Supporting Individuals with Intellectual and Developmental Disabilities – COVID-19 Vaccine: Overcoming Fears and Myths

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Disclosure and Purpose of CEE

I work for an Agency that that provides different types of services across the US. In Colorado, we provide Residential Services to adults on or getting on the DD waiver and needing or wanting residential support. We also provide LTC Pharmacy services, Neuro-rehab, and workforce services.

With the onset of COVID, access to regular events that provided education, information about services and connections to individuals with IDD, families, guardians and support staff supporting them have fallen away.

This is our attempt to scratch that surface of making connections and providing support to the IDD community.

This will be recorded for later viewing.

Community Advantage of Colorado

- Community Advantage, a ResCare Community Living Agency, was established here in Colorado over 25 years ago. Our goal is to make a difference in the lives of adults with intellectual and developmental disabilities, and “helping people live their best life”.

- Counties Served: Adams, Arapahoe, Boulder, Broomfield, Denver, Douglas, El Paso, Gilpin, Jefferson, Larimer, Park, Pueblo, Teller, Weld

- Community Advantage, Inc.
  11990 Grant Street
  Suite 550
  Northglenn, Colorado 80233

Our Company

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ResCare® Community Living

SpringHealth Behavioral Health and Integrated Care

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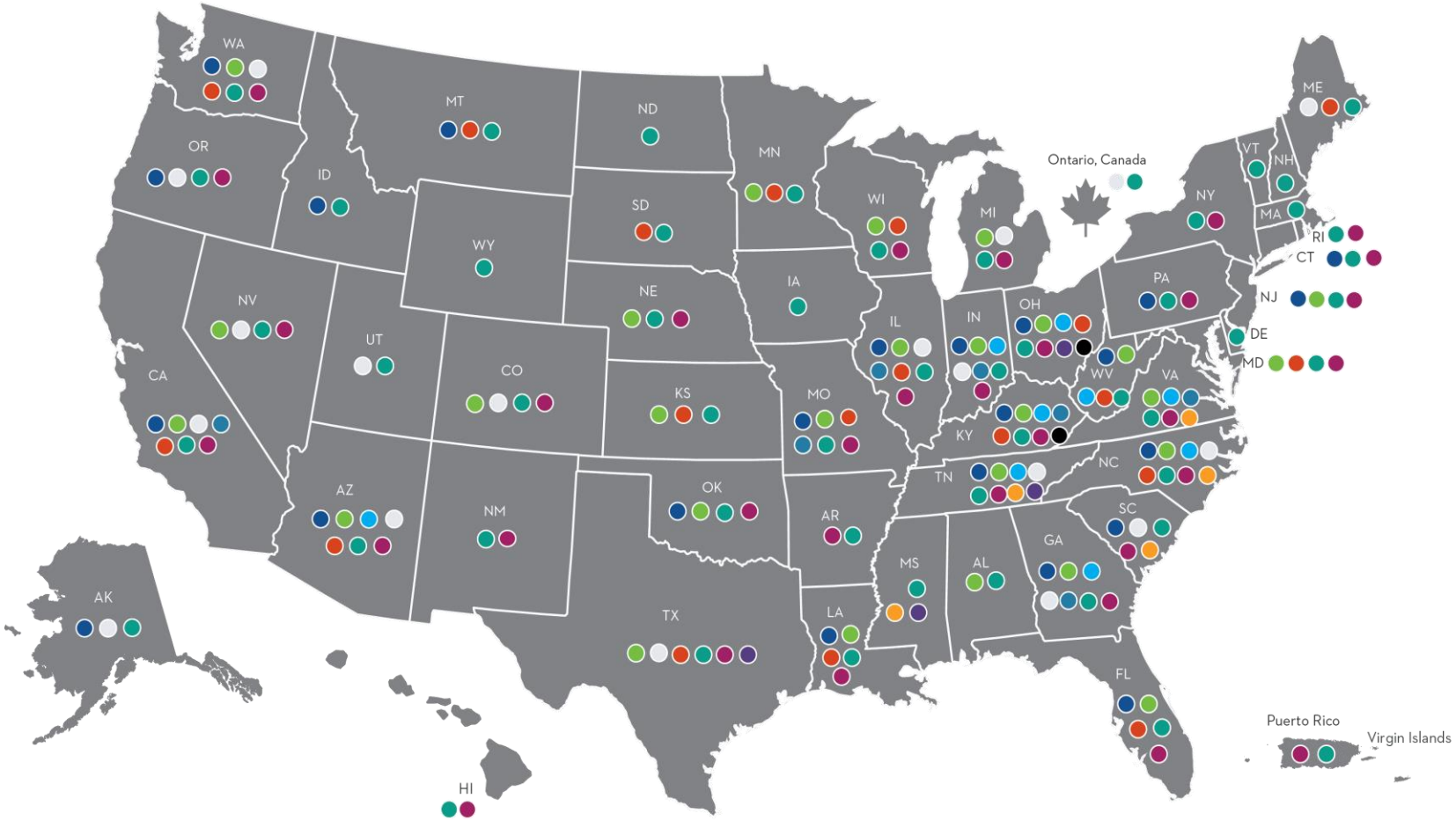

- HomeCare Services
- Community Living Services
- Family & Youth Services
- Neurorehabilitation Services
- Behavioral Health Services
- TeleCare & Remote Support Services
- Pharmacy Services
- Workforce Services
- Home Health Services
- Hospice Services
- Home-Based Primary Care Services

Res-Care, Inc. DBA BrightSpring Health Services

BrightSpringHealth.com

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Master of Ceremonies

William Webb
Account Executive - CO
Pharmacy Alternatives by
PharMerica

Featured Presenter

Rebecca Wingate,
Pharm.D.
Director, Clinical
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Featured Presenter

