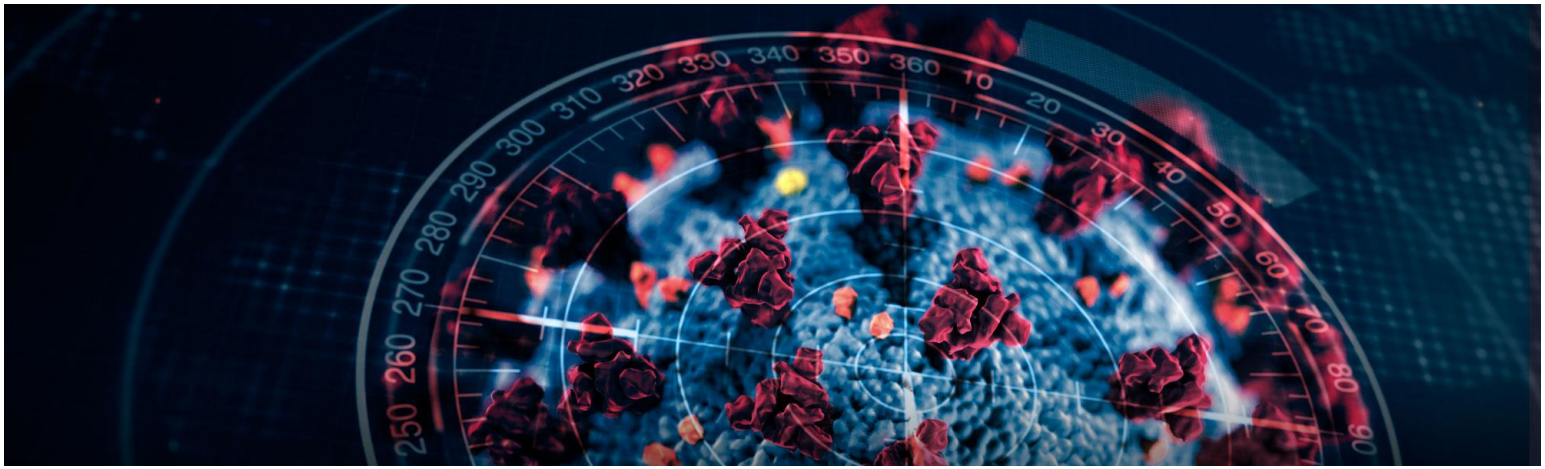
Update on COVID-19 Vaccines

Dallas Regional Chamber Board of Advisors

Friday, March 12, 2021



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Key Messages

- COVID-19 vaccines are effective and safe
  - **Strongly protective against severe disease and death**
  - Provide protection even against new variants
  - Currently in U.S. – Pfizer and Moderna vaccines (mRNA), Johnson & Johnson/Janssen (viral vector-based vaccine)
  - 2 additional vaccines on the horizon
    1. AstraZeneca (viral vector-based vaccine)
    2. Novavax (protein-based vaccine)
- Healthy workplaces: continuous education, screening, flexible work policies
- NPIs (non-pharmacologic interventions) are a key factor in reducing the spread of COVID-19

Key Facts about COVID-19 vaccinations

COVID-19 vaccines can not give you COVID-19

People who have already gotten sick with COVID-19 may still benefit from getting vaccinated

Getting vaccinated can help prevent getting sick with COVID-19

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/facts.html

COVID-19 vaccines will not cause you to test positive on COVID-19 **viral** tests*

*https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-overview.html

Types of COVID-19 Vaccines

COVID-19

What are the different kinds of vaccine?

RNA

RNA vaccines work by introducing an mRNA sequence (the molecule which tells cells what to build) to the system which is coded for a specific antigen.

DNA

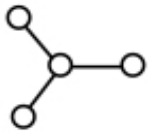
Short for deoxyribonucleic acid, DNA is another of the crucial macromolecules for life. A DNA vaccine involves the direct introduction into appropriate tissues of a plasmid - a doubled-stranded molecule which exists in bacterial cells.

Viral vector

Vaccines use live viruses to carry DNA into human cells.

Virus-like particle

This type of vaccine contains molecules that mimic the virus but are not infectious and, therefore, not a danger. VLP has been an effective way of creating vaccines against diseases such as human papillomavirus (HPV), hepatitis and malaria.



Protein sub-unit

This kind of vaccine uses a part of the virus, in this case the protein component. These vaccines can also be used on almost anyone, including people with weakened immune systems and long-term health problems.

