

COVID-19 Vaccine Update

Pause on the Johnson & Johnson/Janssen COVID-19 Vaccine Due to Safety Concerns

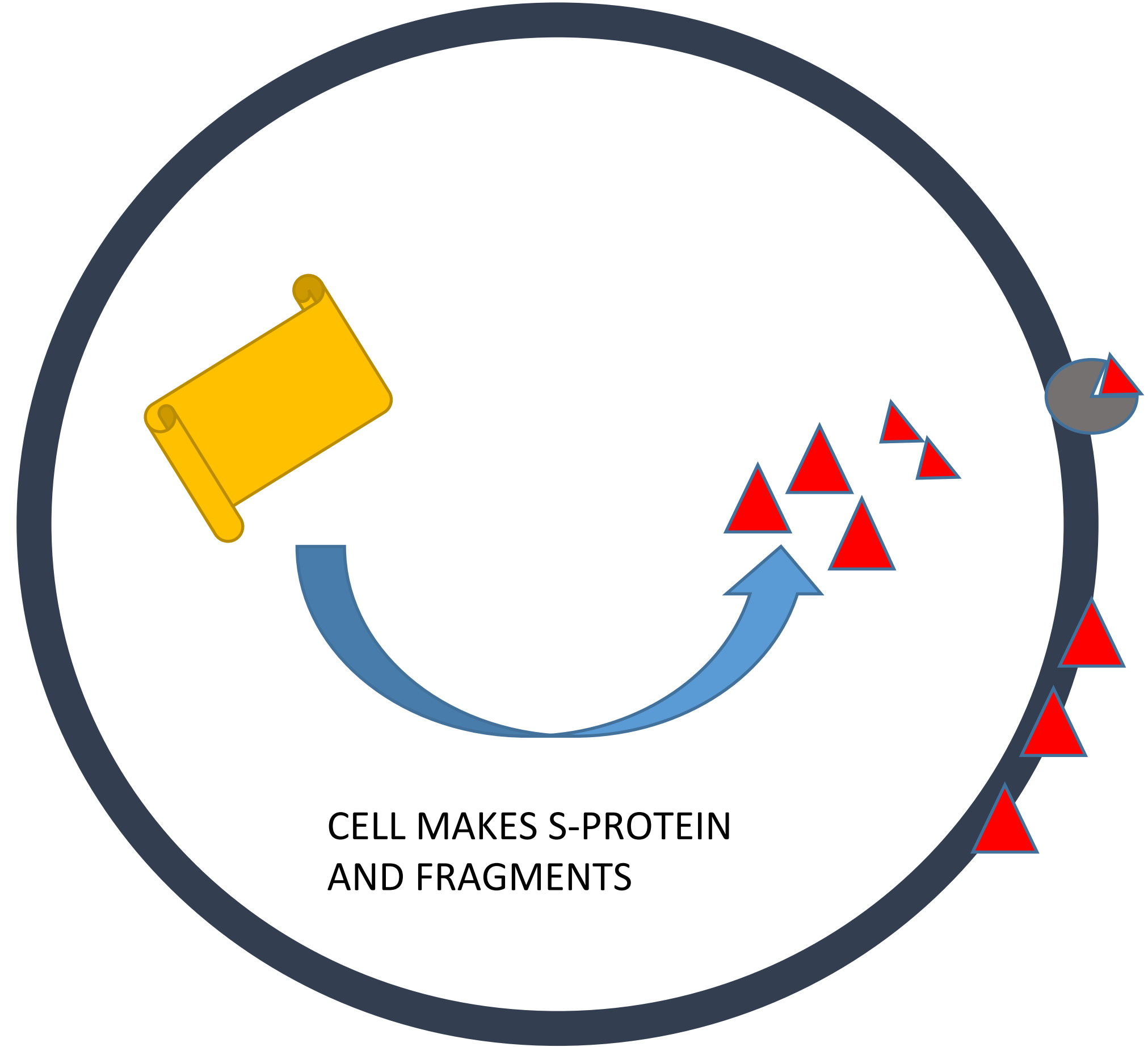
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How COVID Vaccines Work