Stephen Creasy, Pharm.D.
Director, Clinical Services
PharMerica

Agenda

1. Current and Upcoming Vaccines
2. Vaccine Administration Updates
3. Vaccine Hesitancy

Current and Upcoming Vaccines

- **Emergency Use AUTHORIZATION (EUA) vs FDA APPROVAL (BLA)**
  - VRBPAC and the FDA
  - ACIP and the CDC
- **Safe and Effective Vaccine Development**
  - Immunogenicity vs. Reactogenicity
- **mRNA Vaccines**
  - Moderna – mRNA-1273
  - Pfizer/BioNTech – mRNA BNT162b2
- **Viral-Vectored Replication-Deficient Recombinant-Protein Vaccines**
  - Johnson & Johnson – Ad26.COV2.S
  - AstraZeneca - AZD1222

EUA vs BLA

- Emergency Use Authorization (EUA)
  - Allows the use of currently unapproved medical products in an emergency to diagnose, treat or prevent serious or life-threatening diseases
  - Can be no adequate, approved, and available alternatives
  - Must be adequate manufacturing information to ensure quality and consistency
  - Requires 2 months of follow-up after patients' second vaccination prior to EUA
  - FDA must determine that the known and potential benefits outweigh the risks

- Biologics License Application (BLA)
  - Is an approval from the FDA that a biological product (a vaccine) can be introduced to interstate commerce
  - Approval requires substantial evidence of safety and effectiveness from adequate, controlled trials

Source: FDA: Vaccine Development - 101

VRBPAC and ACIP

- VRBPAC – Vaccines and Related Biological Products Advisory Committee – FDA
  - Reviews and evaluates data concerning the safety, effectiveness and appropriate use of vaccines and related biological products
  - The committee consists of 15 voting members including the Chair
  - Members are selected from authorities knowledgeable in fields related to vaccine development and safety
  - Their role is to consider the quality, relevance and scientific support for the regulation of these products and make recommendations to the Commissioner of the FDA

- ACIP – Advisory Committee on Immunization Practices – CDC
  - Is made of medical and public health experts who develop recommendations on the use of vaccines in the civilian population
  - Their purpose is to provide public health guidance for the safe use of vaccines and make recommendations to the CDC
  - The committee is comprised of 15 voting members selected by the U.S. department of Health and Human Services (DHHS)
  - Also, 8 ex officio members who represent other federal agencies and 30 non-voting members who represent liaison organizations
  - Members and representatives serve on the committee voluntarily

Sources: FDA: VRBPAC and CDC: ACIP

Safe and Effective Vaccine Development

- In the history of vaccine production, 90 to 95% reveal their long-term side effects within **30 to 45 days** after their final dose.
- In considering the Emergency Use Authorization of Pfizer and Moderna's mRNA vaccines
  - Phase III safety data was assessed over an **8 week look-back period** by the 2 aforementioned independent unbiased groups
    - Vaccines and Related Biological Products Advisory Committee (VRBPAC) that informs the FDA, *and*
    - Advisory Committee on Immunization Practices (ACIP) that informs the CDC

Sources: FDA: EUA

Safe and Effective Vaccine Development

Vaccines pursuing EUA are HERE

	PRE-CLINICAL TRIAL	PHASE 1	PHASE 2	PHASE 3	PHASE 4 (POST-MARKETING)
SUBJECTS	• Trials in animals	• Small number of healthy subjects (<100)	• Larger number of subjects (100s)	• Largest number of subjects (1,000s) • More diverse population	• General population, including those with immunocompromising conditions
OBJECTIVES	• Safety • Immunogenicity • Feasibility	• Safety • Immunogenicity • Safe dose range	• Safety • Immunogenicity	• Safety (uncommon adverse events) • Efficacy (how well vaccine prevents disease)	• Safety (very rare adverse events) • Effectiveness (how well vaccine prevents disease in general population over time
KEY POINTS	• Critical step before proceeding to human trials	• First human trial	• Determine the final does and schedule	• Typically randomized, controlled, double-blind trial	• Post-licensure safety effectiveness surveillance

Source: FDA: Vaccine Development - 101

FDA Track Record for Vaccine Approval

Pfizer/BioNTech received approval in the U.S. on 12/11/20, Moderna approved 12/18/20, and Janssen approved 02/27/21

- Surveillance of side effects will be closely watched by US FDA

Current Post-Marketing Safety Assessment is being prioritized throughout the phased rollout of EUA-authorized COVID19 Vaccines

- Vaccine Adverse Event Reporting System (VAERS)
  - VAERS is a long-standing established safety monitoring system that is critical to monitoring new vaccines during the early uptake period and acts as an early warning system for vaccine safety
  - One of many venues to report adverse effects for residents and HCPS
- V-Safe After Vaccination Health Checker
  - Text-message and web-survey based system intended for HCP who receive vaccine
  - Daily 1st week; weekly thru 6 weeks; then 3, 6, and 12 mo.

CONCLUSIONS

- The vast majority of vaccines approved by FDA were found to be remarkably safe
- The FDA approval process, and the VAERS surveillance program, are excellent

Source: FDA: Post-Marketing Surveillance

Status: Vaccine Development

TERMINOLOGY

IMMUNOGENICITY

Extent to which a vaccine produces the desired immune response and the intensity of immunity conferred.

REACTOGENICITY

Extent to which a vaccine produces "expected" adverse reactions, especially indicative of excessive immunological responses and associated signs and symptoms

- E.g., fever, malaise, sore arm at injection site.
- Other manifestations of reactogenicity typically identified in clinical trials include bruising, redness, induration, and swelling.

