

Covid-19 Vaccine Update: Pfizer-BioNTech Vaccine

COVID-19 ECHO Presentation

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Harry J Brown, MD

USET Tribal Epidemiology Center

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Objectives for Today's Presentation



- 1) Become familiar with the safety and efficacy of BNT162b2 (Pfizer-BioNTech Covid-19 vaccine)
- 2) Become familiar with safety measures taken with vaccine development

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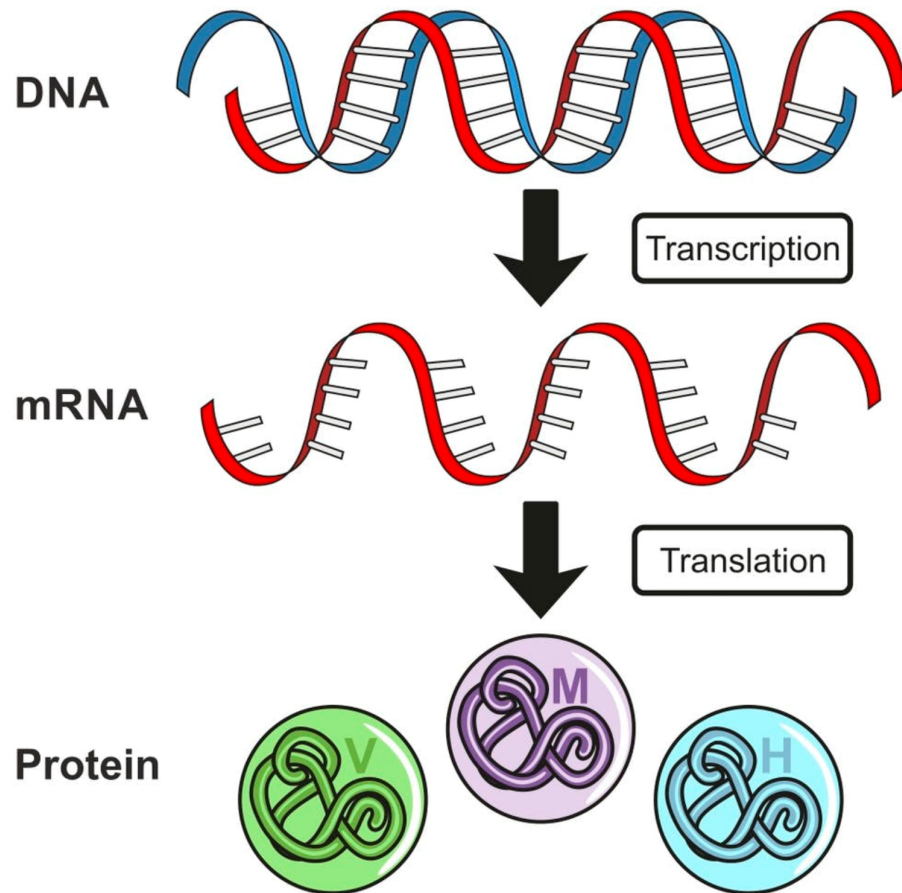
Current Major Vaccine Technologies

