# Ethical Implications of Vaccine Hesitancy

### COVID-19 EDITION

### Rachel La Costa, MPAS, PA-C

# UC San Diego Health





### Disclosures

• No relevant commercial relationships to disclose.

# Objectives

- At the conclusion of this session, participants should be able to:
  - Discuss common motivations for vaccine hesitancy.
  - Identify the ethical principles involved in vaccine administration and hesitancy.
  - Formulate an ethical response that the PA can utilize to respond to vaccinehesitant persons.





### **Multiple Layers Improve Success**

The Swiss Cheese Respiratory Pandemic Defense recognizes that no single intervention is perfect at preventing the spread of the coronavirus. Each intervention (layer) has holes.



Source: Adapted from Ian M. Mackay (virologydownunder.com) and James T. Reason. Illustration by Rose Wong



# **OPERATION WARP SPEED** ACCELERATED VACCINE PROCESS

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







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# **PRINCIPLES OF ETHICS**



### BE COVIDSAFE V

### **Know Your Vaccination Phase**

Getting the COVID-19 vaccine not only helps to protect you and others around you, but is also a vital step for the recovery of San Diego County. COVID-19 vaccinations will become available in phases. Groups within each phase and distribution timelines are subject to change. For the latest vaccination information, please visit coronavirus-sd.com/vaccine.

### Phase 1A: Vaccinating NOW

Phase 1A includes Healthcare Personnel (includes healthcare support occupations) and Long-Term Care Facility Staff & Residents

#### **Tier One**

- Acute care, psychiatric hospitals
- Skilled nursing facilities, assisted living facilities, similar settings
- Paramedics, EMTs, other emergency medical services
- Dialysis centers
- Behavioral health residential facilities
- ☑ Vaccinators

#### **Tier Two**

- Intermediate care, for persons who need non-continuous nursing supervision, and supportive care
- Home health-care and in-home supportive services
- D Community health workers, including promotores
- D Public Health field staff
- D Primary care clinics
- D Federally Qualified Health Centers
- 2 Rural Health Centers
- D Correctional facility clinics
- D Urgent care clinics
- Behavior health non-residential or outpatient facilities

#### **Tier Three**

Other settings and healthcare workers not identified in tiers above, including specialty clinics, laboratory workers<sup>†</sup>, dental/oral health clinics, pharmacy staff, funeral workers and others<sup>§</sup>

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Laboratory workers must work in a facility that has CLA licensure or is conducting research with SarsCOV2. Additional Phase LA priority groups determined by the California Department of Public Health (CDPH) and the County of San Diego as of 01/05/21.8 01/21/2021 respectively are listed on <u>www.VaccinstitionSucentationSD.com</u>. \*Phases determined by Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunitation Practices (ACIP) and tiers approved by CDPH are subject to change. \*\*Information on specific job-types within the Essential Worker categories can be found at covid19.ce.as/vessentife-workforce/.



### **BE COVIDSAFE** Know Your Vaccination Phase

#### Phase 1B: February 2021\*

Phase 1B includes People Aged 65 and Older and Frontline Essential Workers\*\*

#### Tier One

- Individuals 65 years and older
- Those at risk of exposure at work in the following sectors: education, childcare, emergency services, and food and agriculture

#### **Tier Two**

- Those risk of exposure at work in the following sectors: transportation and logistics; industrial, commercial, residential, and sheltering facilities and services; critical manufacturing\*\*
- Congregate settings with outbreak risk, including incarcerated and homeless

#### Phase 1C: To be determined

Phase 1C includes People 50-64 Years Old, People 16-49 Years Old <u>with</u> High-Risk Conditions, and Other Essential Workers\*\*

#### Individuals 50-64 years of age

- People 16-49 years of age who have an underlying health condition or disability which increases their risk of severe COVID-19
- Those at risk of exposure at work in the following sectors: water and wastewater; defense; energy; chemical and hazardous materials; communications and IT; financial services; government operations/community-based essential functions\*\*

#### Phase 2: To be determined

General population over 16 years of age

Laboratory workers must work in a facility that has CLIA licensure or is conducting research with SarsOOV2. Additional Phase 1A priority groups determined by the California Department of Public Health (CDPH) and the County of San Diego as of 01/05/21 & 01/21/2021 respectively are listed on <u>www.VeccinetionBupendationBD.com</u>. \*Phases determined by Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) and tiers approved by CDPH are subject to change.

\*\*Information on specific job-types within the Essential Worker categories can be found at covid19.ce.dov/essential-workforce/





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#### Help Prevent the Spread of Coronavirus

See the latest information from the World Health Organization so you can help prevent the spread of COVID-19.