Source: FDA: Vaccine Development - 101

Status: Vaccine Development

Immunogenicity

	PFIZER	MODERNA	JANSSEN
EUA Date	12/11/2020	12/18/2020	02/27/2021
Indicated Age	≥ 16 years	≥ 18 years	≥18 years
Primary Endpoint - Overall Efficacy	95% effective 7 days after the **second dose**	94.5% effective 14 days after the **second dose**	66.9% effective 14 days after the **single dose***
Primary Endpoint - Subgroup Efficacy	Similar efficacy point estimates across age groups, genders, racial and ethnic groups, and participants with medical comorbidities associated with high risk of severe COVID-19		
Regimen	Two doses 21 days apart (second dose can be given as early as 17 days)	Two doses 28 days apart (second dose can be given as early as 24 days)	One dose

Status: Vaccine Development

Reactogenicity

	PFIZER	MODERNA	JANSSEN
Injection Volume	0.3ml	0.5ml	0.5ml
Adverse Reactions	Depending on vaccine product (Pfizer vs. Moderna), age group, and vaccine dose, approximately 80–89% of vaccinated persons develop at least one local symptom and 55–83% develop at least one systemic symptom following vaccination. Most systemic post-vaccination symptoms are mild to moderate in severity, occur within the first three days of vaccination, and resolve within 1–3 days of onset. These symptoms are more frequent and severe following the second dose and among younger persons compared to older persons (i.e., >55 or ≥65 years [for Pfizer-BioNTech or Moderna vaccines, respectively]). Hypersensitivity-related adverse events were observed in 0.63% of Pfizer-BioNTech and 1.5% of Moderna COVID-19 vaccine clinical trial participants who received the vaccine, compared to 0.51% and 1.1%, respectively, in the placebo groups.	Depending on age group, approximately 50% of vaccinated persons developed at least one local symptom and 55% developed at least one systemic symptom following vaccination. Most systemic post-vaccination symptoms are mild to moderate in severity, occur within 1-2 days of vaccination, and resolve within 1–2 days of onset. These symptoms were more frequent among younger persons compared to older persons (i.e., >60) Hypersensitivity-related adverse events were observed in 0.35% of Janssen COVID-19 vaccine clinical trial participants who received the vaccine, compared to 0.30% in the placebo group.

Vaccine Types

Different vaccine technologies can be used to trigger the desired immune response:

1. Live Attenuated Vaccines (Influenza [Flumist], MMR)
2. Inactivated Vaccines (Influenza [IM vaccines],Hepatitis A, Polio)
3. mRNA Vaccines (**Pfizer: mRNA BNT162b** and **Moderna: mRNA-127**)
4. Viral-Vectored Replication-Deficient Recombinant-Protein Vaccines (**AZ: AZD1222** **J&J:Ad26.COV2.S**)

Vaccine Types

Of these various types, two vaccines are currently approved for emergency use in the U.S. at this time, with a third submitted and pending approval:

1. **mRNA Vaccines**
   a. ✓ **Pfizer mRNA BNT162b**
   b. ✓ **Moderna mRNA-127**
2. **Viral-Vectored Recombinant-Protein Vaccines**
   a. ✓ **J&J – Ad26.COV2.S**
   b. **AZ – AZD1222**

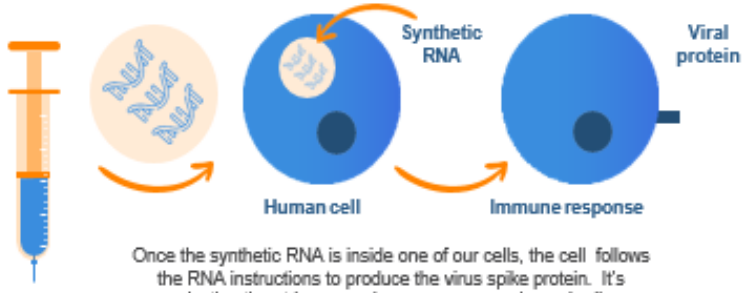
PFIZER-BioNTech / MODERNA

WHAT ARE RNA VACCINES & HOW DO THEY WORK?

What are RNA Vaccines?

The genetic code of the SARS-CoV-2 virus is made up of RNA. Scientists isolated the part of this genetic code that contains the instructions for making the virus's spike protein.

Synthetic RNA which codes for the virus spike protein is packed in lipid nonparticles (very small fat droplets). This stops our bodies' enzymes breaking it down and helps our cells take it in.



Once the synthetic RNA is inside one of our cells, the cell follows the RNA instructions to produce the virus spike protein. It's production then triggers an immune response in our bodies.

RNA Vaccines: Benefits & Challenges

Vaccine Production

RNA is easy to make in a lab, so RNA vaccines can be developed quicker than other vaccines.

Safety of the Vaccines

RNA can't cause infection and is broken down by normal processes in our cells. An RNA vaccine hasn't been licensed for use in humans before but they've been under development for several years for other viruses, including influenza, HIV, and Zika.

Storage and Transport

Some RNA vaccines must be stored at low temperatures to remain stable, which makes storage and transport more challenging.

