



THE UNIVERSITY OF TEXAS AT EL PASO

UTEP COVID-19 Vaccination Clinic
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WHY?

Outline

- Application to Texas HHS and ImmTrac2
- Ordering, receiving and storing the vaccine
- The vaccine
- Texas HHS priority tiers for vaccinations
- UTEP questionnaire
- CDC screening questions
- Scheduling of volunteers and participants
- Using technology
- PPE and sterile compounding equipment
- Vaccine preparation
- Vaccine administration
- Post vaccine observation
- Reporting
- Research

History of Vaccines

Type	Example	Comment
Live-attenuated vaccines	MMR combined vaccine	High response with single dose/more side effects Caution: immune deficiency
Inactivated vaccines	Polio (injection)	Booster injections may be necessary
Subunit, recombinant, polysaccharide, and conjugate vaccines	Hepatitis B	Booster injections may be necessary
Toxoid	Diphtheria, tetanus	Booster injections
mRNA	COVID-19	Two dose for full response/fewer side effects

<https://www.vaccines.gov/basics/types>

Applications

- Texas HHS
 - Qualifications of clinical personnel - sterile compounding, vaccination training, NPI, etc.
 - Chief Medical Officer (CMO) – MD, PharmD, NP under the PREP Act
 - Storage capacity for vaccine – secured limited access, types of freezers, electronic digital temperature control, backup generators
- ImmTrac2
 - Texas Immunization Registry
 - Electronic exchange of data
 - Report all COVID-19 vaccinations within 24 hours

PREP Act = Public Readiness and Emergency Preparedness Act



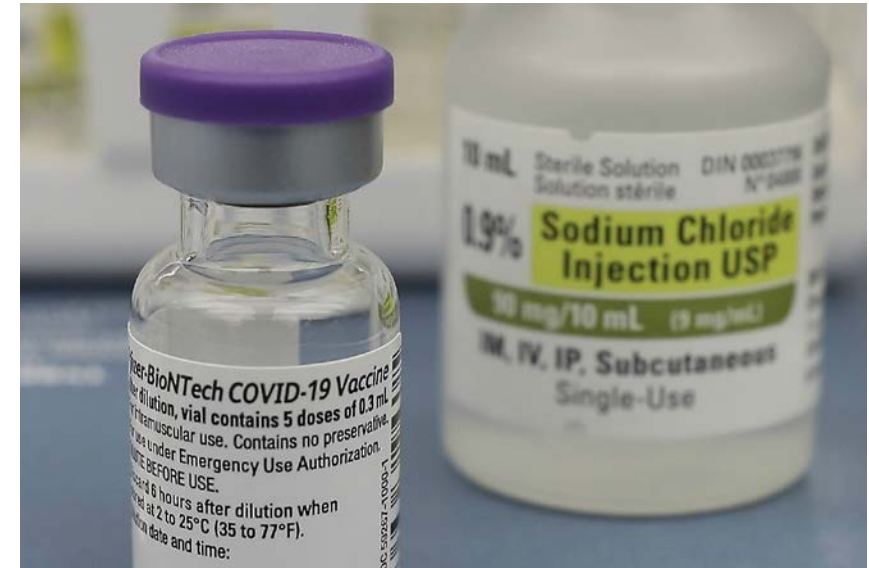
Ordering, receiving, and storing the vaccine

- Texas Vaccine Allocation & Ordering System (VAOS)
 - Select vaccine, quantities, and vaccination group
- Receiving
 - Shipping containers with the vaccine in dry ice with digital temperature control devices
- Storing
 - Ultra cold (-80°C), cold (-20°C), and/or refrigerator (2-6°C)
- Inventory Control
 - From receiving, transporting, preparing to administration



Pfizer/BioNTech COVID-19 vaccine

- BNT162b1 and BNT162b2 - mRNA technology
- FDA approval – emergency approval use (EAU) on December 12, 2020 for ≥ 16 year old and older
- Clinical Trials - Population: participants without prior evidence of SARS-CoV-2 infection (n=43,661 enrolled) Design: phase 3, global, randomized, placebo-controlled trial ▪ 2 vaccinations delivered 21 days apart of BNT162b2 or placebo



