

### 2023 SDIC General Meeting

#### 10/06/2023

Greta Suydam, MPH || SDIC Co-Chair Heidi DeGuzman, BSN || SDIC Co-Chair Nidal Naser || SDIC Chair Elect Cynthia To, MPH, CHES || Community Health Program Specialist Ashley McKay, MPH || Health Information Specialist II



## SDIC Mission Statement

The San Diego Immunization Coalition's mission is to increase immunization rates and improve the health of the residents of San Diego County by raising awareness and providing education about vaccine-preventable diseases. One of the ways we do this is by hosting a General Meeting that consists of presentations from guest speakers, County, and State public health staff.



## Agenda



- Formal Welcome and Announcements (10 min)
- Perinatal Hepatitis B Prevention Program (30 min)
- Vaccines in Pregnancy: COVID-19, Flu, Tdap, and RSV (30 min)
   BREAK
- > CAIR2 Updates (10 min)
- > Vaccines for Children, Vaccines for Adults (15 min)
- San Diego Epidemiology IZ Data (10 min)
- > COVID-19 Vaccine California Bridge Access Program (10 min)
- State Flu Update (15 min)
- Announcements (5 min)



















#### Rachel Jonas, BSN, RN, PHN

Rachel Jonas is a public health nurse with the County of San Diego. She has been working in the immunization unit of the county's Epidemiology and Immunization Services branch for the last 4 years after being part of the county's nurse residency program. Fun facts about Rachel include that she has an unhealthy obsession with Diet Coke, loves long walks down the aisles of Costco, and named her dog Archie after the main character in the Archie comics.





# PERINATAL HEPATITIS B PREVENTION PROGRAM

**SDIC General Meeting** 

Rachel Jonas, Public Health Nurse

October 6, 2023











- Provide general information about hepatitis B and the burden of disease
- Explain the history of hepatitis B vaccine, safety, and effectiveness as well as Hepatitis B Immune Globulin (HBIG)
- Explain what the Perinatal Hepatitis B Prevention Program (PHPP) is and our role.
- Review the role of prenatal care providers, labor and delivery hospitals, and pediatricians in preventing perinatal hepatitis B transmission
- Show available resources for patients and providers



# **HEPATITIS B INFECTIONS**



- The hepatitis B virus can cause both acute and chronic infection.
- Chronic hepatitis B infections can lead to liver cancer and cirrhosis.
  - With 15%-25% of those with chronic hepatitis B dying from one of these complications<sup>1</sup>
- Estimated that between 580,000 to 1.17 million people in the U.S. are living with hepatitis B<sup>2</sup>



# HEPATITIS B INFECTIONS AND ITS EFFECT ON INFANTS



- "Each year in the US, more than 24,000 infants are born to mothers who are chronically infected with HBV"<sup>3</sup>
- Risk of developing chronic hepatitis B infection is up to 90% among those infected as infants, compared to approximately 5% among those infected as adults<sup>1</sup>



# **HISTORY OF HEPATITIS B VACCINE**

- The first hepatitis B vaccine became commercially available in the US in 1982<sup>1</sup>
- Since 1986, hepatitis B vaccines produced by recombinant DNA technology have been available<sup>5</sup>

Single-antigen Hepatitis B Vaccines							
Vaccine	Age Group	Volume	# Doses				
Engerix-B	0-19 years	10 µg	0.5 ml	3			
Recombivax HB	bivax HB 0-19 years 5 µg		0.5 ml	3			
Combination	Combination Hepatitis B Vaccines (not to be used for the birth dose)						
Vaccine Age Group Antigens Used Volur				# Doses			
Pediarix	6 weeks thru 6 years.	10 mcg recombinant HBsAg plus DTaP, IPV (Engerix-B + Infanrix + IPV)	0.5 ml	3			
Vaxelis	6 weeks thru 4 years.	10mcg recombinant HBsAg plus DTaP, IPV, Hib (Pentacel + Recombivax HB)	0.5 ml	3			





## SAFETY AND EFFECTIVENESS



#### SAFETY

"Since 1982, more than an estimated 70 million adolescents and adults and more than 60 million infants and children have received at least one dose of hepatitis B vaccine in the US"<sup>1</sup>



#### **EFFECTIVENESS**

 "At least 9 out of 10 healthy young adults and more than 9 out of 10 infants, children, and adolescent develop protective antibodies and subsequent immunity to hepatitis B virus infection"<sup>1</sup>



# HEPATITIS B IMMUNE GLOBULIN (HBIG)



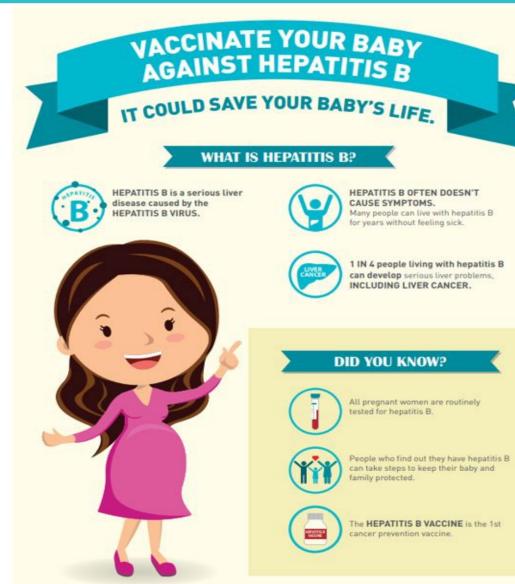
- Provides antibodies to fight the hepatitis B virus (HBV)<sup>6</sup>
- Provides temporary protection<sup>6</sup>
- Prepared from the plasma of donors with high concentrations of anti-HBs<sup>6</sup>
- It is 71% effective at preventing hepatitis B from being passed to a baby during birth<sup>6</sup>





## PERINATAL HEPATITIS B TRANSMISSION





- 85%-95% of perinatal hepatitis B infections can be prevented with appropriate post exposure prophylaxis and vaccination<sup>7</sup>
- Per CDC:
  - "Without postexposure immunoprophylaxis, approximately 40% of infants born to HBV-infected mothers in the United States will develop chronic HBV infection, approximately one-fourth of whom will eventually die from chronic liver disease."<sup>8</sup>

## PERINATAL HEPATITIS B PREVENTION PROGRAM



- Provides case management and support to mothers, families, and providers.
  - Goal: to prevent transmission of hepatitis B from mother to baby.
- Reviews all positive Hepatitis B labs for females of childbearing age 14 -45-year-olds.
  - In the state of CA, all pregnant women are required to be tested for hepatitis B under California Health and Safety Codes (125080 and 125085)<sup>8</sup>



## PERINATAL HEPATITIS B PREVENTION PROGRAM





- Opens new cases once it is identified that a woman is hepatitis B positive and pregnant.
- Provides education to mothers/families about hepatitis B, our program, and gather additional information.
- Works with prenatal care providers, labor and delivery hospitals, and pediatricians.



## RESPONSIBILITIES OF PROVIDERS







# PRENATAL CARE PROVIDERS



#### **Responsibilities**<sup>7</sup>

- Test pregnant women for hepatitis B surface antigen (HBsAg) and hepatitis B Virus DNA (HBV DNA "viral load")
  - Individuals with viral loads ≥ 200,000 are at an increased risk of perinatal transmission and are recommended to receive antiviral treatment.
- Re-test before delivery if patient is diagnosed with hepatitis or was at risk of acquiring hepatitis B during their pregnancy
- Refer all hepatitis B positive pregnant women to a PCP or liver specialist for further medical management
- Report cases to San Diego County PHPP
- Send hepatitis B surface antigen positive lab report to planned delivery hospital

#### Educate

#### **Discrepant HBsAg Results**

Order the following labs:

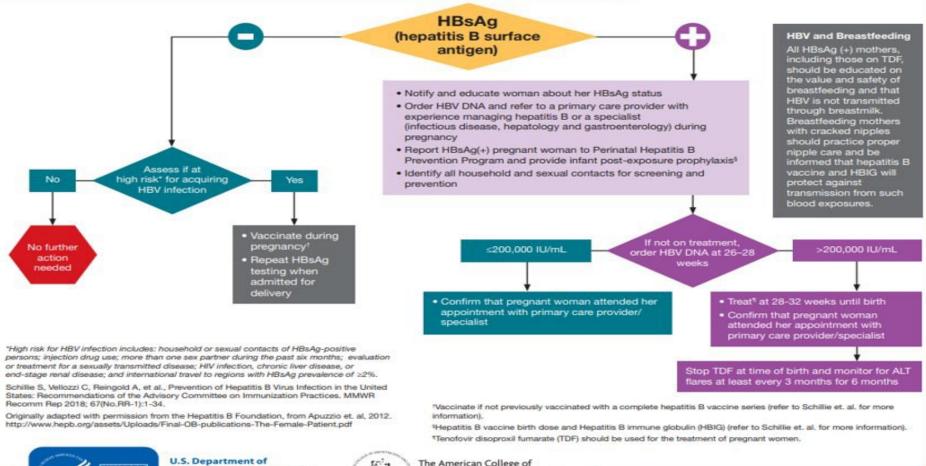
- Repeat HBsAg
- Hepatitis B Core Antibody Total (total anti-HBc)
- Hepatitis B Core Antibody IgM (IgM anti-HBc)
- Hepatitis B Virus DNA (HBV DNA)



## **CDC SCREENING ALGORITHM**







www.cdc.gov/hepatitis



U.S. Department of Health and Human Services Centers for Disease Control and Prevention



Updated December 2021

## **MANAGING DISCREPANT RESULTS**

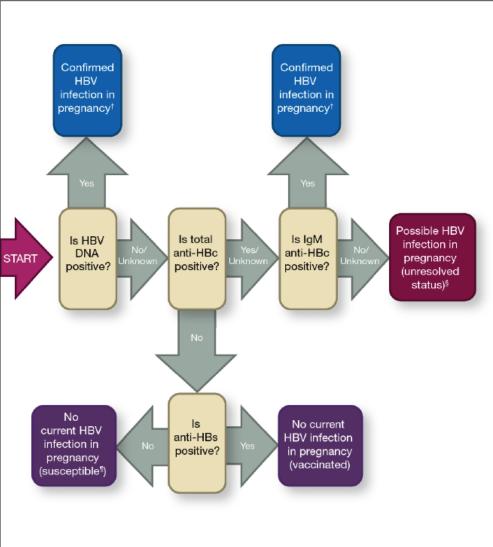


#### Table. Interpretation of HBV markers of infection following discrepantHBsAg lab results during pregnancy

HBsAg results: First HBsAg positive and second HBsAg negative in same pregnancy

Additional Tests*	Results of additional testing <sup>†</sup>	Interpretation	Action
HBV DNA Total anti-HBc IgM anti-HBc Anti-HBs	Detected Positive Positive Positive	Resolving acute infection <sup>6</sup>	<ul> <li>Refer to PHBPP</li> <li>Infant needs post- exposure prophylaxis<sup>®</sup></li> </ul>
HBV DNA Total anti-HBc IgM anti-HBc Anti-HBs	Not detected Positive Negative Negative	False positive HBsAg** (first test) with a history of HBV infection cleared prior to pregnancy OR False negative HBsAg (second test) possible mutant <sup>++</sup>	<ul> <li>Refer to PHBPP</li> <li>Infant needs post-exposure prophylaxis<sup>55</sup></li> </ul>
HBV DNA Total anti-HBc IgM anti-HBc Anti-HBs	Detected Positive Negative Negative	Occult infection	<ul> <li>Refer to PHBPP</li> <li>Infant needs post- exposure prophylaxis</li> </ul>
HBV DNA Total anti-HBc IgM anti-HBc Anti-HBs	Detected Positive Positive Negative	Chronic HBV infection with false negative HBsAg (possible mutant <sup>++</sup> )	<ul> <li>Refer to PHBPP</li> <li>Infant needs post- exposure prophylaxis</li> </ul>
HBV DNA Total anti-HBc IgM anti-HBc Anti-HBs	Not detected Positive Negative Positive	False positive HBsAg**(first test) with a history of HBV infection cleared prior to pregnancy OR resolved acute infection during pregnancy	<ul> <li>Refer to PHBPP</li> <li>Infant needs post- exposure prophylaxis<sup>§5</sup></li> </ul>
HBV DNA Total anti-HBc IgM anti-HBc Anti-HBs	Not detected Negative Negative Negative	False positive HBsAg**(first test) and potentially susceptible <sup>**(</sup>	<ul> <li>Do not refer to PHBPP</li> <li>Vaccinate infant per routine guidelines</li> </ul>
HBV DNA Total anti-HBc IgM anti-HBc Anti-HBs	Not detected Negative Negative Positive	False positive HBsAg**(first test) and potentially vaccinated	<ul> <li>Do not refer to PHBPP</li> <li>Vaccinate infant per routine guidelines</li> </ul>

#### Algorithm for managing pregnant persons with discrepant HBsAg results\*



# LABOR AND DELIVERY HOSPITALS



#### **Responsibilities**<sup>7</sup>

- Review mother's HBsAg lab report at time of admission
- Administer post-exposure prophylaxis (PEP) appropriately
- Report any infants born to hepatitis B positive mothers to San Diego County PHPP
- Investigate any errors in PEP administration and report it to our program
- Education

#### Examples of PEP errors include:

- Vaccine and HBIG were administered in the same thigh
- Hepatitis B vaccine and/or HBIG were administered more than 12 hours after birth
- Hepatitis B vaccine and/or HBIG were not administered at all





MATERNITY HOSPITAL

## PEP FOR INFANTS < 2000 GRAMS AT BIRTH



Hepatitis B Vaccine Schedules for Preterm Infants Weighing < 2000 gm by Maternal Hepatitis B Surface Antigen (HBsAg) Status°

MATERNAL HBsAg	RECOMMENDATION			
STATUS	DOSE	AGE		
	Hep B vaccine & Hepatitis B immune globulin (HBIG) <sup>+</sup>	$\leq$ 12 hours		
	Vac1 Hep B vaccine*	1 month		
POSITIVE	Vac2 Hep B vaccine	2-4 months		
	Vac3 Hep B vaccine <sup>Θ</sup>	6-7 months (Pediarix or monovalent vaccine) 12-15 months (Comvax)		
	Serology testing	9 months or 1-2 months after Vac 3. Do not test before 9 months of age or ≤ 4 weeks of the most recent vaccine dose.		
	Hep B vaccine & HBIG <sup>+</sup>	$\leq$ 12 hours of birth		
UNKNOWN	Test mother for HBsAg immediately: If positive, continue series as above↑ If negative, continue series as below↓			
	Vac1 Hep B vaccine	At 1 month, or at hospital discharge*		
NEGATIVE	Vac2 Hep B vaccine	2-4 months		
	Vac3 Hep B vaccine	6-18 months <sup>⊕</sup>		

# PEP FOR INFANTS ≥ 2000 GRAMS AT BIRTH



MOTHER'S HBsAg	SINGLE ANTIGEN VACCINE			
RESULT	DOSE	AGE		
	1 Hep B vaccine and HBIG	within 12 hrs of birth		
	2 Hep B vaccine	1-2 months		
POSITIVE	3 Hep B vaccine	6 months $^{\Theta}$		
	Serology testing for HBsAg and anti-HBs	9 months		
	1 Hep B vaccine	within 12 hrs of birth		
UNKNOWN	1 Hep B vaccine HBIG, if test result is positive	within 12 hrs of birth within 7 days		
UNKNOWN		within 7 days liately. If positive, continue		
UNKNOWN	HBIG, if test result is positive Test mother for HBsAg immed	within 7 days liately. If positive, continue		
	HBIG, if test result is positive <b>Test mother for HBsAg immed</b> series as above <sup>1</sup> . If negative, con	within 7 days liately. If positive, continue ntinue series as below↓		
<b>UNKNOWN</b> NEGATIVE	HBIG, if test result is positive <b>Test mother for HBsAg immed</b> series as above↑. If negative, con 1 Hep B vaccine <sup>√</sup>	within 7 days liately. If positive, continue ntinue series as below↓ Before discharge		



## PEDIATRICIANS



#### **Responsibilities**<sup>13</sup>

- Ensure PEP was administered correctly
- Notify our program you are providing care to an infant exposed to a hepatitis B positive mother
- Administration and documentation of hepatitis B vaccines
- Order Post-Vaccine Serology Testing
- Refer infants who are positive for hepatitis B to a gastroenterologist for further follow-up



## **HEPATITIS B VACCINE SCHEDULE**



#### VACCINATING INFANTS BORN TO HBsAg POSITIVE PATIENTS: ≥ 2,000G

Infants Born to HBsAg Positive Patients: ≥ 2,000 grams (≥4.4 lbs) at birth						
	≤ 12 Hours of Birth	1 month	2 months	4 months	6 months	
Single Antigen Vaccine Series	1 <sup>st</sup> Dose	2 <sup>nd</sup> Dose			3 <sup>rd</sup> Dose	
Single Antigen + Combination Vaccine Series	1 <sup>st</sup> Dose (single antigen vaccine)		2 <sup>nd</sup> Dose	3 <sup>rd</sup> Dose	4 <sup>th</sup> Dose	



## **HEPATITIS B VACCINE SCHEDULE**



#### VACCINATING INFANTS BORN TO HBsAg POSITIVE PATIENTS: < 2,000G

Infants Born to HBsAg Positive Patients: < 2,000 grams (<4.4 lbs) at birth						
	≤ 12 Hours of Birth	1 month	2 months	3 months	4 months	6 months
Single Antigen Vaccine Series	1 <sup>st</sup> Dose	2 <sup>nd</sup> Dose	3 <sup>rd</sup>	Dose		4 <sup>th</sup> Dose
Single Antigen + Combination Vaccine Series	1 <sup>st</sup> Dose (single antigen vaccine)		2 <sup>nd</sup> Dose		3 <sup>rd</sup> Dose	4 <sup>th</sup> Dose

**G** 

## POST VACCINATION SEROLOGIC TESTING



#### Pediatricians should order post-vaccination serologic testing (PVST) for hepatitis B exposed infants once the following criteria are met:<sup>13</sup>

- Infant received their full vaccine series.
- 1-2 months have passed since the infant received their last dose of hepatitis B vaccine.
- Child is at least 9 months of age (ideally PVST should be collected between 9-12 months of age).





## POST VACCINATION SEROLOGIC TESTING



Post vaccination serologic testing consists of the following tests:<sup>7</sup>

#### 1) Hepatitis B surface antigen (HBsAg)

#### <u>AND</u>

2) Hepatitis B surface antibody (quantitative) (anti-HBs)



## **INTERPRETING PVST RESULTS**



HBsAg Result	Anti-HBs Result	Interpretation	Next Steps
Negative	Positive (anti-HBs ≥10 mIU/mL)	Immune	Test results should be reported to our program.
Negative	Negative (anti-HBs <10 mIU/mL)	Susceptible	Infants should receive an additional dose of hepatitis B vaccine, followed by repeated PVST 1-2 months after vaccination. If the infant remains susceptible after this additional dose, administer the rest of the second three- dose vaccine series and retest for both HBsAg and anti-HBs 1-2 months after.
Positive	Negative (anti-HBs <10 mIU/mL)	Infected	HBsAg-positive infants should be referred to appropriate medical follow-up and reported to our program as a perinatal hepatitis B case.

## **INFORMATION SHEETS**





#### County of San Diego Perinatal Hepatitis B Prevention Program <u>Prenatal Care Provider Information Sheet</u>

The **County of San Diego Perinatal Hepatitis B Prevention Program (PHPP)** provides case management and support to local mothers, families, and medical providers with the goal of preventing perinatal, or mother-to-baby, transmission of Hepatitis B virus infection.

#### Prenatal Care Providers and Prenatal Clinics please:

- Order Hepatitis B Surface Antigen (HBsAg) for all pregnant women
  - · Required by California Health and Safety Codes (125080 and 125085)
  - The recommendation is to be tested for Hepatitis B with each pregnancy, even if she has been tested during a previous pregnancy
- Contact County of San Diego's PHPP to notify us when a pregnant patient under your care is Hepatitis B positive
- Order Hepatitis B Virus DNA (HBV DNA) quantitative testing to determine the woman's level of infectivity
  - Hepatitis B Virus DNA (HBV DNA) ≥ 200,000 IU/mL is associated with an increased risk of perinatal transmission of hepatitis B virus
  - All Hepatitis B positive women should be referred to a specialist to see if any further evaluation and/or treatment is warranted
  - Please refer to Screening and Referral Algorithm for Hepatitis B Virus Infection Among Pregnant Women on CDC's website: https://www.cdc.gov/hepatitis/hbv/pdfs/prenatalhbsagtesting\_508.pdf
- Document a clear note in patient's prenatal record indicating patient's Hepatitis B positive status
- Send patient's Hepatitis B lab to the planned delivery hospital

Phone: 866-358-2966 Option 5 and Fax: 619-692-5677

- Notify and educate your patient that she will receive a call from one of our nurse case managers to
  introduce her to the PHPP
  - Please provide your patient our county's parents and guardians' brochure that has information
    about our program. Please email or call us if you do not currently have the brochure
  - · Please have these brochures readily available in your office to give to patients when they visit
  - Please contact us if you would like to receive additional Hepatitis B resources for your patients and we would be happy to send them to you

#### County of San Diego Perinatal Hepatitis B Prevention Program <u>Labor and Delivery Hospital Information Sheet</u>

The **County of San Diego Perinatal Hepatitis B Prevention Program (PHPP)** provides case management and support to local mothers, families, and medical providers with the goal of preventing perinatal, or mother-to-baby, transmission of Hepatitis B virus infection.

