Welcome to Talking with Patients about COVID-19 Bivalent Booster Doses





September 8, 2022

12:00PM-1:00PM





Housekeeping



For Panelists: Please remember to mute yourself when not speaking.



For Attendees: This webinar is being recorded. Please access today's slides and recording through the following link: https://eziz.org/covid/crucialconversations



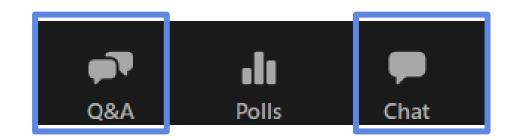
Please use "Q&A" to ask questions.

For post-webinar questions, contact rachel.jacobs@cdph.ca.gov.



Questions & Answers

During today's session, please use the Q&A panel to ask your questions.





Resource links will be dropped into, "Chat"



Agenda: Thursday, September 8, 2022

No.	Item	Speaker(s)	Time (PM)
1	Welcome	Rachel Jacobs (CDPH)	12:00 – 12:05
2	Talking with Patients about Bivalent Booster Doses	Ilan Shapiro, MD, MBA, FAAP, FACHE	12:05 – 12:40
Questions & Answers			12:40 – 12:55
3	Resources, Poll, and Wrap-Up	Rachel Jacobs (CDPH)	12:55 – 1:00



Webinar Objectives

Participants will learn:

- The evolving landscape of COVID-19 variants
- Updated recommendations for bivalent booster doses
- Communication strategies for effective patient conversations



Poll: CDPH appreciates your feedback!

How confident are you in your ability to effectively discuss COVID-19 bivalent booster doses with patients?

- Very confident
- Confident
- Somewhat confident
- ☐ Slightly confident
- ☐ Not confident

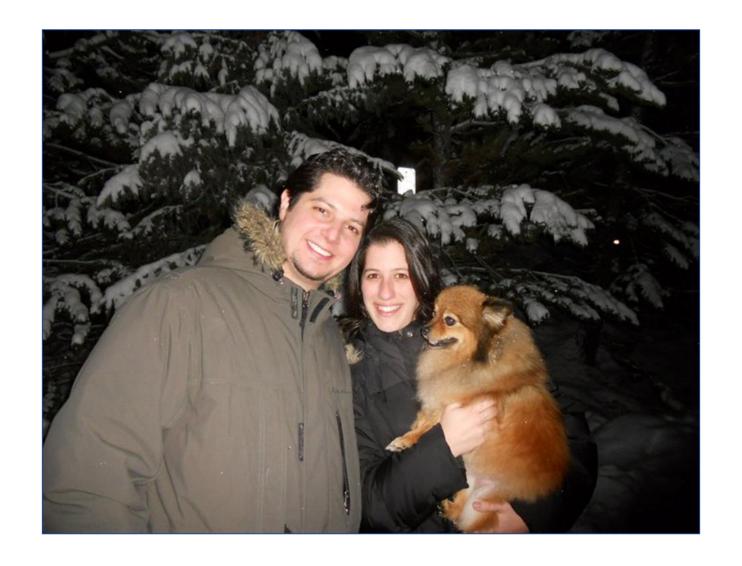


Talking with Patients about Bivalent Booster Doses

Ilan Shapiro, MD, MBA, FAAP, FACHE #VacunateYa









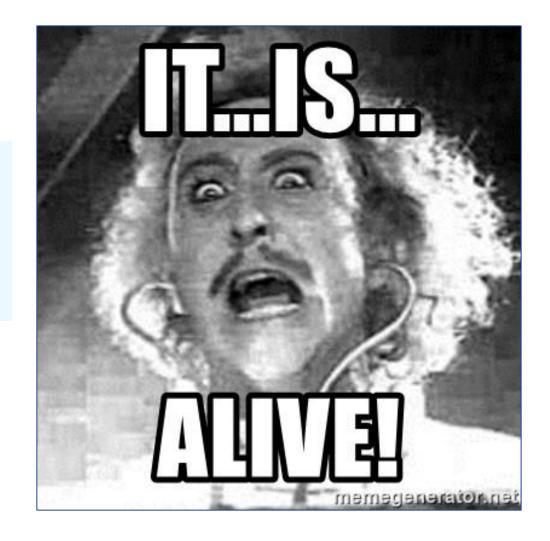
How Did We Get Here?