RNA Vaccines for COVID-19

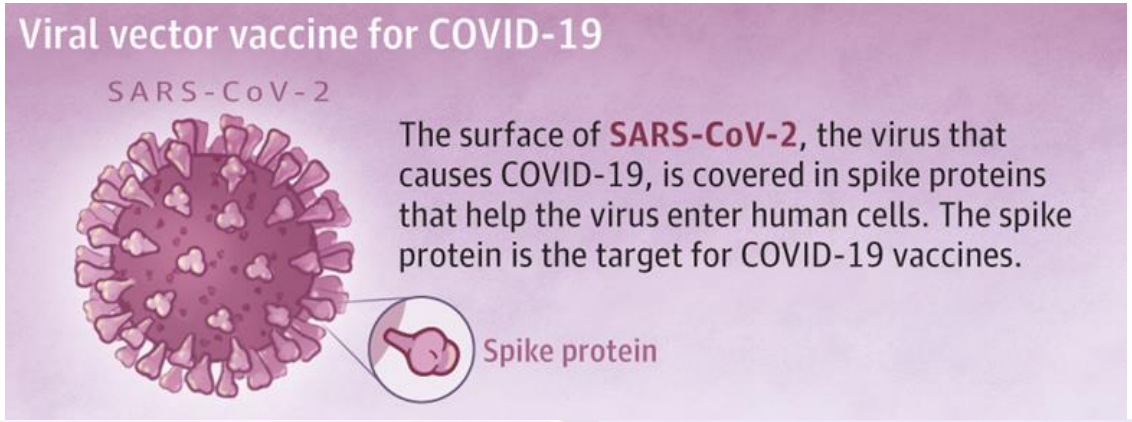
Several proposed vaccines for COVID-19 are RNA vaccines.

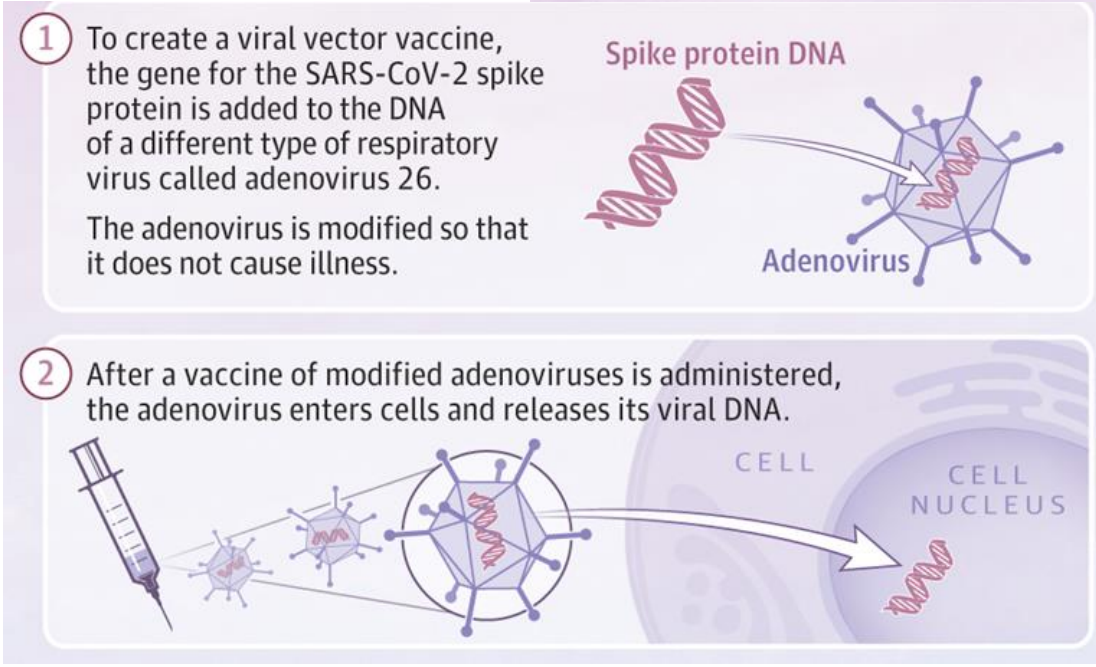
mRNA vaccines: Moderna • Pfizer & BioNTech • CureVac

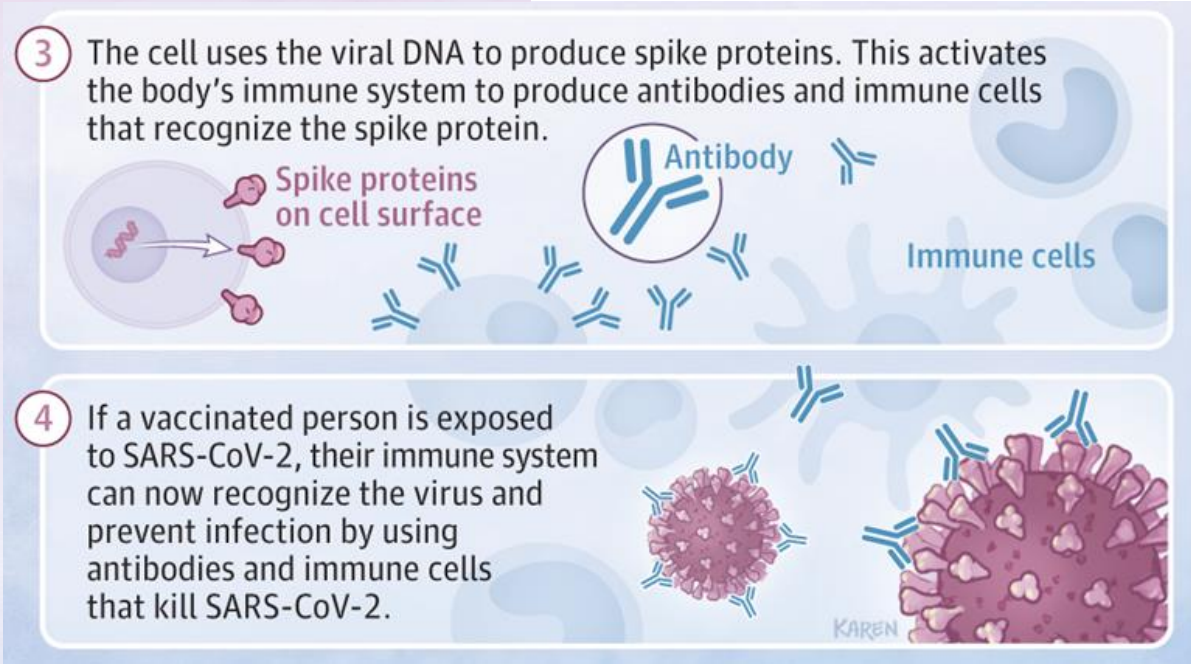
Source: CDC: Understanding mRNA Vaccines

AstraZeneca / Johnson & Johnson

What is a viral-vector recombinant-protein Vaccine & How does it work?