#### Labor and Delivery Hospitals please:

- Review pregnant woman's Hepatitis B Surface Antigen (HBsAg) lab report at time of admission
  - The only acceptable lab to determine Hepatitis B status is Hepatitis B surface antigen (HBsAg), but if there is only a positive Hepatitis Be Antigen (HBeAg) lab or a positive Hepatitis B Virus DNA (HBV DNA) lab, these women should be treated as being Hepatitis B positive
  - Please DO NOT determine status by reading transcription notes
- Order Hepatitis B Surface Antigen (HBsAg) lab for women with unknown Hepatitis B status at the time they are admitted
- Follow the guidelines below for Hepatitis B vaccine and Hepatitis B immune globulin (HBIG) administration for the infant based on the woman's Hepatitis B status

MATERNITY HOSPITAL

	Infant birth weight <u>&gt;</u> 2000 grams	Infant birth weight < 2000 grams	
Mother's Hepatitis B status is POSITIVE	Administer Hepatitis B vaccine and HBIG within 12 hours of birth in separate		
Mother's Hepatitis B status is UNKNOWN	Administer Hepatitis B vaccine within 12 hours of birth. If you find out that mother is Hep B positive, HBIG should be given as soon as possible, and no later than 7 days after birth	Administer Hepatitis B vaccine and HBIG within 12 hours of birth	
Mother's Hepatitis B status is NEGATIVE	Administer Hepatitis B vaccine within 24 hours of birth	Administer 1 dose at 1 month of age or hospital discharge (whichever is earlier and even if weight is still <2,000 grams)	

- · Please complete the form from our website when a Hepatitis B positive pregnant woman has delivered
- Post-exposure Prophylaxis (PEP) Error protocol (if applicable)
  - PEP Errors include: HBIG or Hepatitis B Vaccine given after 12 hours of birth, HBIG and Hepatitis B Vaccine given in same site, or HBIG or Hepatitis B Vaccine was not administered
  - Please use and send the PEP Error form on our website to explain the error and why it occurred. This needs to be reported back to CDPH within 5 business days
  - · Please call us at 866-358-2966 option 5 as soon as you discover the PEP error has occurred



The **County of San Diego Perinatal Hepatitis B Prevention Program (PHPP)** provides case management and support to local mothers, families, and medical providers with the goal of preventing perinatal, or mother-to-baby, transmission of Hepatitis B virus infection.

#### Pediatricians and Pediatric Clinics please:

- Ask about maternal history regarding Hepatitis B status
- Contact PHPP to notify us that an infant exposed to Hepatitis
   B at birth is under your care
- Check infant's hospital birth record to ensure post exposure prophylaxis (PEP) (Hepatitis B vaccine and Hepatitis B Immune Globulin-HBIG) were administered within 12 hours of birth at the delivery hospital (refer to the table below)



Review and educate parents on Hepatitis B vaccine schedule
 (Follow the guidelines below for children born to Hepatitis B positive mothers)

	Infant birth weight ≥ 2000 grams		Infant birth weight < 2000 grams	
	Single antigen	<u>Combination</u>	Single antigen	<u>Combination</u>
Birth dose (within 12 hrs of birth)		1 <sup>st</sup> dose of Hepatitis B vaccine* (administer in s ose is always single antigen vac	eparate limbs)	
1 months	nd		2 <sup>nd</sup> dose	
2 months	2 <sup>nd</sup> dose	2 <sup>nd</sup> dose	3 <sup>rd</sup> dose (between 2-	2 <sup>nd</sup> dose
4 months		3 <sup>rd</sup> dose	3 months)	3 <sup>rd</sup> dose
6 months	3 <sup>rd</sup> dose	4 <sup>th</sup> dose	4 <sup>th</sup> dose	4 <sup>th</sup> dose

- Administration and documentation of Hepatitis B vaccines
  - Send us child's current immunization record after every Hepatitis B vaccine administration
- Complete Post-Vaccine Serology Testing (PVST) once the following criteria are met:
  - Child has completed 3-4 dose Hepatitis B vaccine series
  - + Child is at least 9 months old and last dose of Hepatitis B vaccine was 1 to 2 months ago
  - PVST includes Hepatitis B surface antigen (HBsAg) AND Hepatitis B surface antibody quantitative (anti-HBs)
  - · Once results are available, please send us a fax or encrypted email with the infant's lab reports

Phone: 866-358-2966 Option 5 and Fax: 619-692-5677 Secure Email: <u>PHS-PerinatalHepB.HHSA@sdcounty.ca.c</u> Website: <u>https://tinyurl.com/PHBPP-SanDiego</u>





### **NEW WEBSITE**





#### SanDiegoCounty.gov Home

# Health & Human Services Agency

#### **Perinatal Hepatitis B Prevention Program**

The County of San Diego Perinatal Hepatitis B Prevention Program provides case management and support to local mothers and medical providers with the goal of preventing perinatal, or mother-to-baby, transmission of hepatitis B virus infection.

Hepatitis B is a viral liver disease that can be spread via:

- sexual transmission
- · injection drug use
- · blood borne/body fluid exposures
- · mother to baby at birth

Individuals that are diagnosed with Hepatitis B may be asymptomatic or can experience symptoms such as fatigue, fever, yellow skin and eyes (jaundice), abdominal pain, and change in color of stool.

When an infant is born to a Hepatitis B positive mother, 70-95% of those infants will develop a chronic infection if they do not receive the appropriate vaccines at birth and early childhood. Chronic Hepatitis B can cause many health issues including liver cancer, liver failure, and death.

#### Perinatal Hepatitis B Prevention Program (sandiegocounty.gov)









Parents and Guardians



Vaccine & Lab Info



Prenatal Care Providers

Pediatricians



Labor and Delivery Hospitals



**Resources & Materials** 

# **CONTACT INFORMATION**



#### **COUNTY OF SAN DIEGO**

#### PERINATAL HEPATITIS B PREVENTION PROGRAM

- Email: <u>PHS-PerinatalHepB.HHSA@sdcounty.ca.gov</u>
- Fax: 619-692-5677
- Website: <u>https://tinyurl.com/PHBPP-SanDiego</u>
- Phone: 866-358-2966 option 5 leave a message and a public health nurse will return your call
- After hours / Weekends 858-565-5255 and ask to speak to the Immunization nurse on call



The Public Health Services department, County of San Diego Health and Human Services Agency, has maintained national public health accreditation, since May 17, 2016, and re-accredited by the Public Health Accreditation Board on August 21, 2023.



Scan here to learn more!

#### References



1) Hepatitis B: Questions and Answers. (2023). https://www.immunize.org/catg.d/p4205.pdf

2) Centers for Disease Control and Prevention (CDC). (2022). Viral Hepatitis: Frequently Asked Questions for Health Professionals. https://www.cdc.gov/hepatitis/hbv/hbvfaq.htm

3) Immunization Action Coalition. (2016). Hepatitis B: What Hospitals Need to Do to Protect Newborns. https://www.immunize.org/protect-newborns/guide/birth-dose.pdf

4) Hepatitis B Foundation. Hepatitis B Vaccine History. *Hepatitis B Foundation*. https://www.hepb.org/prevention-and-diagnosis/vaccination/history-of-hepatitis-b-vaccine/

5) Centers for Disease Control and Prevention. (2021). *Epidemiology and Prevention of Vaccine-Preventable Diseases.* Public Health Foundation

6) Centers for Disease Control and Prevention. Hepatitis B Immune Globulin (HBIG): What Parents Need to Know. https://www.cdc.gov/vaccines/programs/perinatal-hepb/downloads/HBIGinfosheet-508.pdf

7) California Department of Public Health. (2021). California Department of Public Health: Perinatal Hepatitis B Prevention Program – Coordinator Handbook. https://eziz.org/assets/docs/VPD/PHPPCOORDINATORHANDBOOK.pdf

8) Centers for Disease Control and Prevention. (2022). Viral Hepatitis – Perinatal Transmission. https://www.cdc.gov/hepatitis/hbv/perinatalxmtn.htm

#### References



9) Centers for Disease Control and Prevention (2021). Screening and Referral Algorithm for Hepatitis B Virus (HBV) Infection Among Pregnant Women. https://www.cdc.gov/hepatitis/hbv/pdfs/prenatalhbsagtesting\_508.pdf

10) Centers for Disease Control and Prevention. (2023). Discrepant Hepatitis B surface antigen (HBsAg) lab results during pregnancy: recommended next steps. https://www.cdc.gov/vaccines/programs/perinatal-hepb/downloads/discrepant-HBsAg-labs-508.pdf

11) California Department of Public Health. (2022). Perinatal Hepatitis B Post-Exposure Prophylaxis Recommendations: Guidelines for Labor and Delivery Hospitals. https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/Immunization/PerinatalHepB-LaborDeliveryQuicksheet.pdf

12) California Department of Public Health. Hepatitis B Vaccine Schedules for Newborn Infants < 2000 gm. https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/Immunization/PerinatalHepB-VaccineSchedule\_PretermUnder2000gm.pdf

13) California Department of Public Health. Hepatitis B Vaccine Schedules for Newborn Infants ≥ 2000 gm. https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/Immunization/PerinatalHepB-VaccineSchedule\_InfantsGE2000gm.pdf

14) California Department of Public Health. (2022). Preventing Hepatitis B in Children: Guidelines for Pediatric Providers. https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/Immunization/PerinatalHepB-PediatricProviderQuicksheet.pdf

15) Centers for Disease and Control. (2021). Management of Infants Born to Women with Hepatitis B Virus Infection for Pediatricians. https://www.cdc.gov/vaccines/programs/perinatal-hepb/downloads/HepB-Provider-tipsheet-508.pdf



### Kirstie Perrotta, MPH

Kirstie is a member of the SDIC steering committee since 2020. She currently works as a Teratogen Information Specialist with the MotherToBaby program where she counsels people who are pregnant and breastfeeding about a variety of exposures, including medications, supplements, and vaccines, during pregnancy and lactation. She serves on the board as the affiliate liaison and co-chair of the Emerging Issues Task Force, which is responsible for keeping up with the latest data and recommendations related to emergent issues such as Zika, monkeypox, and COVID-19. In addition to having an interest in the prevention of infectious diseases during pregnancy, she enjoys the opportunity to counsel women on the risks vs. benefits of using medication during pregnancy to treat mental health conditions such as depression and anxiety. Please welcome Kirstie!





#### COVID-19, Flu, Tdap, and RSV

Kirstie Perrotta, MPH MotherToBaby California San Diego Immunization Coalition General Meeting - October 6, 2023



#### Vaccines Currently Recommended For Use In Pregnancy



## Learning Objectives:

- 1. Understand what the MotherToBaby service can offer and how to reach us
- 2. Understand the risks of a COVID-19 and flu infection during pregnancy
- 3. Understand the risks of pertussis and RSV in infants and the importance of prenatal vaccination
- 4. Understand the available data and current recommendations for COVID-19, flu, Tdap, and RSV vaccines during pregnancy



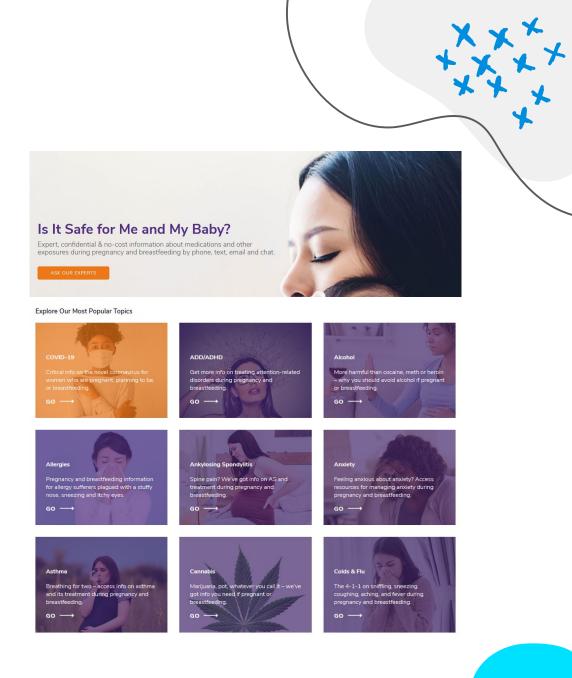
### **MotherToBaby**

 MotherToBaby provides evidence-based information on various exposures during pregnancy and while breastfeeding

We specialize in answering questions about medications, vaccines, chemicals, herbal products, substances of abuse, maternal health conditions and

much (

MotherToBaby California



## **MotherToBaby**

Our free service is available to people who are pregnant, breastfeeding, healthcare professionals, and the general public via chat, text, phone, and email in both English and Spanish



Resources include fact sheets, blogs, and podcast episodes

More than 100,000 women and their health care providers seek information from MotherToBaby every year

#### 🗿 MotherToBaby | FACT SHEET

#### COVID-19 mRNA Vaccines (Moderna | Spikevax<sup>®</sup> and Pfizer | Comirnaty<sup>®</sup>)

This sheet is about exposure to COVID-19 mRNA vaccines in pregnancy and while breastfeeding. This information should not take the place of medical care and advice from your healthcare provider.

#### What Is COVID-19?

COVID-19 (short for Coronavirus Disease 2019) is an illness caused by a virus (called SARS-CoV-2). The virus easily spreads from person to person through respiratory droplets that come from our mouths and noses here we breathe, talk, cough, or sneeze. For more information on COVID-19, prease see the MotherToBaby fact sheet at https://mothertobaby.org/fact-sheets/covid-19/

#### What are COVID-19 mRNA vaccines

COVID-19 messenger RNA (mRNA) vaccines help protect against the virus that causes COVID-19. The COVID-19 mRNA vaccines approved for use in the United States are known as Moderna/Spikevax® and Pfizer/Comim-vaccines do not contain live virus that could cause COVID-19. The Centers for Disease Control and have more information about mRNA vaccines here:

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/mRNA.html. The mRNA va effective at preventing COVID-19, but can greatly reduce the chance of getting very sick from the For most people who are pregnant, recently pregnant, or breastfeeding, COVID-19 mRNA vaccines

doses (called a primary series), followed by recommended booster doses. People who have weake systems have different dosing recommendations. Talk to your healthcare provider, contact a Mott or visit the CDC website to learn how to stay up to date with your COVID-19 vaccines: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html.

For more information on other types of COVID-19 vaccines that are available, please see the Mothat https://mothertobaby.org/fact-sheets/covid-19-viral-vector-vaccine/ and https://mothertobabv.org/fact-sheets/covid-19-protein-subunit-vaccine/.

Are COVID Organizatio

Gynecologis become pre mRNA vacci Having a CO Studies have likely to get Sertraline (Zoloft®) Does gettli There is no This sheet is about exposure to sertraline in pregnancy and while breas

undergoing ovaries (the embryo imp place of medical care and advice from your healthcare providers. treatment's What is sertraline? postpone fe

Sertraline is a medication that has been used to treat depression, obse Some peopl traumatic stress disorder, premenstrual dysphoric disorder (a severe for having a slip

phobia. Sertraline belongs to the class of antidepressants known as selprand name for sertraline is Zoloft®.

I Just got a I take sertraline. Can it make it harder for me to get pregnant?

```
It is not known if sertraline can make it harder to become pregnant. Or Does having the flu increase the chance of miscarriage?
a slightly lower chance of achieving a pregnancy
```

the benefits of staying on the medication during pregnancy can outwei medication, your healthcare provider might suggest that you slowly low Stopping this medication suddenly can cause some people to have with may have a relapse of their symptoms if they stop this medication duri

ession during pregnancy please see our fact sheet at https://mothertobaby.org/fact-sheets/depression-pregnancy/pdf/

```
Does taking sertraline increase the chance for miscarriage?
```

Miscarriage can occur in any pregnancy. Use of sertraline and the char One study found no differences in the chance for miscarriage in people first 35 days of pregnancy and those who stopped filling prescriptions I

```
Does taking sertraline increase the chance of birth defects?
```

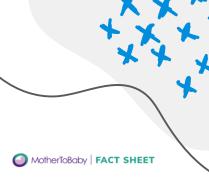
```
Every pregnancy starts out with a 3-5% chance of having a birth defect
reports of more than 20,000 pregnancies exposed to sertraline. While 4
chance for heart defects or other birth defects, most studies have not
when sertraline is used. Overall, the available data do not suggest that Does having the flu cause long-term problems in learning and behavior for the baby?
above the background risk
```

Could taking sertraline cause other pregnancy complications?

Some pregnancy complications have been reported more often when S Some studies show a higher chance of having babies with low birthweight and preterm delivery (delivery before 37 weeks of pregnancy). Research has also shown that when depression or anxiety is left untreated during pregnancy, there could be an increased chance for pregnancy complications. This makes it difficult to know if it is the medication the untreated depression (or anxiety), or other factors that may increase the chance for these problems.

Some, but not all, studies have suggested that when people who are pregnant take SSRIs during the second half of the pregnancy, their babies might have an increased chance for a serious lung condition called persistent pulmonary hypertension. Persistent pulmonary hypertension happens in 1 or 2 out of 1,000 births. Among the studies looking at this, the overall chance for pulmonary hypertension when an SSRI was used in pregnancy was less than 1/100 (less

A recent analysis which combined results from several studies reported that the chance for persistent pulmonary hypertension might be increased if an SSRI was used during pregnancy, but could not determine if this was actually due to medication exposure or to other exposures that pregnant people who take SSRIs have in common, such as higher rates of smoking.



#### Seasonal Influenza (the Flu)

This sheet is about exposure to seasonal influenza in pregnancy and while breastfeeding. This information is based on available published literature. It should not take the place of medical care and advice from your healthcare provider What is influenza Influenza is an infection of the respiratory (breathing) tract. It is often called the flu. The symptoms of influenza are fever, headache, chills, muscle aches, coughing, congestion, runny nose, and sore throat. Influenza sometimes causes vomiting and diarrhea The typical flu season is from October through May of each year, and usually has the most activity between December and February. The types (strains) of viruses that cause seasonal influenza can change each year. Is the flu contagious? How does the virus spread? Yes the flu is very contactions. The virus is spread through contact with respiratory droplets from the nose and mouth of infected individuals a day before they feel sick until their symptoms are gone. When people cough, sneeze, or talk droplets containing the virus are spread through the air. These droplets can travel up to 6 feet from the person and can enter the mouth/noses of people nearby or fall and land on surfaces, such as tables and toys. The time between exposure to a flu virus and the onset of symptoms (incubation period) is between 1 and 4 days. Adults who have the flu are most contagious in the first 3 to 4 days after their illness starts. Children can be infectious for a longer period Can having the flu make it harder for me to become pregnant Studies have not looked to see if having the flu will make it harder to become pregnant.

A singlicity lower chance of achieving a pregnancy of the studies suggest a higher chance for pregnancy loss while other studies I just found out I am pregnant. Should I stop taking sertrailine? Miscarriage can occur in any pregnancy. Some studies suggest a higher chance for pregnancy loss while other studies do not. Based on the available data, it is not known if the flu will increase the chance for miscarriage.

Talk with your healthcare providers before making any changes to how Can having the flu during pregnancy cause birth defects?

Every pregnancy starts out with a 3-5% chance of having a baby with a birth defect. This is called the background risk Having the flu during pregnancy has not been proven to cause birth defects

Fever is a possible symptom of the flu. A high fever in the first trimester can increase the chance of certain birth defects. Acetaminophen has been recommended to reduce fever in pregnancy. If you get sick with the flu or any other illness and develop a fever, talk with your healthcare provider to confirm if taking acetaminophen is okay for you. For more information about fever and pregnancy, see the related fact sheet

at https://mothertobaby.org/fact-sheets/hyperthermia-pregnancy/, and for information on acetaminophen, please see https://mothertobaby.org/fact-sheets/acetaminophen-pregnancy/.

Does having the flu increase the chance for pregnancy complications?

Being pregnant can increase the chance of developing serious complications from the flu compared to persons with the flu who are not pregnant. Some of the serious complications reported include respiratory distress (severe breathing problems) and being hospitalized. If a person who is pregnant becomes very sick from the flu, this can also increase the chance of pregnancy complications, such as delivery before 37 weeks of pregnancy (pretern delivery). If is important to talk with your healthcare provider if you are pregnant and have symptoms of the flu

Studies on long-term problems have looked at whether having the flu in pregnancy could lead to later mental health conditions like schizophrenia. These studies have not been able to prove that having the flu during pregnancy will increase the chance for the baby to later develop a mental health condition

- Miscarriage: The available studies on COVID-19 infections in pregnancy have not suggested an increased chance of miscarriage above the background risk in all pregnancies of 15-20%.
- **Birth Defects**: There is a background risk for birth defects in all pregnancies of 3-5%. The available studies on COVID-19 infection in pregnancy have not reported an increased chance for birth defects.



• **Fever**: Fever is a possible symptom of COVID-19. A high fever in the first trimester can increase the chance of neural tube defects. If a pregnant person develops a fever early in pregnancy it is important to treat it.

#### **Pregnancy Complications:**

Does having COVID-19 increase the chance of other pregnancy related problems?

Studies have shown that people who are pregnant or recently pregnant and get COVID-19 have higher chances of becoming very sick, being admitted to intensive care, and needing to be put on a ventilator (machine that helps you breathe). Some studies have also reported a higher chance of death. The chance of these outcomes is higher among people who also have other underlying health conditions, such as obesity, pre-pregnancy diabetes, and/or chronic hypertension. Just as in the general population, pregnant people who are up to date on COVID-19 vaccines are less likely to get infected, and less likely to get severely ill, be hospitalized, or die from a COVID-19 infection.