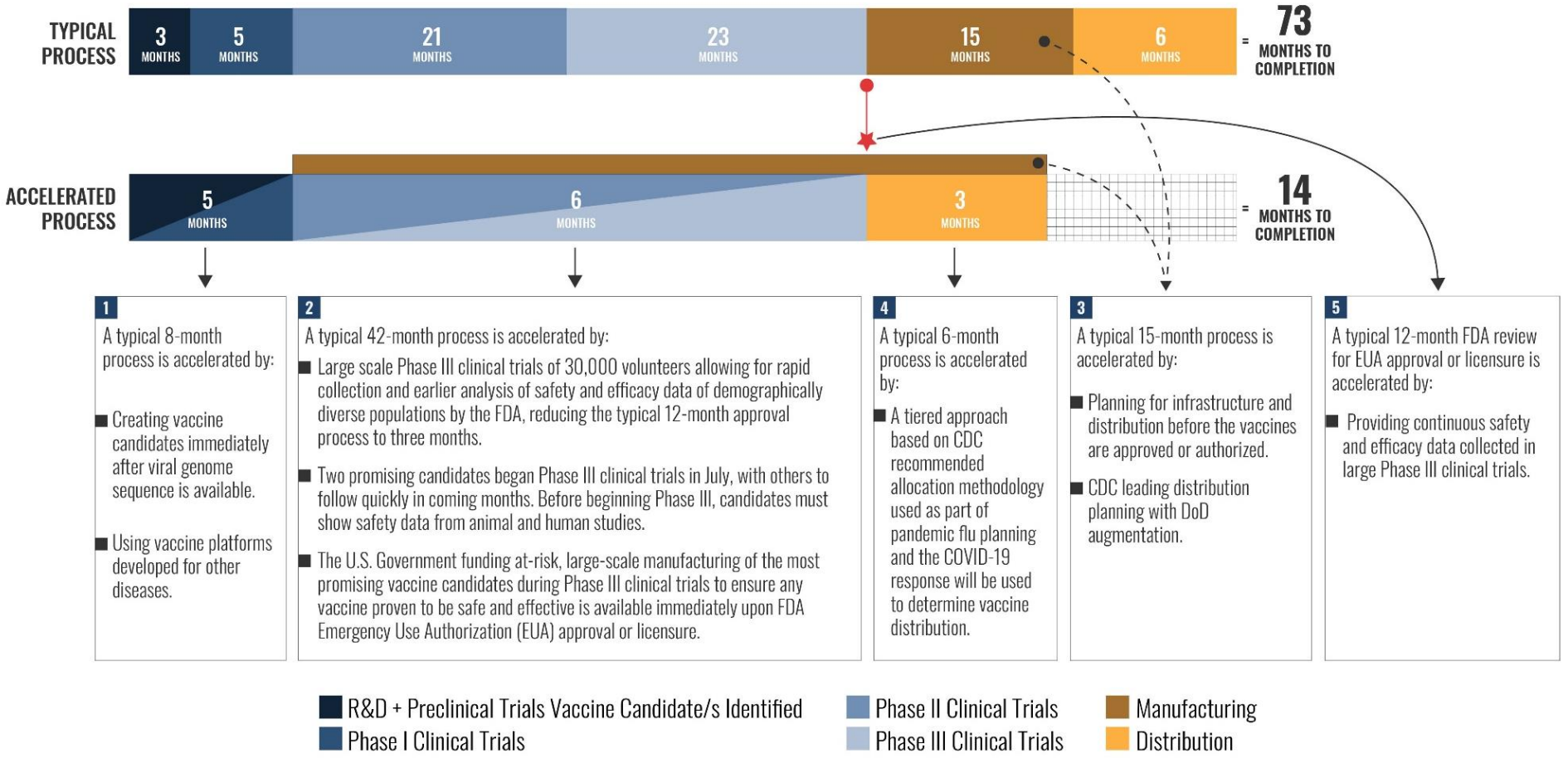
Inactivated virus

These vaccines use the dead version of the virus that causes a disease.