Changes in COVID-19

- Let's talk about the percent: did it change?
- And now... what?



Some Important Questions

- Are we going to have multiple "boosters"?
- Are they going to be updated all the time?
- Do we need to move to...?





Where Are We Now? Bivalent Booster Dose Authorization & Recommendations

August 31, 2022
FDA Emergency Use
Authorization for Pfizer
Bivalent, Covid-19
vaccine for use as a
booster in individuals
12 and older and
Moderna Bivalent,
Covid-19 Vaccine for
use as a booster in 18
and older

September 1, 2022
ACIP meeting, CDC
issued
recommendation

September 3, 2022
Western States
Scientific Safety
Review Workgroup
Recommendation



Booster Dose Vaccination Trends: California

as of September 1, 2022

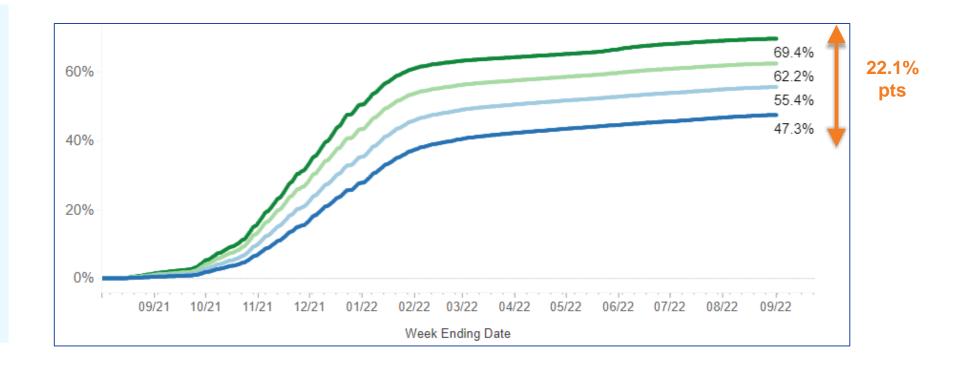
- 72% of Californians
 have received their
 primary series; 58.8% of
 eligible Californians
 have received a booster
 dose.
- Graph shows booster vaccination rates by county
 - Darker blue = higher rates of vaccination



Disparities in Booster Dose Vaccination Rates: California

as of September 1, 2022

- Disparities in vaccination coverage rates by Vaccine Equity Metric Quartile
- People living in the Most Healthy Places are much more likely to have received a booster dose than people living in Least Healthy Places





What Do We Know?

- The authorized bivalent COVID-19 vaccines, or updated boosters, include
 - an mRNA component of the original strain to provide an immune response that is broadly protective against COVID-19 and
 - an mRNA component in common between the omicron variant BA.4 and BA.5 lineages to provide better protection against COVID-19 caused by the omicron variant.
- Individuals who receive a bivalent COVID-19 vaccine may experience side effects commonly reported by individuals who receive authorized or approved monovalent mRNA COVID-19 vaccines.