#### Pregnant San Diego Woman Dies from COVID-19



#### NEWS

#### After Unvaccinated Pregnant Woman Dies of COVID, Family Urges Vaccinations

BY XANDER LANDEN ON 2/10/22 AT 12:33 PM EST

## Large new review underscores the risks of Covid-19 during pregnancy

By Brenda Goodman Updated 6:37 AM EST, Tue January 17, 2023

By José A. Álvarez, County of San Diego Communications Office

#### **Pregnancy Complications:**

Having COVID-19 in pregnancy can increase the chance of preterm delivery (birth before 37 weeks of pregnancy). Some studies have also reported increased chances of stillbirth, preeclampsia (dangerously high blood pressure), blood clots, and the need for emergency c-section. Sometimes the virus can infect the placenta (called placentitis), which can lead to problems with how well the placenta works to support the pregnancy and the baby's growth and development. Having COVID-19 can also make it harder to manage other health conditions that are common in pregnancy, such as other infections or high blood pressure. People who are up to date with COVID-19 mRNA vaccines in pregnancy are less likely to experience pregnancy complications from a COVID-19 infection than people who are not up to date.





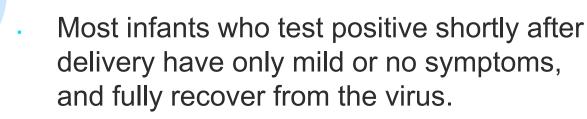
#### Coronavirus May Increase Premature Births, Studies Suggest

New studies provide more evidence that pregnant women may get severe Covid-19 symptoms and have an increased risk of pregnancy loss.

🖀 Share full article 🖉 🏳

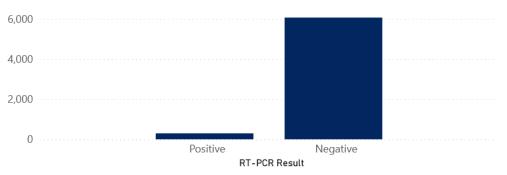


- Vertical Transmission: The virus can pass from a pregnant person to their baby during pregnancy, but this appears to be rare.
- The chance of the baby getting the virus during or shortly after delivery may be higher if the mother has an active infection at the time of delivery.





Laboratory Testing Results for SARS-CoV-2 among Infants Born to People with COVID-19 Who Were Tested at the Birth Hospitalization\* Laboratory testing information was available for 6,398 (7.8%)\*\* infants.



\*Within the first three days of life or at the birth hospitalization and less than 14 days after birth. \*\*All positive SARS-CoV-2 results are reported, but negative results may not be reported or monitored in all jurisdictions.

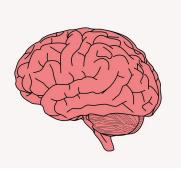


#### Does having COVID-19 in pregnancy cause long-term problems in learning or behavior for the baby?

Two studies have looked at the development of infants ages 5-11 months born to people who had COVID-19 during pregnancy. Most of the COVID-19 infections were mild or asymptomatic (no symptoms). These studies found no differences in cognition (thinking), communication, motor (movement) skills, problem solving, or personal-social skills in the infants.

Two other studies reported that infants born to people who had COVID-19 during pregnancy were more likely to be diagnosed with a neurodevelopmental (brain-related) issue by one year of age. In one of these studies, the issues were mostly related to motor skills and speech and language, and were more common following COVID-19 infection in the 3rd trimester. In the other study, only male infants were more likely to have been diagnosed with a neurodevelopmental issue. Since these studies could not control for all the things that might have affected the children's development (such as the home environment, other possible exposures in pregnancy, and stress from the pandemic), it is not clear if having COVID-19 in pregnancy affects long-term development in children. More research is needed to fully understand the possible long-term effects of a COVID-19 infection during pregnancy.







# COVID-19 Vaccines in Pregnancy



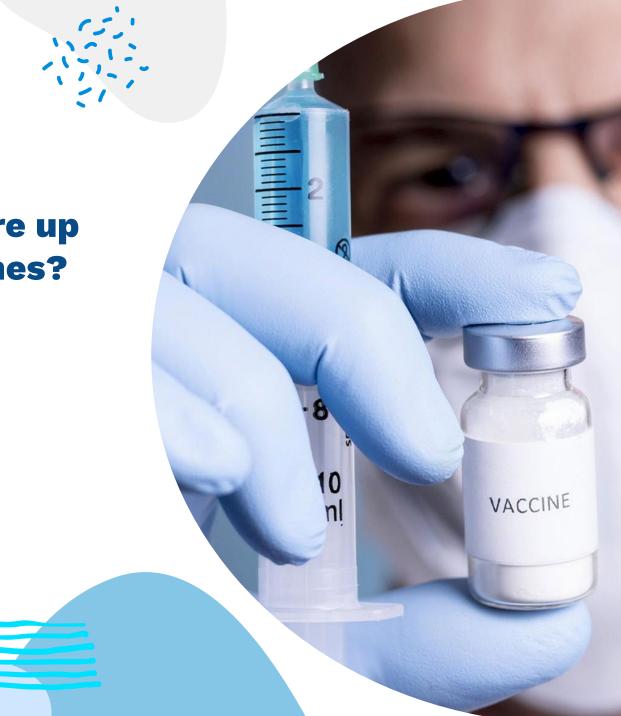




#### **Audience Question:**

## How many pregnant people are up to date with COVID-19 vaccines?

1. 16%
 2. 43%
 3. 22%



COVID-19 vaccination among pregnant people aged 18-49 years overall, by race and ethnicity, and date reported to CDC - Vaccine Safety Datalink,\* United States

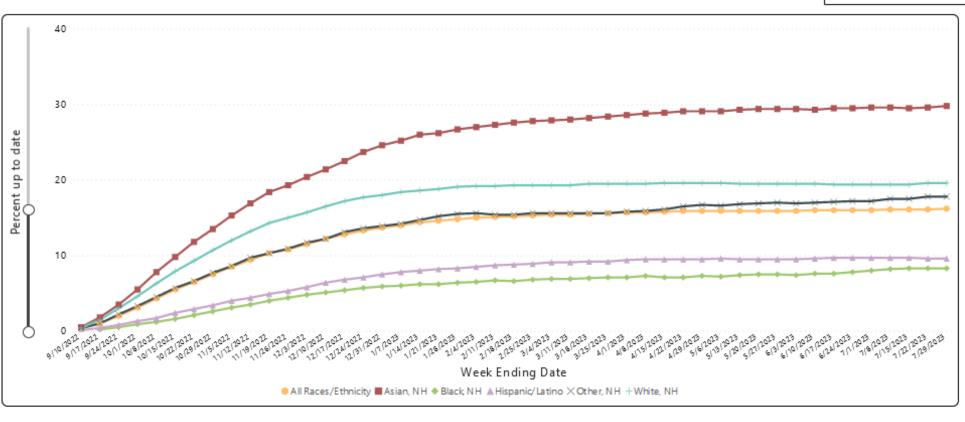
View Footnotes and Download Data

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Figure : Percent of pregnant people ages 18–49 years who are up to date with COVID-19 vaccines overall and by race and ethnicity — Vaccine Safety Datalink, September 1, 2022 – July 29, 2023

Week Ending Date

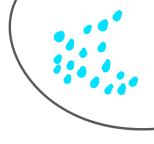
9/10/202



\*CDC recommended bivalent boosters to persons age ≥12 years starting September 1, 2022. Data on bivalent boosters among pregnant persons was available starting September 4, 2022, and includes doses received starting September 1, 2022.

#### 

#### **Reasons for Vaccine Hesitancy**



COVID-19 vaccine hesitancy and acceptance among pregnant people contacting a teratogen information service

Kirstie Perrotta, <sup>1,2</sup> Angela Messer, <sup>1,2</sup> Sonia Alvarado, <sup>1,2</sup> Mara Gaudette, <sup>1,2</sup> Cindy Tran, <sup>2</sup> and Gretchen Bandoli<sup>2</sup>

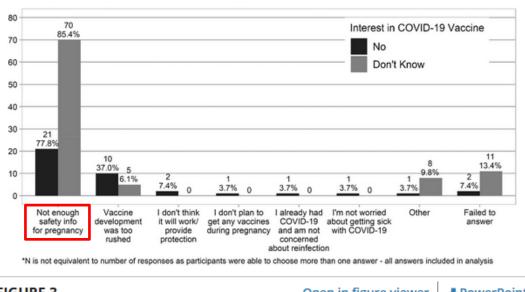


FIGURE 3

Open in figure viewer **PowerPoint** 

Answers to survey question 7: 'Why do you NOT want to get vaccinated during pregnancy?' among those that

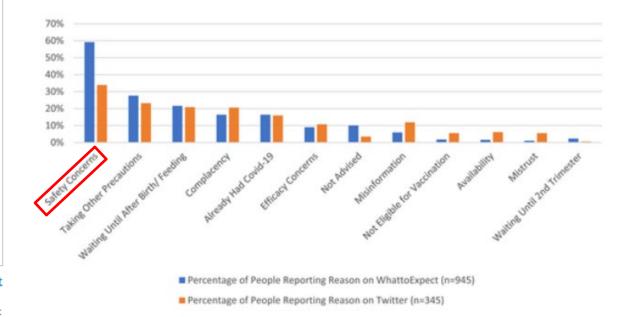
said 'No' (n = 27) and 'Don't Know' (n = 82) to vaccination



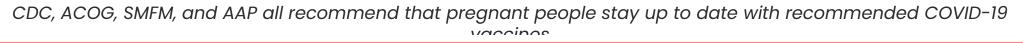


### Social media and COVID-19 vaccination hesitancy during pregnancy: a mixed methods analysis

S. Golder 🔀, A. C. E. McRobbie-Johnson, A. Klein, F. G. Polite, G. Gonzalez Hernandez



#### **COVID-19 Vaccines in Pregnancy**



#### **Recommendation for Everyone Aged 5 Years and Older**

#### Get 1 updated COVID-19 vaccine

Everyone aged 5 years and older should get **1 updated COVID-19 vaccine**, at least two months after getting the last dose of any <u>COVID-19 vaccine</u>.

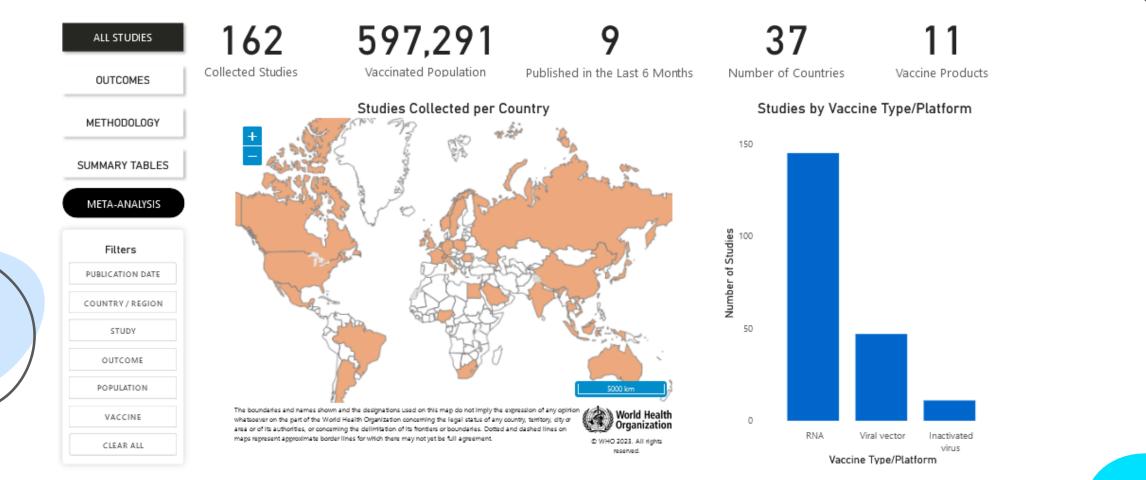




#### COVID-19 Vaccines for Pregnant Persons: A Living Systematic Review and Meta-Analysis

#### Last update was made on 9/22/2023

This is a regularly updated, comprehensive database and synthesis of published literature relating to COVID-19 vaccines in pregnancy. To start your search, click on any given country on the map to see all collected studies or click on the Outcomes tab for details on studies reporting on Maternal Pregnancy Outcomes, Maternal Adverse Events Following Immunization, Infant Safety Outcomes, Vaccine Efficacy/Effectiveness Outcomes, and Immunogenicity. For more information on the Living Systematic Review (LSR) and inclusion criteria, click the Methodology and About tabs. Filters applied: None



Available from the CDC, Safe in Pregnancy

## **COVID-19 mRNA Vaccines in Pregnancy**

- **Miscarriage**: Multiple studies have found that getting a COVID-19 mRNA vaccine during pregnancy does not increase the chance of miscarriage.
- **Birth Defects**: The available studies have not found an increased chance for birth defects when a person receives a COVID-19 mRNA vaccine during the first trimester of pregnancy.
  - Fever is a possible side effect of COVID-19 vaccines. A high fever in the first trimester can increase the chance of certain birth defects.
  - If a pregnant person develops a fever early in pregnancy it's important that they treat it



## **COVID-19 mRNA Vaccines in Pregnancy**

 Pregnancy Complications: Studies have found no increased chance for pregnancy-related problems or newborn complications such as stillbirth, preterm delivery (before 37 weeks of pregnancy), babies born smaller than expected, low Apgar scores, NICU admission, or neonatal death when a COVID-19 mRNA vaccine is given anytime during pregnancy.



**Long Term Effects**: It will take time to follow the children of people who were vaccinated in pregnancy in order to answer this question. However, based on what is known about how these vaccines work in the body, getting a COVID-19 mRNA vaccine is not expected to cause longterm problems for the child.



## **COVID-19 mRNA Vaccines in Pregnancy**

Does getting a COVID-19 mRNA vaccine during pregnancy protect the baby from the virus after delivery?

The antibodies that a person makes after getting a COVID-19 mRNA vaccine during pregnancy can pass to the developing baby. Research has shown that more antibodies pass to the baby after getting COVID-19 mRNA vaccines in pregnancy than after having a COVID-19 infection in pregnancy. Studies have also shown that the infants of people who became up to date with COVID-19 vaccines during pregnancy have greater protection against COVID-19 after delivery and are less likely to be hospitalized with COVID-19.



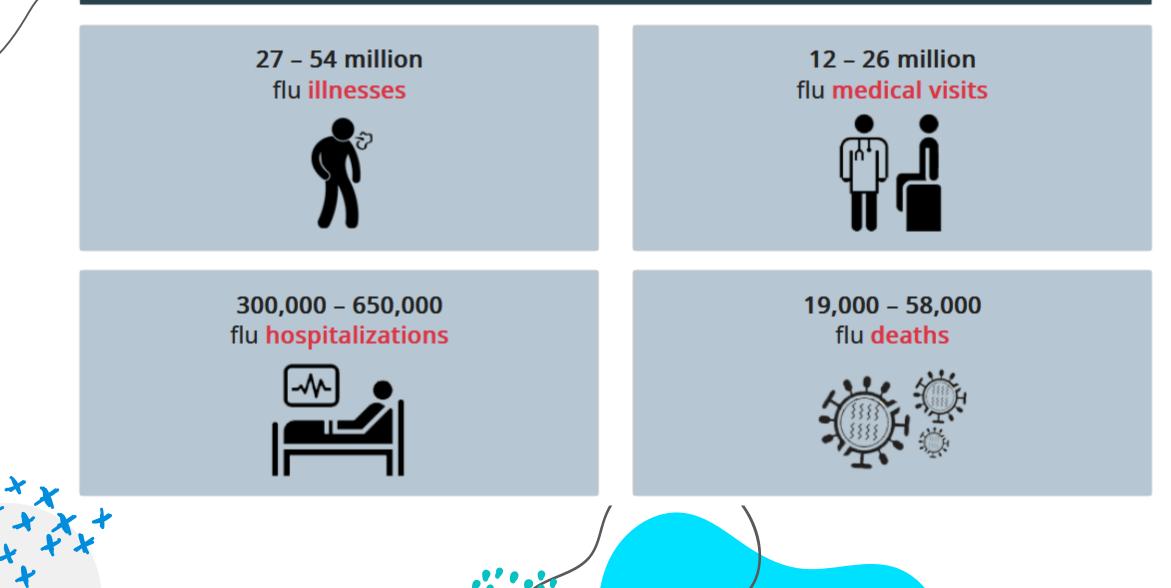
When a person who is pregnant gets a COVID-19 vaccine, the antibodies produced can cross the placenta and reach the developing baby.



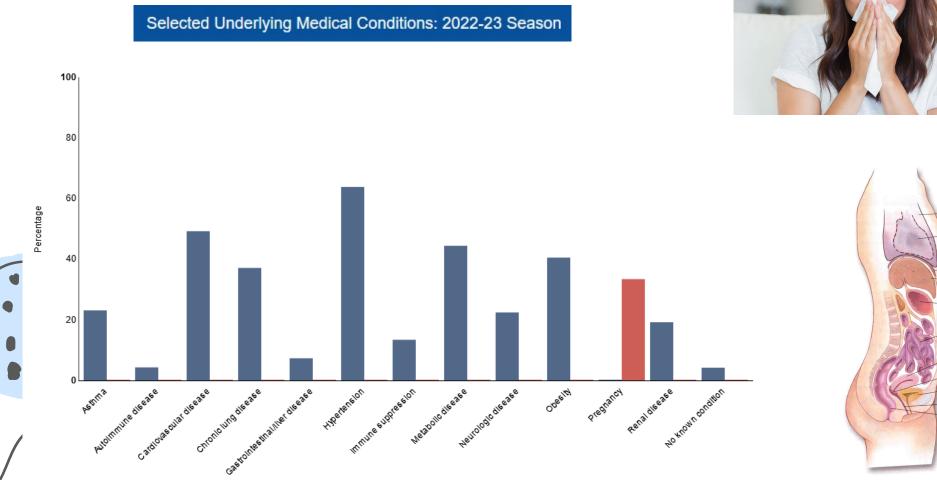


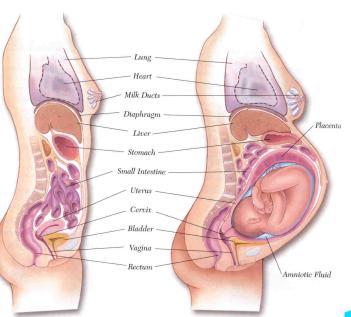


CDC estimates\* that, from October 1, 2022 through April 30, 2023, there have been:



## Influenza in Pregnancy







## Influenza in Pregnancy

- **Miscarriage**: It is not known if the flu will increase the chance for miscarriage
- Birth Defects: The available studies have not found an increased chance for birth defects when a person gets the flu during pregnancy
  - **Fever**: Fever is a possible symptom of the flu. A high fever in the first trimester can increase the chance of certain birth defects.
  - If a pregnant person develops a fever for any reason early in pregnancy it's important that they treat it.







## **Influenza in Pregnancy**

**Pregnancy Complications**: Being pregnant can increase the chance of developing serious complications from the flu compared to persons with the flu who are not pregnant. Some of the serious complications reported include respiratory distress and being hospitalized. If a person who is pregnant becomes very sick from the flu, this can also increase the chance of pregnancy complications, such as preterm delivery.



**Long Term Effects**: Studies on long-term problems have looked at whether having the flu in pregnancy could lead to later mental health conditions like schizophrenia. These studies have not been able to prove that having the flu during pregnancy will increase the chance for the baby to later develop a mental health condition.

# Flu Vaccine in Pregnancy









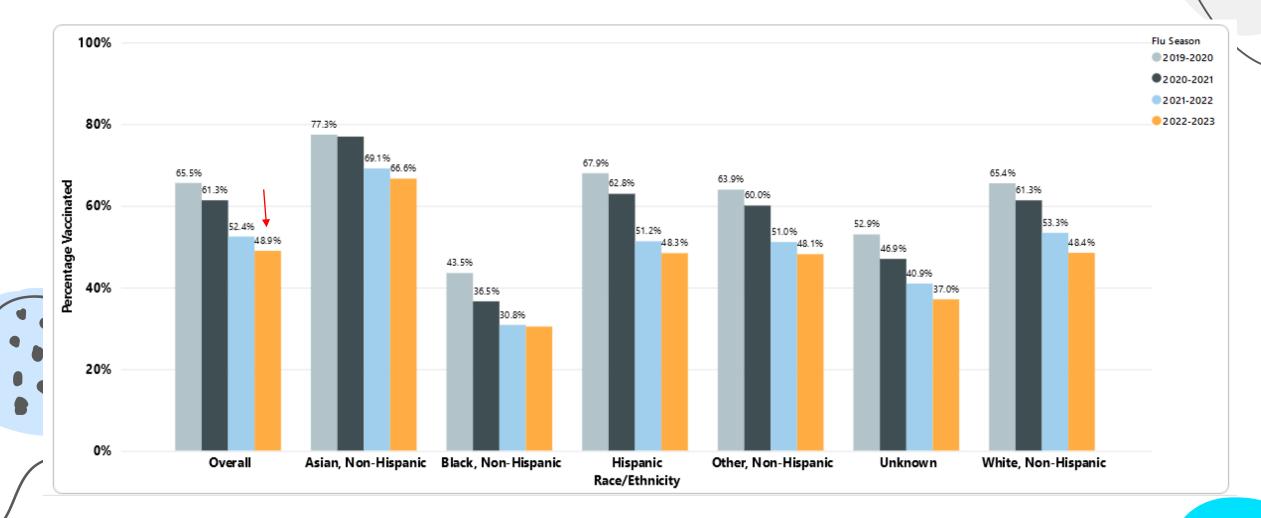
#### **Audience Question:**

#### How many pregnant people received the flu vaccine during the 2022-2023 season?

33%
 49%
 56%



#### Figure 3B. Cumulative Influenza Vaccination Coverage\*, by Month, Flu Season, and Race/Ethnicity, Pregnant Persons 18–49 Years, United States Data Source: Vaccine Safety Datalink Data are current through April 22, 2023



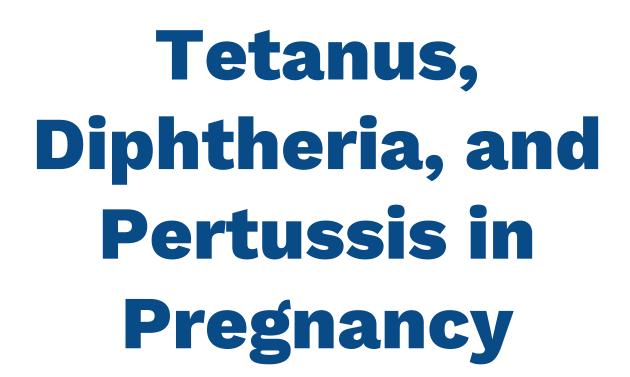
## **Flu Vaccine in Pregnancy**

- The flu shot has been recommended in pregnancy since 1960. The vaccine offers protection for the mom and protective antibodies for the baby.
- Numerous studies have shown that the flu vaccine is not associated with a risk for miscarriage, birth defects, pregnancy complications, or ong-term effects.