**VACCINE: mRNA
or DNA +
Envelope**



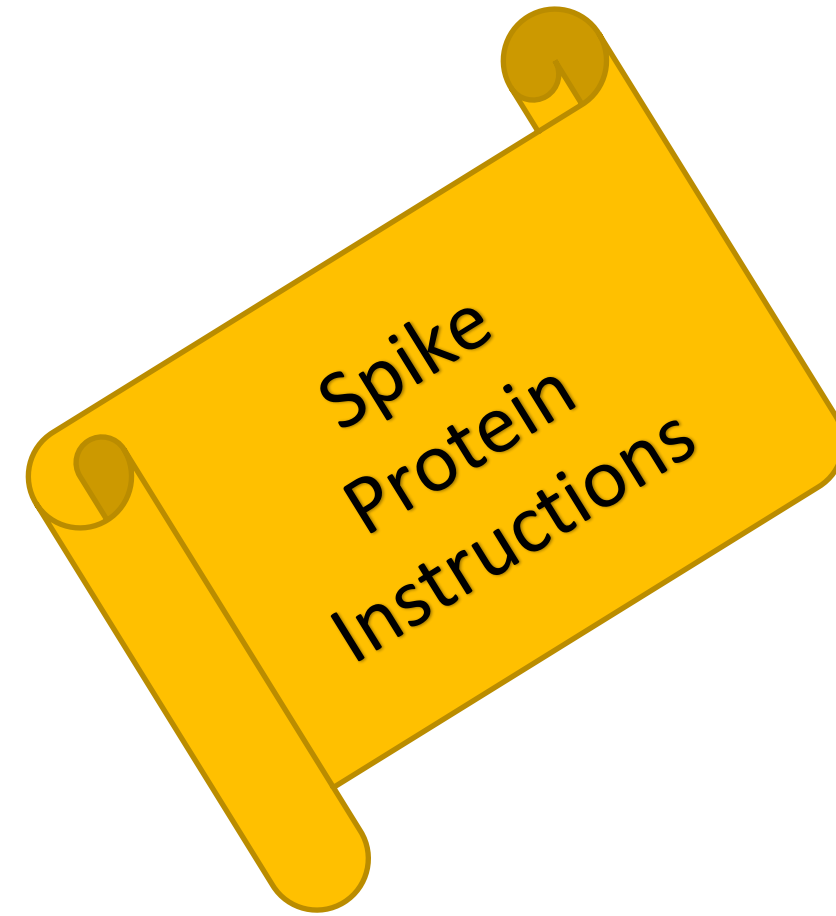
CELL MAKES S-PROTEIN
AND FRAGMENTS

PATIENT

The Spike protein and fragments are then seen by the immune system.

Inflammation happens, causing immune memory to happen.

The Envelope and the Blueprint



- Pfizer and Moderna vaccines use mRNA in a lipid nanoparticle (fat bubble)
- JNJ and Astra Zeneca use DNA in an inactivated Adenovirus particle
- This difference is the **MOST LIKELY** reason why the safety issue only applies to the JNJ & AZ vaccines

Basic Terminology to Understand the Next Slide

- **Platelets:** cells in our blood that help make clots
- **Thrombocytopenia:** low levels of platelets
- **Thrombosis:** simply put, a blood clot
- **Autoimmune/Autoantibodies:** your own body starts making antibodies against something in your own body

Reports of Rare and Unusual Clotting Issue with JNJ Vaccine in US (and AZ in Europe)

- Cerebral Venous Sinus Thrombosis (CVST) with Thrombocytopenia
- Autoimmune reaction that makes **platelets** count drop and causes clotting at the same time
 - A similar reaction is seen with some patients who get heparin (blood thinner), and they develop auto-antibodies against the heparin bound to platelets
- The treatment is to NOT give heparin, use of a different blood thinner plus high doses of immunoglobulin infusion

Reports of CVST to VAERS after COVID-19 vaccines as of April 12, 2021

- Janssen/JNJ
 - 6 reports of CVST with thrombocytopenia following 6.86 million doses administered
 - Reporting rate of 0.87 cases per million doses administered

- Pfizer-BioNTech
 - 0 reports following 97.9 million doses administered

- Moderna
 - 3 reports following 84.7 million doses administered
 - All 3 with normal platelet counts

Source of doses administered: <https://covid.cdc.gov/covid-data-tracker/#vaccinations>

Description of Cases in US (these are after EUA*)

- All females
- Age 18-49 years old
- Symptom onset between 6-13 days after vaccination
- None had COVID infection
- None had a known clotting or bleeding disorder
- None had a history of heparin use

- *There were 3 cases in the clinical trials, one was male

For the Public (from the CDC)

- If you have received the Janssen/Johnson & Johnson COVID-19 vaccine, contact your healthcare provider, or seek medical care if you have any of the following symptoms within 3 weeks of vaccination:
 - severe headache,
 - abdominal pain,
 - leg pain,
 - shortness of breath
- Report adverse events following receipt of any COVID-19 vaccine to VAERS.
- If you are scheduled to receive the J&J vaccine, please contact your healthcare provider, vaccination location, or clinic to learn about additional vaccine availability of Pfizer or Moderna vaccines.

Final Items

- This is actively unfolding...information will change by next week.
- The CDC/FDA warning systems WORKED. This safety issue was identified early and swift actions were taken.
- There is no similar safety concern regarding Pfizer or Moderna vaccines, but it is understandable that the public is concerned and will ask questions.
- Clinicians: ask a vaccination history, have a reasonable index of suspicion, and follow CDC treatment guidelines.
 - Submit an RL report for any concerning adverse events after immunization