Go to who.int





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According to family, one of the first nurses in Alabama to receive the new vaccine was found dead. Anaphylaxis, maybe? We'll see what happens with the official reporting, I guess.

Update: The nurse was age 42, Caucasian female. Time of death was 8-10 hours after getting the vaccine. An autopsy is being conducted. The family wants people to know, but they want to remain anonymous for



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**BILL GATES ON VACCINE DISINFORMATION** W.H.O. ESTIMATES VACCINES SAVE 2-3 MILLION LIVES EVERY YEAR

#### Figure 1

### Compared To December, Larger Share Now Want COVID-19 Vaccine "As Soon As Possible," Fewer Want To "Wait And See"

Have you personally received at least one dose of the COVID-19 vaccine, or not? When an FDA approved vaccine for COVID-19 is available to you for free, do you think you will...?





What is the biggest factor driving vaccine hesitancy?

# VACCINE ANXIETY

#### Figure 11

### Many Express Concern About COVID-19 Vaccine's Long-Term Effects, Side Effects, Safety, and Effectiveness

Percent who say they are very or somewhat concerned about each of the following:



NOTE: Among those who have not been vaccinated against COVID-19 SOURCE: KFF COVID-19 Vaccine Monitor (conducted Jan. 11-18, 2021). See topline for full question wording. KFF COVID-19 Vaccine Monitor



Figure 2

### Vaccine Enthusiasm Increased Across Racial/Ethnic Groups, But Black And Hispanic Adults Remain More Wary Than White Adults

Percent who say they will get a COVID-19 vaccine:



SOURCE KFF COVID-19 Vaccine Monitor (Nov. 30-Dec. 8, 2020 and Jan. 11-18, 2021). See topline for full question wording.

(»))

Vaccine Monitor

# It is OK to ask questions about vaccines!



# How can PAs mitigate vaccine anxiety?

### **EDUCATION!**

### As a PA, you must EDUCATE YOURSELF!

For your own health.

For your family.

For your patients.

For your coworkers.

For your neighbors.

For your community.

For HERD IMMUNITY!



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COLINE MACCINE

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# Was the vaccine process rushed?



So how were we able to develop a COVID-19 vaccine in a matter of months?

- Urgency
- Funding → Operation Warp Speed
- Phases 1 & 2 were done in tandem
- Recruitment
- Widespread pandemic  $\rightarrow$  easier to assess efficacy

Prospective, double-blinded, placebo-controlled, randomized controlled trian

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# **Coronavirus Vaccine Tracker**

By Carl Zimmer, Jonathan Corum and Sui-Lee Wee Updated Jan. 30, 2021

PHASE 1 PHASE 2 PHASE 3 LIMITED APPROVED ABANDONED 8 20 37 24 ) Vaccines Vaccines Vaccines Vaccines Vaccines Vaccines testing safety in expanded in large-scale in early or abandoned approved and dosage safety trials efficacy tests for full use after trials limited use

Vaccines typically require years of research and testing before reaching the clinic, but in 2020, scientists embarked on a race to produce safe and effective coronavirus vaccines in record time. Researchers are currently testing **67 vaccines** in clinical trials on humans, and 20 have reached the final stages of testing. At least 89 preclinical vaccines are under active investigation in animals.

The New York Eimes

### **COVID-19 Vaccines**

### mRNA Vaccines

### Adenovirus Viral Vector Vaccines

Beth Israel Lahey Health

### **Protein Vaccines**



fizer BIONTECH EUA for age >16 y/o

VACCINE NAME: <u>Comirnaty</u> (also known as <u>tozinameran</u> or <u>BNT162b2</u>) EFFICACY: <u>95%</u> DOSE: 2 doses, 3 weeks apart TYPE: <u>Muscle injection</u> STORAGE: Freezer storage only at -94°F (-70°C) **43,548 participants** 

#### PHASE 3 EMERGENCY USE IN U.S., E.U., ELSEWHERE



National Institutes of Health

EUA for age >18 y/o

VACCINE NAME: mRNA-1273 EFFICACY: 94.5% \* DOSE: 2 doses, 4 weeks apart TYPE: Muscle injection

STORAGE: 30 days with refrigeration, 6 months at -4°F (-20°C)

#### 30,420 participants

VACCINE NAME: Ad26.COV2.S EFFICACY: 72% in United States, 66% in Latin America, 57% in South Africa DOSE: 1 dose \* TYPE: Muscle injection STORAGE: Up to two years frozen at -4° F (-20° C), and up to three months refrigerated at 36-46° F (2-8° C).