SOURCE: VACCINES.GOV, NEWS MEDICAL LIFE SCIENCES, SCIENCE MEDIA CENTER | NOVEMBER 24, 2020

ALJAZEERA

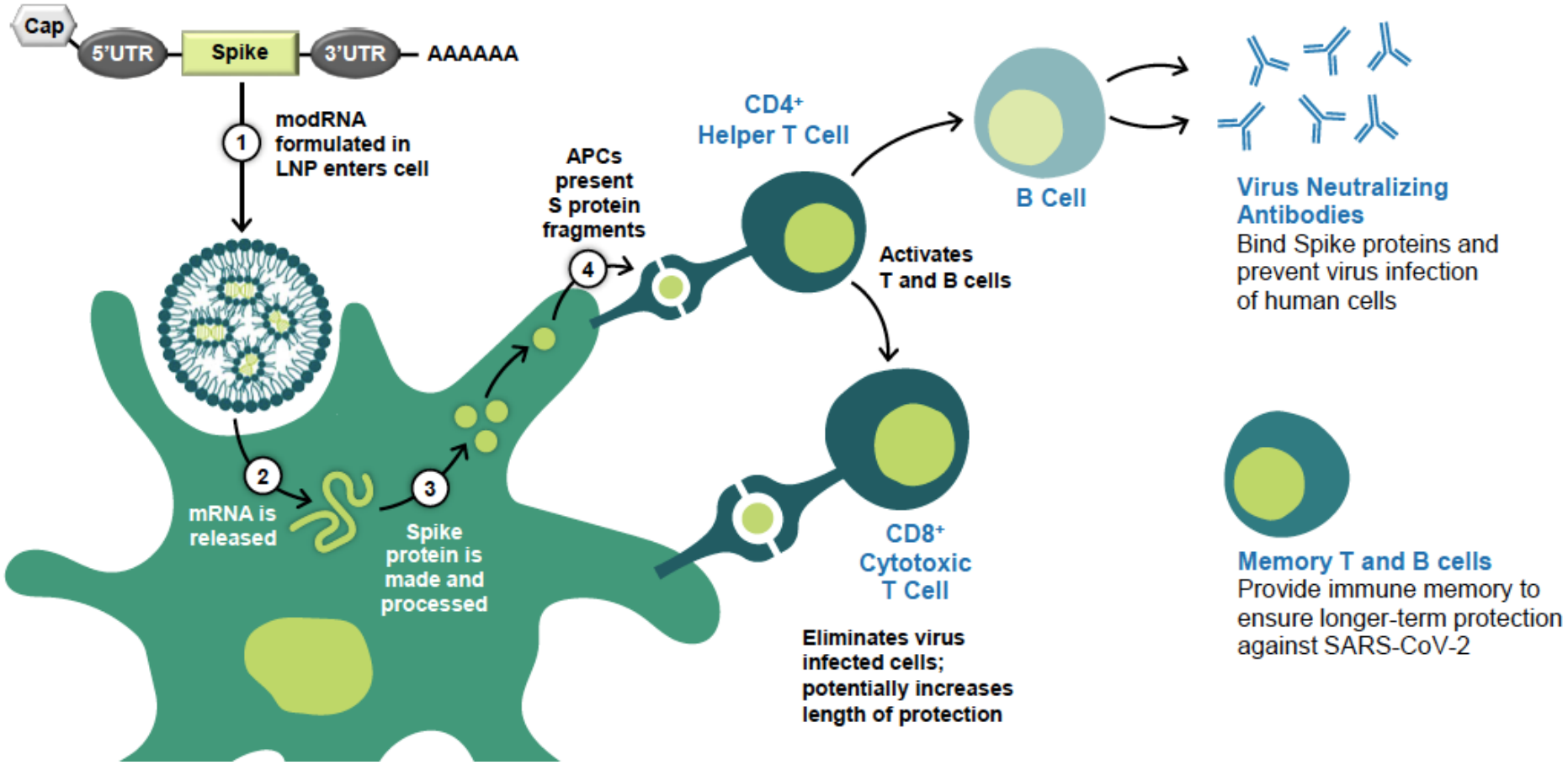
How Did We Get Here So Fast: Operation Warp Speed



Financial and government risk increased, not product or safety risk

https://media.defense.gov/2020/Aug/13/2002476369/-1/-1/0/200813-D-ZZ999-100.JPG

How mRNA Vaccines Work



mRNA vaccines cannot give you COVID or alter your own DNA!

