

COVID-19 Vaccine Update

Indian Country COVID-19 ECHO Presentation

October 14, 2020

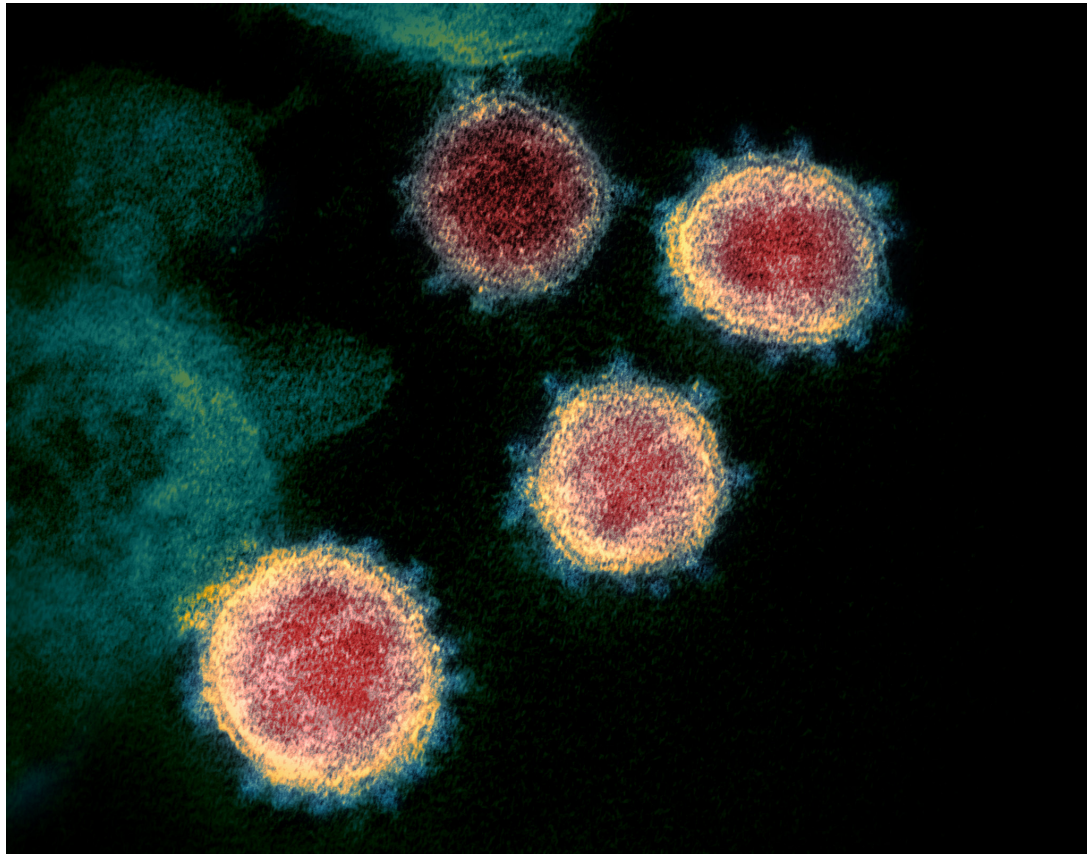
Harry J Brown, MD

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Day 218 of the COVID-19 Pandemic



- Review of immunology and vaccine science
- A new Phase 3 candidate
- Vaccine safety update
- Vaccine storage requirements
- Resources

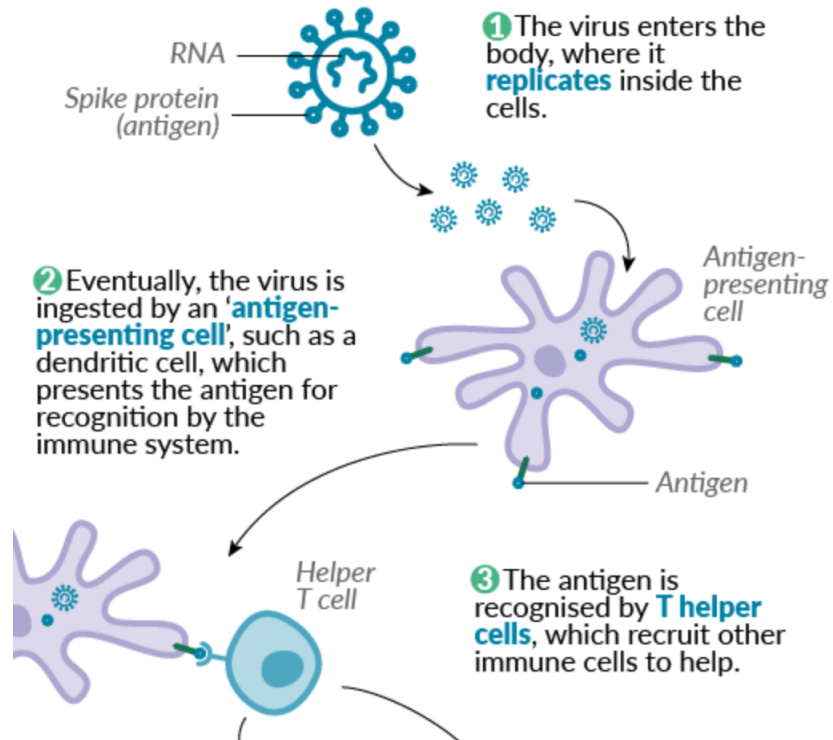
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Immunology in Brief