Pfizer/BioNTech COVID-19 vaccine

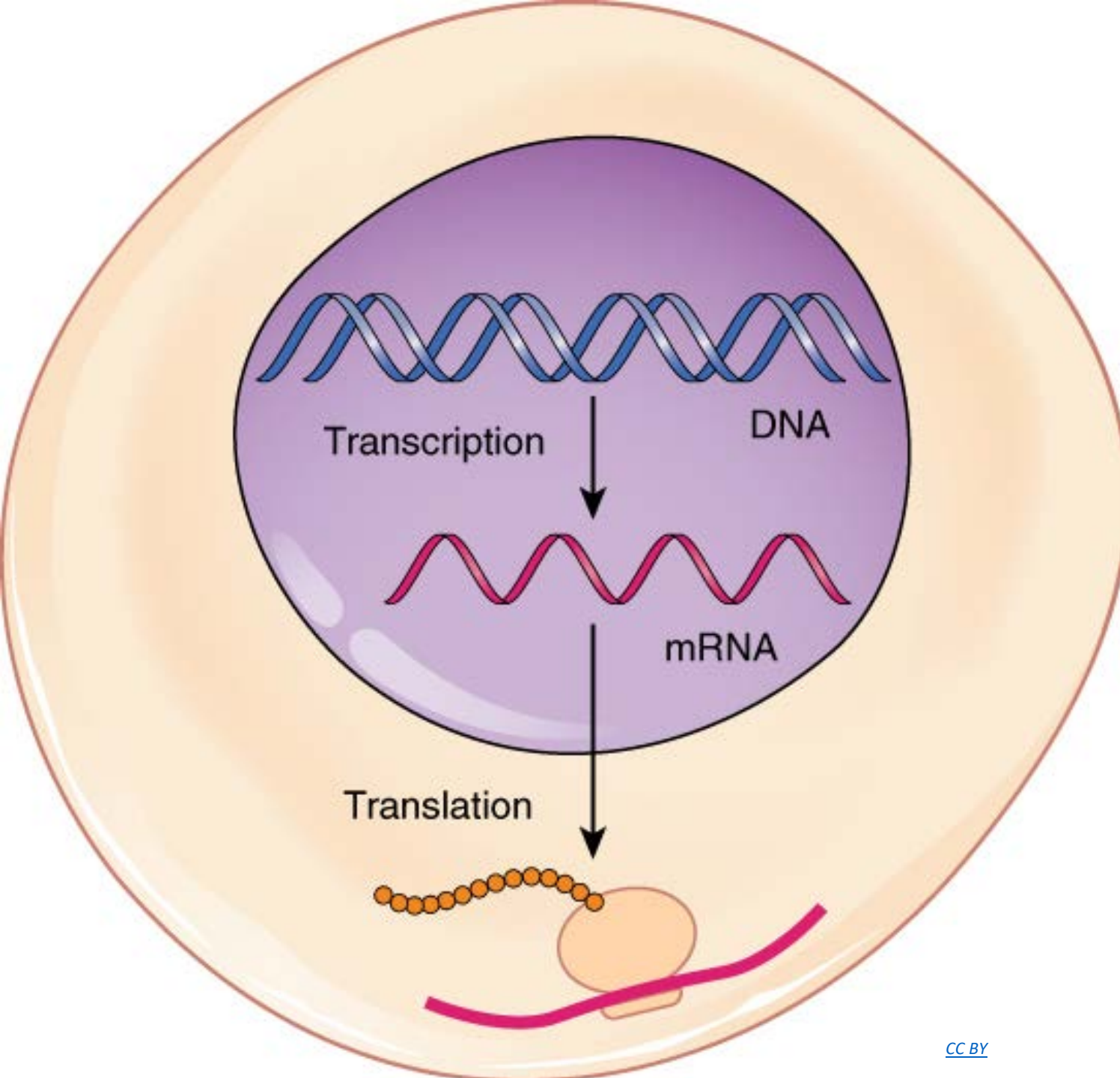
- Efficacy - 95% at 28 days after first dose
- Safety - Injection-site pain (58-100%), redness, and swelling, systemic adverse effects included fever, chills, **fatigue**, **headache**, muscle pain, and joint pain
Local and systemic reactions were more frequent after the second dose
No serious adverse events reported in clinical trials
Post EAU approval – **anaphylactic reactions** in patients with a history of anaphylactic reaction to other vaccines
- Storage and administration - Ultra-cold (-94° F/-70° C) freezer (~5 month expiration), 30 days in thermal shipper, Refrigeration 5 days, Two-dose vaccine (21 days apart) 30mcg (0.3ml) IM



