HIC UPDATE

MARCH 2024

Activities of the Hawaii Immunization Coalition

Helping Communities Move on From Vaccine Hesitancy to Vaccine Confidence

Thursday March 7, 2024 @ 12 PM/ Noon HST

Amy Pisani, MS
Vaccinate Your Family
Chief Executive Officer

Sandra Chang, PhD
Professor of Tropical Medicine,
JABSOM, UHM

Registration and CEUs

No Cost to Registrant.
Zoom link will be sent after registration.

https://forms.gle/rAWpeCTzySPWgity5

OBJECTIVES

1. Demonstrate increased knowledge and confidence to engage communities in vaccine conversations.
2. Identify methods to navigate people of all ages to vaccination services.
3. Describe recent ACIP updates.

For more upcoming immunization meetings & training opportunities, visit Immunize.org' s Calendar of Events.

IN THIS ISSUE

The Hawaii Immunization Coalition (HIC) is a statewide, community-based non-profit 501(c)3 coalition of public and private organizations and concerned individuals whose mission is to promote effective strategies to ensure that all of Hawaii's families are appropriately vaccinated against vaccine-preventable diseases.

16th National Conference for Immunization Coalitions and Partnerships

April 9-11, 2024 • Philadelphia PA

Gain invaluable insights, exchange innovative ideas, and join a passionate community committed to immunization at the 16th National Conference for Immunization Coalitions and Partnerships.

Scholarships are available!
Please contact Erin Babe or Dr. Angela Shen using the contact form for scholarship information

REGISTRATION

Regular Registration	$575
Student Registration	$100

Find out more information at the conference website: https://www.ncicp.org/

Older Adults Now Able to Receive Additional Dose of Updated COVID-19 Vaccine

February 28, 2024 - CDC Director Mandy Cohen endorsed the CDC Advisory Committee on Immunization Practices' (ACIP) recommendation for adults ages 65 years and older to receive an additional updated 2023-2024 COVID-19 vaccine dose. The recommendation acknowledges the increased risk of severe disease from COVID-19 in older adults, along with the currently available data on vaccine effectiveness.

Press Release

Local Vaccine Research Highlight

ELSEVIER

Vaccine

Volume 42, Issue 3, 25 January 2024, Pages 598-607

Thermostable bivalent filovirus vaccine protects against severe and lethal Sudan ebolavirus and marburgvirus infection

Albert To [a], Teri Ann S. Wong [a], Aquena H. Ball [a], Michael M. Lieberman [a], Jake Yalley-Ogunro [b], Mehtap Cabus [b], Sara Nezami [b], Fabian Paz [b], Hanne Andersen Elyard [b], Viktoriya Borisevich [c d], Krystle N. Agans [c d], Daniel J. Deer [c d], Courtney Woolsey [c d], Robert W. Cross [c d], Thomas W. Geisbert [c d], Oreola Donini [e], Axel T. Lehrer [a]

[a] Department of Tropical Medicine, Medical Microbiology, and Pharmacology, John A. Burns School of Medicine, University of Hawai'i at Mānoa, Honolulu, HI 96813, USA
[b] Bioqual Inc., Rockville, MD 20850, USA
[c] Department of Microbiology and Immunology, University of Texas Medical Branch, Galveston, TX 77550, USA
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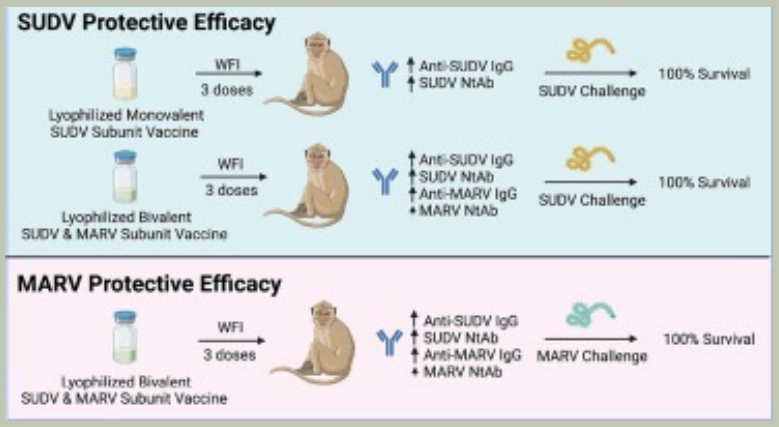
[e] Soligenix, Inc., Princeton, NJ 08540, USA

Received 10 June 2023, Revised 15 December 2023, Accepted 18 December 2023, Available online 28 December 2023, Version of Record 1 February 2024.

Vaccine researcher Dr. Axel Lehrer, Ph.D., at the University of Hawaii at Manoa, John A. Burns School of Medicine recent work on on the development of a novel filovirus vaccine was recently accepted for publication in the Journal *Vaccine*. Please find link to publication and graphical abstract.

Link to Publication



Alarming Vaccine Exemption Rates in Hawai‘i

Hawaii has seen an alarming rise in vaccine exemptions in school age children; from 3.4% in 2021 to 6.5% in 2023. This represents the largest change in exemptions in the United States during this time period. The Department of Hawaii - Immunization Branch will be convening a workgroup to assess and address this change in February 2024, please monitor HIC emails for details on how you and/your organization can participate.