Source: JAMA 3-1-2021

Status: Vaccine Development

Status: **Pfizer/BioNTech mRNA BNT162b2**

- Started phase 3 clinical trials July 27th
- Phase 3 study enrolled over 43,000 participants
- Two doses using 21-day interval; ultra-cold storage*
- Phase 1 data:
  - Reactogenicity: Mostly mild to moderate side effects, increasing with second dose
- Phase 3 data:
  - Immunogenicity: Yielded 95% efficacy in preventing confirmed COVID-19 at least 7 days after second dose
- FDA authorized Pfizer vaccine December 11, 2020 for Emergency Use
- As of March 1st, 2021 over 38 million doses administered in the US
  - Expect up to 1.3 billion doses by the end of 2021

Source: Pfizer Press Release

Status: Vaccine Development

Status: **Moderna's mRNA-1273**

- Started phase 3 clinical trials July 27th
- Phase 3 study enrolled over 30,000 participants
- Two doses using 28-day interval; cold storage
- Efficacy via Press Release of 94%
- FDA authorized Moderna vaccine December 18, 2020 for Emergency Use
- As of March 1st, 2021 over 36.5 million doses administered in the US
  - Expect up to 1 billion doses by the end of 2021

Source: Moderna Press Release

Status: Vaccine Development

Status: **Johnson & Johnson – Ad26.COV2.S**

- Started phase 3 clinical trials September 7th
- Phase 3 study enrolled over 44,000 participants
- One dose; normal refrigerated storage
- Efficacy via Press Release of 66.9% in US
- Phase 3 data:
  - Reactogenicity: Mostly mild to moderate side effects, generally milder in older adults (≥ 60 years old)
- FDA authorized Janssen vaccine February 27th, 2021 for Emergency Use

Source: Johnson & Johnson Press Release

Status: Vaccine Development

Status: **AstraZeneca – AZD1222**

- Started phase 3 clinical trials August 28th, 2020
- As of December 2020, had administered vaccine to 15,000 trial participants out of a target of 30,000
- One dose; normal refrigerated storage
- Efficacy via Press Release of 76%
- Phase 1 data:
  - Reactogenicity: Mostly mild to moderate side effects, generally milder in older adults (≥ 65 years old)
- Britain authorized vaccine for emergency use on December 30th; anticipated submission for FDA EUA review in April 2021

Source: Astrazeneca Press Release

Status: Vaccine Differentiators – Side by Side Comparison

	Vaccine Candidates			
	mRNA vaccines		Replication-defective vectored vaccines	
	Moderna	Pfizer/BioNTech	AstraZeneca	Janssen
Potential Advantages	• Safety – mRNA is non-infectious and non-integrating. There is no potential risk for infection. Additionally, mRNA is rapidly degraded by normal cellular processes • Scalable production • Potency – capable of generating humoral and cellular immunity • Efficacy – structural modifications during engineering improves		• Stability at refrigerated temperatures • Experience with platform	
			• Previous use in immunocompromised patients • Circumvents existing antivector immunity	
Potential Disadvantages	• Lack of commercial vaccine precedent in humans • Local and systemic inflammatory response • Biodistribution and persistence of the induced antigen expression • Possible development of autoreactive antibodies		• No commercial vaccine precedent in humans	• Possibility of preexisting antivector immunity