Experience with Other RNA Vaccines

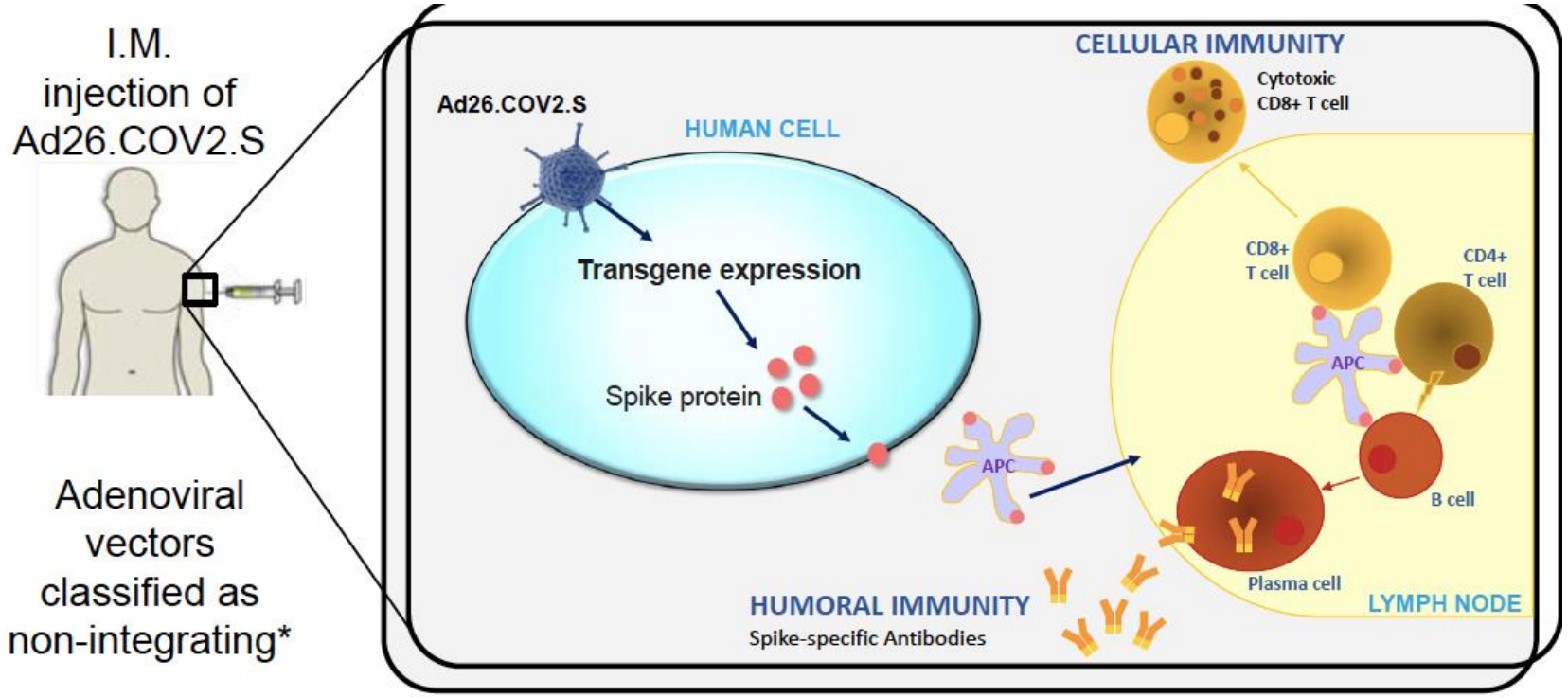
RNA vaccine trials in humans
(not including a large number of cancer vaccines and therapeutic approaches based on mRNA)

Target	Started in	Individuals enrolled[2]	Company	Status	Phase	Registration numbe
CMV	2017	181	Moderna	Fully enrolled	Phase 1	NCT03382405
hMPV/PIV3	2019	114	Moderna	Recruiting	Phase 1	NCT04144348
Zika	2019	120	Moderna	Fully enrolled	Phase 1	NCT04064905
Influenza	2017	156	Moderna	Fully enrolled	Phase 1	NCT03345043
Rabies	2018	53	Curevac	Fully enrolled	Phase 1	NCT03713086
Rabies	2013	101	Curevac	Completed	Phase 1	NCT02241135
Rabies	2014	72	Curevac	Completed	Phase 1	NCT02238756
CMV	2020	452	Moderna	Recruiting	Phase 2	NCT04232280
Chikungunya[1]	2019	39	Moderna	Fully enrolled	Phase 1	NCT03829384

[1]Passive immunity based on *in vivo* mAb expression

[2]Includes individuals who received placebo, some trials are still recruiting

How Viral Vector Vaccines Work



Adenovirus vector vaccines use a non-replicating viral vector, and cannot give you COVID or alter your own DNA!