What Do We Know? Bivalent Booster Dose Authorization & Recommendations

- People ages 12 years and older are recommended to receive 1 age-appropriate bivalent mRNA booster dose after completion of any Food and Drug Administration (FDA)approved or FDA-authorized monovalent primary series or previously received monovalent booster dose(s).
 - Updated boosters can be administered at least 2 months after completion of the primary series or at least 2 months after the last monovalent booster dose
 - Bivalent booster recommendation is the same for immunocompromised and immunocompetent people



What Do We Know? Bivalent Booster Dose Authorization & Recommendations

- Individuals 18 years of age and older are eligible for a single booster dose of the
 Moderna COVID-19 Vaccine, Bivalent if it has been at least two months since they have
 completed primary vaccination or have received the most recent booster dose with any
 authorized or approved monovalent COVID-19 vaccine.
- Individuals 12 years of age and older are eligible for a single booster dose of the
 <u>Pfizer-BioNTech</u> COVID-19 Vaccine, Bivalent if it has been at least two months since
 they have completed primary vaccination or have received the most recent booster dose
 with any authorized or approved monovalent COVID-19 vaccine.

What Do We Know? Deauthorization of Monovalent Booster Doses

- The new booster recommendation replaces all prior booster recommendations for this age group.
 - Monovalent mRNA vaccines are no longer authorized as a booster dose for people ages 12 years and older.
- Children ages 5–11 years are recommended to continue receiving 1 monovalent mRNA booster dose if eligible.
- Only monovalent vaccines are approved or authorized for primary series doses.
- J&J vaccine remains available as first booster for <u>certain people</u>.

Booster "Reset"

- Recommendations are now simplified
- Change from dose counting to 1 bivalent booster for everyone eligible
- If eligible, a bivalent booster should not be denied based on total number of doses.

Vaccination history	\rightarrow	Next dose
Primary series	At least 2 months	1 bivalent booster dose
Primary series + 1 booster	At least 2 months	1 bivalent booster dose
Primary series + 2 booster	At least 2 months	1 bivalent booster dose



Summary: Clinical Trial Data

- Bivalent booster doses of both Moderna & Pfizer-BioNTech COVID-19 vaccines increase immune response in those who have completed a primary series and a previous booster
 - Compared with ancestral booster dose
 - Demonstrated superior response to Omicron
 - Demonstrated non-inferior response to ancestral strain
- Similar reactogenicity profile to primary series (and ancestral booster dose)
- Data from clinical trial limited in size, age, and bivalent booster type



Bivalent COVID-19 Vaccines: Data to Inform Recommendations

- Experience from using COVID-19 vaccine mRNA platform for nearly 2 years and over 600 million doses in the United States alone
 - Extensive vaccine effectiveness studies as well as robust post-authorization safety data across multiple platforms
- Clinical (human) data from bivalent COVID-19 vaccines in >1700 persons
 - Includes bivalent vaccines with Beta and Omicron variants, both from manufacturers and NIH studies
 - Over 1400 individuals received bivalent vaccine with Omicron component specifically
 - While there are subtle differences in mutations between BA.1 and BA.4/BA.5 spike protein sequences,
 do not anticipate differences in safety or reactogenicity of vaccines based on these limited mutations
 - Overall composition of the vaccine as well as total antigenic load are the same as current booster doses
- Antigenic cartography and antibody studies
- Modeling data



Summary: Balance of Benefits and Harms for Bivalent Booster Doses

- Bivalent booster dose of both Moderna & Pfizer-BioNTech COVID-19 vaccines increases
 immune response in those who have completed a primary series and a previous booster
- Similar reactogenicity profile to primary series and ancestral booster dose
- Myocarditis risk following a bivalent booster dose is unknown, but anticipate similar risk to what is seen after monovalent booster doses
- Modeling projects more hospitalizations and deaths averted when booster doses are recommended for persons ≥18 years compared to only persons ≥50 years, and when the booster campaign begins in September compared to November 2022
- Benefits and harms for the U.S. population are best assessed when clinical trial and study populations are optimally representative of the U.S. population



Looking to the Future

- Pfizer is planning to submit an application for an Omicron-adapted bivalent vaccine for children 5 through 11 years of age to the FDA in early October.
- Bivalent vaccine for children 6 months through 4 years application to follow



Q: Can I get a bivalent booster dose now, if I just recently got my second monovalent booster?





A: You will need to wait until two months have passed since your last booster dose. Get the bivalent booster shot as soon as you are eligible, and you will have expanded protection!