Source: Vizientic Side-by-Side Comparison

Vaccine Administration Updates from CDC

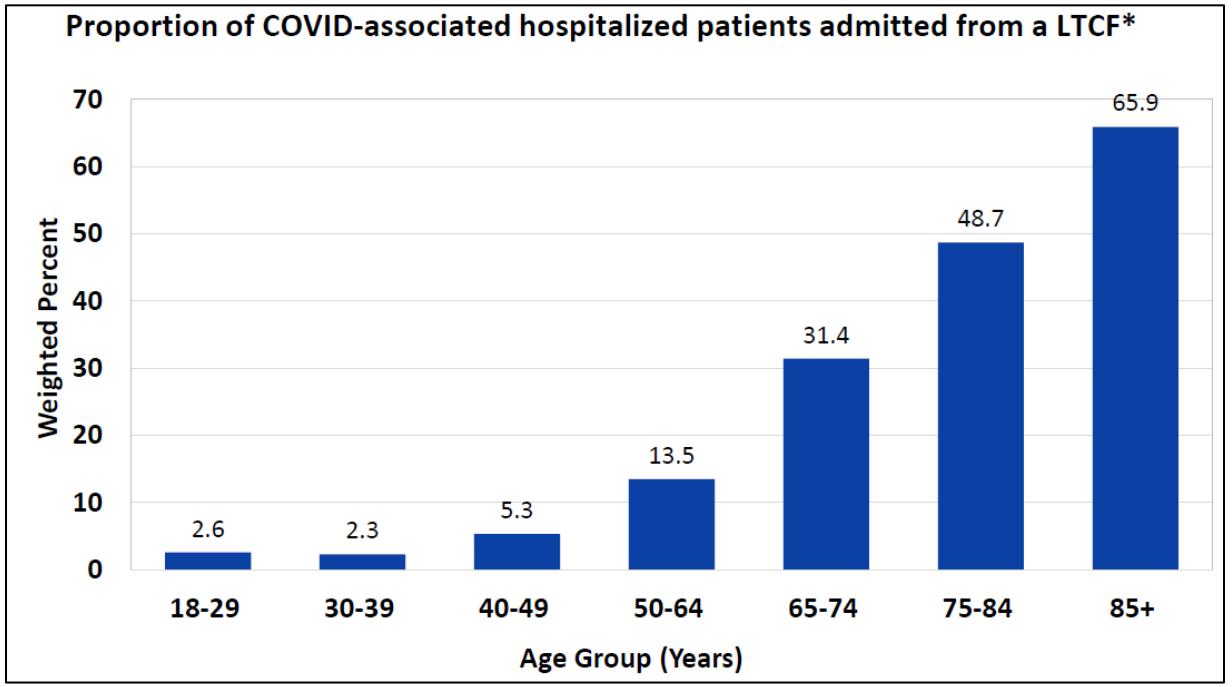
Health Care Personnel

- As of 3/2/21 there have been at least 416,222 confirmed cases among HCPs, with 1,371 deaths
- More cases and deaths have been shown to be averted by vaccinating staff
  - Staff are much more mobile inter- and intra-facility than residents
- HCP staffing already affected by absenteeism due to quarantine, infection, and illness.

Residents

- LTC residents account for only 6% of the cases, but 40% **of** the deaths in the U.S.

- The majority of COVID-associated hospitalized patients older than 75 years, were admitted from a LTCF



Source: CDC Data Tracking

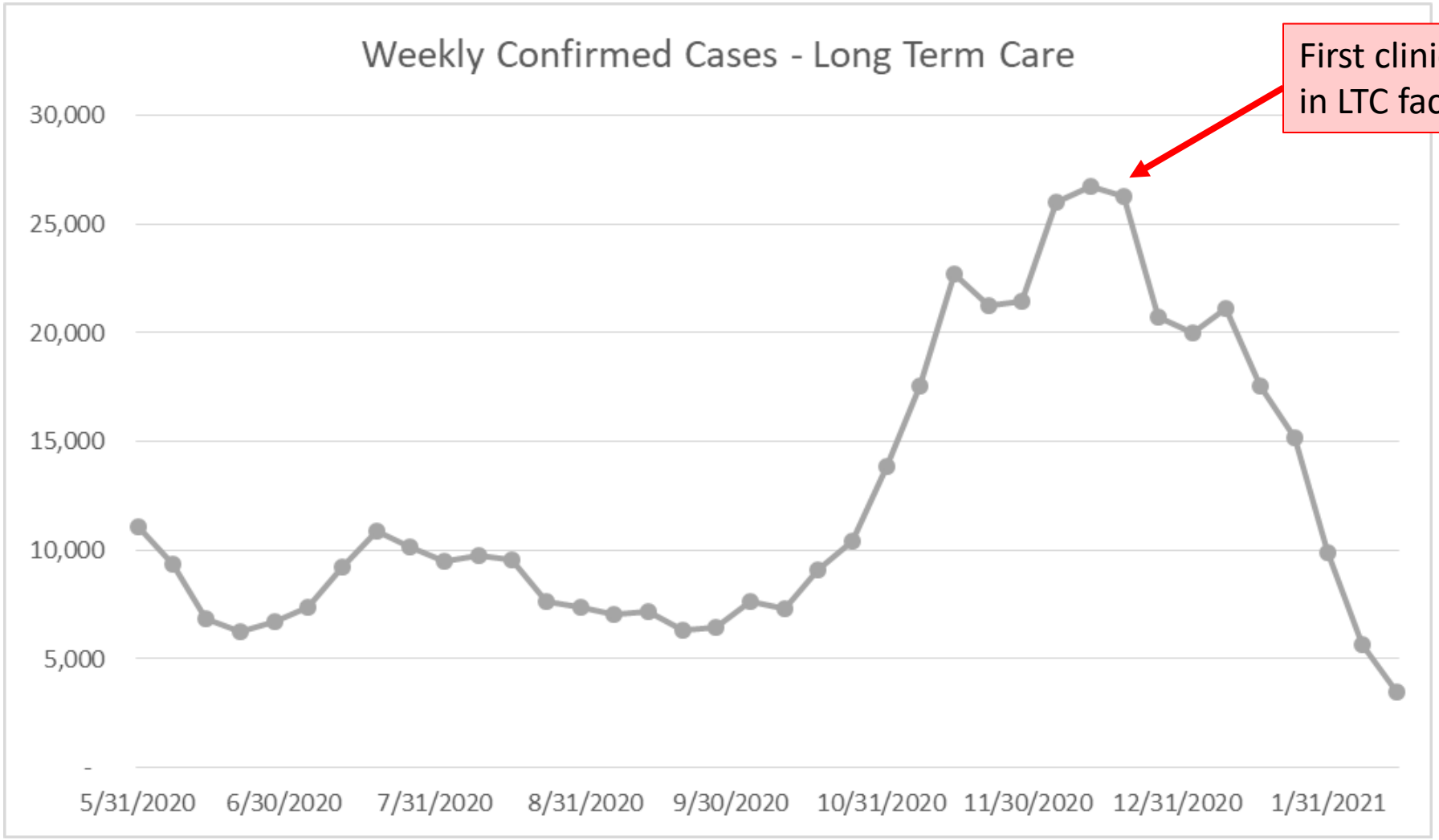
Vaccine Administration Updates from CDC

- Current reported phases of vaccine distribution as of 2/15/2021
  - Phase 1a: 4 states
  - Phase 1b: 41 states
  - Phase 1c: 6 states
  - Congregate settings included in Phase 1: 31 states
- Doses administered as of 3/2/2021