#### <u>CDC recommends that all pregnant people receive</u> a flu vaccine at any time during pregnancy

The flu shot should be administered by the end of October, but vaccination later in the flu season can still provide some benefit

Vaccination during July and August can be considered for pregnant



## Tetanus, Diphtheria, Pertussis in Pregnancy

TETANUS (T)	<b>DIPHTHERIA</b> (D)	PERTUSSIS (P) (whooping cough)
Causes painful stiffening of the muscles. Tetanus can lead to serious health problems, including being trable to 20 open the mouth, having trouble swallowing and breathing, or	Can lead to difficulty breathing, heart failure, paralysis, or death	Can cause uncontrollable, violent coughing that makes it hard to breathe, eat, or drink. It can cause weight loss, loss of bladder control, passing out, and rib fractures from severe 2020 6,124 coughing.
0 1950 1960 1970 1980 1990 2000 2010 2021	1996 – 2018: 14 cases and 1	All data from CDC, 2023

## **Whooping Cough in Infants**

#### About one third of babies younger than 1 year old who get whooping cough need care in the hospital.



2 in 3 (68%) will have **apnea** 1 in 5 (22%) get **pneumonia** 1 in 50 (2%) will have **convulsions** 1 in 150 (0.6%) will have **encephalopathy** 1 in 100 (1%) will **die** 



**PERTUSSIS CASES:** 

2017	18,975
2018	15,609
2019	18,617
2020	6,124
2021	2,116

# Tdap Vaccine in Pregnancy







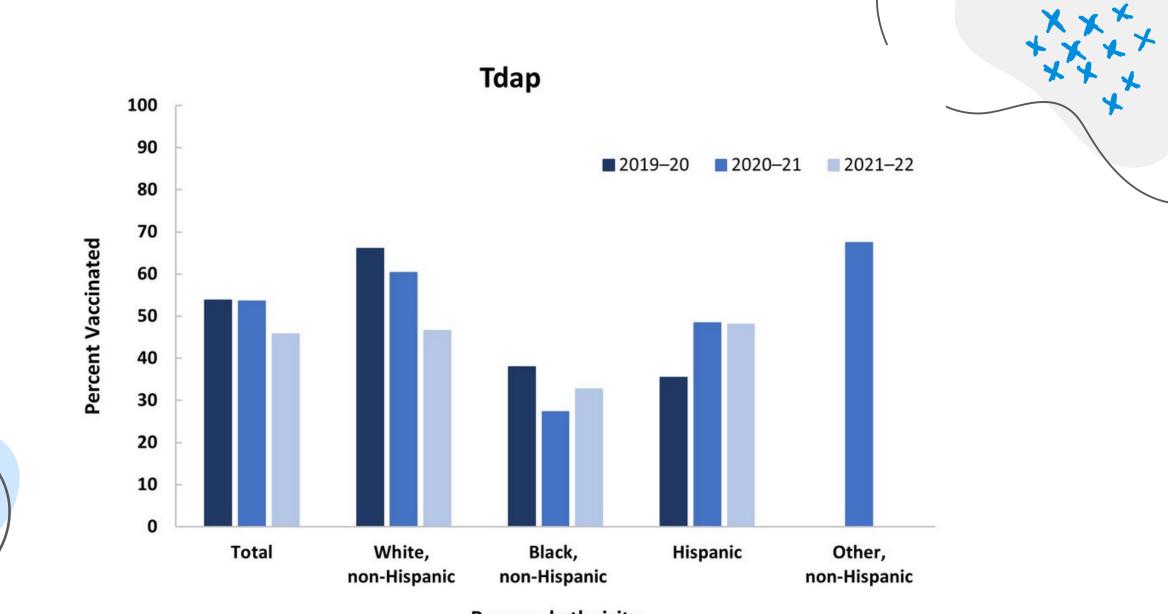
#### **Audience Question:**

## How many people received the Tdap vaccine during pregnancy in 2021-2022

54%
 39%
 46%







**Race and ethnicity** 

## **Tdap Vaccine in Pregnancy**

- The Tdap vaccine has been recommended in pregnancy since 2011.
- No increased risk for miscarriage, birth defects, or pregnancy complications has been seen in numerous studies looking at the use of Tdap in pregnancy.
- When pregnant people receive the Tdap vaccine, the antibodies that are produced can cross the placenta and reach the developing baby, which can provide some protection for the baby during the first few months of life.

#### <u>CDC recommends that all pregnant people receive a</u> Tdap vaccine between 27 and 36 weeks of *every* pregnancy

This recommendation is supported by the American College of Obstatricians and Cynacolegiste American College of

## Pertussis/Tdap vaccine ("Whooping Cough" vaccine)

#### Help Us Better Understand the Tdap ("Whooping Cough") Vaccine in Pregnancy

MotherToBaby is currently enrolling pregnant people in a study examining the use of the Tdap (tetanus, diphtheria, and pertussis) vaccine during pregnancy. All of our pregnancy research is observational and is conducted by phone — no changes to your normal routine or travel required.

"We believe our study results can help women and their doctors become better informed about the Tdap vaccine during pregnancy."

— Christina Chambers, PhD, MPH, Lead Investigator, MotherToBaby Pregnancy Studies

Are you currently pregnant? Did you receive the Tdap vaccine at any point in your current pregnancy? If you answered "yes" to both of these questions, then you have the opportunity to help us learn more about the Tdap vaccine in pregnancy.

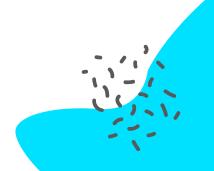
Will you take the step and become our partner? Make an impact on the health of future families today by joining our Tdap Vaccine & Pregnancy Study!

JOIN A STUDY

REFER A PATIENT



# RSV in Pregnancy



### **RSV in Pregnancy**



### **REPROTOX®** Documents - **RESPIRATORY** SYNCYTIAL VIRUS

Synonyms/Related Agents:

1. RSV (RESPIRATORY SYNCYTIAL VIRUS)

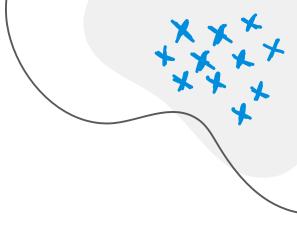
Last Revision Date: 8/26/2022

Quick take: We did not locate adequate information on the possible pregnancy effects of respiratory syncytial virus infection.

- Data on RSV infections in pregnancy is very limited
- RSV infections in pregnancy are rare as most people have had the virus initially in childhood. However, re-infection can occur.
- Mild cold-like symptoms in most adults, not typically tested for
- In one small study, half of the infants born to women who had RSV in the third trimester developed respiratory problems



### **RSV in Infants**





### **RSV Burden Estimates**

Each year in the United States, RSV leads to approximately:

- 2.1 million outpatient (non-hospitalization) visits among children younger than 5 years old.<sup>(1)</sup>
- 58,000-80,000 hospitalizations among children younger than 5 years old.<sup>(1,2,3)</sup>
- 60,000-160,000 hospitalizations among adults 65 years and older.<sup>(4-8)</sup>
- 6,000-10,000 deaths among adults 65 years and older.<sup>(9-11)</sup>
- 100–300 deaths in children younger than 5 years old.<sup>(11)</sup>

RSV treatment for hospitalized infants costs \$709.6 million annually





# RSV Vaccine in Pregnancy







### **Audience Question:**

# When is the RSV vaccine recommended during pregnancy?

- 27-36 weeks
   36-40 weeks
   22 26 weeks
- 3. 32-36 weeks



### **RSV Vaccine in Pregnancy**

The CDC recommends the RSV vaccine for people who are 32-36 weeks pregnant during RSV season. In most of the US, RSV season takes place from September to January

• The RSV vaccine that has been approved for use in the US is a protein subunit vaccine called Abrysvo<sup>TM</sup>.



 Getting the RSV vaccine causes a person to develop antibodies against RSV. These antibodies can pass from the person who is pregnant to the developing baby, helping protect the infant from severe RSV infection for about 6 months after they are born.



### **RSV Vaccine in Pregnancy**

- Miscarriage No data
- Birth defects No data
- Pregnancy Complications: A clinical trial compared over 3,600 people who received the RSV vaccine between 24 and 36 weeks of pregnancy to a group that did not receive the vaccine. Between the two groups, there were no significant differences in pregnancyrelated problems, such as low birth weight. Slightly more preterm deliveries were seen in those who received the vaccine compared to those who did not. In most cases, the preterm deliveries happened a month or more after getting the vaccine. It is not clear from this study if preterm deliveries were due to the vaccine or to other factors. The recommendation to get the vaccine closer to the end of pregnancy (32-36 weeks) allows time for antibodies to pass to the baby before delivery but lowers the chance of delivering early from the vaccine (if there is a chance) since the vaccine is given closer to full term.
- Long-term outcomes: No data

### **RSV Vaccine in Pregnancy**

Most infants will either receive antibodies from the maternal vaccination or nirsevimab, a monoclonal antibody given after delivery

### The CDC recommends nirsevimab be given to infants younger than 8 months born during or entering first RSV season if:

- Their mother did not receive RSV vaccine
- Mother's vaccination status is unknown
- The infant is born less than 14 days after the mother's vaccination



In rare cases, the antibody can be given in addition to maternal vaccination:

- Conditions in pregnant people resulting in an inadequate immune response to vaccine or decrease in transplacental antibody transfer
- Infants who have undergone cardiopulmonary bypass (loss of maternal antibodies)
- Infants with sufficiently increased risk for severe disease

# Main Takeaways

• Flu and COVID-19 can increase risks for the pregnant person and the developing baby.

• RSV and whooping cough are known concerns for infants and prenatal vaccination offers a way to protect babies from birth.

• There are now 4 vaccines recommended for use in pregnancy. All 4 vaccines are not expected to increase risks to the pregnancy.

• Seasonal administration of flu and RSV vaccines is taking place now, and updated COVID-19 shots are available. Pregnant people should be vaccinated!

• MotherToBaby is an excellent resource that is available to answer questions about any exposures in pregnancy and while breastfeeding.

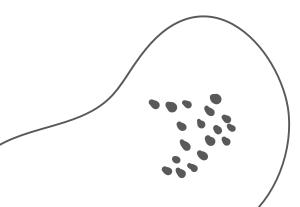
#### MotherToBaby Pregnancy Studies

Ongoing Studies: Providing Better Information on Medication Safety in Pregnancy Mother Bably Pregnancy Studies provide much-readed information on medication and vacche suffet in pregnance. Our studies are observational, people with are preprint and valued to like any medications or change their conservativationets. Vie kinglish bables people who are appropriate tab have — and with base — alian in medicion of their with the Web and the Studies and their studies of people of them are table. We called themation forging the way

Did you know that 9 out of 10 people who are pregnant in the U.S. take medication, yet many medications currently don't have enough information on how safe it is to use them during pregnancy?

In Mather Bally surgency student research transforded by 15 Ser Togol. Series to Baller Ballyring has here hadrened in electricity products research and students to Amorth 25 programs, and a study of a baller ball in the their metalence durings to product proof the held products and the reduces based information that they well in mather mather information of an observation of the the held of a student and has produce and the reduces based information that they well in mather mather information of an observation of the held products and the reduces based information that they well in mather mather Metaletone decisions during pregnancy for the held of students and the product pregnancy. To Stude well as grant Metaletone decisions during pregnancy for the held of students and the students and th

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### MotherToBaby Pregnancy Studies

MotherToBaby Pregnancy Studies are observational research studies designed to gather much-needed information on exposures in pregnancy. People who are pregnant are not asked to take any medications or change their current treatments. We simply follow people who are pregnant who have – and who have not – taken a medication of interest and collect data on their babies for a period of time after birth. This helps us determine if the medication/vaccine may pose a risk to a pregnancy or a developing baby.

Refer your patients today!



Call: 877.311.8972 Visit: https://mothertobaby.org/pregnancystudies/



# Contact MotherToBaby Today!

We are happy to answer your questions about any exposures in pregnancy or lactation!

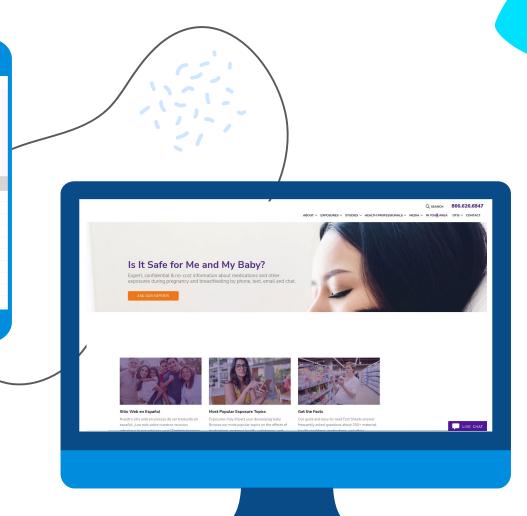
Call: 866.626.6847 Visit: www.mothertobaby.org





wse By Category Cosmetic Treatments Drugs & Substance Use Environment & Natural Disaste Fetal Development

Food & Beverages





### **Thank You!**



Happy to take any questions now, or by email: kpc motherToBaby Adu California

### 15 minute break!





# VFC and VFA Program Updates

Mary Rebbert, Senior Field Representative California Department of Public Health October 6<sup>th</sup> 2023



# **VFC Updates**



# VFC Shipping Schedule

- Due to the increased volume of orders, VFC's vaccine distributor McKesson is currently experiencing a backlog of shipping routine non-COVID vaccine orders, resulting in delayed shipments. McKesson is working to significantly reduce the backlog and plans to ship older orders first until the backlog is cleared.
- Flu and COVID vaccine orders are shipping separately and are NOT affected by the delay.
- Vaccine orders and shipments will not be impacted by a government shutdown. Vaccine orders will continue to be reviewed and processed as normal.





# Shipping Delays can be found on EZIZ.org



VFC Memos	Vaccine Order Status	From CDPH
Order Processing Update		

There are currently no delays in the processing of federally-supplied vaccine requests. Received requests are promptly reviewed, approved and processed by the VFC Program's Customer Service Center. As of Thursday, March 16, 2023, McKesson has resumed regular shipping of all VFC vaccine orders.

Due to the COVID-19 pandemic, UPS has temporarily adjusted their signature guidelines for all shipments within the United States. Signatures may not be required, meaning vaccine orders may be left unattended at provider offices or delivered.

#### Regular Vaccine Supply Information:

Through June 2023, CDC has instituted temporary ordering controls to mitigate a potential supply constraint for Td vaccine. Once our allocation is exceeded for the month, Td vaccine will be unavailable to order until our allocation is refreshed the following month. Please remember to order and administer Tdap instead of Td whenever possible.



# Vaccine Supply

 CDC has instituted ongoing ordering controls to mitigate a potential supply constraint for Td vaccine. Once our allocation is exceeded for the month, Td vaccine will be unavailable to order until our allocation is refreshed the following month. Please remember to order and administer Tdap instead of Td whenever possible.

BRAND	NDC	NDC Description	Currently Unavailable?
TENIVAC	49281-0215- 15 TD; 10-pack of syringes		Yes
TENIVAC	49281-0215- 10	TD; 10-pack of single dose vials	No
TDVAX	13533-0131- 01	TD; 10-pack of single dose vials	Yes



# Transition from Prevnar 13<sup>®</sup> to Prevnar 20<sup>®</sup>

- Pfizer's Pneumococcal Conjugate Vaccine Prevnar 20<sup>®</sup> builds on Prevnar 13<sup>®</sup> and includes 7 additional serotypes.
- Beginning September 1, 2023, Prevnar 20<sup>®</sup> (PCV-20) will be available for ordering through the VFC Program.
  - Prevnar 13<sup>®</sup> (PCV 13) will be turned off from ordering at the same time.
- To minimize vaccine waste, current Prevnar 13<sup>®</sup> orders may be reduced.
- Vaccine requests will continue to be reviewed and approved based on existing on-hand inventory and usage.
- Continue to vaccinate your patients with your existing stock of Prevnar 13<sup>®</sup> until you are ready to
  order more pneumococcal conjugate vaccine.
- The "VFC Provider Request Form to Update Vaccine Brand Products Administered" will NOT be required for PCV-13 to PCV-20, unless provider is switching from VAXNEUVANCE<sup>®</sup> (PCV-15)



### Menveo 1-vial®

- GSK's new Meningococcal Conjugate Vaccine **Menveo 1-vial**<sup>®</sup> will be available for VFC ordering starting September 1, 2023.
- How is this different from the current 2-vial presentation?
  - The new Menveo 1-vial<sup>®</sup> presentation (10 pack) does not require reconstitution and is approved for use in persons 10 years through 55 years
  - The existing **Menveo 2-vial**<sup>®</sup> presentation (5 pack) requires reconstitution and is approved for use in persons aged 2 months through 55 years.
- GSK will continue to make both products available to support vaccination for children as young as 2 months of age.
- Menveo 2-vial<sup>®</sup> should be prioritized for use in children aged 2 months through 2 years of age at <u>high risk for Meningococcal disease</u>, as it will be the only meningococcal conjugate vaccine approved for use in this age group.
- Menveo 2-vial<sup>®</sup> will still be available in limited allocations from CDC and will have a minimum order quantity of 1-dose.



### VFC Flu Shipments, 10/03/23

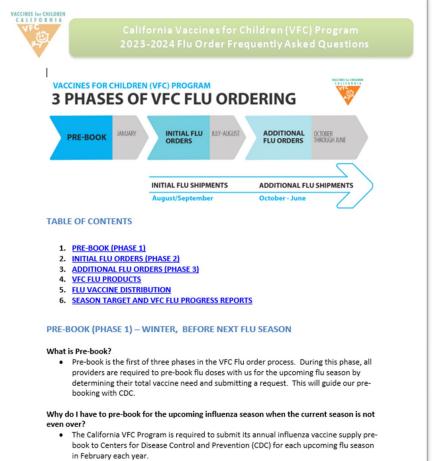
• The California Vaccines for Children (VFC) Program will process remaining initial orders of flu vaccine. Percentages of initial orders are listed below. Orders will be processed on **Friday**, **October 6**, **2023**, for shipments arriving the **week of October 9**.

• IMPORTANT: If your clinic will be closed in the next few weeks, please notify the VFC Program immediately at 1 877-243-8832 to prevent any shipping incidents. Orders <u>cannot</u> be cancelled once they have been processed and shipments <u>must not</u> be refused when delivered!

nitial tial	<u>Product</u>	<u>Age Group</u>	<u>Supply</u>
for	Fluarix <sup>®</sup> Quadrivalent Preservative Free 0.5mL, Single-Dose Syringes, GSK	6 months-18 years	<u>All initial orders have been</u> shipped in full.
r 9.	Flucelvax <sup>®</sup> Quadrivalent Preservative Free	6 months-18 years	<u>All initial orders have been</u> shipped in full.
	0.5mL, Single-Dose Syringes, Seqirus FluLaval <sup>®</sup> Quadrivalent Preservative Free 0.5mL, Single-Dose Syringes, GSK	6 months-18 years	<u>All initial orders have been</u> shipped in full.
at 1- J d	Fluzone <sup>®</sup> Quadrivalent Preservative Free 0.5mL, Single-Dose Syringes, Sanofi	6 months-18 years	Orders of 100 doses or less have been shipped in full. Orders over 100 doses: remaining 30% of initial order will be processed
1	FluMist <sup>®</sup> Quadrivalent Preservative Free 0.2mL, Intranasal Sprayer, AstraZeneca	2 years-18 years	Orders of 100 doses or less have been shipped in full. Orders over 100 doses: remaining 50% of initial order will be processed



### **VFC Flu Resources**



 The number of doses requested by California VFC providers during the Influenza Pre-Book process is used to guide the California VFC Program to know how many doses will be needed in the upcoming season to adequately support providers in their efforts to ensure that all VFC eligible patients are provided their annual influenza vaccination.

2023-2024 VFC Flu Order Frequently Asked Questions Page 1 of 7 IMM-1291 (8/23)



#### California Vaccines for Children (VFC) Program 2023-2024 Initial Flu Order Confirmation Quick Guide

The VFC Program's Initial Flu Order Confirmation system will be available to VFC Providers through WLY VFCVACCINES from August 14, 2023 through August 24, 2023.

#### **ORDER SUBMISSION**

Not all providers need to confirm their initial order! For providers who submitted a 2023-2024 pre-book. VFC has automatically confirmed 50% of your confirmed pre-book for your initial order. Vaccine will arrive in multiple shipments once supply is available. No further action is required.

