# Covid-19 Vaccine Update: Janssen/Johnson & Johnson Vaccine

COVID-19 ECHO Presentation

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# Objectives for Today's Presentation

1) Become familiar with the safety and efficacy of Ad26.COV2.S (Janssen Covid-19 vaccine)
2) Become familiar with safety measures taken with vaccine development

No disclosures, conflicts of interest

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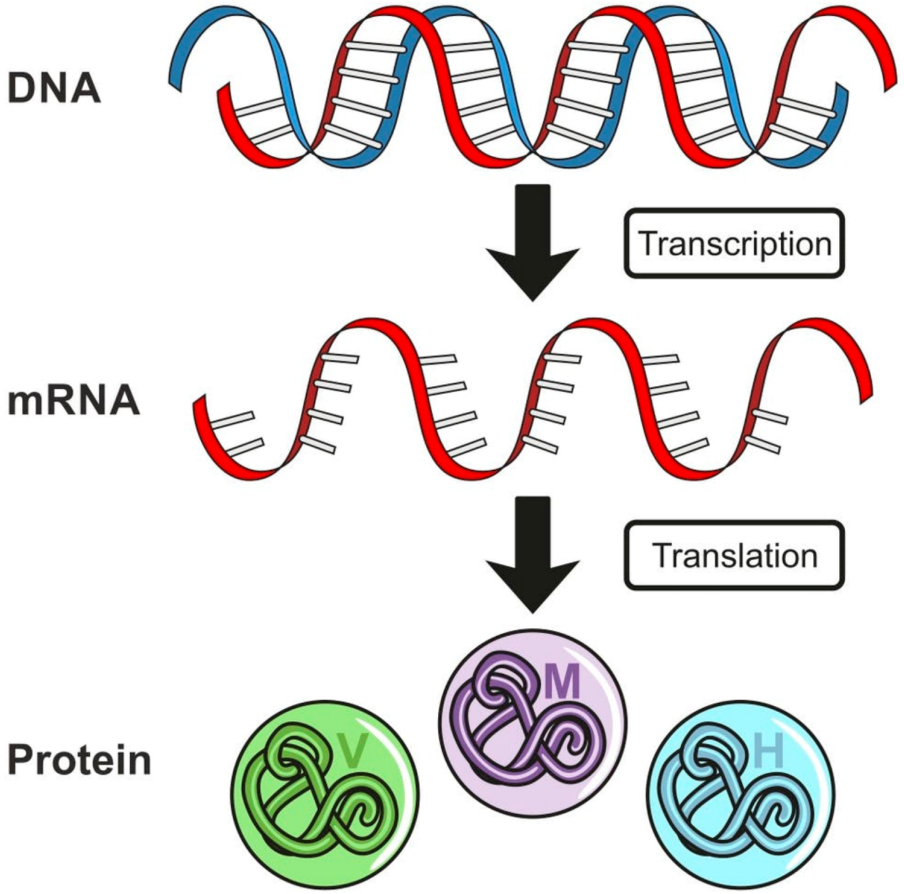
# Current Major Viral Vaccine Technologies

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

# Brief Review of Genetics




- In cellular organisms, the genetic code is carried in DNA
- DNA is **transcribed** into mRNA
- mRNA is then **translated** in the ribosomes to make proteins
- mRNA is rapidly degraded after being used by the ribosomes, and does not go back into the nucleus