Synthetic mRNA Vaccine Technology

January, 2021

From DNA to Protein: The Gene Expression Process



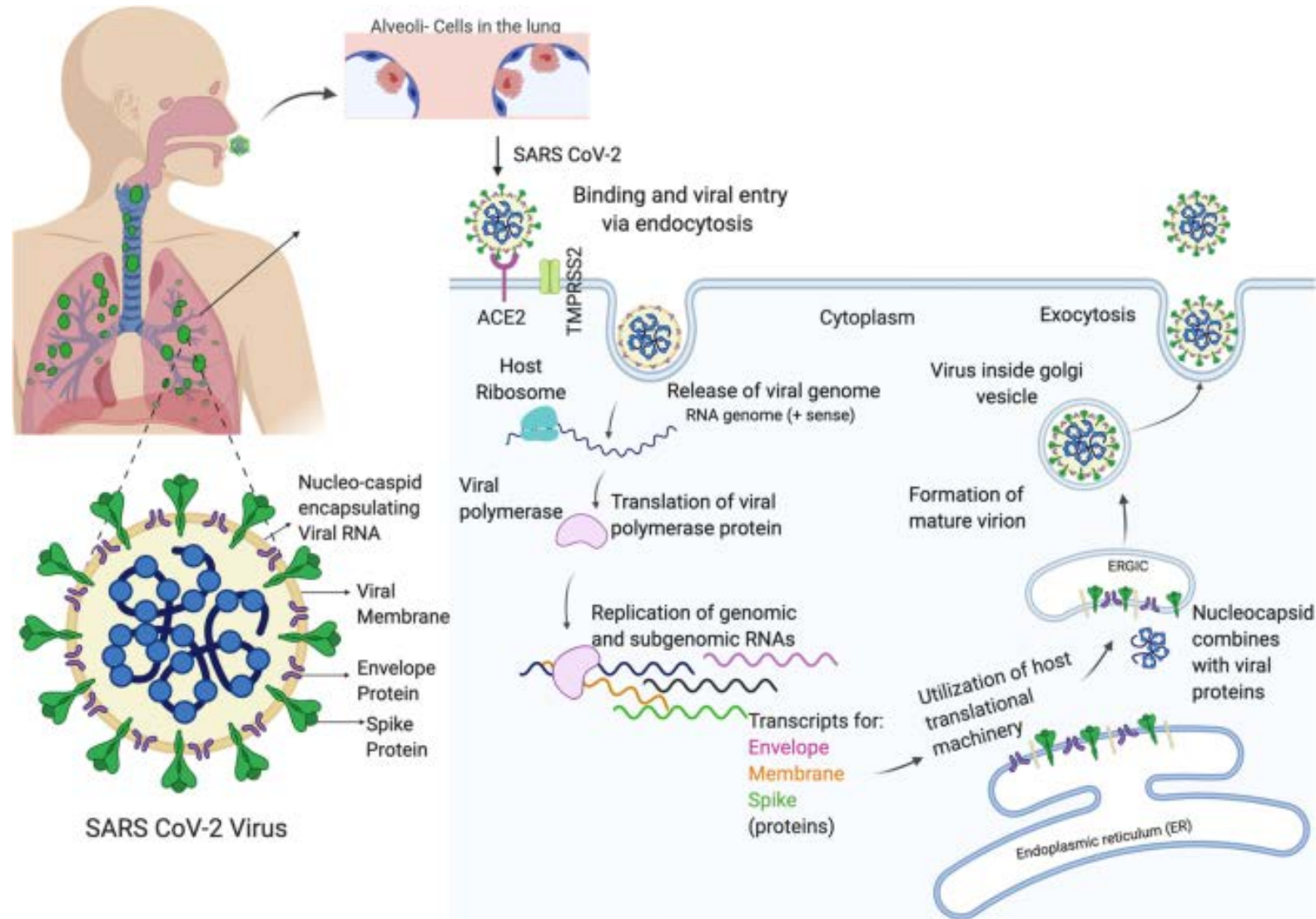
Our DNA genes contain the necessary information to produce specific proteins in our cells. Our DNA genes are transcribed in the cell nucleus into messenger RNA (mRNA). The mRNA carries that information to the ribosomes in the cytoplasm of the cell; the major site of protein synthesis. The ribosomes translate the mRNA sequence into a protein product.