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

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Brief Review of Genetics

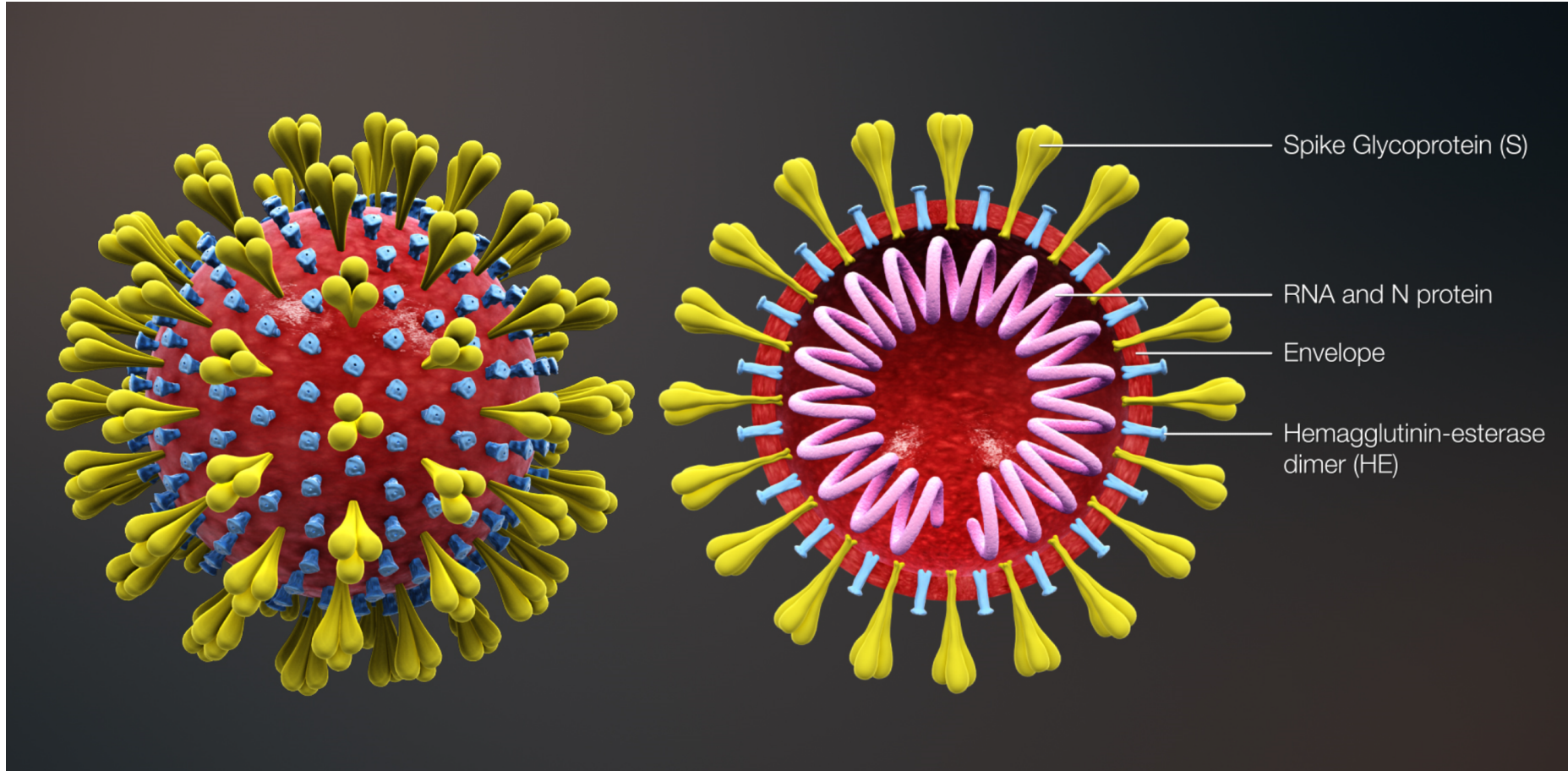


- In cellular organisms, the genetic code is carried in DNA
- DNA is **transcribed** into mRNA
- mRNA is then **translated** in the ribosomes to make proteins
- mRNA is rapidly degraded after being used by the ribosomes, and does not go back into the nucleus

