



What you need to know about the Pfizer-BioNTech COVID-19 vaccine

Bryna Warshawsky
Medical Advisor



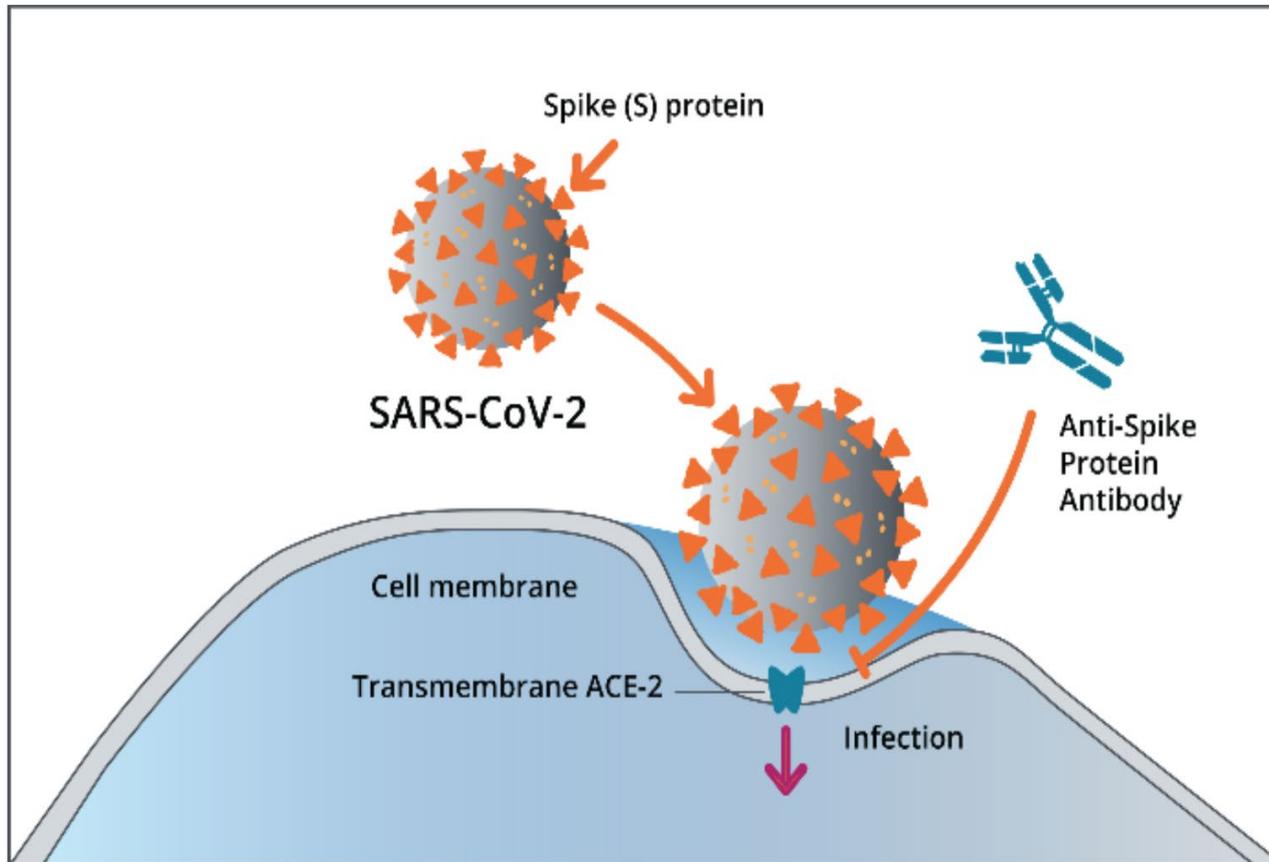
Declaration of interests – Bryna Warshawsky

- Nothing to declare

Objectives

- To describe the characteristics of the Pfizer-BioNTech COVID-19 vaccine
- To summarize key information on handling and administering the Pfizer-BioNTech COVID-19 vaccine

Characteristics of the Pfizer-BioNTech COVID-19 vaccine



Berkley Lights: <https://www.berkeleylights.com/blog/everything-you-need-know-about-coronavirus/>

What is the Pfizer-BioNTech COVID-19 vaccine?