Adaptive immunity

Vaccines work based on the body's **adaptive immune response**. This simplified graphic shows the principles of the adaptive response to **SARS-CoV-2**, the virus that causes COVID-19.

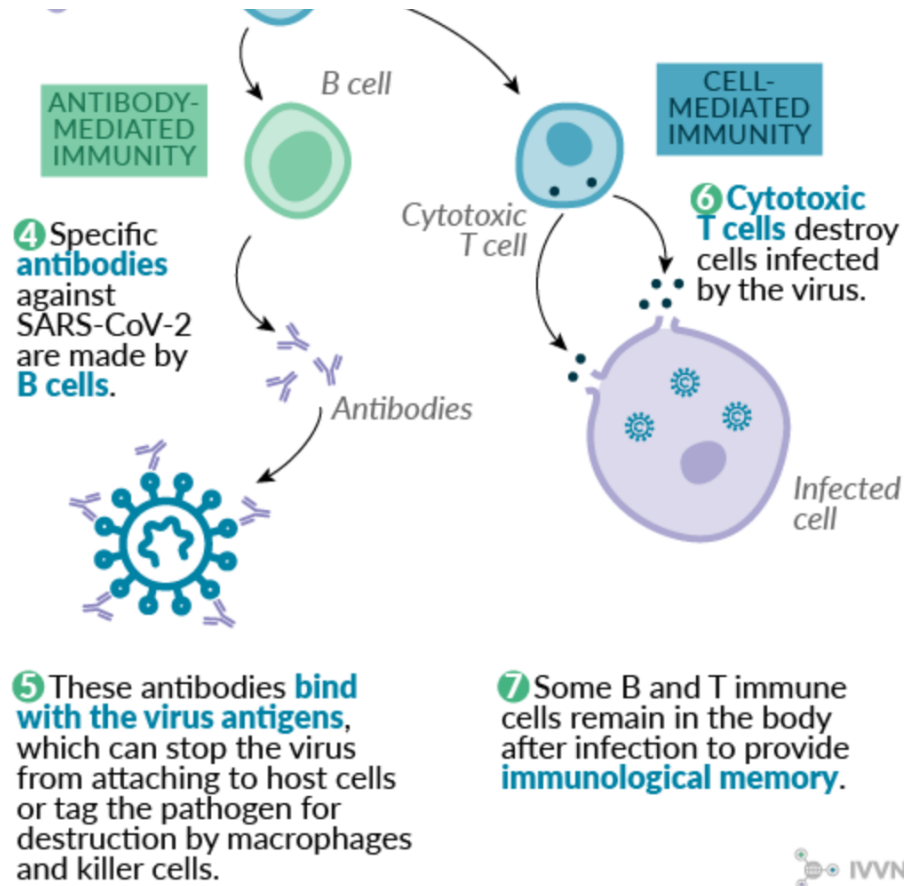


- Virus enters the body, attaches to and enters cells, and replicates
- The virus is taken up by an Antigen Presenting Cell (APC), which presents the virus for recognition by the immune system as foreign
- T helper cells recruit other immune cells