Beth Israel Deaconess Medical Center

#### 43,783 participants

Johnson Johnson

PHASE 3

PHASE 2 PHASE 3 COMBINED PHASES EMERGENCY USE IN BRITAIN, E.U., ELSEWHERE



VACCINE NAME: AZD1222 (also known as Covishield in India) EFFICACY: 62% to 90%, depending on dosage DOSE: 2 doses, 4 weeks apart TYPE: Muscle injection STORAGE: Stable in refrigerator for at least 6 months 11,636 participants PHASE 3

**NOVAVAX** Creating Tomorrow's Vaccines Today

VACCINE NAME: NVX-CoV2373 EFFICACY: 89.3% against most variants DOSE: 2 doses, 3 weeks apart TYPE: Muscle injection STORAGE: Stable in refrigerator >37,000 participants

EUA = Emergency Use Authorization



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### The SARS-CoV-2 mRNA Vaccines



#### Antibody production in lymph nodes



#### **Key Facts**

1. Both mRNA vaccines are >94% effective at preventing symptomatic COVID infections

2. mRNA from these vaccines cannot integrate into the human genome. It quickly degrades after use for protein synthesis.

3. All patients should receive 2 doses of the vaccine to induce long-term immunological memory & protection

### Advantages of mRNA Vaccines

Quick and easy to produce mRNA sequence can be updated (variants) Not grown in egg culture No preservatives No gelatin No latex

### Disadvantages of mRNA Vaccines

Fragile  $\rightarrow$  require specialized freezers Polyethylene glycol allergy

## VACCINE INGREDIENTS

Each dose of the Pfizer-BioNTech COVID-19 Vaccine also includes the following ingredients: lipids (0.43 mg (4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 0.05 mg 2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 0.09 mg 1,2-distearoyl-sn-glycero-3-phosphocholine, and 0.2 mg cholesterol), 0.01 mg potassium chloride, 0.01 mg monobasic potassium phosphate, 0.36 mg sodium chloride, 0.07 mg dibasic sodium phosphate dihydrate, and 6 mg sucrose. The diluent (0.9% Sodium Chloride Injection, USP) contributes an additional 2.16 mg sodium chloride per dose.

The Pfizer-BioNTech COVID-19 Vaccine does not contain preservative. The vial stoppers are not made with natural rubber latex.

Each dose of the Moderna COVID-19 Vaccine contains the following ingredients: a total lipid content of 1.93 mg (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), 0.31 mg tromethamine, 1.18 mg tromethamine hydrochloride, 0.043 mg acetic acid, 0.12 mg sodium acetate, and 43.5 mg sucrose.

Moderna COVID-19 Vaccine does not contain a preservative.

The vial stoppers are not made with natural rubber latex.



# Will an mRNA vaccine alter my DNA?









### Does the COVID-19 vaccine CAUSE COVID-19 disease?

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### What are the side effects of mRNA vaccines?

	Side Effects Am			Reactogenicity = immediate side effect Immune response!			
	Injection Site Reactions	Fatigue	Chills	Muscle Pain	Joint Pain	Headaches	
Moderna	91.6%	68.5%	43.4%	59.6%	44.8%	63%	
Pfizer- BioNTech	84.10%	62.90%	31.90%	38.30%	23.60%	55.10%	

\*Fever was the least common side effect reported; see text above for data on frequency of fever

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*Pfizer Vaccine Data*: "Mild reactogenicity, low incidence of severe or serious events, and <u>no clinically</u> <u>concerning safety observations</u>. The vaccine appears to be <u>safe and well-tolerated</u> across the safety population and within demographic subgroups based on age, sex, race/ethnicity, country, and baseline SARSCoV-2 status."



### What to Expect after Getting a COVID-19 Vaccine

Accessible version: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/expect/after.html

COVID-19 vaccination will help protect you from getting COVID-19. You may have some side effects, which are normal signs that your body is building protection. These side effects **may feel like flu** and **may even affect your ability** to do daily activities, but they should go away in a few days.

#### **Common side effects**

On the arm where you got the shot:	Throughout the rest of your body:		
• Pain	Fever     Tiredness		
Swelling	Chills     Headache		

### **Helpful tips**

If you have pain or discomfort, talk to your doctor about taking an over-the-counter medicine, such as ibuprofen or acetaminophen.

To reduce pain and discomfort where you got the shot: To reduce discomfort from fever:

- · Apply a clean, cool, wet washcloth over the area.
- Drink plenty of fluids.

• Use or exercise your arm.

Dress lightly.