SARS-CoV-2 Gene Expression and Replication in Host Cells:

SARS-CoV-2 has an RNA genome so there is no need for the first step (DNA transcription) in the gene expression process. SARS-CoV-2 entry into the host cell releases the viral RNA which is then translated into viral protein products by the host cell ribosomes. Those viral proteins are then packaged by way of the host cell secretory system and released as new virus.

Spike Protein:

The Spike protein on the surface of the viral membrane is essential for virus attachment to, and entry into, host cells and has become the primary target for SARS-CoV-2 vaccines.



Creative Commons, unknown author

SARS-CoV-2 Synthetic mRNA Vaccines

- The SARS-CoV-2 vaccines (also commonly referred to as COVID-19 vaccines) are **synthetic mRNA molecules** whose coding sequence (CDS) encodes for all or part of the **spike protein**. In addition, these synthetic mRNA molecules are **modified for stability and to prevent them from being recognized** by the immune system. Again, we want patients to raise an immune response against the protein product, in this case the spike protein, and not the mRNA itself. Finally, these synthetic mRNA molecules are **packaged in a liposomal membrane with some carbohydrate molecules** to aid in **stability and delivery to the tissues and cells**.
- This approach allows for **high levels of spike protein** (antigen) production within cells and leads to an immune response at the cellular level; considered a much stronger immune response leading to much greater chance of protection.
- Ultimately, the immune system of vaccinated patients will rapidly **recognize the spike protein upon initial exposure** and prevent the virus from replicating, thereby preventing infection.
- We do not yet know **how long that protection will last**, how often one would need to be vaccinated, and how much protection the vaccine will provide against potential viral mutations.
- The good news is that the **technology can rapidly adapt** to new mutations as all it would require is changing the mRNA sequence to account for those mutations.

Common Myths Related to the New mRNA Vaccines

- *The SARS-CoV-2 vaccine is **produced in or on embryonic stem cells*** - This is false. The vaccine is synthesized *in vitro* and has absolutely nothing to do with stem cells. It is true that scientists initially tried to use synthetic RNA technology to make stem cells in the lab and some of that work led to some of the modifications that made their use as a therapeutic possible.
- *The SARS-CoV-2 vaccine is made of **live or attenuated virus and could cause infection*** – This is false. As detailed in this slide deck, the vaccines consist of a synthetic mRNA molecule made in a test tube in addition to some commonly used lipids and sugar molecules.
- *The SARS-CoV-2 vaccine has been **rushed and not properly assessed for safety*** - It is true that the vaccine has been developed in record time but the technology that led to these vaccines was mature and ready for prime time. The vaccines could be made rapidly once the spike protein and RNA sequence were known. Thus, scientists could develop a product that was ready for human trials in record time. The vaccines were tested in phase III trials and have demonstrated an excellent safety profile to-date. Of course, there will always be anecdotal cases of an individual having an unusual, severe reaction or side effect and this is the case with any therapeutic.

Additional Reading

Maruggi G, Zhang C, Li J, Ulmer JB, Yu D. mRNA as a Transformative Technology for Vaccine Development to Control Infectious Diseases. *Mol Ther*. 2019 Apr 10;27(4):757-772. doi: 10.1016/j.ymthe.2019.01.020. Epub 2019 Feb 7. PMID: 30803823; PMCID: PMC6453507.

Pardi N, Hogan MJ, Porter FW, Weissman D. mRNA vaccines - a new era in vaccinology. *Nat Rev Drug Discov*. 2018 Apr;17(4):261-279. doi: 10.1038/nrd.2017.243. Epub 2018 Jan 12. PMID: 29326426; PMCID: PMC5906799.