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Immunology in Brief

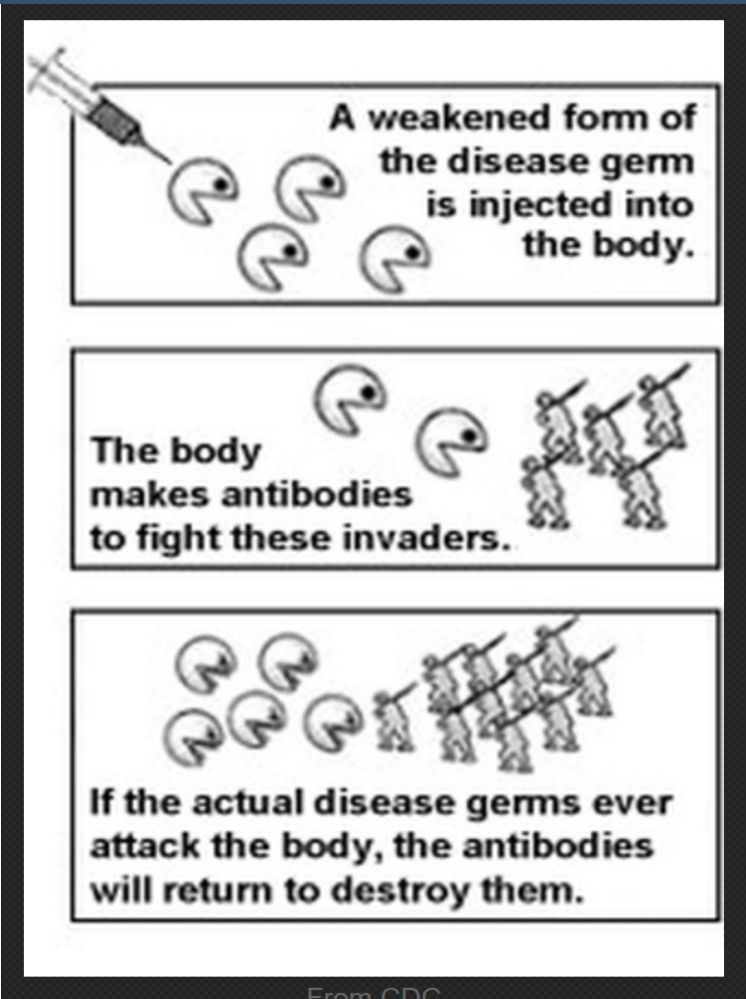


- B cells make antibodies that can bind to viral antigens
- Cytotoxic T cells recognize viral antigens and destroy cells infected by virus
- Memory cells remain to provide humoral immunity (B cells) and cellular immunity (T cells)

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How do viral vaccines work?



- A weakened virus (“live attenuated”), or inactivated virus, or a part of a virus is made into a vaccine
- The vaccine is injected
- The immune system responds to make antibodies (and sometimes a T cell response)
- Immune memory is created



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Desired Vaccine Characteristics

- Safe
 - No serious adverse effects
 - Minor adverse effects acceptable and expected
- Effective – produce neutralizing antibodies and T cell response
- Proven efficacy in diverse populations
 - At least 50% efficacy for FDA approval
- Inexpensive
- Easy to manufacture in large quantities, deliver, and store
- Easy to administer to large populations

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Current Major Vaccine Technologies

- Inactivated Virus
- Live Attenuated Virus
- Protein Subunit
- Viral Like Particle (VLP)
- Replicating Viral Vector
- Nonreplicating Viral Vector
- DNA
- RNA

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This Is Only A Test

How many current COVID-19 vaccine candidates are in Phase 3 Trials?

- a) 6
- b) 9
- c) 10
- d) 14
- e) None of the above

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WHO Vaccine Candidate Tracker

September 21, 2020

- 38 vaccine candidates in human trials
- 9 candidates in Phase 3
- 149 in pre-clinical
- 187 total vaccine candidates

October 2, 2020

- 42 vaccine candidates in human trials
- 10 candidates in Phase 3*
- 151 in pre-clinical
- 193 total vaccine candidates in some phase of development