Cellular and Humoral Immune Responses

- The Pfizer-BioNTech COVID-19 vaccine is an mRNA vaccine
 - New technology
 - mRNA is delivered directly into the cell within a lipid nanoparticle
 - mRNA coding for spike protein gets translated into the spike protein
 - Elicitation of antibodies and T-cells to the spike protein
- Fast manufacturing timeline which is why they are the first available vaccines

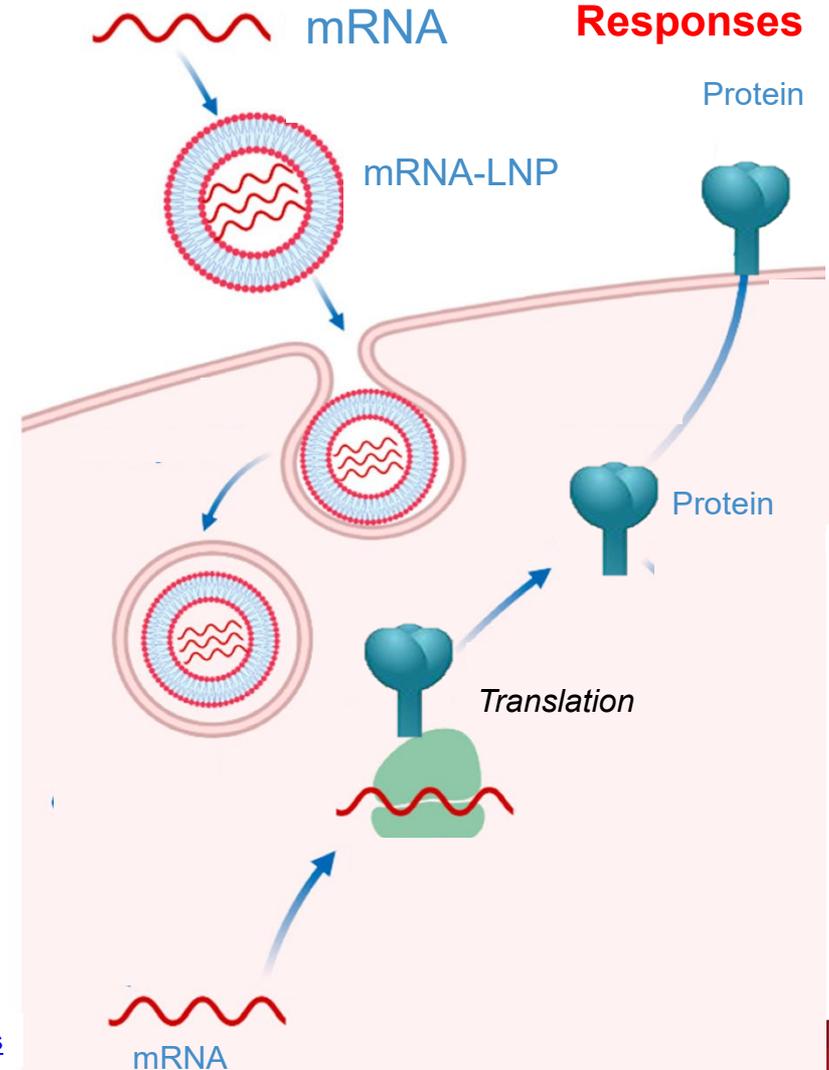
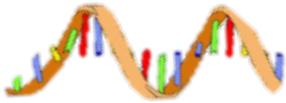


Image: [Opportunities and Challenges in the Delivery of mRNA-Based Vaccines](#)

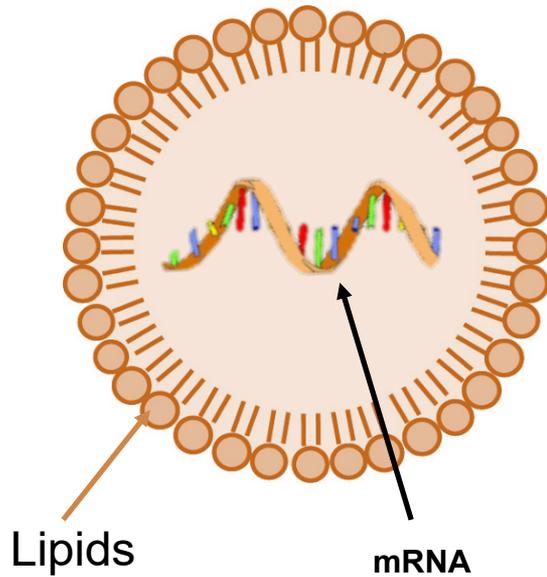
How does the Pfizer-BioNTech COVID-19 vaccine work?