Jackson NAC, Kester KE, Casimiro D, Gurunathan S, DeRosa F. The promise of mRNA vaccines: a biotech and industrial perspective. *NPJ Vaccines*. 2020 Feb 4;5:11. doi: 10.1038/s41541-020-0159-8. PMID: 32047656; PMCID: PMC7000814

Messengers of hope. *Nat Biotechnol*. 2020 Dec 29:1. doi: 10.1038/s41587-020-00807-1. Epub ahead of print. PMID: 33376248; PMCID: PMC7771724.

Courtesy of Dr. Marc Cox



UTEP questionnaire

- Online questionnaire
- Purpose
 - Determine number of faculty, staff, and students that want vaccination
 - Place individuals in self-reported categories for prioritization
 - Provide consent
 - Pre-screen using CDC guidelines
- Importance

ABILITY TO PLAN



TEXAS
Health and Human
Services

Texas Department of State
Health Services

We Are Here

LIMITED SUPPLY

- 1A: Direct Care - Hospital, Long-Term Care, EMS 9-1-1, Home Health, Outpatient, ER/Urgent Care, Pharmacies, Last Responders, School Nurses
- 1A: Long-Term Care - Residents of Long-Term Care Facilities
- 1B: Persons 65+ or 16+ with at least one chronic medical condition, including pregnancy

ADDITIONAL SUPPLY

- 1C: Under consideration
- 2: Under consideration

BROAD SUPPLY

- 3: Under consideration

Prevaccination Checklist for COVID-19 Vaccines



For vaccine recipients:

The following questions will help us determine if there is any reason you should not get the COVID-19 vaccine today.

Patient Name _____

Age _____

If you answer “yes” to any question, it does not necessarily mean you should not be vaccinated. It just means additional questions may be asked.

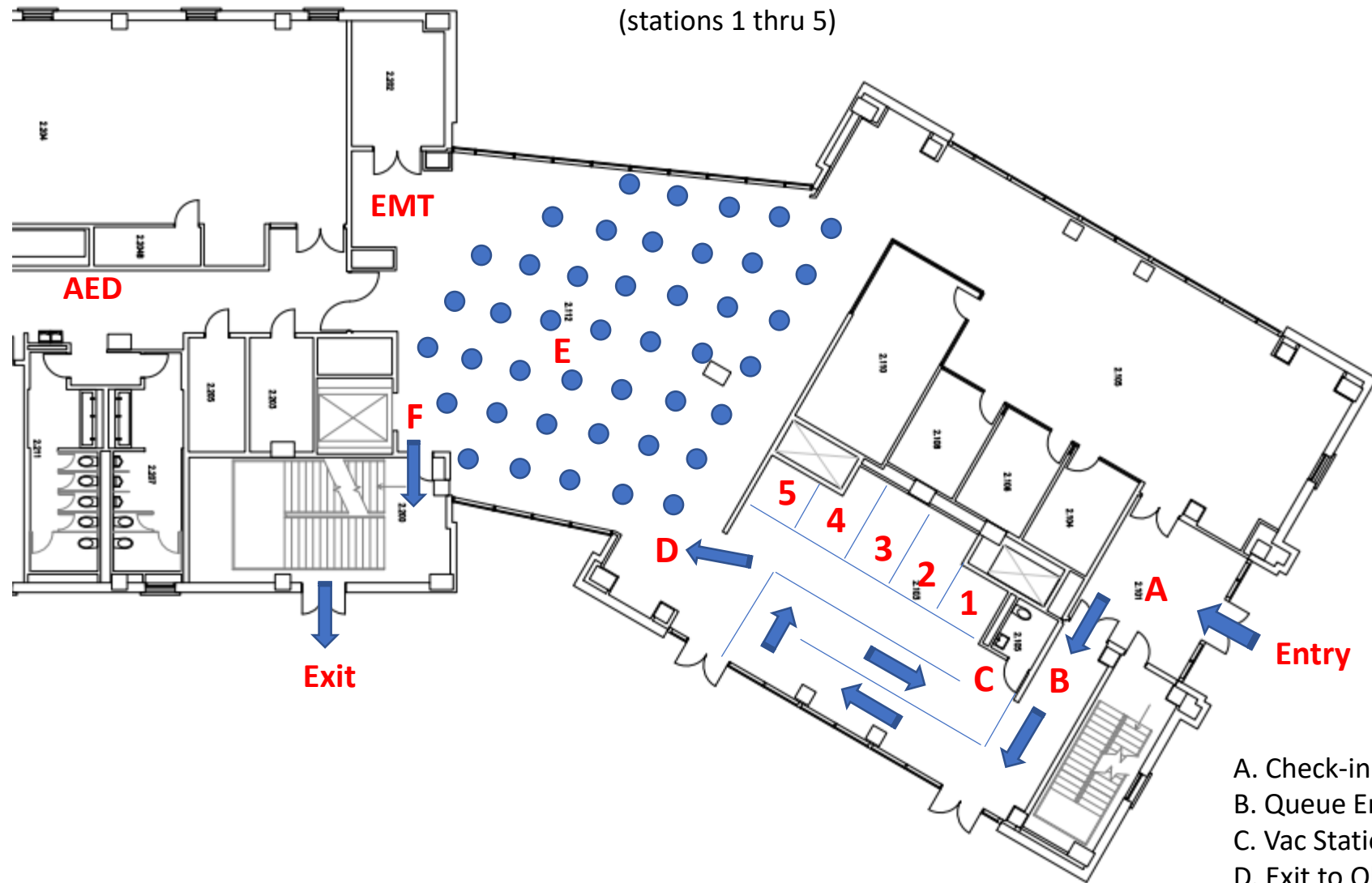
If a question is not clear, please ask your healthcare provider to explain it.