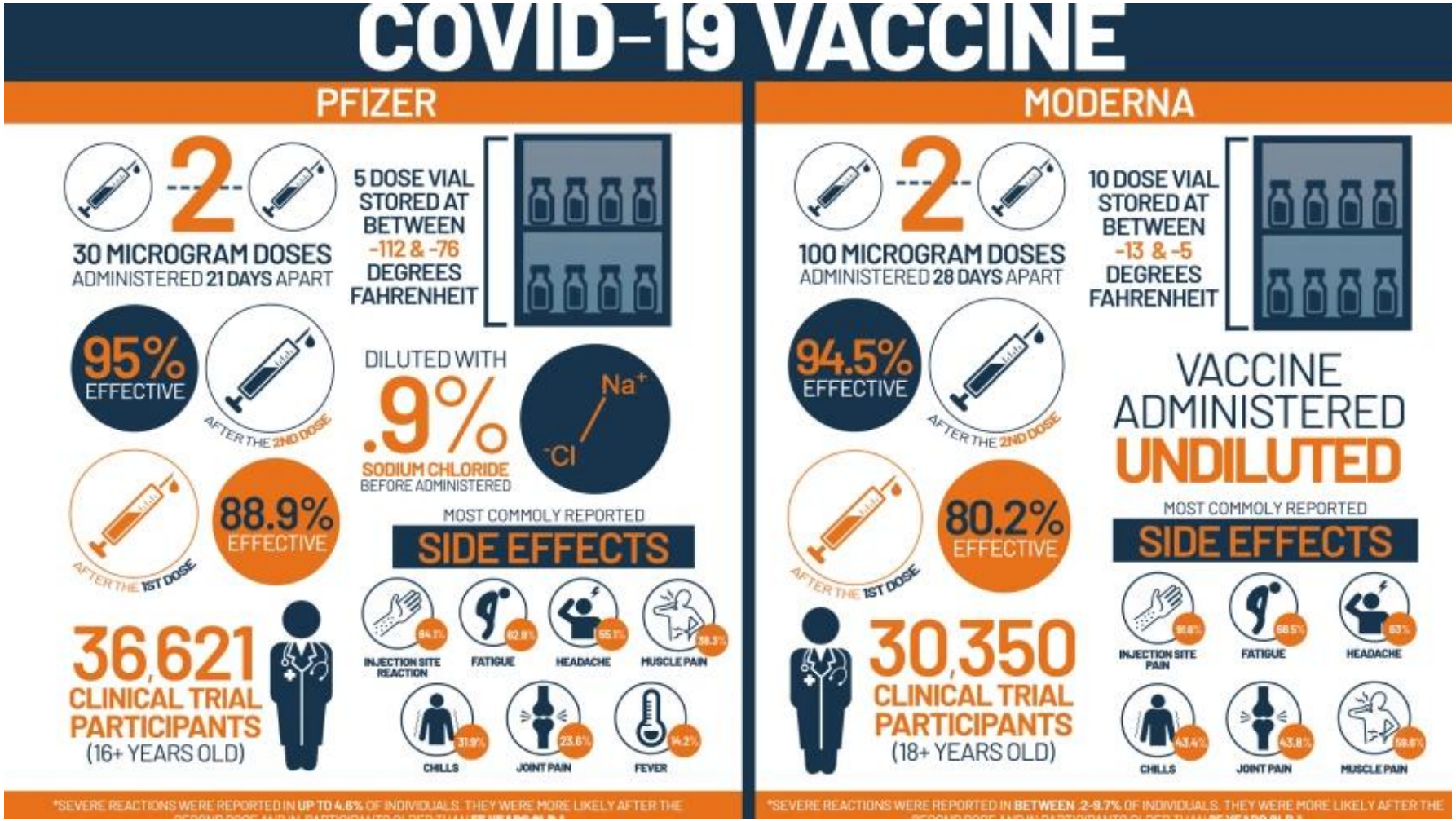
Vaccines Tested in Diverse Populations

Vaccine	Pfizer mRNA	Moderna mRNA	J&J viral vector
Trial participants	N= 43,448	N=30,351	N= 43,783
Female Gender (%)	49.1%	47.4%	45%
Age > 65 (%)	20.9%	24.8%	19.5%
Race: Non-white (%)	17.9%	20.8%	41%
Ethnicity: Hispanic or Latino (%)	26.1%	20.5%	46%
Medical Comorbidities (%)	46%	42%	40.8%

Similar efficacy generally seen across all subgroups based on age gender, race, ethnicity and medical conditions.

Pfizer FDA VRBPAC Presentation 12/10/20; Moderna FDA VRBPAC Presentation 12/17/20; J&J FDA VRBPAC Presentation 2/26/21

Comparing the first two vaccines: Pfizer and Moderna



news10.com/news/pfizer-vs-moderna-covid-19-vaccine-whats-the-difference/

Reactogenicity: Comparison to Other Vaccines

(After dose #2 for the two-dose regimens, age <60 – the highest side effect group found)

	SHINGRIX (ZOSTER VACCINE RECOMBINANT, ADJUVANTED) Shingrix	moderna messenger therapeutics COVID-19 mRNA-1273	Pfizer COVID-19 BNT162b2	Johnson & Johnson Ad26.COV2.S	Influenza Vaccine FLUCELVAX QUADRIVALENT Flu
Local Pain	88.4%	90.1%	77.8%	58.6%	45.4%
Redness	38.7%	9.0%	5.9%	9.0%	13.4%
Swelling	30.5%	12.6%	6.3%	7.0%	11.6%
Myalgia	56.9%	61.3%	37.3%	39.1%	15.4%
Fatigue	57%	67.6%	59.4%	43.8%	17.8%
Headache	50.6%	62.8%	51.7%	44.4%	18.7%
Chills	35.8%	48.3%	35.1%	2%* (unsolicited)	6.2%
Fever	27.8%	17.4%	15.8%	12.8%	0.8%
Overall Grade 3%	5.2%	4.1%	1.5%	0.54%	0.45%
Overall SE %	48%	46%	36%	27% *31% not counting chills	15%
	1	2	3	4	5

Summary of COVID-19 Vaccine Trials

Company	Platform	Doses	Number in trial vaccinated	Protection from Hospitalized COVID-19	Protection from severe COVID-19	Protection from all sx COVID-19
Pfizer/ BioNTech	mRNA	2	~18,600	100%	100%	95%
Moderna	mRNA	2	~15,000	97% (1 after 2nd dose)	97%	94.1%
J&J/ Janssen	Human adeno vector	1	~22,000	100%	85% (none hospitalized)	72% US, 66% Latin America, 57% S Africa
Oxford/ AstraZeneca	Chimp adeno vector	2	~8588	100%	100%	70% overall; S Africa trial halted for mild
Novavax	Protein + Adjuvant	2	~9700	100%	100%	89% UK; 60% S. Africa

