

COVID-19 Vaccine Safety and Efficacy

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Agenda



- What is warp speed and how do we know the vaccine is safe?
- What is the COVID-19 vaccine and how does it work?
- What are the side effects?
- Who can get it?
- Q&A

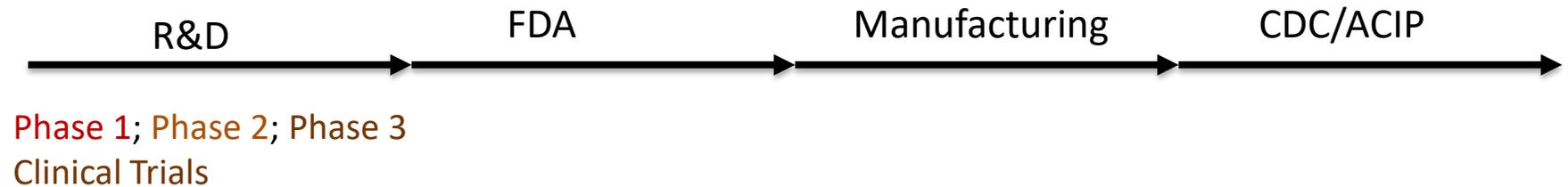
COVID-19 Vaccination

What is Warp Speed?

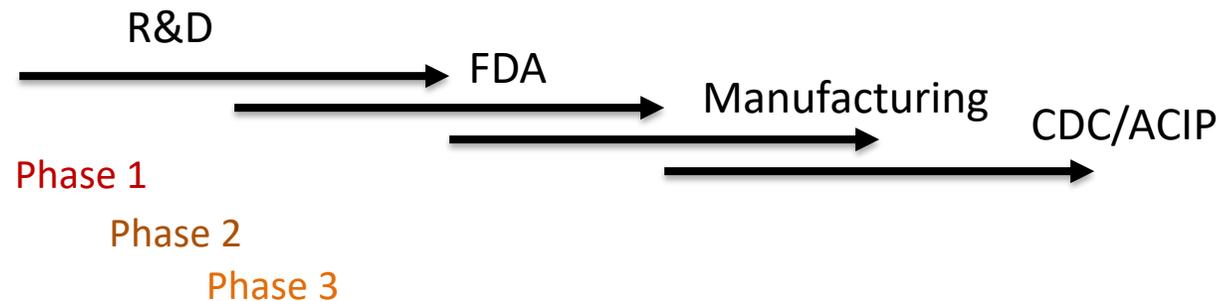


- No steps were skipped

— Traditionally



— Now

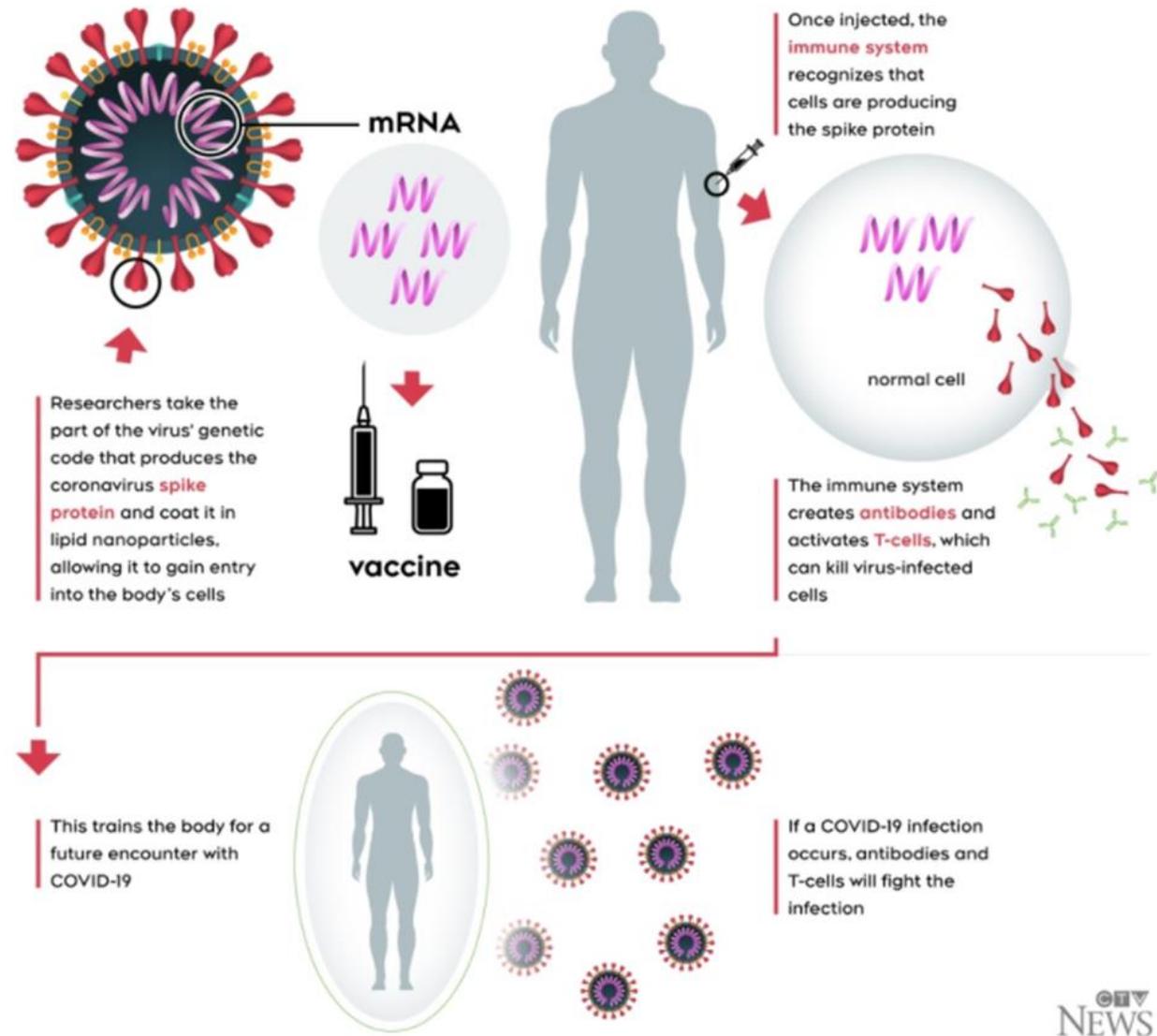


COVID Vaccine Approval and Prioritization



- FDA evaluates safety and efficacy; independent review panel makes recommendation to FDA → awards **emergency use authorization**
- Advisory Committee on Immunization Practices (ACIP), an independent committee under CDC organization, reviews EUA and makes recommendation for prioritization and administration
- AZ Vaccine and Antiviral Prioritization Advisory Committee (AZ-VAPAC) reviews EUA and ACIP recommendations and makes recommendations for AZ
- MCDPH plans for allocation and administration of vaccine according to EUA, ACIP, AZ-VAPAC and local independent review

mRNA Vaccines



COVID-19 Vaccines: Pfizer and Moderna



- Both authorized vaccines are mRNA vaccines
 - They do NOT contain the complete virus or the complete viral genome
 - They do contain a segment of the viral genome that makes the recipient's body generate an immune response as if it encountered the live virus
 - This results in the immune system creating antibodies to the virus without becoming infected first

Pfizer-BioNTech Vaccine



- Received FDA EUA December 11
- Highly effective (95%)
- Requires 2 doses (**minimum** 21 days apart)
- Available to individuals 16 years and older
