactions

- ▶ Onset: 12-24 hours post injection
- ▶ Minor: 10-20% Injection site pain, low fever, mild headache
- ▶ Major: 2%* (defined as side effect that prevents normal daily activity; fever, chills, nausea, malaise, joint pain, severe headaches, vertigo, and “flu-like” symptoms.

*While 2% is low, with 35 million people immunized by the year’s end, that translates into 700,000 severe reactions.

Considerations:

- Education: It’s critical that patients and staff receive both doses on time. They should understand what can be expected and the importance of coming back for the booster.
- Staff vs. patient immunization days: Consider staggering immunization days for staff and patients. While the percentage is low, you can assume a certain level of vaccine “reactogenic” illness over the next 1-2 days. Avoid a situation of increased patient illness requiring more support and care and with less staff available to provide that care.

Unanswered Questions

- ▶ Does the vaccine protect against both severe and mild illness?
- ▶ Does the vaccine protect against transmission of the virus?
- ▶ How long is protection efficacy over time?
- ▶ Which vaccine is best?
- ▶ When will the vaccine be available?
- ▶ Who will get access first?
- ▶ How safe are the vaccines (really)?

Registry Questions at time of injection*

- ▶ Name
- ▶ DOB
- ▶ Gender
- ▶ Address
- ▶ Phone
- ▶ Email
- ▶ Injection site/route
- ▶ Injection number (1,2)
- ▶ Vaccine lot and expiration date
- ▶ Administrator's NPI number
- ▶ Ever tested positive for COVID?
- ▶ Ever screened positive for COVID antibodies?
- ▶ Co-morbidity status
- ▶ Race/Ethnicity
- ▶ Documentation of any injection reaction at time of administration

* Some questions may differ from state to state

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Cost Consideration

▶ Vaccines:

- No Charge: At time of the release, all vaccines will be provided free of charge by the federal government.

▶ Ancillary Supplies: Syringes and some others will also be provided as needed

▶ PPI will not be provided:

- Masks
- Gloves
- Sharps containers
- Adhesive bandages (e.g., “Band-Aids”)
- Alcohol Swabs



Questions?

References

- ▶ <https://www.kcra.com/article/despite-mild-reaction-to-moderna-vaccine-ca-trial-participant-encourages-everyone-vaccinated/34827287>
- ▶ <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines.html>
- ▶ <https://www.clinicaltrials.gov/ct2/show/NCT04283461?cond=covid+vaccine&draw=2&rank=3>
- ▶ <https://www.nih.gov/news-events/news-releases/promising-interim-results-clinical-trial-nih-moderna-covid-19-vaccine>
- ▶ <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-conclude-phase-3-study-covid-19-vaccine>
- ▶ <https://www.astrazeneca.com/media-centre/press-releases/2020/azd1222h1r.html>
- ▶ <https://www.sciencemag.org/news/2020/11/fever-aches-pfizer-moderna-jabs-aren-t-dangerous-may-be-intense-some>
- ▶ <https://www.sandiegouniontribune.com/news/science/story/2020-06-06/race-for-vaccine>