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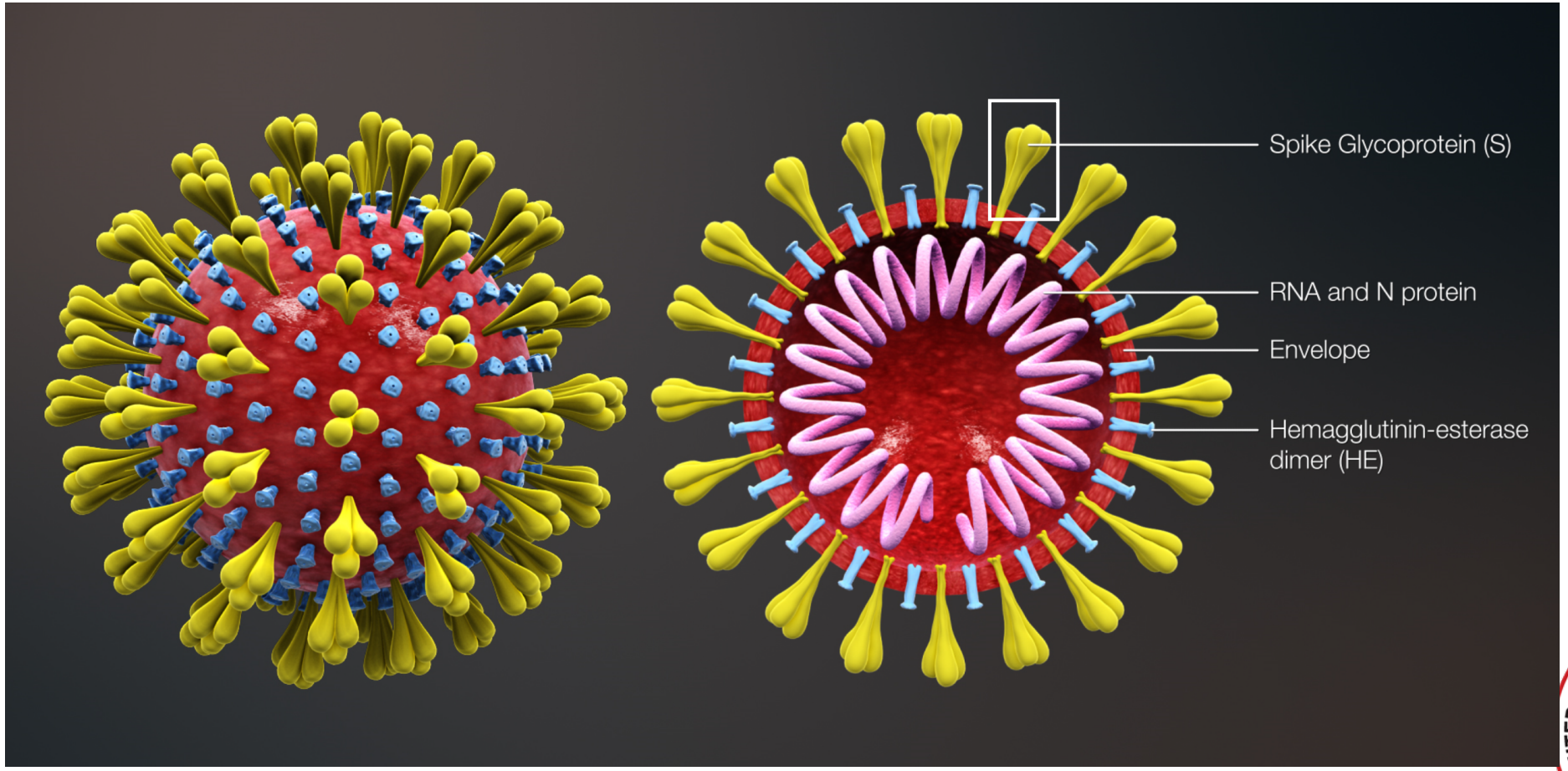
# Coronavirus Structure

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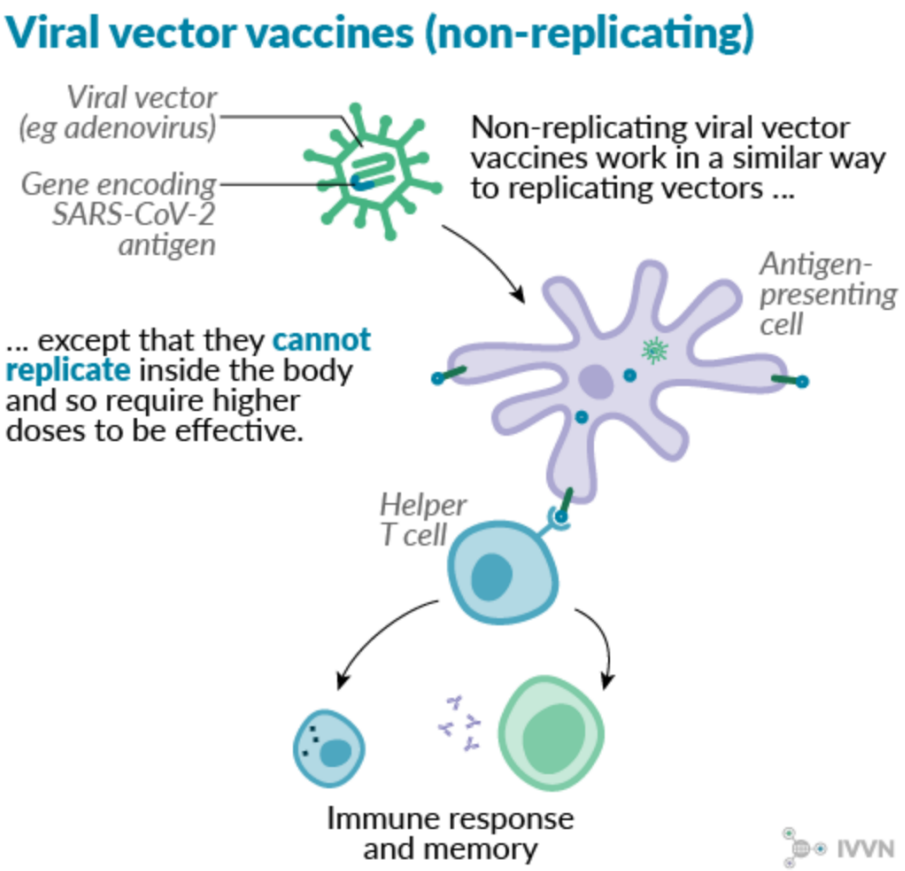
# Non-replicating Viral Vector Vaccine