mRNA



- Vaccine delivers mRNA encoding for SARS-CoV-2 spike protein
- mRNA is inherently unstable

mRNA lipid nanoparticle



- mRNA lipid nanoparticles are made of two parts:
 - mRNA
 - Lipids
- The lipids allow the mRNA to avoid degradation and enter into the cell
- The spike gene is then translated into protein

Image adapted from: [Solid Lipid Nanoparticles: A Potential Approach for Dermal Drug Delivery](#)

Pfizer-BioNTech COVID-19 vaccine characteristics

Type of vaccine	COVID-19 mRNA
Mechanism of action	mRNA translated to prefusion spike protein
Date of authorization in Canada	December 9, 2020
Authorized ages for use	16 years of age and older
Diluent	0.9% sodium chloride (provided by manufacturer)
Dose	0.3 mL (after dilution); 30 mcg of mRNA
Schedule	2 doses, 21 to 28 days apart (minimum interval 19 days)
Route of administration	Intramuscular (IM)
Adjuvant	None
Formats available	Multi-dose vial (5 doses per vial), preservative-free
Storage	-80°C to -60°C until expiry +2–8°C for 5 days

Handling and administering the Pfizer-BioNTech COVID-19 vaccine

Storage and handling

- **Storage:**
 - -80°C to -60°C for up to expiry date (6 months from manufacturing).
 - +2 to 8°C for up to 5 days. Do not refreeze.
 - Protection from light during storage by keeping vaccine in its original carton or other similar container
 - The diluent can be stored at room temperature.
- **When product is received in thermal shipper**, within 24 hours will need to be inspected, data logger stopped, and then one of three choices:
 - 1) **Maintain in an ultra-low freezer** at -80°C to -60°C for up to expiry date; OR
 - 2) **Replenish the dry ice in the thermal shipper** – initially and then up to 5 additional times, 5 days apart for up to a total of 30 days. Will need to insert a new data logger to monitor the temperature; OR
 - 3) **Put in the refrigerator** at +2 to 8°C for up to 5 days.
- Training and personal protective equipment are required to handle dry ice
- **Transport to another site – not currently permitted**
 - Additional information is expected

Subject to change

Thawing

- Do not touch items from the freezer with bare hands and wear protective equipment if entering the thermal shipper
- Thaw at:
 - **Room temperature** for 30 minutes
 - Can stay at room temperature for 2 hours before mixing with diluent
 - OR
 - **Refrigerator** for about 3 hours to thaw a tray
 - Can stay at refrigerator temperature +2–8°C for 5 days
 - Should come to room temperature before mixing with diluent (to ensure it is thawed)
- Indicate the appropriate dates and times on the product, so that the expiry point is clear:
 - Indicate the start times
 - Can also indicate the end times, but be clear which time is which
- The thawed suspension may contain white to off-white amorphous particulates

Dilution

1. Allow to come to room temperature before mixing with diluent
 - Can stay at room temperature for 2 hours before mixing with diluent
2. Gently invert 10 times (**do not shake**)
3. Use alcohol-based hand rub to clean hands
4. Wipe the vial stoppers for the vaccine and diluent with alcohol swabs and allow to dry
5. Using aseptic technique and a 21 gauge or thinner needle, take 1.8 ml of 0.9% sodium chloride provided by the manufacturer (diluent) and inject it into the vaccine vial
6. With the needle still in the vial, withdraw 1.8 ml of air from the vaccine vial
7. Discard the needle and syringe in the sharps container
8. Discard the remaining diluent in the sharps container (use only once)
9. Gently invert 10 times (**do not shake**)
10. Check for particulates or discolouration (expect an off-white colour)
11. Mark the vial with the date and time of dilution
12. Use within 6 hours after dilution
 - Can be stored at room temperature during this time; avoid direct sunlight
 - Discard in sharps container if not used within 6 hours after dilution (try not to waste any)