	Yes	No	Don't know
1. Are you feeling sick today?			
2. Have you ever received a dose of COVID-19 vaccine?			
• If yes, which vaccine product did you receive? <input type="checkbox"/> Pfizer <input type="checkbox"/> Moderna <input type="checkbox"/> Another product _____			
3. Have you ever had an allergic reaction to: <small>(This would include a severe allergic reaction [e.g., anaphylaxis] that required treatment with epinephrine or EpiPen® or that caused you to go to the hospital. It would also include an allergic reaction that occurred within 4 hours that caused hives, swelling, or respiratory distress, including wheezing.)</small>			
• A component of the COVID-19 vaccine, including polyethylene glycol (PEG), which is found in some medications, such as laxatives and preparations for colonoscopy procedures			
• Polysorbate			
• A previous dose of COVID-19 vaccine			
4. Have you ever had an allergic reaction to another vaccine (other than COVID-19 vaccine) or an injectable medication? <small>(This would include a severe allergic reaction [e.g., anaphylaxis] that required treatment with epinephrine or EpiPen® or that caused you to go to the hospital. It would also include an allergic reaction that occurred within 4 hours that caused hives, swelling, or respiratory distress, including wheezing.)</small>			
5. Have you ever had a severe allergic reaction (e.g., anaphylaxis) to something other than a component of COVID-19 vaccine, polysorbate, or any vaccine or injectable medication? This would include food, pet, environmental, or oral medication allergies.			
6. Have you received any vaccine in the last 14 days?			
7. Have you ever had a positive test for COVID-19 or has a doctor ever told you that you had COVID-19?			
8. Have you received passive antibody therapy (monoclonal antibodies or convalescent serum) as treatment for COVID-19?			
9. Do you have a weakened immune system caused by something such as HIV infection or cancer or do you take immunosuppressive drugs or therapies?			
10. Do you have a bleeding disorder or are you taking a blood thinner?			
11. Are you pregnant or breastfeeding?			

Form reviewed by _____

Date _____

Vaccination Administration
(stations 1 thru 5)



- A. Check-in Credential
- B. Queue Entry
- C. Vac Station Assignment
- D. Exit to Observation
- E. Observation Area
- F. Observation Area Exit

Vaccine preparation

- Transport vaccine from -80°C to refrigerator wait for 3 hours
- Dress with sterile equipment (gown, mask , face shield, and gloves)
- Prepare area by cleaning surface with disinfectant
- Using sterile technics dilute vaccine with 0.9% NaCl, gently swirl 10 times (expiration 6 hours)
- Draw 30mcg in 0.3ml in 1 ml syringe with 1-1½ inch needle 22 gauge
- Label the vaccine with name of vaccine, dose, lot number and original expiration date
- Communicate with vaccination stations to supply vaccines