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SARS-CoV-2 Structure

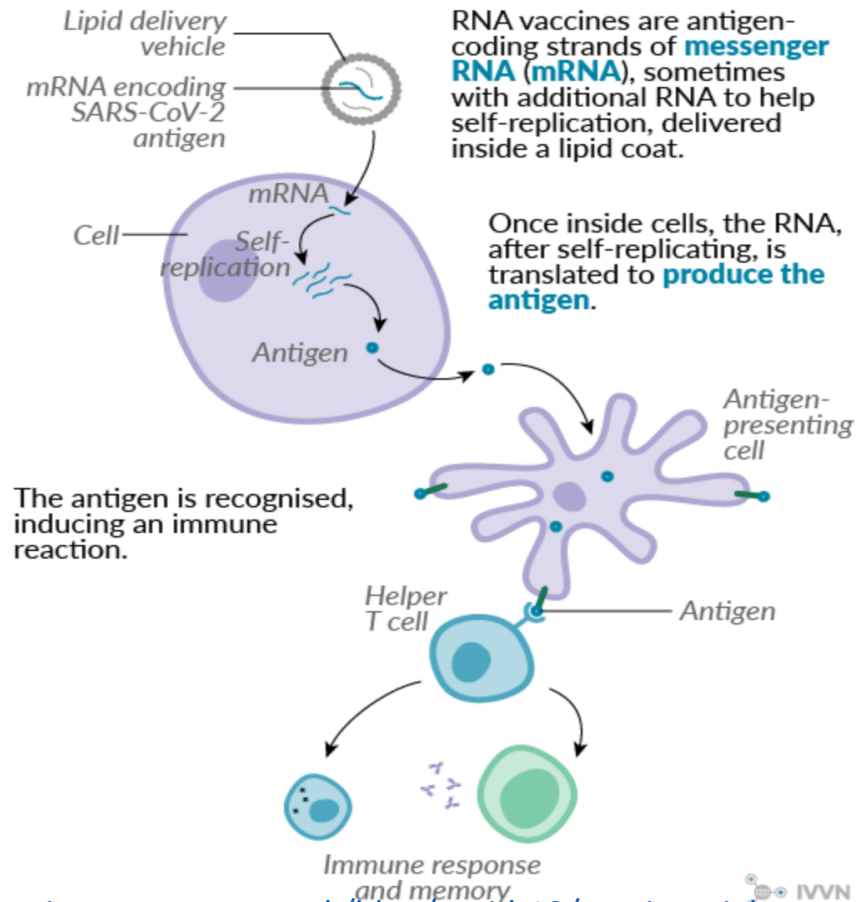


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How do RNA vaccines work?

RNA vaccines



- mRNA is made that codes for the SARS-CoV-2 spike protein
- mRNA is packaged in lipid nanoparticles
- Inside cells, mRNA is used by ribosomes to make spike protein
- Immune system produces antibodies and T-cells targeted for spike protein

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

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BioNTech/Pfizer Vaccine

- BioNTech SE (Germany) partnered with Pfizer (USA)
- mRNA encapsulated in lipid nanoparticles
- BNT162b1 and BNT162b2 used in Phase 1 trials
- All participants developed neutralizing antibodies
- No serious adverse effects reported
- Injection site pain, fatigue, headache common
- BNT162b2 advanced to Phase 2 and 3 trials due to fewer side effects

medRxiv preprint doi: <https://doi.org/10.1101/2020.06.30.20142570>

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BioNTech/Pfizer Vaccine – Phase 3 Results

- Phase 3 trial began late July
- Phase 3 trial results released on 11/9 and 11/18
- n = 43,661 Ages 12 – 91 (efficacy only age 16+)
- Argentina, Brazil, Germany, South Africa, Turkey, USA
- 30% of participants racially/ethnically diverse
- 253 AI/AN
- 2 vaccinations 21 days apart

[Vaccines and Related Biological Products Advisory Committee
December 10, 2020 Meeting Briefing Document- FDA
https://www.fda.gov/media/144245/download](https://www.fda.gov/media/144245/download)

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BioNTech/Pfizer Vaccine – Phase 3 Results

- Primary Efficacy Endpoint: Incidence of Covid-19 at 7 or more days after 2nd dose
- 170 cases of Covid-19; 162 in placebo group, 8 in vaccine group, yielding an efficacy of 95%
- Efficacy similar across gender, ethnic/racial groups, age, comorbidities
- Efficacy in >64 yr old group = 94%
- 10 severe cases – 9 in placebo group, 1 in vaccine group
- EUA application submitted to FDA Nov 20, 2020
- Emergency approval in UK granted Dec 2, 2020

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BioNTech/Pfizer Vaccine – Phase 3 Safety Results

- No vaccine-related serious adverse events
- Side-effects common, but only 4.6% were rated severe (more frequent in younger participants after 2nd dose)
 - Injection site reaction 84.1%
 - Fatigue 62.9%
 - Headache 55.1%
 - Myalgias 38.3%
 - Chills 31.9%
 - Joint Pain 23.6%
 - Fever 14.2%
- 4 cases of Bell’s palsy in vaccine group, 0 in placebo (frequency not above that expected in general population)
- Rare anaphylactoid reactions reported in Britain

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BNT162b2

- Vaccine contains mRNA, 4 different lipids, and buffers
- Multidose vials (5 doses), preservative free
- 2 dose series spaced 21 days apart
- Stable for 6 months at -80 to -60 C (-112 to -76 F)
- Stable for 5 days refrigerated at 2 to 8 C (36 to 46 F)
- Stable for 6 hours once diluted with sterile saline

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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
- Perfection of new technologies (mRNA vaccines)
- 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

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References

- FDA website – materials for VRBPAC meeting for Dec 10, 2020

[Vaccines and Related Biological Products Advisory Committee December 10, 2020 Meeting Announcement - 12/10/2020 - 12/10/2020 | FDA](#)

FDA Review –

<https://www.fda.gov/media/144245/download>

Pfizer Document –

<https://www.fda.gov/media/144246/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!

Harry J Brown, MD
Medical Epidemiologist
USET Tribal Epidemiology Center

hbrown@usetinc.org

615-467-1547

615-917-7526

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