#### When to call the doctor

In most cases, discomfort from fever or pain is normal. Contact your doctor or healthcare provider:

- . If the redness or tenderness where you got the shot increases after 24 hours
- · If your side effects are worrying you or do not seem to be going away after a few days

#### Remember

- · Side effects may feel like flu and even affect your ability to do daily activities, but they should go away in a few days.
- With most COVID-19 vaccines, you will need 2 shots in order for them to work. Get the second shot even if you have side effects after the first one, unless a vaccination
  provider or your doctor tells you not to get a second shot.
- It takes time for your body to build protection after any vaccination. COVID-19 vaccines that require 2 shots may not protect you until a week or two after your second shot.
- It's important for everyone to continue using all the tools available to help stop this pandemic as we learn more about how COVID-19 vaccines work in real-world
  conditions. Cover your mouth and nose with a mask when around others, stay at least 6 feet away from others, avoid crowds, and wash your hands often.



#### Ask your healthcare provider about getting started with v-safe

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 dose

> Learn more about v-safe. www.cdc.gov/vsafe

### Printable pdf from the CDC in English and Spanish: https://www.cdc.gov/coronavirus/2019

-ncov/vaccines/expect/after.html



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### Does the COVID-19 vaccine cause Bell's palsy?

### Rate of Bell's Palsy Occurrence in COVID-19 Vaccine Phase 3 Trials

	Vaccine Group	Placebo Group	Total	Rate per 10,000	Bell's palsy: 2-3 cases per	
Pfizer/BioNTech	4	0	4	0.9	10,000 people per year	
Moderna	3	1	4	1.3		

### Correlation vs. Causation

### THE LANCET

The Lancet, Volume 351, Issue 9103, Pages 637 - 641, 28 February 1998 doi:10.1016/S0140-6736(97)11096-0

This article was retracted

RETRACTED: Ileal-lymphoid-nodular hyperplas pervasive developmental disorder in children

Dr AJ Wakefield FRCS # 10, SH Murch MB b, A Anthony MB b, J Linnell PhD b, DM Casson MRCPath s, MA Thomson FRCP b, P Harvey FRCP d, A Valentine FRCR s, SE Davies MRCPath s, JA Walker-Smith FRCP s

#### Summary

Background We investigated a consecutive series of children with chronic enterocolitis and regressive developmental disorder. Methods 12 children (mean age 6 years [ringe 3–10], 11 boys) were referred to a paediatric gastroenterology unit with a history of normal development

followed by loss of acquired skills, including language, together with diarrhoea and abdominal pain. Children underwent gastroenterological, neurological, and developmental assessment and review of developmental records. Ileocolonoscopy and biopsy sampling, magnetic-resonance imaging (MRI), electroencephalography (EEG), and lumbar puncture were done under sedation. Barium follow-through radiography was done where possible. Biochemical. haematological. and immunological profiles were examined.

MMR vaccine

& autism


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### What about the risk of anaphylaxis?

# Centers for Diseases Control and Prevention

Morbidity and Mortality Weekly Report

January 15, 2021

#### Vaccine Adverse Event Reporting System (VAERS)

- 21 cases of anaphylaxis after administration of a reported 1,893,360 first doses of the Pfizer-BioNTech COVID-19 vaccine (11.1 cases per million doses)
- 17 in persons with a documented *history of allergies or allergic reactions*, seven of whom had a history of anaphylaxis.
- 71% of these occurred within 15 minutes of vaccination.

#### What are the implications for public health practice?

- <u>Screen</u> recipients for contraindications and precautions
  - Polyethylene glycol allergy
  - Polysorbate allergy
- Prepare necessary supplies available to manage anaphylaxis
- Implement the recommended postvaccination <u>observation periods</u>
- Immediately treat suspected cases of anaphylaxis with intramuscular injection of <u>epinephrine</u>

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#### Ashish K. Jha, MD, MPH 🤣 @ashishkjha

Physician, researcher, advocate for the notion that an thousand pounds of opinion

Views here surely my own

Professor, Dean @Brown\_SPH

Providence, RI & brown.edu/academics/publ...

559 Following 168.4K Followers

Vaccine trial	Approximate # of people who received the vaccine	Of people vaccinated in the trial			
		# hospitalized for COVID	# who died from COVID	# who died from the vaccine	
Moderna	15,000	0	0	0	
Pfizer	18,600	0	0	0	
Novavax*	13,000	0	0	0	
Astra-Zeneca	5,800	0	0	0	
J&J*	22,000	0	0	0	

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What about people who are pregnant or breastfeeding?

- Limited data!
- Pregnancy is a risk factor for severe COVID-19 illness.
- Risks vs. benefits
- Offer the vaccine.
- Respect autonomy. Personal choice!





Does the vaccine cause infertility?