Q: How long do I need to wait to get the bivalent booster if I have had COVID-19?





A:

- People with known current SARS-CoV-2 infection should defer any COVID-19 vaccination, including booster vaccination, at least until recovery from the acute illness (if symptoms were present), and <u>criteria</u> to discontinue isolation have been met.
- People who recently had SARS-CoV-2 infection may consider delaying a primary series dose or booster dose by 3 months from symptom onset or positive test (if infection was asymptomatic).

Q: Can I receive the COVID-19 bivalent booster and the flu vaccine together?





A: Yes. Extensive experience with non-COVID-19 vaccines has demonstrated that immune response and adverse event profiles are generally similar when vaccines are administered simultaneously as when they are administered alone.

Coadministration with Flu Vaccine

- Providers should offer influenza and COVID-19 vaccines at the same visit, if eligible.
- With both influenza and SARS-CoV-2 circulating, getting both vaccines is important for prevention of severe disease, hospitalization, and death.
- Getting both vaccines at the same visit increases the chance that a person will be up to date with their vaccinations.



Can we "mix and match" the new bivalent booster dose brand with another brand?





Yes. Any homologous or heterologous age-appropriate mRNA vaccine can be used if a booster dose is FDA-authorized for use in a specified population.



Talking with Our Patients and Communities





COVID-19 Vaccine Language Tips

Do Say	Don't Say
Vaccination	Injection or shot
A safe and effective vaccine	A vaccine developed quickly
Authorized by FDA based on clinical testing	Approved by FDA; Operation Warp Speed; Emergency Use Authorization*
Get the latest information	There are things we still don't know
Keep your family safe; keep those most vulnerable safe	Keep your country safe
Public Health	Government
Health/medical experts and doctors	Scientists
People who have questions	People who are hesitant, skeptical, resistant, or "anti- vaxxers"

^{*} The perceived speed of vaccine development is a current barrier among many audiences.

These recommendations are based partly on research conducted by the de Beaumont Foundation.



Conversation Methodology



To address patients concerns related to myths and misinformation, use the 3-5-3 method.





3 Steps to Initiating Conversations

1

2

3

Ask and listen to the answer

"What do you think about the vaccine?"

"Why do you feel that way?"

"What concerns do you have about the vaccine?"

Create an alignment of safety

"I would be scared too. Let's do what's safe here."

"We both want what's safest for you."

Find common goals

"We all want to be able to safely be with our loved ones again."

"What reasons would motivate you to get vaccinated?"

Find their personally motivating reason.





The vaccine will keep you safe.

The vaccine will protect you from getting very sick. Over 220 million Americans have been safely vaccinated and are now protected. Over 100 million Americans have received a booster dose.





2

Mild side effects are common.

Side effects are a sign that your body is protecting you.

For a few days after vaccination, many people temporarily feel:

- Sore arm (at administration site)
- Tired or fatigue
- Headache
- Muscle pain
- Joint pain







Vaccines are very effective.

Each vaccine is extremely effective at preventing hospitalization and death from COVID-19 and its variants.







The vaccine is built on 20 years of research and science.

It is good to be careful when new things come along. Health experts took all the necessary steps to produce a safe vaccine, and it was built on 20 years of research and science.





Key Messages



Have questions? Please ask.

I am glad you want to know more. Ultimately, the choice is yours. Today or when you're ready, go to myturn.ca.gov or text your zip code to GETVAX or VACUNA to get your vaccine.





3 Steps Post-Conversation

1

2

3

Acknowledge their agency and personal choice

"I want you to get vaccinated today, but ultimately it's your choice."

"I'm here as a resource to help you."

Keep lines of communication open

Trust is a journey. Give folks a way to reach you that you are comfortable with as they consider their decision.