- Needs ultra-cold storage and comes in 1000 dose batches
- That's why we need these large regional PODs

Moderna Vaccine



- Received FDA EUA December 18
- Highly effective (>90%)
- Requires 2 doses (**minimum** 28 days apart)
- Available to individuals 18 years and older
- Can be stored in standard freezer and allocated in smaller quantities than Pfizer vaccine
- This vaccine is better suited for smaller school/district PODs

Both Vaccines



- Not approved for use in youth under
 - Age 16 (Pfizer)
 - Age 18 (Moderna)
- Second doses given later than the MINIMUM interval still work
- Vaccine does not have live virus
 - It does not cause COVID
 - You cannot spread infection from getting the vaccine
 - It is possible to get COVID infection, especially before 2nd dose

Janssen (Johnson & Johnson) Vaccine



- Pending submission for FDA EUA
- 72% efficacy (US) at preventing moderate-severe disease at 28d
- 100% protection against COVID-19 related hospitalization and death
- Requires 1 dose
- Studied in individuals 18 years and older

Vaccine “Side Effects”



- “Side Effects” are expected & evidence that the vaccine is working
- When the body’s immune system mounts a response to a natural infection OR vaccination the result is local and/or systemic inflammation
- Local inflammation includes injection site soreness, redness, swelling
- Systemic inflammation includes fever, muscle aches, headache

Vaccine Side Effects



- The stronger the immune response, the stronger the side effects
- The healthier the individual, the stronger the immune response
- Side effects are stronger after second doses because the body mounts a stronger response when it has already seen the virus