- The adenovirus vector is genetically modified to carry a gene for the SARS-CoV-2 spike protein (and made incapable of replication)
- Our own cells make the spike
- The spike protein provokes an immune response
- Immune response is both antibody and T cell

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

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# Janssen/J&J Covid-19 Vaccine

- Janssen (Belgium) owned by Johnson&Johnson (USA)
- Adenovirus serotype 26 (AdVac platform) modified to carry gene for SARS-CoV-2 and grown in PER.C6 tissue culture
- Phase 1/2a trials conducted in US and Belgium
- >90% participants developed neutralizing antibodies 4 wks after 1 dose
- No serious adverse effects report
- Injection site pain, fatigue, headache, myalgia, fever reported

NEJM- J Sadoff et al – DOI:10.1056/NEJMoa2034201

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# ENSEMBLE Trial – Phase 3 Results

- n = 43,783
- Argentina, Brazil, Chile, Colombia, Mexico, Peru, South Africa, USA
- 62% of participants classified as White
- 8.5% AI/AN (only 175 in the USA)
- 35% were age 60 or older
- 40% had medical co-morbidities

https://www.fda.gov/media/146217/download

# Janssen Vaccine – Phase 3 Results

- Efficacy Endpoints: Incidence of Covid-19 occurring 14 or more days after vaccination and 28 or more days after vaccination
- 66% effective at preventing symptomatic disease (at 14 and 28 days)
- For severe disease, 77% effective after 14 days, 85% effective after 28 days
- Hospitalization: 93% efficacy at 14 days, 100% efficacy after 28 days
- Death: no Covid deaths in vaccine group, 7 Covid deaths in placebo group
- Efficacy for asymptomatic disease about the same as for symptomatic
- Efficacy similar across gender, ethnic/racial groups, age, comorbidities

https://www.fda.gov/media/146217/download

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# Janssen Vaccine – Phase 3 Safety Results

- No vaccine-related serious adverse events

Side-effects common, but very few were rated Grade 3 (more frequent in younger participants than older)

| | | | |
|---|---|---|---|
| • Injection site reaction | 48.6% | | |
| • Fatigue | 38.2% | Myalgias | 33.2% |
| • Headache | 38.9% | Fever | 9.0% |

Events numerically more common in vaccine group vs placebo:
Urticaria (5 vs 1), Thromboembolic Events (15 vs 10) and Tinnitus (6 vs 0)

https://www.fda.gov/media/146217/download

# Ad26.COV2.S – (Janssen Vaccine)

- Vaccine contains adenovirus vector and buffers in solution
- Multidose vials (5 doses), preservative free
- Single dose injection of 0.5 mL
- Stable for at least 3 months at 2 to 8 C  (36 to 46 F)
- Once vial punctured, may store 6 hours in refrigerator or 2 hours at room temperature

https://www.fda.gov/media/146217/download

# Summary: Ad26.COV2.S – (Janssen Vaccine)

- Not as effective as mRNA vaccines at preventing symptomatic disease
- Not as effective against B.1.351 variant in South Africa (but still very effective at preventing severe disease and death)
- No data (yet) on effectiveness against B.1.1.7 variant in UK
- 85% effective at preventing severe disease
- Highly effective at preventing hospitalization and death (almost 100%)
- Single dose!!!
- Refrigerator storage
- Lower rate of side-effects

# How Can These Vaccines Be Released So Fast?

- Worldwide Pandemic – Necessity is the mother of invention
- Internet allows much faster communication and sharing of knowledge
- Advances in genetics
- Previous work on SARS and MERS
- Ad26 vaccine platform already proven in Ebola vaccine
- Financial support of governments, removing financial liability from developers and producers
- During a pandemic, a Phase 3 trial can be done in a few months rather than years

# References

- FDA website – materials for VRBPAC meeting for Feb 26, 2021

https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-february-26-2021-meeting-announcement#event-materials

FDA Review –

https://www.fda.gov/media/146217/download

Janssen Document –

https://www.fda.gov/media/146219/download

Basic Vaccine Technology Article:

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

https://www.intvetvaccnet.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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