#### However, the Initial Flu Order Confirmation system is available at My VFCVACCINES for.

- Providers who did not submit a pre-book in January 2023. The number of doses available for the initial flu order are a percentage of your 2023-2024 season target. Additional doses may be requested in Phase 3 of VFC Flu Ordering starting this Fall.
  - OR
- 2. Providers who would like to receive less than 50% of their confirmed pre-book.

#### Keep in mind:

- . The maximum number of doses that may be requested for the initial flu order will be displayed by brand.
- Doses allocated for the initial order cannot be shifted between brands.
- Providers have two (2) weeks to review and confirm their initial flu order.

#### TIPS FOR A SUCCESSFUL FLU VACCINATION SEASON

#### PLAN for upcoming flu season

Discuss and outline key strategies to achieve high influenza vaccination coverage rates for your patients and decrease missed opportunities for vaccination.

- Review the <u>Flu Action Plan; 3 Habits of Highly Successful VFC Clinics</u> (IMM-1274) with staff and implement strategies not currently in use.
- Use the presumptive approach don't ask! Tell patients they are due for flu vaccination.
- Review talking points for vaccine hesitant parents on EZIZ.org and CDC.gov

#### PREPARE for your initial flu order:

Return expired flu from the previous season. If your practice has any expired flu doses from the previous flu season, immediately remove them from your refrigerator and submit an online Return/Transfer form.

Make sure you can store all the doses. Initial orders will be sent in multiple shipments as vaccine supply arrives at VFC's national vaccine distribution center. Orders cannot be canceled once sent for fulfillment.

Watch out for email notifications that will be sent to the practice's vaccine coordinator and back-up coordinator upon processing of the order. Flu vaccine orders are processed as VFC receives inventory and orders are sent to the VFC Program's national vaccine distributor for fulfiliment.

Ensure your clinic's open hours for vaccine delivery are up-to-date at all times, especially for the weeks that initial flu orders will be delivered. Successful and timely delivery of your shipment depends on your delivery information listed in your 'MV/ECVaccines' account.

#### AFTER initial orders:

Order additional doses during Phase 3 of VFC Flu Ordering (starting this Fall) as needed throughout the season. The initial order is to get your practice started for the season.

Report flu vaccine doses administered since the previous order and current on-hand inventory before accessing the routine vaccine order form during Phase 3 of VFC Flu Ordering.

IMM-1290 (8/23)



### 3 Phases of VFC Flu Ordering

### **VFC Flu Resources**

			CALIFORNIA
2023-2024 FLU USAGE LOG			VFC
VACCINES FOR CHILDREN (VFC) PROGRAM	PIN:	Usage Period:/_/_ to/_/	49

INSTRUCTIONS: Keep this log near your vaccines. Fill in today's date, patient info and then make a check for each vaccine administered. Upon completion of this form, count the number of checks for each vaccine and write in the Usage Period Total. VFC flu vaccine usage since the previous order and current flu vaccine inventory must be reported with each vaccine order. File all usage logs for 3 years.

Today's Date	Patient Name (or medical record)	Date of Birth	Fluarix* 0.5 mL syringes	Flulaval* 0.5 mL syringes	Fluzone* 0.5 mL syringes	Flumist® 0.2 mL sprayer	Flucelvax" 0.5 mL syringes
1.							
2.							
3.							
4.							
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6.							
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9.							
10.							
11.							
12.							
13.							
14.							
15.							
16.							
17.							
18.							
		Usage Period Total:					
Log taken by:	PAGEOF						IMM-1053F (8/

Flu Usage Log - Updated!

#### PEDIATRIC/ADULT INFLUENZA VACCINE 2023-2024 FluLaval® Quadrivalent 🍟 Fluarix® Quadrivalent 6 MONTHS GlaxoSmithKline Biologicals 200 GlaxoSmithKline Biologicals & OLDER 0.5 mL single-dose syringe 0.5 mL single-dose syringe And Street Bernstein Flucelvax® Quadrivalent 🦋 Fluzone" Quadrivalent 😿 Segirus Sanofi Pasteur, Inc. 0.5 mL single-dose syringe 0.5 mL single-dose and the second second ----Fluzone<sup>®</sup> Quadrivalent Afluria<sup>®</sup> Quadrivalent Sanofi Pasteur, Inc. Balant Segirus 0.5 mL single-dose vial 0.5 mL single-dose syringe Fluzone<sup>®</sup> Quadrivalent **3** YEARS Sanofi Pasteur, Inc. & OLDER 5.0 mL multi-dose vial\* Afluria® Quadrivalent Seqirus 5.0 mL multi-dose vial Flucelvax® Quadrivalent Seairus 5.0 mL multi-dose vial\* FluMist® Quadrivalent 🏹 2-49 65 YEARS FLUAD<sup>®</sup> Adjuvanted MedImmune Vaccines, Inc. Quadrivalent Segirus Information Stationers, Name YEARS OLD & OLDER 0.2 mL single-dose nasal sprayer 0.5 mL single-dose syringe & HEALTHY many and Wanne 2007 65+ Fluzone® High-Dose **18** YEARS FluBlok\* Quadrivalent Quadrivalent Sanofi Pasteur, Inc. Protein Sciences A later to factor & OLDER 0.7 mL single-dose syringe 0.5 mL single-dose syringe - I Re 1 654 (September 1 (Sept STORE ALL INFLUENZA Children under 9 years of age with a history of fewer than 2 doses of influenza vaccine are VACCINES IN THE recommended to receive 2 doses this flu season. See CDC Website REFRIGERATOR. Vaccines available through the Vaccines for Children Program in 2023-24 should only be VFC Questions: used for VFC-eligible children 18 years of age or younger. Call 877-2Get-VFC \* Multi-dose flu vaccines, which contain thimerosal, should NOT be given to pregnant (877-243-8832) women and children under 3 years of age unless Secretary of the Health and Human Services Agency issues an exemption (CA Health & Safety Code 124172). • CDPH Preferred vaccine product for persons 65 or older. If not available, any other 65+ age-appropriate inactivated product may be given California Department of Public Health IMM-859 (8/23)

### Pediatric/Adult Influenza Vaccine 2023-2024



# **RSV Immunization Products Recap**

- On 9/22/2023, members of CDC's Advisory Committee on Immunization Practices (ACIP) voted to recommend Pfizer's bivalent RSVpreF vaccine (trade name Abrysvo) for prevention of RSV lower respiratory tract infection in infants
- New immunization products now available for the following groups:
- Infants & Toddlers
  - One dose of nirsevimab is recommended for all infants younger than 8 months of age who are born during — or entering — their first RSV season
  - One dose of nirsevimab is recommended for infants 8 through 19 months of age who are at higher risk of severe disease shortly before or during their second RSV season
- Pregnant People
  - RSV vaccine administered between 32-36 weeks of pregnancy, between September-January
- Older adults
  - Adults 60 years and older may be eligible for an RSV vaccine, under shared clinical decision making with their health care provider



### Resources – RSV Vaccine in Pregnancy

- ACIP Meeting Slides September 22, 2023
- Bivalent Prefusion F Vaccine in Pregnancy to Prevent RSV Illness
   in Infants
- Be on the lookout for future materials:
  - Updated CDC RSV webpages, VIS
  - Morbidity and Mortality Weekly Report (MMWR)

### Updated CDC Vaccines & Preventable Disease Pages

#### What Parents of Young Children Should Know

Over

Adults 60 Years of Age and

What Older Adults Should Know

For Healthcare Professionals: Immunization for Young Children

#### Immunization Information Statement

For Healthcare Professionals: Vaccination for Older Adults

FAOs about RSV Immunization for Young Children

FAQs About RSV Vaccine for Adults

accines and Prev	ental	ble Diseases			
cines & Preventable Disease	es Home	> Vaccines by Disease > RSV			
Vaccines & Preventabl Diseases Home	e	RSV Vaccination for Older	Adults 60 Yea	ars	s of Prevention Inf
Vaccines by Disease		Age and Over			RSV Immuniza
Chickenpox (Varicella)	+	Print			
Dengue	+				and Young Ch
Diphtheria	+	What types of RSV vaccines are	there?		
Flu (Influenza)	+	There are two RSV vaccines licensed by the U.S. Food and D and older in the United States:	orug Administration for use in	n adult	ults 60
Hepatitis A	+	RSVPreF3 (Arexvv)			
Hepatitis B	+	RSVpreF (Abrysvo)			
Hib	+	Both vaccines contain a part of the RSV virus. Both vaccines that can protect you from respiratory disease if you are infe		e respo	sponse
Human Papillomavirus	+	that can protect you non respiratory disease in you are inte	Vaccines and Preve	ntabl	hle Diseases
(HPV)		Who should talk to their heal	Vaccines & Preventable Diseases		
Measles	+	RSV vaccination?	vaccines & Preventable Diseases	Home >	e > vacones by Disease > KsV
Meningococcal	+	Adults 60 years and older should talk with their health or right for them. There is no maximum age for getting RS	<ul> <li>Vaccines &amp; Preventable</li> <li>Diseases Home</li> </ul>		Frequently Asked Questions About RSV
Mumps	+	dose.	Vaccines by Disease		Vaccine for Adults
Pneumococcal	+	If you're 60 or older, your health care provider might re	Chickenpox (Varicella)	+	Print
Polio	+	you have a weakened immune system from illness (e.g. medications (e.g., treatment for cancer or organ transp	Dengue	+	Two Respiratory Syncytial Virus (RSV) vaccines are approved for people ages 60 years and older.
Rotavirus	+	such as heart or lung disease, or if you live in a nursing be at higher risk of severe RSV disease and an RSV vace	Diphtheria	+	Arexvy (GSK adjuvanted RSV vaccine)     Abrysvo (Pfizer RSV vaccine)
RSV		Even if you had RSV infection in the past, RSV vaccinatio	Flu (Influenza)	+	CDC recommends that adults ages 60 years and older may receive RSV vaccination, using <u>shares</u> <u>clinical decision-making (SCDM)</u> . This means that health care providers should talk to these
What Parents of Young		from RSV. There is no specific length of time that you ne you can receive an RSV vaccine, but generally, if you ha	Hepatitis A	+	individuals about whether RSV vaccination is appropriate for them.
Children Should Know		wait until you recover before receiving an RSV vaccine. I can get an RSV vaccine.	Hepatitis B	+	Is RSV an important cause of disease among older adults?
What Older Adults Shou Know	ld	·	Hib	+	
For Healthcare		Who should not get RSV vacc	Human Papillomavirus (HPV)	+	What vaccines are approved for prevention of RSV, and is there a difference between them?
Professionals: Immunization for Young	;	You should not get the RSV vaccine Arexvy if you've eve component of Arexvy. Information about Arexvy can be	Measles	+	between them?
Children		Component of Arexvy, miormation about Arexvy can be ☑.	Meningococcal	+	What does it mean to use a shared clinical decision-making (SCDM)
Immunization Informati Statement	on	You should not get the RSV vaccine Abrysvo if you've ev component of Abrysvo. Information about Abrysvo can	Mumps	+	recommendation for RSV vaccine?
For Healthcare Professionals: Vaccinatio	on	Component of Abrysvo. Information about Abrysvo can	Pneumococcal	+	Which adults are most likely to benefit from RSV vaccination?
			Polio	+	
			Rotavirus	+	What should I tell patients about the side effects of RSV vaccine?
		ation for Older	RSV What Parents of Young		How should Ladminister RSV vaccine?

**Healthcare Providers: RSV Prevention Information RSV Immunization for Infants** and Young Children

#### IMMUNIZATION INFORMATION STATEMENT

**Respiratory Syncytial Virus (RSV) Preventive Antibody:** What You Need to Know

#### Why get immunized with a RSV preventive antibody? A respiratory syncytial virus (RSV) preventive antibody can prevent severe lung disease caused by RSV.

RSV is a common respiratory virus that usually causes mild, cold-like symptoms but can also affect the lungs. Symptoms of RSV infection may include runny nose, decrease in appetite, coughing, sneezing, fever, or whe

Vaccines and Preventable Diseases

A Vaccines & Preventab

Diseases Home

Vaccines by Disease

Dengue

Diphtheria

Flu (Influenza)

Hepatitis A

Measles

Meningoo

Mumps

Polio

RSV

Rotavirus

What Older Adults Should

Human Papillomavirus

Chickenpox (Varicella)

Anyone can become infected by RSV, and almost all children get an RSV infection by the While most children recover from an RSV infection in a week or two, RSV infection can be and some young children, causing difficulty breathing, low oxygen levels, and dehydrati RSV is the most common cause of bronchiolitis (inflammation of the small airways in th (infection of the lungs) in children vounger than 1 year of age. Children who get sick from hospitalized, and some might even die

#### **RSV Preventive Antibodies**

The RSV preventive antibody (generic name nirsevimab, trade name Beyfortus) is a sho disease in infants and young children. Antibodies are proteins that the body's immune harmful germs. Like traditional vaccines, preventive antibodies are immunizations that a specific pathogen. While both are immunizations, the way they provide immunity is d an immunization that provides antibodies directly to the recipient. Traditional vaccine timulate the recipient's immune system to produce antibodies Vaccines and Preventable Diseases

#### A Vaccines & Prever Healthcare Providers: RSV Prevention Information Vaccines by Disease RSV Immunization for Infants and Young Children Print On This Page ons for using Nirsevimab Timing of Nirsevimab Administratio Contraindications and Precautions Storage and Handling of Nirsevir About Nirsevimab Administering Nirsevimal piratory syncytial virus (RSV) is the mos

sericus illness and death in infants and young children There are two injectable monoclonal antibody products that help protect infants and young childre from lower respiratory tract infection caused by RSV

 Nirsevimab (Beyfortus) Palivizumab (Synagis)

Dengue

Diphtheria

Flu (Influenz

Hepatitis A

Hepatitis B

Measles

Mumps

Polio

RSV

Rotavirus

Aeningococc

#### Recommendations for Using Nirsevimab

One dose of nirsevimab is recommended for all infants younger than 8 months of age who are born during - or entering - their first RSV seasor Additionally, a dose of nirsevimab is recommended for some children aged 8 through 19 months old

who are at increased risk for severe RSV disease and entering their second RSV season. The following children aged 8 through 19 months are recommended to get a dose shortly before or during their second RSV season: American Indian/Alaska Native children

Children with chronic lung disease of prematurity who require medical support during the six months before the start of their second RSV season

· Children with severe immunocompromis Children with severe cystic fibrosis

#### **Respiratory Syncytial Virus** (RSV) Preventive Antibody: Immunization Information Statement (IIS)

Home > Vaccines by Disease > RSV Frequently Asked Questions About RSV Immunization for Children 19 Months and Younger Print What is the difference between nirsevimab and a traditional vaccine? Nirsevimab Indication, Dosage and Schedule Who is recommended to receive nirsevimab? Can children at increased risk for severe RSV disease receive nirsevimab during their first RSV season if 8 through 11 months? For children ages 8 through 19 months who are recommended to receive nirsevimab during their second RSV season, what is the minimum interval between doses given in first and second RSV season? Can I give nirsevimab to children ages 20 months and older who at increased risk for severe RSV disease? Do the recommended ages for nirsevimab refer to the age at time of immunization?

**Frequently Asked Questions About RSV Immunization for Children 19 Months and** Younger

**Frequently Asked Questions About RSV** Vaccine for Adults

Do I need to reconstitute RSV vaccine?

Where should I store RSV vaccine

What Older Adults Shoul

Professionals:



### **Unannounced Storage and Handling Visits**

- In July 2023, VFC Field Reps will resume Unannounced Storage and Handling Visits for VFC Providers
- These were on pause during the COVID-19 pandemic
- Allow Field Reps to spot check providers
- CDPH-issued memo about resuming these activities will be sent to VFC Providers this month



# **CAIR2** Requirement

- It is a VFC Program Requirement to submit doses administered to CAIR2.
- Program letter sent 4/21/2023
- VFC Field Reps and Local CAIR Reps are conducting outreach to providers not submitting doses and providers that are not enrolled in CAIR2.



State of California—Health and Human Services Agency California Department of Public Health



Governo

April 21, 2023

IZB-FY-22-23-15

- TO: California Vaccines for Children (VFC) Providers
- Robert Schechter, M.D., Chief Mt suc FROM: Center for Infectious Diseases Division of Communicable Disease Control, Immunization Branch
- SUBJECT: AB 1797 New Requirement to Submit Immunization Data

#### Key takeaways from this letter:

- ✓ State law (AB 1797) now requires all California providers to report vaccine administration information into a California Immunization Registry.
- ✓ VFC Program requirements also include reporting vaccine administration into a California Immunization Registry.
- ✓ Steps and Tips for your practice to submit required vaccine administration information.



# COVID-19 Vaccines and the VFC Program



### Ordering Covid-19 Vaccines - VFC

- COVID-19 vaccine is now available to order from the VFC Program. To allow for smaller but more frequent orders, the VFC Program is allowing all providers to order COVID-19 vaccines monthly, but you may need to report your full VFC vaccine inventory if your last order was more than 30 days ago.
- Order enough COVID-19 vaccine that can be used within the monthly order timeframe, but keep in mind that vaccine requests may be reduced based on available supply allocations from CDC.
- For more information, please refer to the <u>VFC communication that</u> <u>was sent on September 19, 2023</u>. The COVID-19 clinical program letter, with detailed clinical information about the updated COVID-19 vaccines will be sent soon.



### Vaccine and Clinic Eligibility Guidelines by Funding Source

For Health Departments and CDPH Approved Health Department Authorized Sites (Effective 10/01/2023 through 9/30/2024)



Program	义 VFC Vaccines for Children Program	BAP Bridge Access Program	<b>317</b> Local Health Departments <sup>1</sup>	<b>VFA</b> Vaccines for Adults Program	<b>SGF</b> State General Funds <sup>2</sup>
Funding	VFC-Federal entitlement program for eligible children. Funds are used to pay for vaccines recommended by ACIP and approved into the VFC program.	BAP-Limited federal funds (Section 317) for eligible adult populations to maintain access to COVID-19 vaccines through existing public health infrastructure.	317-Limited federal funds (Section 317) used to pay for adult vaccines recommended by ACIP and support limited vaccine supply for outbreak activities via Public Health Departments.	317-Limited federal funds (Section 317) used to pay for adult vaccines recommended by ACIP and included in the VFA Program.	Limited state funds for the purchase of vaccines to prevent respiratory illness.
Age and Eligibility	<ul> <li>Children Birth–18 years:</li> <li>Medi-Cal/CHDP eligible</li> <li>Uninsured (no health insurance)</li> <li>American Indian or Alaskan Native</li> <li>Underinsured: health insurance does not cover vaccines (ONLY if the LHD has a FQHC or RHC designation).</li> </ul>	<ul> <li>Adults 19 years and older:</li> <li>Uninsured (no health insurance)</li> <li>Underinsured (vaccines are not covered by insurance)</li> </ul>	<ul> <li>Adults 19 years and older:</li> <li>Uninsured adults (no health insurance)</li> <li>Underinsured adults (vaccines are not covered by insurance)</li> <li>Insured exceptions-Adults part of outbreak control, post-exposure prophylaxis, or disaster relief efforts as approved by CDPH &amp; LHDs.</li> <li>Household contacts or sexual contacts of HBsAg+ pregnant woman</li> </ul>	<ul> <li>Adults 19 years and older:</li> <li>Uninsured adults (no health insurance)</li> <li>Underinsured adults (vaccines are not covered by insurance)</li> </ul>	All ages: • No restrictions
Clinic Type	<ul> <li>Federally Qualified Health Center (FQHC), Rural Health Center (RHC), and State-licensed</li> <li>Community Health Centers</li> <li>Health Department and CDPH Approved Health Department Authorized Sites</li> <li>Juvenile halls/youth correctional facilities</li> <li>Private providers, School-based clinic, Hospitals, Pharmacies (pilot program)</li> </ul>	<ul> <li>Health Department Clinics</li> <li>Federally Qualified Health Center (FQHC), Rural Health Center (RHC)</li> <li>Tribal Clinics</li> <li>Indian Health Services</li> <li>Limited sites designated by Local Health Department as BAP Provider</li> </ul>	<ul> <li>Health Department and CDPH Approved Health Department Authorized Sites (HDAS)</li> <li>Juvenile halls/youth correctional facilities (for 19-25 years of age)</li> </ul>	<ul> <li>VFC enrolled Federally Qualified Health Center (FQHC), Rural Health Center (RHC)</li> </ul>	<ul> <li>State-licensed Community Health Centers</li> <li>Federally Qualified Health Center (FQHC), Rural Health Center (RHC)</li> <li>Health Department and CDPH Approved Health Department Authorized Sites (HDAS)</li> <li>Private provider</li> <li>School-based clinic</li> </ul>

California Department of Public Health, Immunization Branch

IMM-1142 (9/18/23) Page 1



Program	Vaccines for Children Program (VFC)	Bridge Access Program (BAP)	317 Local Health Dept.	Vaccines for Adults Program (VFA)	State General Funds (SGF)
Vaccines	<ul> <li>COVID-19</li> <li>DTaP</li> <li>Hepatitis A</li> <li>Hepatitis B</li> <li>Hib</li> <li>HPV</li> <li>Influenza</li> <li>Meningococcal Conjugate (MenACWY)</li> <li>Meningococcal B (MenB)</li> <li>MMR</li> <li>Pneumococcal Conjugate (PCV15 and PCV20)</li> <li>Pneumococcal Polysaccharide (PSV23)</li> <li>Polio (IPV)</li> <li>Rotavirus</li> <li>RSV (coming soon)</li> <li>Td, Tdap</li> <li>Varicella</li> </ul>	• COVID-19	<ul> <li>Hepatitis A</li> <li>Hepatitis B<sup>3</sup></li> <li>HPV</li> <li>Meningococcal Conjugate (MenACWY)</li> <li>MMR</li> <li>Pneumococcal Conjugate (PCV20)</li> <li>Td only when Tdap is not indicated<sup>4</sup></li> <li>Tdap</li> <li>Varicella</li> <li>Zoster</li> </ul>	<ul> <li>Hepatitis A</li> <li>Hepatitis B</li> <li>HPV</li> <li>Meningococcal Conjugate (MenACWY)</li> <li>MMR</li> <li>Pneumococcal Conjugate (PCV20)</li> <li>Td only when Tdap is not indicated</li> <li>Tdap</li> <li>Varicella</li> <li>Zoster</li> </ul>	• Influenza • Tdap (children only)
Ordering Website	, My FC VACCINES	California Vaccine Management	, My VFC VACCINES		California Vaccine Management
		System			System for flu vaccine (refer to your LHD for other vaccines)

1. Fully insured children and adults are not eligible to receive 317 vaccine routinely (adults enrolled in Medi-Cal/Medi-Cal managed care plans are considered fully insured). 317 vaccine may not be used in travel clinic settings.