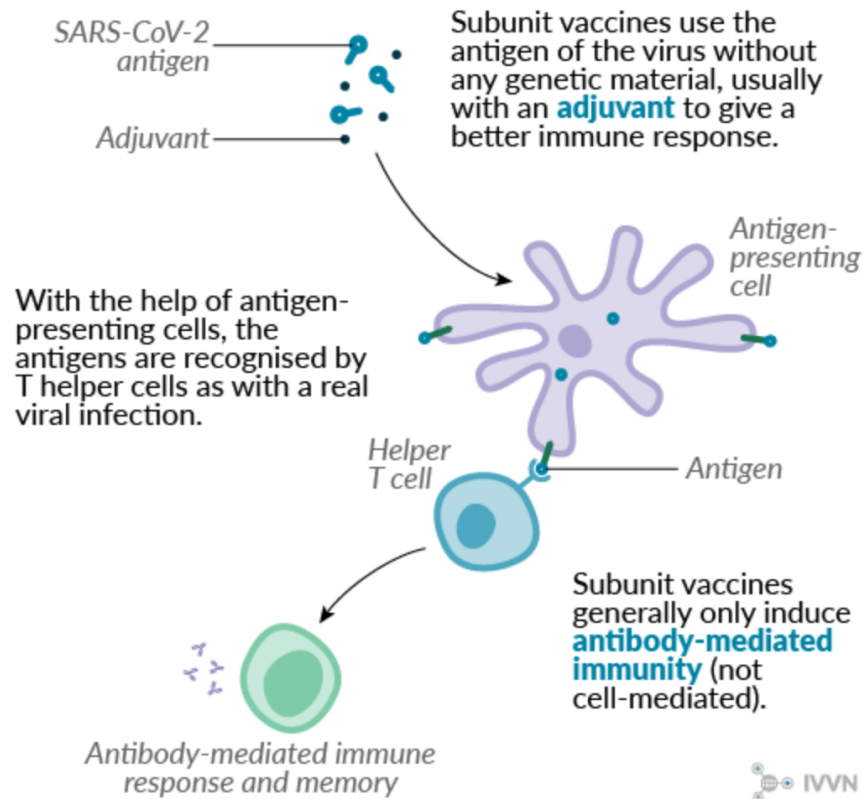
<https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines>

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Protein Subunit Vaccine

Subunit vaccines



- Part of the virus (protein subunit) is made with recombinant technology
- The subunit elicits an immune response to make antibodies
- Adjuvants usually used to enhance the immune response
- Often only produce humoral immunity (not cellular)

<https://www.intvetvacnet.co.uk/blog/covid-19/vaccine-eight-types-being-tested>

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The Latest Phase 3 Candidate

NVX-CoV 2373 (Novavax)

- Recombinant nanoparticle vaccine using the spike protein of the SARS-CoV2 virus
- Phase 3 trial began in UK on Sept 24 (plan for a US trial soon)
- Phase 1/2 trials showed good safety profile and good immune response (both antibody and T cell response)
- Uses *Matrix-M* adjuvant that causes influx of APC
- Phase 2 trial in HIV positive individuals in South Africa

<https://www.nejm.org/doi/pdf/10.1056/NEJMoa2026920>

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Vaccine Safety

- September 8, 2020 - the CEOs of 9 major vaccine manufacturers signed a pledge to make safety and well-being of vaccinated individuals their top priority
- October 6, 2020 – the FDA stated that there should be a median follow-up duration of at least 2 months after completion of the full vaccination regimen before submitting an application for Emergency Use Authorization

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Vaccine Safety

- AstraZeneca/Oxford vaccine trial halted Sept 8 due to serious medical condition in a trial participant
 - Individual developed transverse myelitis, relatively rare condition
 - Trials resumed in UK and Brazil, but not yet in US
- Johnson & Johnson/Janssen vaccine trial halted Oct 12
 - Nature of illness not reported
 - Not known how long pause will last

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Vaccine Storage Requirements

mRNA Vaccines

- BNT 162 (Pfizer)
 - Storage at -70 C (-94 F)
 - May be used for up to 5 days after thawing (at refrigerator temperature)
 - Will be shipped on dry ice, can be stored up to 10 days
- mRNA-1273 (Moderna)
 - Storage at -20 C (-4 F)
 - May be used for a week after thawing (at 2 – 8 C, 36 to 46 F)

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Vaccine Storage Requirements

Viral Vectored Vaccines

- AZD1222 (AstraZeneca/Oxford)
- JNJ-78436735 (J&J/Janssen)
 - Shipped at -8 to -2 C (18 to 28 F)
 - Stored at refrigeration temperature (2 to 8 C, 36 to 46 F)
 - Minimum order: 100 doses???

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Vaccine Storage Requirements

NVX-CoV2373 (Novavax)

- Storage at 2 to 8 C (refrigerator temperature, 36 – 46 F)
- Stable at 25 C (77 F)
- Long shelf life
- Minimum order 100 doses???

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A Few Resources:

Vaccine Tracking Websites:

- Milken Institute: <https://covid-19tracker.milkeninstitute.org/>
- London School of Tropical Medicine: https://vac-lshtm.shinyapps.io/ncov_vaccine_landscape/
- WHO: <https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines>
- NY Times: <https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html>

Basic Vaccine Technology Article:

“Covid-19: the eight vaccine technologies being tested” – from the *International Veterinary Vaccinology Network*:

<https://www.intvetvacnet.co.uk/blog/covid-19/vaccine-eight-types-being-tested>

CDC Vaccine Website for COVID-19:

<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/index.html>

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Thank You for Your Time and Attention!

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Have a great weekend!

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