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syncytin-1 protein
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nyt com/images/2021/01/26/oninion

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## What about long-term side effects?

Most side effects from vaccines are acute! Hours to days to weeks

Remember: the mRNA is only in your body for a short period of time!

Two months of post-vaccination data required to submit for EUA

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### Do the vaccines prevent COVID-19 transmission?

...can vaccinated individuals have asymptomatic disease AND transmit the virus?

### Primary endpoints $\rightarrow$ prevention of <u>symptomatic</u> transmission

#### Pfizer Phase 3 Trial

Trial participants were tested for COVID-19 only if they developed symptoms

Moderna Phase 3 Trial				
	Vaccine Group	Placebo Group		
Pre-dose 1 swab Asymptomatic	0	0		
Pre-dose 2 swab Asymptomatic	14	38		



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Mutations of SARS-CoV-2 that cause COVID-19 have been observed globally. While some mutations may not have a significant impact, others may provide the virus with a selective advantage, such as increased transmissibility



ps://www.astrazeneca.com/content/dam/az/wscd/disease-understanding/mutations-of--sars-cov-2-infographic-4.png/jcr:content/renditions/cq5dam.web.1200.mutations-of--sars-cov-2-infographic-4.pn

### Are the vaccines effective against COVID-19 variants?

	STOP infections → STOP mu B 1 1 7 variant B 1 351 variant P 1 variant			$s \rightarrow STOP$ must
	B.1.1.7 variant	B.1.351 variant	P.1 variant	
Pfizer/BioNTech	No reduction in neutralization	2-fold reduction in neutralization		
Moderna	No significant reduction in neutralization	6-fold reduction in neutralization		Planning a booster
Johnson & Johnson	72% efficacy	57% efficacy	66% efficacy	
AstraZeneca	75% efficacy			
Novavax	85.6% efficacy	60% efficacy		Planning a bivalent vaccine



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COLINE MACCINE Can healthcare workers refuse the COVID-19 vaccine?



Can hospitals require employees to be vaccinated against COVID-19?

No!

EUA

When COVID-19 vaccines are FDA approved, can hospitals require it?



Perceived		
RISK	Risk of COVID-19	<b>Risk of the Vaccine</b>
VS. BENEFIT	Morbidity Mortality Long term sequelae of disease Infecting others immune compromised elderly those with chronic conditions Loss of income No end to this pandemic!	Reactogenicity Anaphylaxis
	Benefit of COVID-19	Benefit of Vaccine
	? Some protection from antibodies	Protection from disease, hospitalization, death Support herd immunity Protect those most vulnerable End this pandemichopefully!

#### Eight In Ten Say They Will Turn To Health Care Providers When Deciding Whether To Get Vaccinated

Doctors, nurses, and health care providers are the source where most people say they will likely to turn for information when deciding to get a COVID-19 vaccine. This is followed by the CDC, family or friends, state or local public health departments, pharmacists, and religious leaders. Despite the fact that health care providers are the source people say they are most likely to turn to for vaccine information, relatively few (24%) of those who have not yet been vaccinated say they have already asked a doctor or other health care professional for information about the vaccine. Percent who say they are likely to turn to each of the following when deciding whether to get a COVID-19 vaccine:



NOTE: Among those who have not yet been vaccinated. See topline for full question wording. SOURCE: KFF COVID-19 Vaccine Monitor (Jan. 11-18, 2021) • Download PNG KFF COVID-19 Vaccine Monitor



### What else can I do as a PA to encourage vaccination?

Ask your family and friends if they plan to get the vaccine!

Help your elderly friends and family locate their local vaccination site!

**NORMALIZE** vaccination!

I GOT MY COVID-19 VACCINE!

Make vaccination exciting!

Display a sticker or badge buddy proudly!



#### Figure 10

### Knowing Someone Who Has Been Vaccinated For COVID-19 Is Correlated With Vaccine Enthusiasm

Do you personally know anyone who has been vaccinated for COVID-19, or not?



NOTE: Among those who have not been vaccinated against COVID-19

SOURCE: KFF COVID-19 Vaccine Monitor (conducted Jan. 11-18, 2021). See topline for full question wording.

KFF COVID-19 Vaccine Monitor

Share your experience on social media!



UNIVERSITY OF **CALIFORNIA SAN** DIEGO San Diego, CA

3:33 AM

COVID-19 Vaccination Record Card

Date

or Clinic Site

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### Volunteer to vaccinate!













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Shank you bo much for your time today! COVID-19 Vaccination Record Card

about the vacones )

Please feel free to contact me with any questions! Rachel La Costa, PA-C rachelmlacosta@gmail.com

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