Adapted from @MonicaGandhi9 (Twitter 3/7/21)

Special Populations: Prior COVID-19 Infection

- CDC recommends vaccination be offered to people regardless of history of COVID-19 infection
  - Vaccine trials show safety
  - Vaccines provide added protection even in those with prior COVID
- Antibody testing not recommended prior to vaccination
- If you currently have COVID-19, it is recommended to wait until acute illness over and cleared to work; if desired, you can wait for almost 90 days to get the vaccine
- Wait at least 90 days for vaccine if you received convalescent plasma or monoclonal Ab treatments

www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/clinical-considerations.html#contraindications-precautions

Special Populations: Pregnancy and Immunocompromised Patients

Pregnancy and Breastfeeding:

- Women known to be pregnant were excluded from vaccine trials
- **No safety concerns identified from > 30,000 pregnant women vaccinated with mRNA vaccines**
- Registry of > 1,800 pregnancies, 275 completed showed miscarriage rate same as baseline community rate
- OB/Gyn groups recommend that pregnant/lactating females should be offered vaccine when eligible

Immunocompromised Patients:

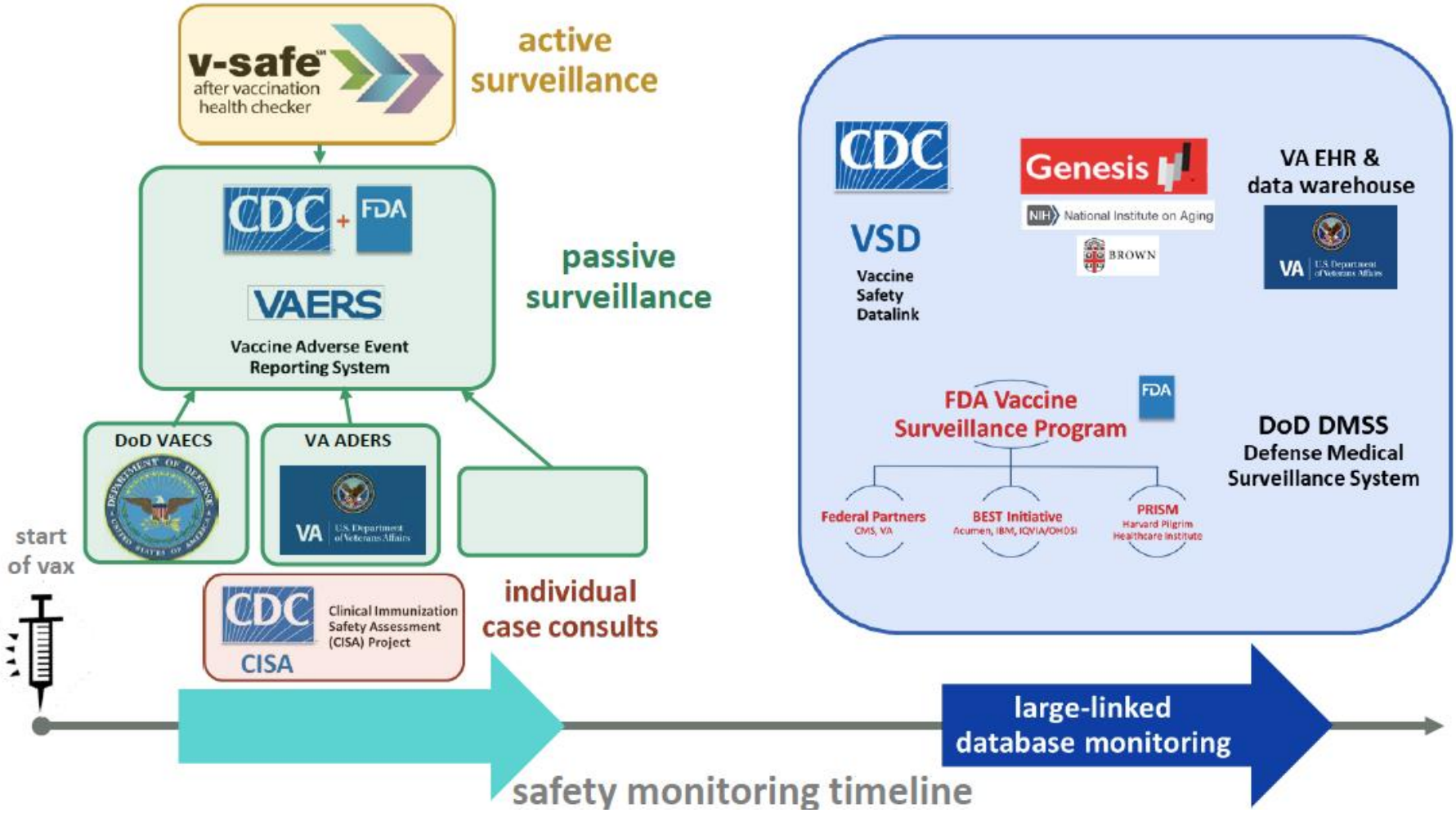
- Such patients may have reduced immune response to vaccine but are still recommended to receive the vaccine