Drawing up

- Stable if pre-drawn for 6 hours
 1. Use alcohol-based hand rub
 2. Swab the vial stopper with the alcohol wipe and let dry
 3. Ensure the needle is tightly attached to the syringe
 4. Using aseptic technique and a new needle and syringe, draw up 0.3 ml into a 1 ml Luer lock syringe (or 3 ml syringe if 0.1 ml graduations)
 5. If necessary to remove any air from the syringe, keep the needle in the vial
 6. Repeat steps 2, 3, 4 and 5 to get 5 doses per vial.

Administering the vaccine

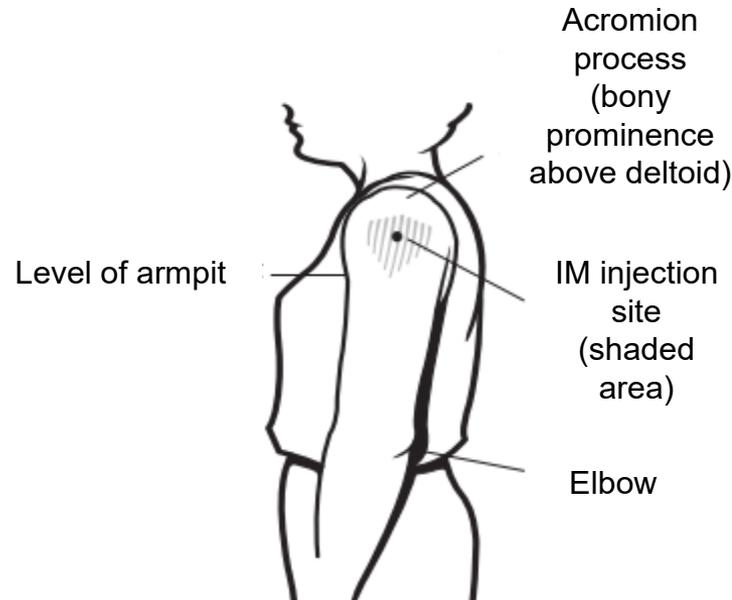
1. Use alcohol-based hand rub
 - Do not wear gloves except if skin is not intact (must be changed between clients)
2. Check syringe for particulates, discoloration (off-white color expected) and correct dose (0.3 ml); ensure it is not cold
3. Prepare the skin with alcohol wipe from the centre moving outwards – allow to dry
4. Give 0.3 ml dose intramuscularly in the deltoid
5. Discard needle and syringe immediately (or after activating the safety engineered device) into the sharps container
 - Do not place used needle on the workstation
6. Use alcohol-based hand rub

Return 21 to 28 days later for second dose

- Do not re-start series if delayed

Landmarking for the deltoid

Intramuscular (IM) injection site for children and adults



Give in the central and thickest portion of the deltoid muscle – above the level of the armpit and approximately 2–3 fingerbreadths (~2”) below the acromion process.

To avoid causing an injury, do not inject too high (near the acromion process) or too low.

Summary of key storage and handling requirements

Storage	-80 to -60°C
Time in refrigerator	5 days at +2 to 8°C
Onward transportation	Information forthcoming
Dilution	1.8 ml 0.9% sodium chloride provided by the National Operation Centre (NOC) / manufacturer
Use after first puncture	Up to 6 hours (first puncture will be for dilution)
Maximum time at room temperature	<ul style="list-style-type: none">• Up to 2 hours before mixing with diluent• Up to 6 hours after mixing with diluent
Preloading in syringe	Stable for 6 hours if pre-loaded
Dose	0.3 ml
Second dose	21 to 28 days (minimum interval 19 days)

Additional resources

- **Webinar: COVID-19 Vaccine Foundations for Health Care Providers**
 - Module 1: Vaccine Approval and Guidance
 - Module 2: Overview of COVID-19 Vaccines
 - Module 3: How to Set Up a COVID-19 Vaccine Clinic
 - Link: <https://www.ammi.ca/?ID=183>