	U.S. Total	Long Term Care
Total Doses Delivered	102,353,940	-
Total Doses Administered	78,631,601	7,178,616
Individuals Receiving ≥ 1 dose	51,755,447	4,656,213
Individuals Receiving 2 doses	26,162,122	2,484,739

Source: KFF Priority Populations

Vaccine Administration Updates from CDC



Source: CDC Data Tracking

Vaccine Administration Updates from ACIP

- Safety data updates from most recent ACIP meeting (03/01/21)
  - Reporting rates:
    - Non-serious AE's: 372 reports per million doses administered
    - Serious AE's: 45 reports per million doses administered
  - Headache, Fever, Fatigue and Chills of the top reported adverse effects

- Updated Anaphylaxis report
  - Pfizer: 4.7 per million doses administered
  - Moderna: 2.5 per million doses administered

V-safe: after vaccination health checker

	Pfizer-BioNTech	Moderna	Total
People receiving 1 or more doses in the United States*	28,374,410	26,738,383	55,220,364
Registrants completing at least 1 v-safe health check-in	1,776,960	2,121,022	3,897,982

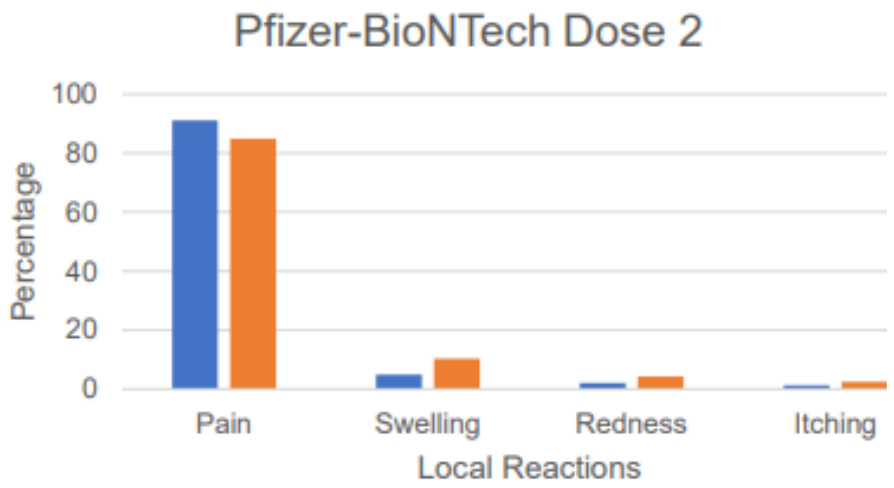
Source: ACIP Safety Data

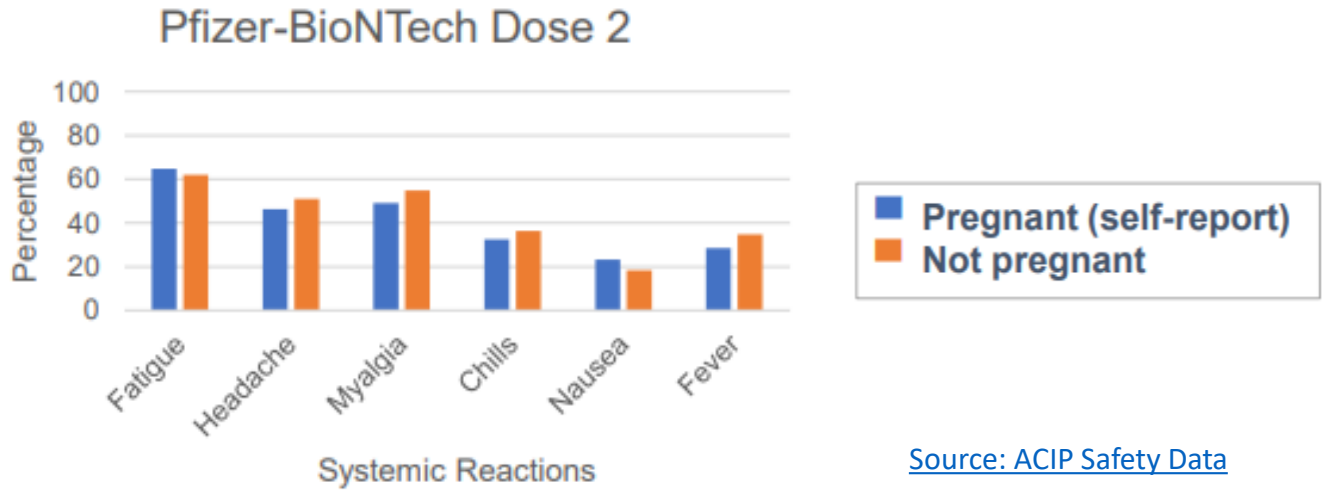
COVID-19 vaccine safety in pregnancy:

V-safe: after vaccination health checker

	Pfizer-BioNTech	Moderna	Total
Pregnancies reported to v-safe†	16,039	14,455	30,494

- Over 30,000 self-reported pregnancies through v-safe health check-in
- Local and systemic reactions on day 1 post-vaccination remain similar between pregnant and not pregnant women aged 16-54





Source: ACIP Safety Data

COVID-19 vaccine safety in pregnancy:

V-safe Pregnancy Registry:

- Of the roughly 30,000 V-safe self-reported pregnancies, 1,949 of those pregnant HCP have been invited to join the V-safe pregnancy registry and 1,815 of those have enrolled
- Enrolled participants are contacted once per trimester, after delivery, and when the infant is 3 months old

V-safe pregnancy registry outcomes of interest in COVID-19 vaccinated pregnant women as of February 18, 2021*