Offer to find a vaccine

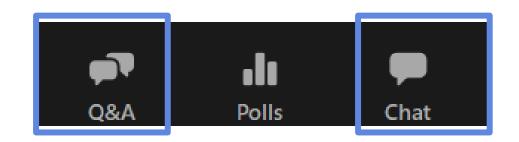
Offer myturn.ca.gov or have them text their zip code to GETVAX or VACUNA to find a free vaccine location in their neighborhood.





Questions & Answers

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Resource links will be dropped into, "Chat"



Poll & Resources

Rachel Jacobs, CDPH



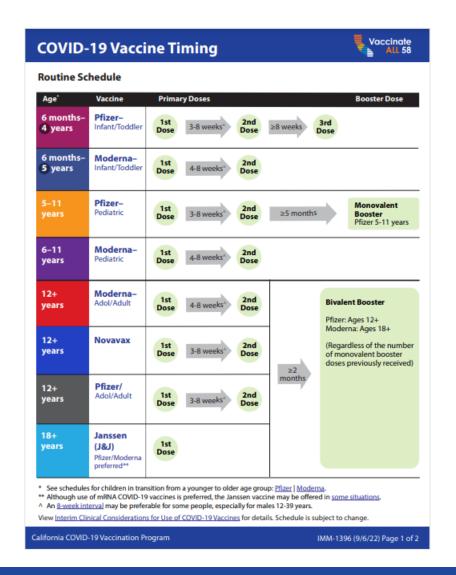
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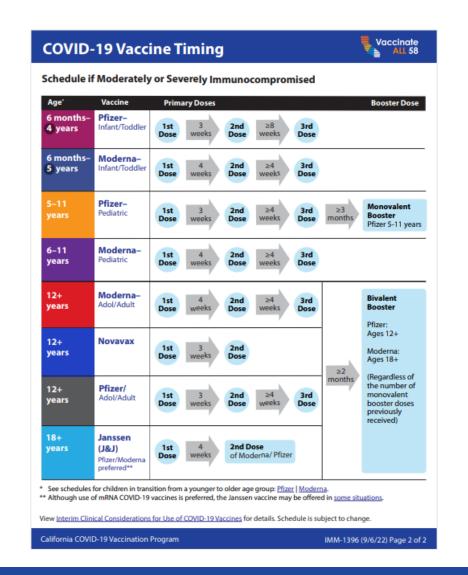
Following this webinar, how confident are you in your ability to effectively discuss COVID-19 bivalent booster doses with patients?

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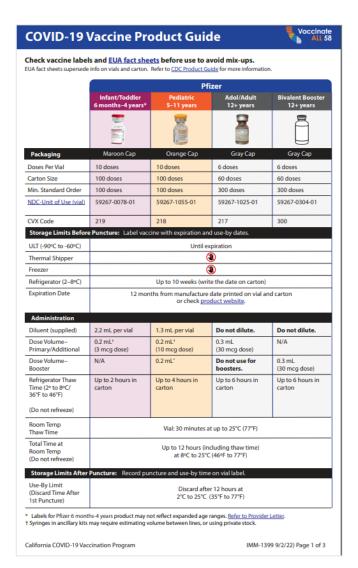