2. Depending on funding, State General Fund vaccines may vary.

3. Adults with Medicare Part B (without Part D) are eligible if they are at low-risk for Hepatitis B. See VFA Eligibility Based on Insurance Status (EZIZ.org/assets/docs/IMM-1247.pdf) for more details.

4. Adults with Medicare Part B (without Part D) are eligible if they are receiving Td as a routine vaccine (i.e., do not have a wound). See <u>VFA Eligibility Based on Insurance Status</u> (EZIZ.org/assets/docs/IMM-1247.pdf) for more details.

California Department of Public Health, Immunization Branch



### **COVID-19 Resources**

Resource Page <u>https://eziz.org/resources/covid vaccine/
 </u>

### COVID-19 Vaccine Information Statements (VISs)

Currently, providers are required by law to provide EUA fact sheets to vaccine recipients or their caregivers for all uses of Novavax and when Moderna or Pfizer vaccines are given to children 6 months through 11 years of age. For recipients who are 12 or older receiving Pfizer or Moderna vaccine, a provider may use the manufacturer's package insert (COMIRNATY Patient Package Insert or SPIKEVAX Patient Package Insert), written FAQs, or any other document (including provider-produced information materials) to inform patients about the benefits and risks of that vaccine. CDC will publish a Vaccine Information Statement this fall. See CDC Vaccine Information Statements Page.

### Updated refrigerator and freezer logs that include instructions for both VFC and BAP.

They are located on the <u>BAP</u> <u>Resources</u> page.

### •VFC/BAP Blended Logs:

o <u>ULT Freezer</u>

- Refrigerator: Fahrenheit | Celsius
- Freezer: Fahrenheit | Celsius

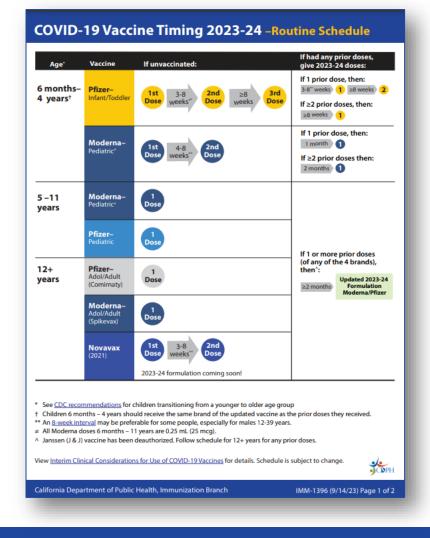


### Manual Temperature Log Update: 9/26/23

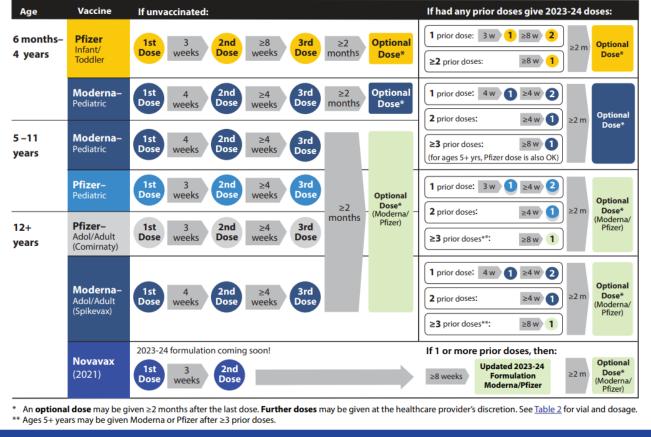
	zer COVID-								MONTH	& YEAR	FREE	ZER LOCATION	I/ID myCAvax ID VFC PIN	Keep freezer in OK range:
IONT	H & YEAR	R	EFRIGI	RATOR LOCAT		mvCAvax IE				-				-58.0°F 5.0°F
AY OF					Ref	riger	ator	Te	mpera	iture l	Log (°F	-)	Instructions	] —**——————————————————————————————————
	TIME 8:00 a.m.	NN	ALAKM	-75.1C	MONT	H & YEAR	R	FRIGE	RATOR LOC	ATION/ID	mvCAvax II	D VFC PIN	Keep refrigerator in OK range:	
ample	4:00pm	NN	~	-65.2C									36.0°F 46.0°F	Check temperatures twice a day
1	a.m.											myCAvax/		<ol> <li>Fill out month, year, refrigerator I myCAvax ID and VFC PIN.</li> </ol>
	p.m.				Day		Initials	Alarm		Min	Max	SHOTS ID	Check temperatures twice a day.	<ol><li>Record the time and your initials.</li></ol>
2	а.т. p.m.				Exam- ple	8:00am	NN		40.5	38,1	43.7		1. Fill out month, year, refrigerator ID,	<ol> <li>Record a check if an alarm went of A Record Current MIN and MAX</li> </ol>
_	am.					4:00pm am	NN	~	37.4	33,0	39,2	12345	myCAvax ID and VFC PIN.	<ol> <li>Record Current, MIN, and MAX.</li> <li>Clear MIN/MAX.</li> </ol>
3	րտ				1	pm							<ol> <li>Record the time and your initials.</li> <li>Record a check if an alarm went off.</li> </ol>	<ol> <li>Ensure data logger is recording.</li> </ol>
4	a.m.				-	am							<ol> <li>Record a check if an alarm went on.</li> <li>Record Current, MIN, and MAX.</li> </ol>	
	р.т. а.т.				2	pm							5. Clear MIN/MAX.	IF ALARM WENT OFF:
5	2.m.				-	am							<ol><li>Ensure data logger is recording.</li></ol>	<ol> <li>Post "Do Not Use Vaccines" sign.</li> <li>Alert your supervisor.</li> </ol>
2	a.m.				3	pm					1	1	IF ALARM WENT OFF:	<ol><li>Report excursion to</li></ol>
6	μm				4	am							1. Post "Do Not Use Vaccines" sign.	myCAvax for BAP vaccine and to MyVFCvaccines.org for VFC vacci
7	a.m.				-	pm							<ol> <li>Alert your supervisor.</li> <li>Report excursion to</li> </ol>	Follow instructions provided.
_	р.т. а.т.				5	am							myCAvax for BAP vaccine and to	<ol> <li>Record incident ID from myCAvax (BAP) and SHOTS (VFC)</li> </ol>
8	p.m.				_	pm							MyVFCvaccines.org for VFC vaccine. Follow instructions provided.	
9	a.m.				6	am							<ol> <li>Record Incident ID from myCAvax (BAP) and SHOTS (VFC).</li> </ol>	Supervisor's Review
	p.m.					pm am							informations (inc).	When log is complete, check all that
10	a.m.				7	pm							Supervisor's Review	apply:
	p.m. a.m.					am							When log is complete, check all that	Month/year/location/ID/PIN are recorded.
11	րու				8	pm							apply:	Temperatures were recorded twi
12	a.m.					am							<ul> <li>Month/year/location/ID/PIN are recorded.</li> </ul>	daily.
	ր.m. 				9	pm							<ul> <li>Temperatures were recorded twice daily.</li> </ul>	I reviewed data files for all the da on this log to find any missed
13	ք.				10	am							I reviewed data files for all the days	excursions.
	a.m.				10	pm							on this log to find any missed excursions.	Date downloaded:
4	p.m.				11	am							Date downloaded:	<ul> <li>Any excursions were reported to myCAvax (BAP) or SHOTS (VFC).</li> </ul>
15	a.m.					pm							<ul> <li>Any excursions were reported to myCAvax (BAP) or SHOTS (VFC).</li> </ul>	<ul> <li>We understand that falsifying the</li> </ul>
	րու				12	am							We understand that falsifying this	log is grounds for vaccine replac ment and termination from the
tes:						pm am							log is grounds for vaccine replace- ment and termination from the	BAP/VFC programs.
					13	pm							BAP/VFC programs.	On-Site Supervisor's Name:
ep all	temperature	e logs ar	nd data	files for three )		am							On-Site Supervisor's Name:	
C Pr	ogram: (8	77) 24	3-883	2 B/	14	pm								Signature: Date:
						am							Signature: Date:	
					15	pm							Staff Names and Initials:	Staff Names and Initials:
					Notes								asan red nes and mittals:	
			_											
	Vac				Keep a	ll temperatur	e logs ar	d data	files for three	MADAR			1	

- Updated manual temperature logs for the VFC and BAP Programs.
- Updated on 9/26/2023, and published on the website, 10/5/2023.
- Outlines how to report temperature excursions for VFC vaccines (on your myVFCVaccines.org account) and BAP vaccines (report to MyCAVax).
- Please start using them 10/16/2023.
- Do not re-write, shred or throw out old manual temperature logs.

# Updated COVID-19 Vaccine Timing Guide 2023-2024



#### COVID-19 Vaccine Timing 2023-24 if Moderately/Severely Immunocompromised



California Department of Public Health, Immunization Branch

IMM-1396 (9/20/23) Page 2 of 2



#### **COVID-19 Vaccine Resources on EZIZ.org**

### COVID-19 Vaccine Product Guide - Updated

OVID-19 Vaccine Product Guide										
		Is before use to avo								
Pfizer										
	Infant/Toddler 6 months–4 years	Pediatric 5-11 years	Comirnaty 12+ years							
	2023-24 Formula	2023-24 Formula	2023-24 Formula							
Packaging	Yellow Cap	Blue Cap	Gray Cap							
Doses Per Vial	3 doses	1 dose	1 dose							
Carton Size	30 doses	10 doses	10 doses							
NDC-Unit of Use (vial)	59267-4315-01	59267-4331-01	00069-2362-10							
CVX Code	302	301	300							
CPT Code	91318	91319	91320							
Program Availability	VFC	VFC	VFC, BAP							
Min. Standard Order*	30 doses	10 doses	10 doses							
Storage Limits Before F		th expiration and use-by dat								
ULT	Until expirat	ion date at -90°C to -60°C (-	130°F to -76°F)							
Thermal Shipper		٩								
Freezer		٢								
Refrigerator		10 weeks at 2° to 8°C (36°F t date on carton-not to excee								
Expiration Date	Check	the label or Pfizer product v	website.							
Administration										
Diluent (supplied)	1.1 mL per vial	Do not dilute	Do not dilute							
Dose Volume & Dose	0.3 mL 3 mcg dose	0.3 mL 10 mcg dose	0.3 mL 30 mcg dose							
Refrigerator Thaw Time (Do not refreeze)		2 hours in carton (2° to 8°C/36°F to 46°F)								
Room Temp Thaw Time (Do not refreeze)	Via	l: 30 minutes at up to 25°C (	77°F)							
Total Time at Room Temp	Up to 12 hours (in	cluding thaw time) at 8°C to	25℃ (46°F to 77°F)							
Storage Limits After Pu	ncture (Mult-dose vials): Re	cord puncture and use-by ti	me on vial label.							
Use-By Limit (Discard Time After 1st Puncture)	Discard 12 hours after dilution. Keep at 2°C to 25°C (35°F to 77°F)	N/A	N/A							
* Orders for privately purcha	ased vaccines may have differen	nt order minimums.								
	lic Health, Immunization Bra		MM-1399 (9/14/23) Page 1 of 3							

**COVID-19 Vaccine Product Guide** 

Vaccinate

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hock vaccine let	als and EDA	atorials befor		aly une			
Check vaccine lak UA fact sheets supersed							
		Moderna		Novavax			
	Pediatric 6 months– 11 years	Spikevax 12+ years	Spikevax 12+ years	Adol/Adult 12+ years			
	Green Label 2023-24 Product	Blue label	2023-24 Product	2021 Product (new product coming soon)			
Packaging	Dark Blue Cap	Dark Blue Cap	Syringe	Royal Blue Cap			
Doses Per Vial	1 dose	1 dose	1 dose	5 doses			
Carton Size	10 doses	10 doses	10 doses	50 doses			
NDC-Unit of Use (vial)	80777-0287-07	80777-0102-04	80777-0102-01	80631-0102-01			
CVX Code	311	312	312	211			
CPT Code	91321	91322	91322	91304			
Program Availability	VFC	VFC, BAP	TBD	TBD			
Min. Standard Order*	10 doses	10 doses	TBD	TBD			
Storage Limits Before							
ULT		۲		(3)			
Thermal Shipper				3			
Freezer	Until expiration	on at -50°C to -15°C	(-58°F to 5°F)	٢			
Refrigerator	Up to 30 day	/s (not to exceed exp at 2–8°C (36-46°F)	piration date)	Until expiration			
Expiration Date	Check Mode	erna product website	e or OR code.	Check product webs			
Administration							
Diluent (supplied)		Do not dilute		Do not dilute			
Dose Volume & Dose	0.25 mL 25 mcg	0.5 mL 50mcg	0.5 mL 50mcg	0.5 mL 5 mcg			
Refrigerator Thaw Time (Do not refreeze)	at	single dose vial or 1 2°C to 8°C (36°F to 46 temp for 15 min bef	5°F).	N/A			
Room Temp Thaw Time (Do not refreeze)		15 minutes for single dose vial or 45 minutes for syringe at 15° to 25°C (59° to 77°F)					
Total Time at Room Temp	Store up to 24	Store up to 24 hours at 8°C to 25°C (46°F to 77°F)					
Storage Limits After P	uncture (Mult-dose	vials) Record use-by	time on vial.				
Use-By Limit (Discard Time After 1st Puncture)	N/A	. Discard after single	use.	Discard 12 hours aft puncture. Keep at 2° 25°C (36° to 77°F)			
Orders for privately purch	hased vaccines may ha	ve different order min	imums.				

#### COVID-19 Vaccine Product Guide

#### JCDPH

#### **Do Not Use Deauthorized Products:**

Use only COVID-19 vaccine products updated for 2023-24.

Pfizer								
Infant/Toddler 6 months–4 years		Pediatric 5–11 years		Adol/Adult 12+ years				
2021 B	livalent	2021	Bivalent	2021	Multi-dose	Single		

Moderna						
Infant/Toddler 6 months– 5 years	Infant/Toddler 6 months- 5 years	6 months+	Pediatric 6-11 years	Adol/Adult 12+ years		
Magenta Border 2021 Monovalent	Bivalent	Gray Border Bivalent	Purple Border 2021 Monovalent	Light Blue Border 2021 Monovalent		



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COVID-19 Vaccine Resources on EZIZ.org

California Department of Public Health, Immunization Branch

# EZIZ COVID-19 Resources Page

# Accessible from BAP Menu and EZIZ Home Page!

#### Vaccine Information

- COVID-19 Vaccine Access & Ordering infographic
- COVID-19 Product & Timing Guides (Updates coming soon!)
- EUA Fact Sheets, package inserts, FDA pages, manufacturer websites
- General resources including guidance about fall products from FDA & CDC

#### Vaccine Administration

#### Communicating with Patients

- Resources for Patients
- Vaccine Confidence



New COVID-19 Vaccine Resources page

#### COVID-19 Vaccine Resources

This landing page provides vaccine-specific resources to support all programs that supply COVID-19 vaccines. Relevant links are still being moved from the former EZIZ/COVID page. Please check back!

#### Vaccine Information

There is not a COVID-19 Vaccine Information Statement. Federal law allows up to 6 months for a new VIS to be used. EUA Fact Sheets for Recipients should be provided to patients at the time of vaccination for approved vaccine products. (See CDC guidance.)

- COVID-19 Vaccine Access & Ordering (Infographic)
- COVID-19 Vaccine Product Guide
- COVID-19 Vaccine Timing Guide | Spanish

#### Pfizer-BioNTech (2023-24 COVID-19 Vaccine, mRNA)

- Approval of Comirnaty for 12Y+: Provider Letter | Package Insert | COMIRNATY (FDA)
- Authorization under EUA for 6M-11Y: Provider Letter | Fact Sheet for HCPs | Fact Sheet for Recipients & Caregivers | Pfizer-BioNTech COVID-19 Vaccine (FDA)
- Websites: Manufacturer | CDC Resources

#### Moderna (2023-24 COVID-19 Vaccine, mRNA)

- Approval of Spikevax for 12V+: Provider Letter | Package Insert | FDA page
- Authorization under EUA for 6M-11Y: Provider Letter | Fact Sheet for HCPs | Fact Sheet for Recipients & Caregivers | Moderna COVID-19 Vaccine (FDA)
- Websites: Manufacturer | CDC Resources

#### Novavax (2021 COVID-19 Vaccine, Adjuvanted)

- Authorization under EUA for 12Y+: Fact Sheet for HCPs | Fact Sheet for Recipients & Caregivers | Novavax COVID-19 Vaccine (FDA)
- Websites: Manufacturer | CDC Resources

#### General Resources

- CDC Recommends Updated COVID-19 Vaccine for Fall/Winter Virus Season (CDC)
- Updated mRNA COVID-19 Vaccines to Better Protect Against Currently Circulating Variants (FDA)
- Updated COVID-19 Vaccines for Use in the United States Beginning in Fall 2023 (FDA)
- Resources for the Fall Respiratory Illness Season (COVID-19, Flu and RSV) (FDA)

#### Vaccine Administration

- Interim Clinical Considerations for Use of COVID-19 Vaccines (CDC)
- ACIP Recommended Immunization Schedules: Child and Adolescent | Adult (CDC)
- Coadministration of COVID-19 Vaccines (CDC) | Coadministration Tips (graphic)
- Reporting Adverse Events to VAERS
- Reporting Race & Ethnicity
- Tips to Ease Anxiety During Vaccination
- Vaccine Administration Checklist (to be updated after FDA authorizations)
- More Job Aids

#### **Communicating with Patients**

- COVID-19 Vaccine Resources for Patients
- COVID-19 Vaccine Confidence



#### COVID-19 Vaccine Resources



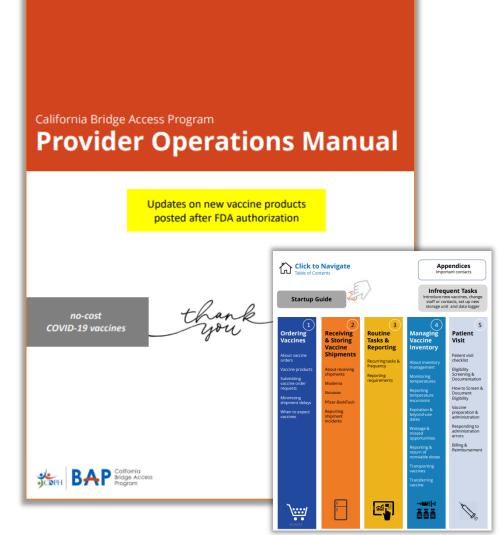
# CA Bridge Access Program Provider Operations Manual

This manual provides step-by-step instructions and links to available resources.

Audience:

- Existing COVID-19 vaccine providers new to BAP
- New BAP organizations & locations







# Mew EZIZ BAP Resources Page! Eligibility Screening & Documentation

317 (VFA & BAP) Eligibility Screening

& Documentation Requirements

#### Eligibility Based on Insurance Status

#### Bridge Access Program

A limited supply of COVID-19 vaccine will be made available through the Bridge Access Program for uninsured and underinsures and older) to prevent tos of access when vaccines transition to the commercial market. Insured patients—including patients covered by Medicare and Medi-Cal—are NOT eligible for the COVID-19 vaccines provided through this program. This temporary program will sunset at the end of 2024.

#### Eligible for COVID-19 Vaccine through BAP (317 Funds)

- Patient health insurance status
- Uninsured/No Insurance (includes those who receive primary care through county safety net programs; these are NOT considered health insurance)
- Underinsured (has health insurance, but the insurance does not include any vaccines; insurance covers
  only selected vaccines; insurance does not provide first-dollar coverage for vaccines.)
- Insurance NOT through Medi-Cal or Medicare (only eligible for COVID-19 vaccines if NOT covered by patient's private insurance plan)<sup>1</sup>

#### X Not Eligible for COVID-19 Vaccine through BAP (317 Funds)

Patient health insurance status:

- Medi-Cal Fee-For-Service/Medi-Cal Managed Care (bit.ly/CAhealthplans)
- Medicare Part B (medical benefit) AND Part D (prescription drug benefit)
   Medicare Part B Alone
- Medicare Part D Alone
- Insurance NOT through Medi-Cal or Medicare<sup>3</sup>

 Fully insured adults whose insurance covers the cost of the vaccine(s) are NOT eligible for COVID-19 vaccine—even if the insurance includes a high deductible or co-pay, the plan's deductible has not been met, or the insurance has cost sharing.