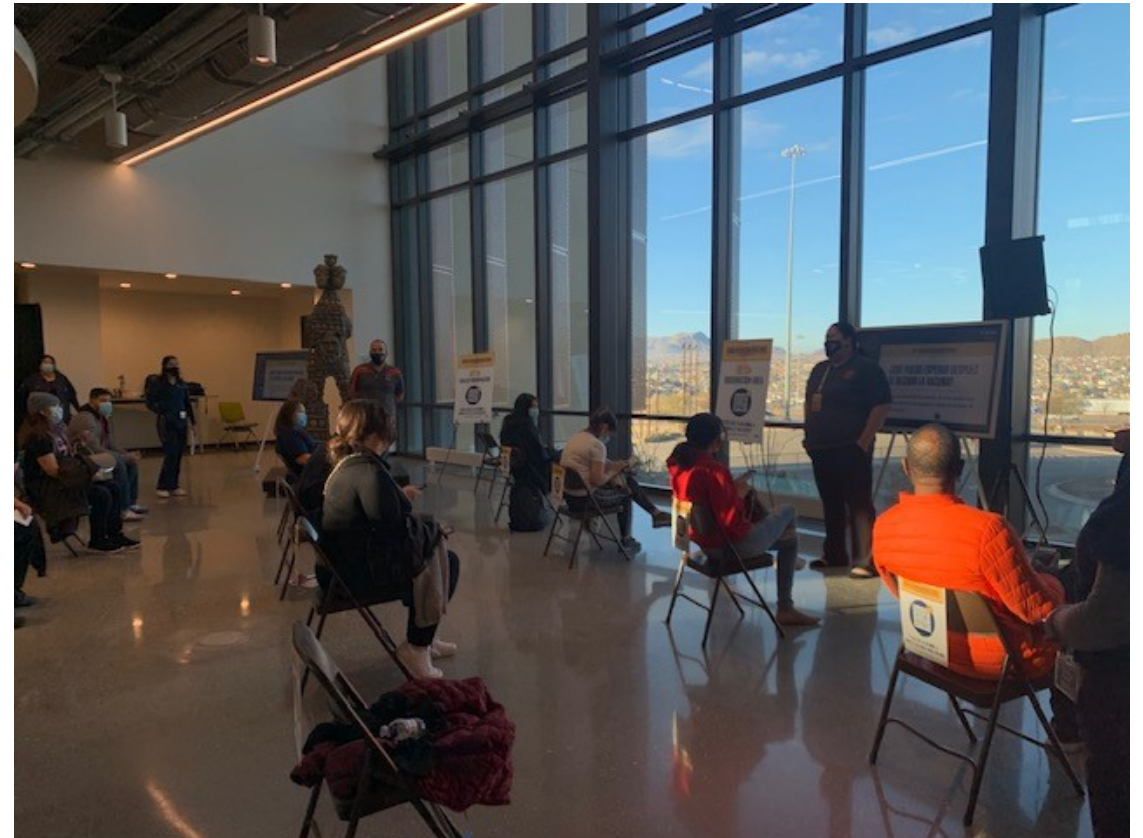


Vaccine administration



Observation

- 15-30 minutes
- What to expect
- Education
- Sign up with V-safe
- Complete perceptions and beliefs research questionnaire



EMT

- Medications
 - **Activated Charcoal**
 - **Albuterol**
 - **Aspirin**
 - **Diphenhydramine (Benadryl®)**
 - **Epinephrine, 1:1,000 via EpiPen® or vial**
 - **Nitroglycerin (Tablet or Spray)**
 - **Oral Glucose Gel**
 - **Tylenol**
- Equipment and supplies
 - Oxygen, bandages, gauges, alcohol swabs, etc.

Reporting vaccinations

- ImmTrac2
- TDEM (Texas Division of Emergency Management)
- VAERS (Vaccine Adverse Events Reporting System)
 - CDC and FDA
 - Types
 - Adverse events
 - Serious adverse events

Handbook of operations

- Fifty pages of details of procedures and forms
- Training
- Cold chain
- Needle sticks
- Communications
- Instructions for faculty
- Instructions for students
- Etc.

SOP team of students and faculty