Outcomes	Background rates*	V-safe pregnancy registry overall
Pregnancy outcome		
Miscarriage (<20 weeks)	26%	15%†
Stillbirth (≥ 20 weeks)	0.6%	1%
Pregnancy complications		
Gestational diabetes	7-14%	10%
Preeclampsia or gestational hypertension§	10-15%	15%
Eclampsia	0.27%	0%
Intrauterine growth restriction	3-7%	1%
Neonatal		
Preterm birth	10.1%	10%
Congenital anomalies‡	3%	4%
Small for gestational age^	3-7%	4%
Neonatal death	0.38%	0%

Source: ACIP Safety Data

Vaccine Administration Updates from CDC

- Update regarding hesitancy in early phase groups from CDC MMWR 2/12/2021
  - COVID-19 Vaccination Intent, Perceptions, and Reasons for Not Vaccinating Among Groups Prioritized for Early Vaccination — United States, September and December 2020

- From September to December, the proportion of adults reporting intent to receive COVID-19 vaccine increased from 39.4% to 49.1%
- Among priority groups, intent increased among
  - Adults aged ≥65 years from 49.1% to 66.2%
  - Essential workers from 37.1% to 45.9%
  - Adults aged 18–64 years with underlying medical conditions 36.5% to 41.8%

- The main reasons most frequently cited for NOT intending to receive were
  - Concerns about side effects and safety of the COVID-19 vaccine (29.8%)
  - Planning to wait to see if the vaccine is safe and consider receiving it later (14.5%)
  - Lack of trust in the government (12.5%)
  - Concern that COVID-19 vaccines were developed too quickly (10.4%)

Source: CDC MMWR

Overcoming Vaccine Hesitancy

- Challenge: overcoming the perception that the EUA authorized vaccines cannot be trusted

- Potential rationales behind vaccine hesitancy:
  - Perception that the vaccine may not be safe or effective
  - Perception that vaccine process was rushed or that essential steps were skipped
  - Perception that the vaccines side effects outweigh the benefits

- Same rigorous trial requirements applied to vaccine development as that which exists outside COVID…
  now just in the public spotlight
  - Study protocols available to scrutinize by entirety of medical science community
  - Clear guidelines set forth by the FDA for a vaccine candidate to be considered for an Emergency Use Authorization
    - Large number of individuals required to be enrolled AND followed up on for at least 2 months post regimen
  - Data is sliced and diced
    - Astra Zeneca performing follow-up studies to determine exact dosing regimen
  - ACIP committee meetings are being held publically
  - VRBPAC Briefing Documents are freely and readily accessible

Source: ACIP Safety Data

Overcoming Vaccine Hesitancy

- COVID-19 vaccine development is moving faster than normal because our top medical experts have made it their highest priority, not because steps in the testing process are being skipped
  - COVID-19 vaccines are following the same rigorous, multi-phased testing process as every other vaccine
  - The FDA will continue to share information about authorized or approved COVID-19 vaccines so you can see the scientific evidence for yourself
  - COVID-19 vaccine developers are trying to make sure their clinical trials reflect the nation's diversity, because these vaccines must be proven safe and effective for everyone
  - Medical experts and career public health officials, not politicians or their appointees, decide when a COVID-19 vaccine is safe, effective, and ready for public use

☒ MYTH ☒	☑ FACT ☑
The COVID-19 vaccine is not safe because it was rapidly developed and tested	*Many pharmaceutical companies invested significant resources into quickly developing a vaccine for COVID-19.* Due to these significant resources, they were able to combine steps, to meet all safety protocols and adequate testing.
I already had COVID-19 and recovered, so I don't need to get a COVID-19 vaccine when it's available	*There is not enough information currently available to say if or for how long after infection someone is protected from getting COVID-19 again.* This is called natural immunity. Early evidence suggests natural immunity from COVID-19 may not last very long, but more studies are needed to better understand this.
There is high risk for severe side effects of the COVID-19 vaccines	*There are short-term mild or moderate vaccine reactions, similar to other vaccines, that resolve without complication or injury.* The early phase studies of the vaccine show that it is safe.
The COVID-19 vaccine will alter my DNA	*The first COVID-19 vaccines to reach the market are messenger RNA (mRNA) vaccines*. According to the CDC, mRNA vaccines work by instructing cells in the body how to make a protein that triggers an immune response. Injecting mRNA into your body will not interact or do anything to the DNA of your cells. Human cells break down and get rid of the mRNA soon after they have finished using the instructions.

Recommending Vaccination

Engaging in Effective COVID-19 Vaccine Conversations:

1. Start from a place of empathy and understanding
2. Assume patients will want to be vaccinated but may not know when to expect it
3. Give your *strong* recommendation
4. Listen to and respond to patient questions
5. Wrap up conversation by scheduling appointment or providing with more resources

Key Points to Share with Your Hesitant Patients

- Like all vaccines, COVID-19 mRNA vaccines have been rigorously tested for safety before being authorized for use in the United States.
- mRNA technology is new, but not unknown. They have been studied for more than a decade.
- COVID-19 vaccines do not contain a live virus and do not carry a risk of causing disease in the vaccinated person.
- mRNA from the vaccine never enters the nucleus of the cell and does not affect or interact with a person's DNA.

Resources

- FDA Emergency Use Authorization Information and Currently Authorized Products
- CDC Clinical Guidance for COVID-19 Vaccines and Immunizations
- CDC Local and National COVID-19 Data Tracker
- CDC ACIP Current and Archived Meeting Information

Questions we get asked…

- What are the psych meds interaction, should someone not take their meds the morning of?
  - Is there any day of or day before prep someone should do to lessen side effects?
- Which Vaccine do you recommend?
- Will it increase behaviors?
- Are there Peanut, shellfish, strawberry Allergic reactions?
- Do you think it is safe? Have you gotten it yet and will you?

Thank You For Joining Us Today!

Questions?

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