California Department of Public Health, Immunization Branch

#### **Eligibility Cheat Sheet**

IMM-1473 (9/23)

1. Screen for Eligibility
1. Screen for Eligibility
Eligibility screening must be conducted prior to the administration of any 317-funded vaccine (e.g., Vaccines for Adults and Bridge Access Programs). Eligibility is self-reported by the patient and verification of eligibility can be obtained verbally from the patient.
✓ Eligible for VFA and/or BAP (COVID) vaccines if at least 19 years of age and
1. Has no insurance, or
<ol> <li>Is underinsured (public or private health insurance does not cover all vaccines or covers vaccines with a fixed dollar limit which has been reached)</li> </ol>
$\checkmark$ Eligible for certain VFA vaccines if at least 19 years of age and
3. Has Medicare Part B, but NOT Part D, patient is eligible for:
<ul> <li>Hep A</li> <li>Hep B (if considered low risk for Hep B)</li> <li>HPV, MMR, Varicella, and Zoster</li> <li>Td (if no wound exposure) and Tdap</li> </ul>
4. Has Medicare Part D, but NOT Part B, patient is eligible for:
• Hep B, PCV20
2. Document Patient's Eligibility
2. Document Patient's Englointy
There are three important elements to include when you document a patient's eligibility:
There are three important elements to include when you document a patient's eligibility:
There are three important elements to include when you document a patient's eligibility: 1. Date of screening
There are three important elements to include when you document a patient's eligibility: 1. Date of screening 2. If patient is eligible for the Vaccines for Adults (VFA) and/or Bridge Access Program (BAP)
There are three important elements to include when you document a patient's eligibility: 1. Date of screening 2. If patient is eligible for the Vaccines for Adults (VFA) and/or Bridge Access Program (BAP) 3. If patient is eligible AND at least 19 years of age, document which of the criterion above is met
There are three important elements to include when you document a patient's eligibility: Date of screening I. If patient is eligible for the Vaccines for Adults (VFA) and/or Bridge Access Program (BAP) I. If patient is eligible AND at least 19 years of age, document which of the criterion above is met I. Use a Compliant Record Keeping System CAIR and Electronic Health/Medical Record (EHR/EMR) Note: if your parkice's EMR/EMR does not capture all the necessary screening elements, they may be

🔧 317 BAP VFA

#### 4. Communicate the Patient's Eligibility

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All staff should be knowledgeable of eligibility. Ensure practice protocols are in place so vaccinators know when 
to use 317-funded versus private vaccines.
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California Department of Public Health, Immunization Branch IMM-1476 (8/31/23

#### Step-by-step Instructions (includes options for reporting to CAIR)

#### 317 (VFA & BAP) Eligibility Screening Record for Adult Patients At each immunization visit, determine if patients are eligible for COVID-19 vaccines (if participating in the Bridge Access Program) and/or other routinely recommended vaccines through 317 funds (e.g., VFA). Patient Name (Last, First, MI): Date of Birth Provider Name Eligibility Criteria for 317-Funded Vaccines (e.g., VFA and BAP Eligible for VFA and/or BAP (COVID) vaccines if at least 19 years of age and 1. Has no insurance, or 2. Is underinsured (public or private health insurance does not cover all vaccines or covers vaccines with a fixed dollar limit which has been reached) Eligible for certain VFA vaccines if at least 19 years of age and 3. Has Medicare Part B, but NOT Part D, patient is eligible for: . Hen A Hep B (if considered low risk for Hep B) · HPV, MMR, Varicella, and Zoster · Td (if no wound exposure) and Tdap 4. Has Medicare Part D, but NOT Part B, patient is eligible for Hen R PCV20 **Document Patient's Eligibility** Write the screening date and check appropriate status. (Note: verification of responses is not required. Keep this record for at least 3 years and make it available to state or federal officials upon request). Eligible for Fligible for ✓Eligible for some ×Not Eligible for ×Not Eligible for VFA vaccines (Medicare Part B or (Medicare Part B or Date VFA and BAP VFA and BAP (COVID) (COVID) Part D only) Part D only) B&D or insurance

					pays for vaccines*)
			Part B Part D	Part B Part D	
			Part B Part D	Part B Part D	
			Part B Part D	Part B Part D	
			Part B Part D	Part B Part D	
			Part B Part D	Part B Part D	
			Part B Part D	Part B Part D	
* Note: adults enrol	led in Medi-Cal or M	ledi-Cal Managed Care are	considered insured.		
California Departm	ent of Public Health,	Immunization Branch			IMM-1226 (8/28/23)

Screening Record (for small practices with no EHR)

#### **BAP Resources**

#### Program Participation

- Requirements at a Glance
- Provider Operations Manual (POM)
- Required Vaccine Product Training

#### Eligibility Screening & Documentation

- BAP Eligibility Based on Insurance Status
- · 317 (VFA & BAP) Eligibility Screening and Documentation Requirements
- 317 (VFA & BAP) Eligibility Screening Record | Spanish
- VFA & BAP Patient Vaccine Poster | Spanish
- Vaccine Program Eligibility Guidelines (for Community Health Centers)
- CAIR Requirement for Documenting 317-Funded Vaccines

#### 2023-24 COVID-19 Vaccine Information

Please see EZIZ's COVID-19 Vaccine Resources for vaccine administration job aids plus materials from FDA, CDC and vaccine manufacturers.





### Commercialization at a Glance: Provider Transition Guide

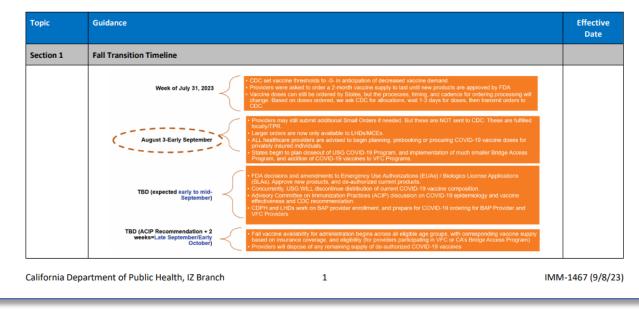
#### **Commercialization at a Glance: Provider Transition Guide**



California COVID-19 Vaccination Program

Commercialization is the transition of COVID-19 medical countermeasures—vaccines, treatments, and test kits—previously purchased by the U.S. Government (USG) to established pathways of procurement, distribution, and payment by both public and private payers. This guide summarizes the <u>HHS Commercialization Transition Guide</u>, <u>HHS Bridge Access Program Fact Sheet</u>, and CDPH guidance as the USG prepares to stop distributing COVID-19 vaccines and vaccines transition to the commercial market. Updated topics highlighted below. Sections include:

- Fall Transition Timeline
- Sunsetting of the Federal COVID-19 Vaccination Program
- Commercialization of COVID-19 Vaccines
- Anticipated Vaccination Schedule for the Fall



CDPH has created a multiple-page "Commercialization Provider Transition Guide".

The current information, and other resources, can be found on EZIZ.org using this link: <u>Commercialization at a Glance: Provider</u> <u>Transition Guide</u>

Updated: 9.8.23





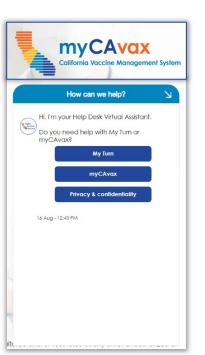
#### **Provider Call Center**

Dedicated to medical providers and Local Health Departments in California, specifically addressing questions about State program requirements, enrollment, and vaccine distribution.

- For myCAvax Help Desk inquiries: <u>myCAvax.hd@cdph.ca.gov</u>
- For My Turn Clinic Help Desk inquiries: <u>MyTurn.Clinic.HD@cdph.ca.gov</u>
- For all other inquiries: providercallcenter@cdph.ca.gov
- Phone: (833) 502-1245, Monday through Friday from 8AM–5PM

#### myCAvax

- Virtual Assistant resolves many questions but will direct you to the Provider Call Center queue for live assistance!
- Knowledge Center houses key job aids and videos that are updated every release. Once logged in, you can access job aids from the myCAvax homepage (or at various places throughout the system) using the links as shown below.





# **COVID-19 Therapeutics Resources**



Type of	Support	Description	Updated 8.31.23	
	Clinical Guidance	<b>U</b>	erapeutics Warmline: 1-866-268-4322 (866-COVID-CA) is no longe questions. For general question Therapeutics questions, @cdph.ca.gov	er staffed for
			page (provides general information for healthcare providers, allocati g facts sheets, and additional resources)	ons,
	General Information	CDPH COVID-19 Treatments Job	<u>Aid</u> (questions and answers for the public on COVID-19 therapeutic	s)
		COVID-19 Therapeutics Best Prac	tices Checklist (testing, prescribing, dispensing, and more)	
		Frequently Asked Questions docu	nent for clinics, providers, and pharmacists	
<u>~@</u>		Finding Providers and Test-to-Trea	Sites	
	Locating Resources	<ul> <li><u>COVID-19 Therapeutics Locat</u></li> </ul>	or (arcgis.com)	
		<ul> <li><u>Test-to-Treat</u> (hhs.gov)</li> </ul>		
	LHJ Therapeutics	Primary source for recorded webina JEOCuser54@cdph.ca.gov)	rs, slides, datasets and HPOP reporting information. (For access, e	mail
ٹ <mark>ت</mark>	SharePoint	<ul> <li><u>Therapeutic Weekly Email Up</u></li> </ul>	date files (SharePoint)	
<u> </u>		<u>CDPH Therapeutics HPoP Ac</u>	count Verification & Reporting information	
Ŕ	Questions	•	uestions, please email <u>COVIDRxProviders@cdph.ca.gov</u> Ining up new HPOP Accounts: please e-mail <u>CDPHTherapeutics@c</u>	dph.ca.gov



# **VFA Updates**



# **VFA Program Updates**

### Q4 VFA and 317 Ordering: Projected October 16-27, 2023

- VFA Providers: 40% reduction of HPV, PCV, and Zoster of April 2022 orders
- 317 LHDs: 40% reduction of HPV, PCV, and Zoster of Q2 2022 (April-June) average

### Winter VFA Webinar: Projected November

### VFA transition to MyCAVax: Early 2024

- Immunization Information System (IIS) Data Reports
  - Now Posted! (Q1 Q2 2023 Report)VFC Admin Site and MyVFCVaccines



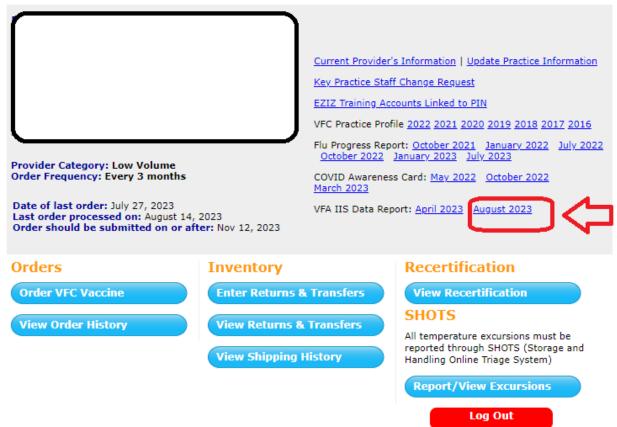
# **VFA Program Updates**

- > No open enrollments this year, 2023
- > VFA Compliance Visits:
  - Goal Review immunization-related practices & assess a clinic's compliance with VFA program requirements





#### MAIN PAGE





# Immunization Information System/ CAIR Data Reports Determine Your Rating:



#### Vaccine Accountability Requirements.

As a Vaccines for Adults (VFA) provider, you are **required** to document immunizations administered to VFA-eligible patients as "317" doses to the California Immunization Registry (CAIR) or Healthy Futures/ RIDE (which now shares data with CAIR). To help you meet this requirement, we have developed a CAIR immunization report for data from Quarter 1 (Q1) and Quarter 2 (Q2) of 2023 (January – June 2023). Providers must review VFA doses reported in the immunization registry before every VFA order or at least every six months to ensure VFA doses administered have been documented accurately. Please use this report to gain insight as to how your practice is doing at submitting 317 doses to the immunization registry. Then, determine next steps to improve data quality and increase the percentage of doses submitted as "317."

#### What does your CAIR data<sup>+</sup> look like from January through June 2023?



#### **NEW!** Data Interpretation:

Starting on January 1, 2024, the VFA Program will require that doses administered reported with each VFA order are based on doses recorded in CAIR as "317." According to this report, the value in Box B (Reported Doses Administered) should closely match the value in Box C (Doses in CAIR as "317"). If that is not the case, this will affect the doses the VFA Program approves for your clinic.

#### +Data Limitations:



"Doses Ordered" and "Reported Doses Administered" were obtained from your submitted 317 orders during the Q1 through Q2 2023 VFA order period. The doses in CAIR were administered January 1, 2023, through June 30, 2023. Only doses that were labeled as "317" were counted. Number of doses may vary as the databases are live data and can be updated after the data was extracted.

Ratings are	based	on	%	of	target
reached:					

EXCELLENT: ≥90% VERY GOOD: 71%-89% GOOD: 51%-70% NEEDS IMPROVEMENT: ≤50% Excellent: Great Job! You did an excellent job of submitting doses for Q1 through Q2 2023. Keep up the amazing work!

Good and Very Good: Congratulations! You submitted most of your doses correctly for Q1 through Q2 2023. Your practice is well-positioned to achieve future excellence. Take steps below to increase accurate data submission.

Needs Improvement: Based on doses reported administered, you submitted less than 50% of doses accurately for Q1 through Q2 2023 Take steps below to increase accurate data submission.

#### Steps to Increase the Accuracy of Doses Entered into CAIR or Healthy Futures:

Ensure you are submitting only your site's doses to the registry using the correct IIS ID. For sites submitting data through Healthy Futures, see contact information below if you have questions.

CAIR data exchange users:

- 1. Confirm with your EHR vendor that Vaccine Eligibility Category (HL7) code "V07" is correctly mapped.
- 2. Ensure staff know how to correctly record 317 vaccine eligibility in your EHR for every administered dose.
- Confirm 317 doses are correctly submitted via data exchange by running a "doses administered" report. Watch this VFA webinar (at 30 mins. 54 sec), consult this guide, and visit CAIR for additional training.
- 4. If staff need access to CAIR, request a Data Exchange Quality Assurance (DX QA) account at CAIR Account Update.
- 5. Contact your Local Data Exchange Representative if you have further questions.

#### CAIR manual entry users:

- If your site uses the CAIR inventory feature, make sure your CAIR Power User selects the "317" "Funding Source" when creating vaccine lots in CAIR. If the "317" funding source is not available to select, contact your Local CAIR Representative.
- Make sure staff selects "317 Vaccine Eligibility" when recording an administered dose in CAIR. If the 317 Vaccine eligibility is not available to select, contact your Local CAIR Representative.
- If staff need access to CAIR, have your authorized site representative request new user accounts in the CAIR Account Update system.
- 4. For more information about recording 317 doses accurately, watch this VFA webinar (at 16 mins. 12 sec) and view these guides and videos. Contact your Local CAIR Representative if you have further questions.

Healthy Future users: Phone: 209-468-2292 Fax: 209-462-2019 Email: support@myhealthyfutures.org URL: http://www.myhealthyfutures.org

# Immunization Information System/ CAIR Data Reports

### IIS/CAIR Data Reports

- 9/15 Communication sent to providers:
  - Starting on January 1, 2024, the VFA Program will require that doses administered reported with each VFA order are based on doses recorded in CAIR as "317." Ideally, the number of reported doses administered and the doses in CAIR as "317" should closely match. If that is not the case, this will affect the doses the VFA Program approves for your clinic. Please work with your EHR vendor, Local CAIR Representative, and/or CAIR Data Exchange Specialist to identify and resolve issues as soon as possible.
- 400+ providers have a 0% grade
- **NEW:** Field staff to review report during VFA Site Visits
- NEW Webpage: Guidance on 317/VFA CAIR Documentation Requirement



# **VFA Program Updates: RSV**

### Reviewing VFA Ordering Policy for 2023-2024 Fiscal Year

- CDC Contract Price for RSV Vaccines still TBD
- Review CAIR data on demand of RSV vaccines in the following months
- Plans to survey LHDs and VFA providers on RSV vaccine plans
- Anticipate making limited amounts available in January 2024
- The VFA Program will make any official announcements as more information becomes available.



• **NEW** - <u>IMM-1476, 317</u> <u>Eligibility Screening and</u> <u>Documentation</u> <u>Requirements</u>

#### 317 (VFA & BAP) Eligibility Screening

& Documentation Requirements

317 BAP VFA

#### 1. Screen for Eligibility

Eligibility screening must be conducted prior to the administration of any 317-funded vaccine (e.g., Vaccines for Adults and Bridge Access Programs). Eligibility is self-reported by the patient and verification of eligibility can be obtained verbally from the patient.

#### Eligible for VFA and/or BAP (COVID) vaccines if at least 19 years of age and

#### 1. Has no insurance, or

Is underinsured (public or private health insurance does not cover all vaccines or covers vaccines with a fixed dollar limit which has been reached)

#### Eligible for certain VFA vaccines if at least 19 years of age and

- 3. Has Medicare Part B, but NOT Part D, patient is eligible for:
- Hep A
- Hep B (if considered low risk for Hep B)
- HPV, MMR, Varicella, and Zoster
- Td (if no wound exposure) and Tdap

Has Medicare Part D, but NOT Part B, patient is eligible for:
 Hep B, PCV20

#### 2. Document Patient's Eligibility

There are three important elements to include when you document a patient's eligibility:

- 1. Date of screening
- 2. If patient is eligible for the Vaccines for Adults (VFA) and/or Bridge Access Program (BAP)
- 3. If patient is eligible AND at least 19 years of age, document which of the criterion above is met

#### 3. Use a Compliant Record Keeping System

 CAIR and Electronic Health/Medical Record (EHR/EMR) Note: if your practice's EMR/EHR does not capture all the necessary screening elements, they may be documented in the system's notes section.

CAIR and <u>317 Eligibility Screening Form</u> (IMM-1226)

Make sure to maintain patient eligibility screening records for a minimum of 3 years. <u>Refer to the 317 CAIR</u> Documentation Requirement.

#### 4. Communicate the Patient's Eligibility

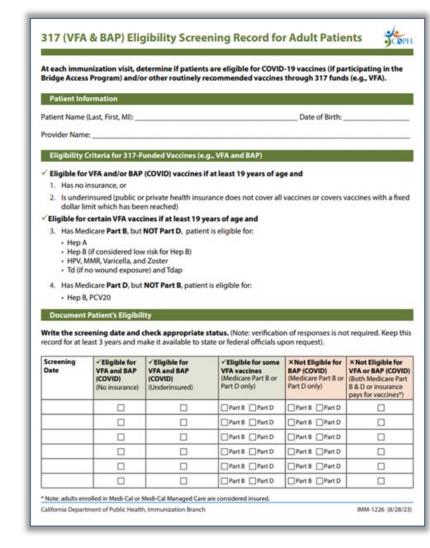
All staff should be knowledgeable of eligibility. Ensure practice protocols are in place so vaccinators know when to use 317-funded versus private vaccines.

California Department of Public Health. Immunization Branch

IMM-1476 (8/31/23)



• UPDATED – <u>IMM-1226</u>, <u>317 Eligibility Screening</u> <u>Record for Adult Patients</u>





• UPDATED – <u>IMM-1222,</u> <u>Vaccine Eligibility</u> <u>Guidelines for Community</u> <u>Health Centers</u>

Program	VFC Vaccines for Children Program	VFA Vaccines for Adults Program	BAP Bridge Access Program
Funding	Federal entitlement program for eligible children. Funds are used to pay for vaccines recommended by ACIP.	Limited federal grant (317) funds for populations not served by the VFC program to purchase selective adult vaccines.	Limited federal grant funds for adult populations to maintain access to COVID-19 vaccines through existing public health infrastructure
Age and Eligibility	Children, Birth-18 years: • Medi-Cal/CHDP eligible • Uninsured (no health insurance) • American Indian or Alaskan Native	Adults, 19 years and older: • Uninsured (no health insurance) • Underinsured (vaccines are not covered by insurance)	Adults, 19 years and older: - Uninsured (no health insurance) - Underinsured (vaccines are no covered by insurance)
Vaccines	<ul> <li>COVID-19</li> <li>DTaP</li> <li>Hepatitis A</li> <li>Hepatitis B</li> <li>Hib</li> <li>HPV</li> <li>Influenza</li> <li>Meningococcal Conjugate (MenACWY)</li> <li>Meningococcal B (MenB)</li> <li>MMR</li> <li>Pneumococcal Conjugate (PCV15 and PCV20)</li> <li>Pneumococcal Polysaccharide (PPSV23)</li> <li>Polio (IPV)</li> <li>Rotavirus</li> <li>Td, Tdap</li> <li>Varicella</li> </ul>	Hepatitis A     Hepatitis A     Hepatitis B     HPV     Meningococcal Conjugate (MenACWY)     MMR     Pneumococcal Conjugate (PCV20)     Td (ONLY when Tdap is not indicated)     Tdap     Varicella     Zoster     For more details about Medicare     Part B and/or D eligibility, see IMM-1247.	• COVID-19
Ordering Website	,&myvFcvaccines	@myvFCvaccines	California Vaccine Management System



Vaccine and Clinic Eligibility Guidelines by Europing Source, continued

• UPDATED- IMM-1142, Vaccine and Clinic Eligibility by Funding Source for LHDs

Program	Vaccines for Children Program (VFC)	Bridge Access Program (BAP)	317 Local Health Dept.	Vaccines for Adults Program (VFA)	State General Funds (SGF)
Vaccines	COVID-19     DTaP     Hepatitis A     Hepatitis B     Hib     Hib     HPV     Influenza     Meningococcal Conjugate     (MenACWY)     Meningococcal B (MenB)     MMR     Pneumococcal Conjugate     (PCV15 and PCV20)     Pneumococcal Polysacharide     (PFSV23)     Polio (IPV)     Rotavirus     RSV (coming soon)     Td, Tdap     Varicella	- COVID-19	Hepatitis A     Hepatitis B <sup>3</sup> HPV     HPV     Meningcocccal Conjugate     (MenACWY)     MMR     Pneumococcal Conjugate     (PCV20)     Td onjy when Tdap is not     indicated <sup>4</sup> Tdap     Varicella     Zoster	Hepatitis A     Hepatitis A     Hepatitis B     HPV     Meningococcal Conjugate     (MenACVVY)     MMR     Pneumococcal Conjugate     (PCV20)     Td only when Tdap is not     indicated     Tdap     Varicella     Zoster	Influenza     Tdap (children only)
Ordering Website		myCAvax	#my <b>vFCvaccines</b>	#my <b>VFCVACCINES</b>	myCAvax
		California Vaccine Management System			California Vaccine Manager System for flu vaccine (refer LHD for other vaccines

1. Fully insured children and adults are not eligible to receive 317 vaccine routinely (adults enrolled in Medi-Cal/Medi-Cal managed care plans are considered fully insured). 317 vaccine may not be used in travel clinic settings. 2. Depending on funding, State General Fund vaccines may vary.