CDC Guidance Regarding Vaccines and Allergies

- Most people, including those with allergies to food, pets or oral medicines, can proceed with usual 15 minute post-vaccine observation
- Those with allergies to other vaccines or injectable medicines should be observed for 30 minutes post-vaccine
- **Only absolute contraindication is prior allergy to COVID-19 vaccine or one of its components** (including PEG and polysorbate)
- Those with allergy to mRNA vaccine can get viral vector vaccine and vice versa
- Consult with your primary care physician or allergy specialist if you have questions

www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/clinical-considerations.html#contraindications-precautions

Post-Vaccine Safety Surveillance



V-safe | After Vaccination Health Tracker

V-safe is a smartphone-based tool that uses text messaging and web surveys to provide **personalized health check-ins** after someone receives a COVID-19 vaccination.

Vaccine recipients can quickly tell the CDC if they have any side effects. The CDC may follow up with them by phone to get more information.

V-safe will also remind them to get their second COVID-19 vaccine dose, if needed.

https://vsafe.cdc.gov

v-safe℠
after vaccination health checker

Use your smartphone to tell CDC about any side effects after getting the COVID-19 vaccine. You'll also get reminders if you need a second vaccine dose.

Other Vaccine FAQs

- Window period for second dose
  - Pfizer: 21 days (4 day grace period)
  - Moderna: 28 or more days (4 day grace period)
  - J&J: single shot
  - If miss window, do not restart but get as soon as can
- When will COVID vaccine be available for everyone?
  - Enough for all U.S. adults by end of May 2021
  - Older adolescents this Fall, young kids likely early 2022
- Timing of other non-COVID-19 vaccines
  - Wait 14 days after COVID-19 vaccine to get other vaccines

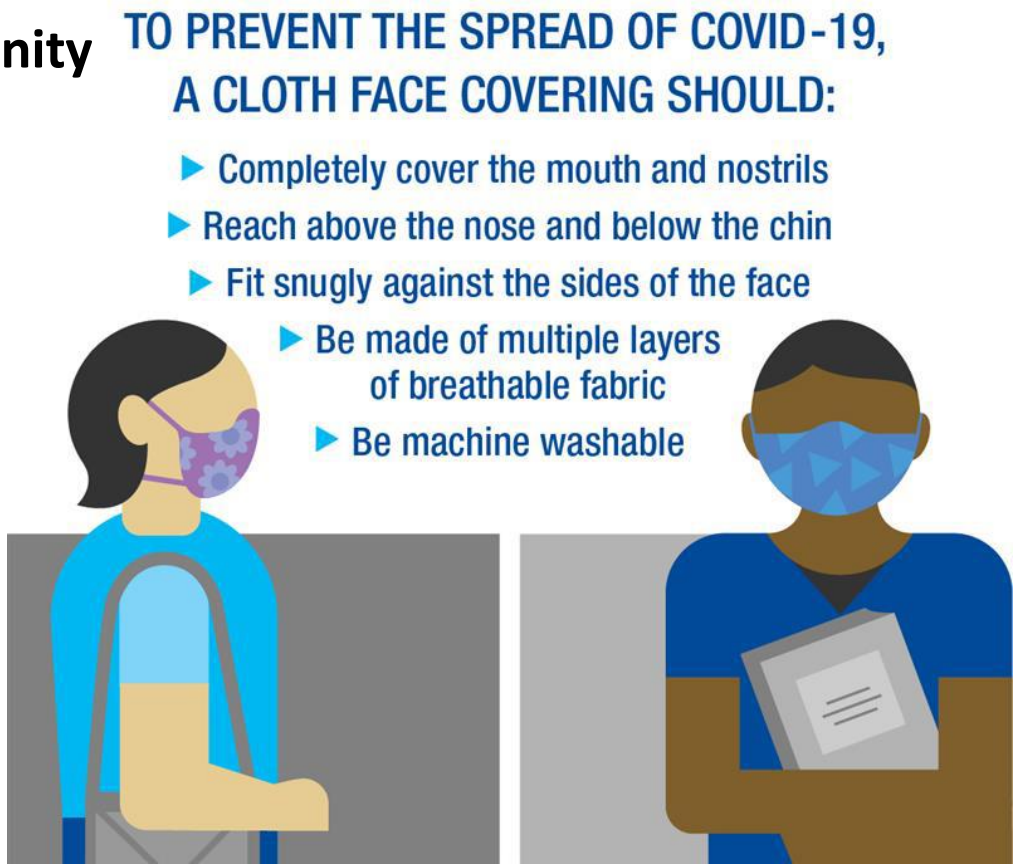
Protection = Vaccinations + NPIs

Herd Immunity = Population Immunity

- When enough in community have protection from vaccine or prior infection, virus no longer able to cause outbreaks
- Estimates ~ 80% for COVID-19

NPIs make a difference!