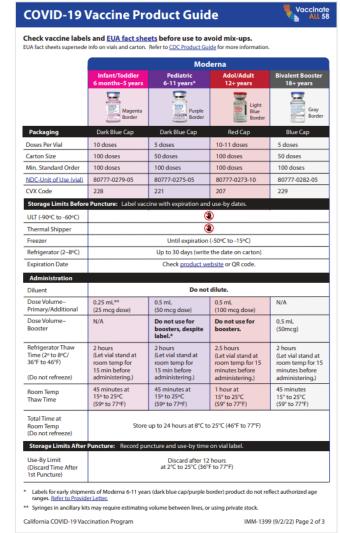
Job Aid: COVID-19 Vaccine Timing Guide

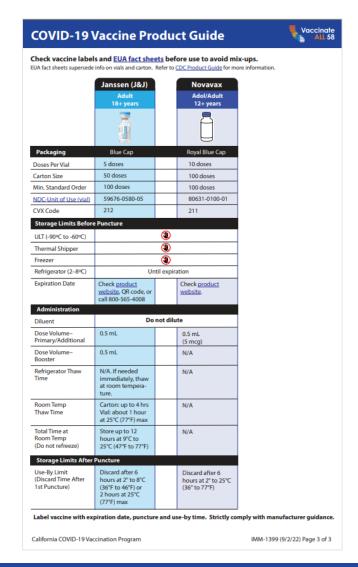




Job Aid: COVID-19 Vaccine Product Guide





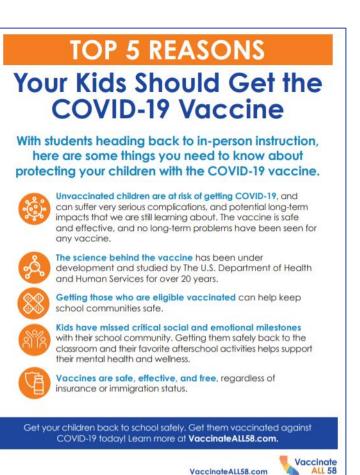


Toolkits, Fliers, Conversation Guides, and Videos

#ThisIsOurShot Toolkit COVID-19 Crucial Conversations Campaign









Next Crucial Conversations Webinar: Talking with Patients about Long COVID

Please join Sharon Goldfarb, DNP, RN, FNP-BC, nurse lead with #ThisIsOurShot, to discuss what your patients need to know about post-COVID conditions.

When: Thursday, September 22 at 12:00PM-1:00PM

Register here!



For California COVID-19 Vaccine Providers



Monday

Provider Therapeutics Webinar

Next session: Monday, September 12, 12PM

My Turn and myCAvax Office Hours

Next session: Monday, September 19, 12PM

Friday

Provider Webinar

Next session: Friday, September 9, 9AM



Additional Support

Type of Support		Description	Updated 6.6.22
	COVID-19 Provider Call Center	The COVID-19 Call Center for Providers and Local Health Departments is dedicated to medical providers in California and their COVID-19 response, specifically addressing questions about State program requirements, enrollment, and vaccine distribution, including the Vaccine Marketplace. • Email: covidcallcenter@cdph.ca.gov	
		 Phone: (833) 502-1245, Monday through Friday from 8AM–6PM 	
	Enrollment Support	For Provider enrollment support, please contact myCAvax Clinic Operations at	
		Email: myCAvaxinfo@cdph.ca.gov	
	myCAvax Help Desk	Dedicated staff provide up-to-date information and technical support on the myCAvax system.	
		Email: myCAvax.HD@Accenture.com	
\Box		 Phone: (833)-502-1245, option 3, Monday through Friday 8AM–6PM 	
		For training opportunities: https://eziz.org/covid/education/	
ر ت	My Turn Clinic Help Desk	For onboarding support (those in the process of onboarding): myturnonboarding@cdph.ca.gov	
		For technical support with My Turn Clinic for COVID-19 and flu vaccines: MyTurn.Clinic.HD@Accenture. (833) 502-1245, option 4: Monday through Friday 8AM–6PM	com or
		For job aids, demos, and training opportunities: flu at https://eziz.org/covid/myturn/flu/ and COVID at https://eziz.org/covid/myturn/flu/ and COVID at https://exiz.org/covid/myturn/flu/ and https:/	//eziz.org/covid/myturn/
₽ [*]	Archived Communications	For archived communications from the COVID-19 Provider Call Center about the California COVID-19 Variety	ccination Program
		Website: <u>EZIZ Archived Communications</u>	



Special Thanks to Today's Presenter:

Ilan Shapiro, MD, MBA, FAAP, FACHE

Webinar Planning & Support:

Rachel Jacobs, Cheri Banks, Leslie Amani, Blanca Corona, Charles Roberts