Vaccine Side Effects



Local and systemic reactions, day 0-7 ^{*,†}	All vaccines %	Pfizer- BioNTech dose 1 %	Pfizer-BioNtech dose 2 %	Moderna dose 1 %
Pain	70.7	67.7	74.8	70.1
Fatigue	33.4	28.6	50.0	29.7
Headache	29.4	25.6	41.9	26.0
Myalgia	22.8	17.2	41.6	19.6
Chills	11.5	7.0	26.7	9.3
Fever	11.4	7.4	25.2	9.1
Swelling	11.0	6.8	26.7	13.4
Joint pain	10.4	7.1	21.2	8.6
Nausea	8.9	7.0	13.9	7.7

Who Should Be Vaccinated



- If you are sick with COVID-19 or other acute illness wait until better
- If you are exposed to COVID-19, wait until quarantine is over
- Pregnant and breastfeeding individuals can get vaccinated and should discuss with their provider
- You can still get vaccinated if you have had COVID-19
- Wait 90 days after antibody therapy to be vaccinated, 14 days after other vaccines

What about allergies?



- Individuals with history of severe allergic reactions:
 - Can be vaccinated except allergy to mRNA vaccine as below
 - Should be observed for 30 minutes after
- Individuals with history of severe or immediate reactions to mRNA vaccines, components of mRNA vaccines or polysorbate should not be vaccinated unless working with their HCP or allergy specialist



Estimated anaphylaxis reporting rates following COVID-19 vaccines based on VAERS reports and reported doses administered*

Reported vaccine doses administered	Anaphylaxis cases	Reporting rate (analytic period Dec 14-Jan 18)
Pfizer-BioNTech: 9,943,247	50	5.0 per million doses admin.
Moderna: 7,581,429	21	2.8 per million doses admin.

- Total COVID-19 vaccine doses administered thru Jan 18 by sex: Female 61%, Male 36%, Unk 3%
- Previously reported rate for Pfizer-BioNTech vaccine: 11.1 per million doses admin (Dec 14-Dec 23)
<https://www.cdc.gov/mmwr/volumes/70/wr/mm7002e1.htm>
- Previously reported rate for Moderna vaccine: 2.5 per million doses admin (Dec 21-Jan 10)
<https://www.cdc.gov/mmwr/volumes/70/wr/mm7004e1.htm>

Hold strong on mitigation measures!



- It takes 1-2 weeks after the 2nd dose to be considered fully vaccinated
- No vaccine is 100% effective
- This is a new vaccination, so information is limited on how well the vaccine works in the general population.
- We are still learning :
 - How much it may reduce disease, severity, or transmission
 - How long protection lasts

Continue to follow all current guidance on reducing the spread of COVID-19

Check for updates and FAQs!



<https://www.maricopa.gov/5641/COVID-19-Vaccine>

Frequently Asked Questions

ELIGIBILITY AND SCHEDULING

+ How will people be screened for eligibility?

+ What will be the process to register?

+ What are some things I can do ahead to prepare for registering?

+ How long will appointments be open at PODs for Phase 1B?

+ Do I have to be a resident to be eligible for vaccination?

+ I'm having issues making an appointment using the ADHS vaccine scheduling website. What should I do?

+ Why do I need to make an appointment?

+ Why are appointments so limited at PODs?

+ What options for vaccination are available for seniors who are 75 years and older?

+ Why are pharmacies only vaccinating those who are 75 and older?

- **2ND DOSE APPOINTMENT UPDATE** Email notifications for private second dose events open for scheduling have been sent to approximately 45,000 people who received their first vaccination at the Chandler or Goodyear PODs through Jan. 20th.
 - Having trouble scheduling or seeing 2nd dose appointments? If you registered for multiple people using the same email address on the AZDHS vaccine website, you may only be able to view 2nd dose appts. for one person under that address. AZDHS is aware of this issue and is working on a solution. In the meantime, we want to ensure everyone who is eligible for a second dose has the opportunity to schedule an appointment. If you are experiencing this scenario or are having other issues scheduling your 2nd dose, [please fill out this brief form](#) so that we can collect the information needed to get in touch with you.
 - Email notifications are sent in batches prioritized by the dates of the person's first vaccination. For those vaccinated with first doses after Jan. 20th at our Chandler or Goodyear PODs, we will send out additional notifications as appointments become available.
 - These events are only viewable in the ADHS vaccine scheduling system by those notified by email (from podvaccine-noreply@azdhs.gov) for a "Dose-2" event, and provided instructions on how to make an appointment. Please check your email, including any spam folders, for these invites.)
 - Appointments for these private second dose events will be offered at the Chandler or Goodyear POD locations or at our new POD location at Grand Canyon University. All PODs use Pfizer vaccine.
 - Public Health is opening these events by invitation only to ensure we allow sufficient opportunity for those vaccinated with first doses at our Chandler and Goodyear POD sites to receive their 2nd doses in the most timely manner possible.