- Continue NPIs (non-pharmacologic interventions) even after being vaccinated in public
- Mask wearing, physical distancing, hand-washing



www.who.int/news-room/q-a-detail/herd-immunity-lockdowns-and-covid-19#:~:text=Herd%20immunity%20is%20achieved%20by,without%20making%20us%20sick

CDC Guidelines for Fully Vaccinated

The following recommendations apply to non-healthcare settings. For related information for healthcare settings, visit Updated Healthcare Infection Prevention and Control Recommendations in Response to COVID-19 Vaccination.

Home/Small, private gatherings

Fully vaccinated people can:

- Visit with other fully vaccinated people indoors without wearing masks or physical distancing
- Visit with unvaccinated people from a single household who are at low risk for severe COVID-19 disease indoors without wearing masks or physical distancing
- Refrain from quarantine and testing following a known exposure if asymptomatic

Public/Work, large gatherings

For now, fully vaccinated people should continue to:

- Take precautions in public like wearing a well-fitted mask and physical distancing
- Wear masks, practice physical distancing, and adhere to other prevention measures when visiting with unvaccinated people who are at increased risk for severe COVID-19 disease or who have an unvaccinated household member who is at increased risk for severe COVID-19 disease
- Wear masks, maintain physical distance, and practice other prevention measures when visiting with unvaccinated people from multiple households
- Avoid medium- and large-sized in-person gatherings
- Get tested if experiencing COVID-19 symptoms
- Follow guidance issued by individual employers
- Follow CDC and health department travel requirements and recommendations

www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated-guidance.html#anchor_1615143336158

UT Southwestern COVID-19 Resources

- COVID-19 Website
  - utsouthwestern.edu/covid-19/
- Vaccination Information
  - utswmed.org/covid-19/covid-19-vaccination/
- DFW COVID-19 Modeling/Forecasting
  - utsouthwestern.edu/covid-19/about-virus-and-testing/forecasting-model.html
- UTSW COVID-19 Screening Program
  - utswmed.org/covid-19/testing/screening-businesses-organizations

UT Southwestern COVID-19 Screening Program

Learn More at
utswmed.org/COVID19ScreeningProgram

Contact us at
COVID19PoolScreening@UTSouthwestern.edu

- Supports DFW business and civic community's continued transition through the pandemic
- Developed for businesses, organizations, and schools
- Accurate screening tool for asymptomatic individuals
- Empowers organizations with the knowledge to structure safe workplace and learning environments

COVID-19 Vaccine Myth Busters

CORONAVIRUS

A Virus Expert Dispels COVID-19 Vaccine Myths

BY ERIC GRIFFEY | DALLAS
UPDATED 5:21 PM CT FEB. 10, 2021 | PUBLISHED 2:41 PM CT FEB. 10, 2021

spectrumlocalnews.com/tx/san-antonio/news/2021/02/10/a-virus-expert-clears-dispels-covid-19-vaccine-myths

UT Southwestern COVID-19 MedBlogs

- Address numerous questions and topics about impact of COVID-19 on health and community

  utswmed.org/medblog/topic/covid/

- Recent MedBlogs:
  - COVID-19 Vaccine Hesitancy: How to Overcome the Culture of Mistrust
  - COVID-19 Vaccines: Separating Myths From Reality
  - COVID-19 Vaccines: The Tough Questions Answered By a Frontline Doctor

UT Southwestern Educational Programs

- "Life After Vaccination," UTSW *What to Know* with Dr. Brad Cutrell (March 2021)

  utswmed.org/whattoknow
- Dr. Kizzmekia Corbett Presentation (Moderna vaccine co-developer) at UTSW Women in Science and Medicine Advisory Committee Ida Green Lecture (February 2021)

  youtube.com/watch?v=JXQKbNyxGFQ&feature=youtu.be
- COVID-19 Vaccines, UTSW *Science Café* with Dr. Trish Perl

  youtube.com/watch?v=jaitHx37M7k (December 2020)

UT Southwestern Multilingual PSAs

Two sets of multilingual PSAs about COVID-19

I. COVID-19 Vaccines

- Please share with your work teams
- 13 languages
- Amharic, Arabic, English, French, Gujarati, Hindi, Igbo, Korean, Spanish, Telugu, Tigrinya, Vietnamese and Yoruba
- vimeo.com/showcase/7463038

II. Value of NPIs to Protect Against COVID Spread

- utsouthwestern.edu/covid-19/media/multilingual-psas.html

Thanks for Your Leadership and Support

- Grateful for your leadership in keeping our community and workplaces safe with thoughtful, evidence-based policies
- Thanks to the DRC for today's program to help organizations traverse pandemic policies
- Appreciate this opportunity to speak with you today

Questions? Send to jennifer.king@utsouthwestern.edu