3. Adults with Medicare Part B (without Part D) are eligible if they are at low-risk for Hepatitis B. See VFA Eligibility Based on Insurance Status (EZIZ.org/assets/docs/IMM-1247.pdf) for more details

4. Adults with Medicare Part B (without Part D) are eligible if they are receiving Td as a routine vaccine (i.e., do not have a wound). See VFA Eligibility Based on Insurance Status (EZIZ.org/assets/docs/IMM-1247.pdf) for more details.

IMM-1142 (9/12/23) Page 2

V	acci	nate
	A	LL 58

#### Vaccine and Clinic Eligibility Guidelines by Funding Source

For Health Departments and CDPH Approved Health Department Authorized Sites (Effective 10/01/2023 through 9/30/2024)

Program	<b>WFC</b>	BAP	317	VFA	SGF
	Vaccines for Children Program	Bridge Access Program	Local Health Departments <sup>1</sup>	Vaccines for Adults Program	State General Funds <sup>2</sup>
Funding	VFC-Federal entitlement program for eligible children. Funds are used to pay for vaccines recommended by ACIP and approved into the VFC program.	BAP-Limited federal funds (Section 317) for eligible adult populations to maintain access to COVID-19 vaccines through existing public health infrastructure.	317-Limited federal funds (Section 317) used to pay for adult vaccines recommended by ACIP and support limited vaccine supply for outbreak activities via Public Health Departments.	317-Limited federal funds (Section 317) used to pay for adult vaccines recommended by ACIP and included in the VFA Program.	Limited state funds for the purchase of vaccines to prevent respiratory illness.
Age and Eligibility	Children Birth-18 years: • Medi-Cal/CHDP eligible • Uninsured (no health insurance) • American Indian or Alaskan Native • Underinsured: health insurance does not cover vaccines (ONLY if the LHD has a FQHC or RHC designation).	Adults 19 years and older: • Uninsured (no health insurance) • Underinsured (vaccines are not covered by insurance)	Adults 19 years and older:         Uninsured adults (no health insurance)         Underinsured adults (vaccines are not covered by insurance)         Insured exceptions-Adults part of outbreak control, post-exposure prophylakis, or disaster relief efforts as approved by CDPH & LHDs.         Household contacts or sexual contacts of HBsAg+ pregnant woman	Adults 19 years and older: • Uninsured adults (no health insurance) • Underinsured adults (vaccines are not covered by insurance)	All ages: <ul> <li>No restrictions</li> </ul>
Clinic Type	<ul> <li>Federally Qualified Health Center (FQHC), Rural Health Center (FQHC), and State-licensed</li> <li>Community Health Centers</li> <li>Health Department and CDPH Approved Health Department</li> <li>Authorized Sites</li> <li>Juvenile halls/youth correctional facilities</li> <li>Private providers, School-based clinic, Hospitals, Pharmacies (pilot program)</li> </ul>	Health Department Clinics     Federally Qualified Health Center (FQHC), Rural Health Center (RHC)     Tribal Clinics     Indian Health Services     Limited sites designated by Local Health Department as BAP Provider	Health Department and CDPH Approved Health Department Authorized Sites (HDAS)     Juvenile halls/youth correctional facilities (for 19-25 years of age)	<ul> <li>VFC enrolled Federally Qualified Health Center (FQHC), Rural Health Center (RHC)</li> </ul>	State-licensed Community Health Centers Federally Qualified Health Center (FQHC), Rural Health Center (RHC) Health Department and CDPH Approved Health Department Authorized Sites (HDAS) Private provider School-based clinic

JCDPH

Thank you! Lindsay.Reynoso@cdph.ca.gov my317vaccines@cdph.ca.gov



# Immunization Schedule Updates, 10/4/23

- In case you were not aware, CDC has issued updated ACIP schedules adding an addenda listing the new or updated 2023 recommendations for COVID-19 vaccine, RSV (Abrysvo vaccine, Nirsevimab monoclonal antibody), Poliovirus vaccine, Influenza vaccine, and Pneumococcal (PCV15, PCV20) vaccines.
- <u>Recommended Child and Adolescent Immunization Schedule,</u>
- United States, 2023
- <u>Recommended Adult Immunization Schedule</u>, United States,
- 2023



# SoCal Region Staff Contacts

- Mary Rebbert, SR Field Representative <u>Mary.Rebbert@cdph.ca.gov</u> 619-838-6360
- Melissa Thun, JR Field Representative <u>Melissa.Thun@cdph.ca.gov</u> 213-407-2878
- Manny Mones, Field Representative San Diego County & Imperial County <u>Manny.Mones@cdph.ca.gov</u> 619-609-6206
- Carol Connell, Field Representative San Bernardino County <u>Carol.Connell@cdph.ca.gov</u> 619-772-1935
- Michelle Miranda, Field Representative SoCal Region Float <u>Michelle.Miranda@cdph.ca.gov</u> 619-577-2247



- Emma Gace, In Training
- Raelene Pellos, In Training

### COVID-19 Vaccine California Bridge Access Program







Naomi Silva MPH, RN

Epidemiology and Immunization Services Branch

**Quality Assurance Specialist | Vaccine Management Program** 

SANDIEGOCOUNTY.GOV/HHSA



# **COVID-19 Vaccine Commercialization**



### What is commercialization?

 Commercialization is the transition of COVID-19 vaccines from purchase by the U.S. Government into more traditional pathways of procurement, distribution, and payment.

### How can COVID-19 vaccine providers prepare for commercialization?

- Screen and assess patient population by insurance type, age and vaccination status.
- Order and administer COVID-19 vaccine through the Vaccines for Children (VFC) program for VFC eligible patients 0-18 years of age.
- Enroll, order and administer COVID-19 vaccine through the California Bridge Access program for uninsured adults 19 years and older.
- Purchase COVID-19 vaccine for insured adults 19 years and older if serving an insured adult patient population.

# California Bridge Access Program for COVID-19 Vaccine



### What is the Bridge Access Program (BAP)?

- Centers for Disease Control and Prevention's Bridge Access Program will provide eligible providers with no-cost COVID-19 vaccine to under/uninsured adults (19 years and older) after these products move onto the commercial market in the Fall of 2023.
- The California Bridge Access Program is funded from **September 2023** to **December 2024**.
- **Eligible** providers include Public Health Departments, Federally Qualified Health Centers, Tribal/Rural Health Services, and Indian Health Services.
- A National Vaccine for Adults program is anticipated to continue providing vaccines for **uninsured** adults in the United States at the conclusion of the BAP.



# California Bridge Access Program for COVID-19 Vaccine in San Diego



### What will the Bridge Access Program (BAP) look like in San Diego County?

- Public Health Component of CA BAP
  - Anticipate 85 active providers
    - County of San Diego Public Health Centers and the Immunization Unit's Vaccine Distribution Center are included in this number.
- Pharmacy Component of CA BAP
  - CVS, Walgreen's and other independent and chain pharmacies are participating
  - Pharmacy receives reimbursement for vaccination of **uninsured** patients.
  - Active locations are required to display availability on Vaccines.gov.
- Allocations (based on estimates of uninsured adults)
  - Public Health Component
    - California: 380,000 doses allocated.
    - **San Diego**: 23,920 doses available to order via myCAvax.
  - Pharmacy Component
    - **California**: 380,000 doses available for reimbursement.

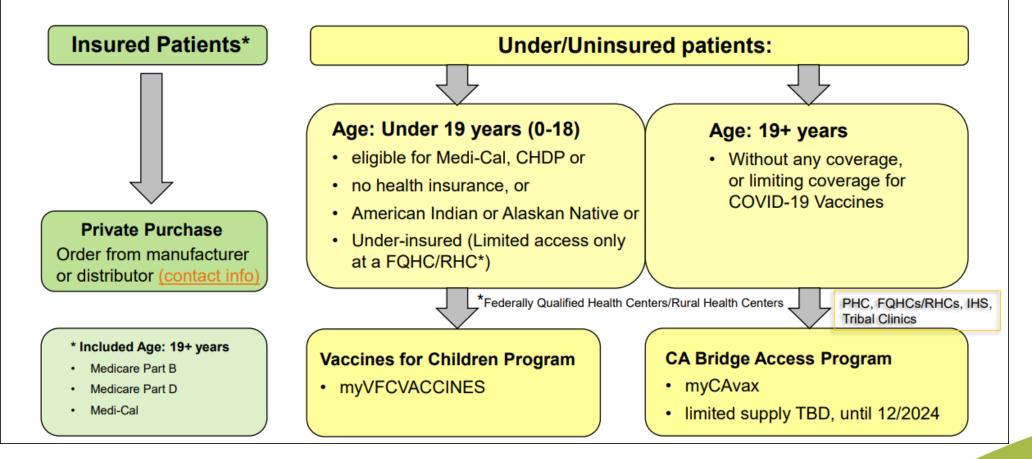
SANDIEGOCOUNTY.GOV/HHSA

# **COVID-19 Vaccine Ordering Pathways**



### Post Commercialization: Vaccine Access & Ordering

Follows more traditional pathways for purchasing vaccines



# California Department of Public Health (CDPH) Resources



COVID-19 Commercialization at a Glance – Providers

Vaccine and Clinic Eligibility Guidelines by Funding Source



Who Can Receive Low-Cost Immunizations at Health Departments

**BAP Program Overview** 

**BAP Requirements at a Glance** 





# **THANK YOU**

SANDIEGOCOUNTY.GOV/HHSA

The Public Health Services department, County of San Diego Health and Human Services Agency, has maintained national public health accreditation, since May 17, 2016, and re-accredited by the Public Health Accreditation Board on August 21, 2023.



# State-Purchased Influenza Vaccine Program Update

Araceli Montera, MPH

State-Purchased Influenza Vaccine Admin Coordinator

October 6, 2023



## 2023-2024 State-Purchased Influenza Program

Provider Resource Webpage

- Vaccine Incident Reporting Process
- Weekly Report Forms
- Mass Vaccination Forms
- Vaccine Information Statement
- Temperature Log Forms
  - Refrigerator temperature logs
  - Vaccine Transport logs
  - CAIR disclosure forms

Please see links b vaccine.	low for important forms and other resources to help y	you manage state-funded influenza	
2	023-2024 Annual State-Purchased Influ	enza Training Map	
• 2023-2024	nnual State-Purchased Influenza Training Map		
	t State-Purchased Influenza Vaccine		
Packet Che     Agreement     State-Purc     Vaccine for     Refrigerator	r State Influenza Vaccine Program Exlist State Influenza Vaccine of use for CDPH Influenza Vaccine ased Influenza Vaccine Management Plan Children Vaccine Management Plan Temp Logs: Fahrenheit   Celsius tate-Purchased Influenza Vaccine Annual Provide	er Training (Flyer)	
Training			
<ul> <li>State Flu V</li> </ul>	ccine Program Annual Requirements Training Sli ccine Program Annual Requirements Training Sli d Influenza Vaccine Program Requirements Train	des Part 2	
Receiving State I	lu Vaccine		
<ul> <li>Refrigerate</li> <li>Vaccine Piere</li> </ul>	for Transporting Refrigerated Vaccine I Vaccine Transport Log k-Up from the County Operations Center /accine Pick-Up from the County Operations Cent aining Flyer	ter-COC	
Managing State I	u Vaccine Inventory		
<ul> <li>Refrigeratories</li> <li>Fahr</li> <li>Cels</li> <li>When to Display</li> </ul>			
Weekly Report F		,	
Outreach E	der 2023-2024 State Flu Program Weekly Report F rent Short 2023-2024 State Flu Program Weekly R ovider 2023-2024 State Flu Program Weekly Repo	eport Form - Fillable	
Resources for O	treach Vaccination Events		
and Arabic) Hourly Ten Storage an Medical So Department	hation Registration and CAIR Disclosure Form Te perature Log for Outreach Events I Handling Reminders for Vaccination Events and id Waste Security—Frequently Asked Questions z of Environmental Health Medical Waste at Tempo Vaccination Registration Form (English)	Transporting Vaccine and Best Practices	ish,
	. <b>J</b> C	FSAN	
	JHIY		

### **Program Enrollment**



#### 2023-2024 State-Purchased Influenza Vaccine Packet Checklist

Please use this checklist to collect all program requirements. Checklist items should be submitted for each facility. You do not have to return this checklist, please make every attempt to name items accordingly and send all required documentation at one time using the online Qualtrics link given to your clinic. Contact the State Flu Vaccine Program Coordinat <u>HISA.CountyInvaccine@stounty.ca.gov</u> or phone (613) 36

Completed and Signed Agreement for Use of CDPH-Pur

- □ Vaccine Management Plan (VMP) with signature page.
- State-Purchased Influenza VMP Or Vaccines for Ch
- If you are using the VFC VMP and have more than c which refrigerator will store the State Purchased In
- <u>Color</u> photos of your vaccine *refrigerator where State*-(front, inside with door open, & label with serial numb)
- <u>Color</u> photos of the front and side of each data logger (in clearly visible, that will be used for the State Purchased
- Data logger report displaying current, MIN and MAX ten settings for the past 30 days (F° | C°)
- □ Refrigerator temperature logs, displaying current, MIN (F°|C°)
- Note: Data logger reports and refrigerator temp
- Copy of calibration certificates for main and backup data
- Confirmation of Scheduling for the Annual State Influer training by the Vaccine Coordinator and Backup Coordin
- Completion of the Annual State Influenza Vaccine Progra
   Vaccine Coordinator and Backup Coordinator
- □ Certificates of Completion on the EZIZ annual required t Backup Vaccine Coordinator, available here: <u>https://eziz</u> show completion dates of 12/15/2022 or later to be val
- Storing Vaccines
- Storing vaccines
   Monitoring Storage Unit Temperatures
- Conducting a Vaccine Inventory

\*When purchasing new data loggers, new devices must be a temperature data since the device was last reset; summary i temperatures, total time out of range (if any), and alarn set Excel spreadsheets are not acceptable. Plaes see Data logg Data Loggers – California Vaccines for Children (VFC) (eziz.or



#### State-Purchased Influenza Vaccine Packet Submission

#### Use this form to submit all program requirements. Each item must be

submitted for <u>each facility</u>. Contact the State-Purchased Influenza Vaccine Program at

HHSA.CountyFluVaccine@sdcounty.ca.gov or by phone (619) 366-7128.

Please have the following documentation ready for upload:

- Agreement for Use of CDPH-Purchased Influenza Vaccine (2023-2024)
- Vaccine Management Plan (VMP) with Signature Page
- Vaccine Refrigerator Color Photos
- Front
- Inside with door open
- Label with the unit serial number
  Primary and Back-up Data loggers Color Photos
- Fronts
- Sides with serial number
- Calibration certificates
- Data Logger Report
- Must show:
  - Alarm settings
  - Current temperature
  - Min and Max temperatures
  - Most recent 30 days
- Refrigerator Temperature Log. Must match data logger timeframe.
- EZIZ Completion Certificates taken after 12/01/2022.
- The following completion certificates for the Vaccine Coordinator and Back-up Coordinator:
  - Storing Vaccines
  - Monitoring Storage Unit Temperatures
- Conducting a Vaccine Inventory

### **Enrollment Packet**

### Received: 108

### Approved in myCAvax : 79





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# **Program Vaccine Incident Reporting Process**

Manufacturer stability report(s),

HHSA.CountyFluVaccine@sdcounty.ca.gov

If you have any questions, please email

Form

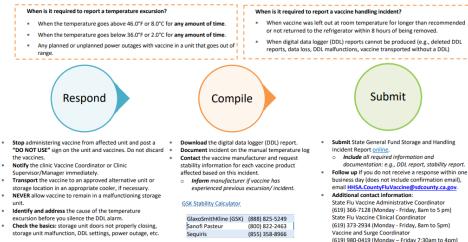
#### Temperature Excursions and Vaccine Handling

- Storage and Handling Incident Reporting Process
- State Flu Vaccine Storage and Handling Incident Report Form

#### State-Purchased Influenza Vaccine Storage and Handling Incident Reporting Process

Temperature excursions and vaccine handling incidents may damage vaccines and impact vaccine viability. All storage and handling incidents must be documented and reported to the State-Purchased Influenza Vaccine Program. The information reported is used to determine whether the vaccine remains viable and can be safely administered to patients. Timely and accurate reporting of all incidents is essential to a successful determination of vaccine viability.

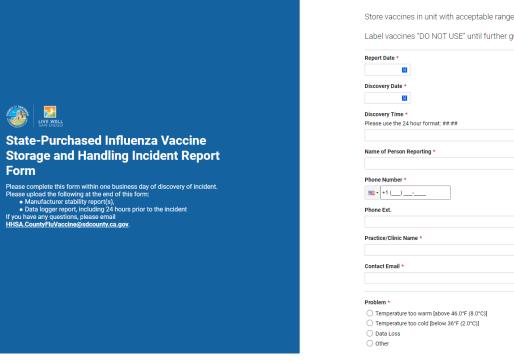
This information refers to state-purchased influenza vaccine only. Incidents involving Vaccines for Children (VFC) products, or vaccine from any other funding source stored in the affected storage unit, must be reported to the appropriate program per specific reporting procedures. Do NOT report state-purchased influenza vaccine storage and handling incidents to VFC/SHOTS.



Epidemiology and Immunization Services Branch

(619) 980-0419 (Monday - Friday 7:30am to 4pm)

Updated July 26, 2023







Label vaccines "DO NOT USE" until further guidance.

Instructions:

ry Date *
ry Time *
ise the 24 hour format: ##:##
Person Reporting *
r cison reporting
umber *
1()
xt.
AC.
/Clinic Name *
Email *
*
<b>x</b>
perature too warm [above 46.0°F (8.0°C)]
merature too cold [helow 26°E (2.0°C)]

## Annual Flu Training 2023-2024 Season



- Tuesday November 7, 2023
   ✓New Incoming Staff
  - ✓ Changes in Vaccine Coordinator or Back-Up Coordinator
  - ✓Program knowledge
- □ Register in Advance
- Provide the information of the intended person during the registration process.



### For more information contact:

State Flu Vaccine Team HHSA.CountyFluVaccine@sdcounty.ca.gov

# 2023-2024 State-Purchased Influenza Program Update

### Allocation from CDPH

- Total Doses: 50,710
  - Fluarix PF Syr: 41,140
  - Fluzone MDV: 5,000
  - Fluad Syr: 3,070
  - FluMist: 1,500

### Allocated to SGF Providers

- Fluarix PF Syr: 36,070 (94%)
- Fluzone MDV: 5,000 (100%)
- Fluad Syr: 2,940 (96%)
- FluMist: 1,500 (100%)

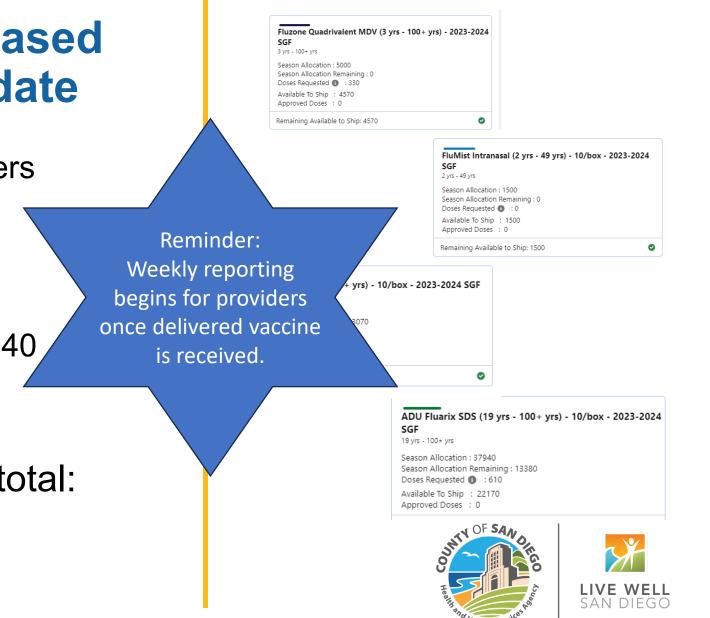




# 2023-2024 State-Purchased Influenza Program Update

Vaccine Orders for SGF Providers

- Received Orders: 68
- Total Doses: 9,040
  - Fluarix PF Syr: 8,280
  - Fluzone MDV Doses: 740
  - Fluad Syr: 0
  - FluMist: 20
- On hand with providers total: 9,040



Jhank you

Araceli Montera, MPH State Influenza Vaccine Admin Coordinator O: (858) 505-6724 | C: (619) 366-7128 <u>HHSA.CountyFluVaccine@sdcounty.ca.gov</u>





# Upcoming Events



- Wednesday, 10/25 Vaccinations for Adults at Long Term Care Facilities Virtual Summit
- Thursday, 11/9 Immunization Skills Institute