Vaccination Coverage with Selected Vaccines and Exemption Rates Among Children in Kindergarten — United States, 2021–22 School Year | MMWR (cdc.gov)

What is already known about this topic?

During the 2020–21 school year, national coverage with state-required vaccines among kindergarten students declined from 95% to approximately 94%.

What is added by this report?

During the 2021–22 school year, coverage decreased again to approximately 93% for all state-required vaccines. The exemption rate remained low (2.6%). An additional start highlight4.4end highlight% without an exemption were not up to date with measles, mumps and rubella vaccine. Despite widespread return to in-person learning, COVID-19–related disruptions continued to affect vaccination coverage and assessment for the 2021–22 school year, preventing a return to prepandemic coverage.

What are the implications for public health practice?

Increasing follow-up with undervaccinated students to reduce the impact of disruptions on vaccination coverage can help protect students from vaccine-preventable diseases.

Coverage with Selected Vaccines and Exemption from School Vaccine Requirements Among Children in Kindergarten — United States, 2022–23 School Year | MMWR (cdc.gov)

What is already known about this topic?

From the 2019–20 to the 2021–22 school year, national coverage with state-required vaccines among kindergartners declined from 95% to approximately 93%, ranging from 92.7% for diphtheria, tetanus, and acellular pertussis vaccine (DTaP) to 93.1% for polio.

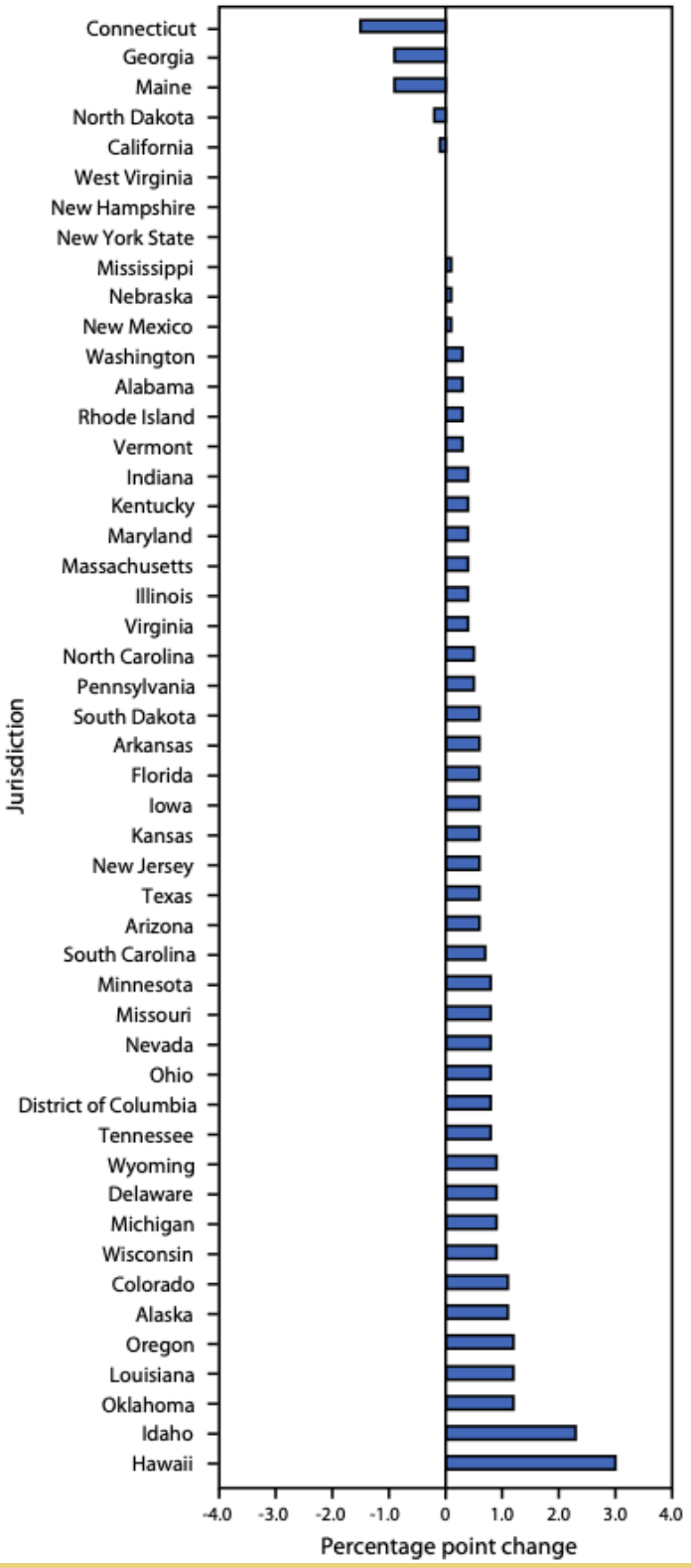
What is added by this report?

During the 2022–23 school year, coverage remained near 93% for all reported vaccines, ranging from 92.7% for DTaP to 93.1% for measles, mumps, and rubella and polio. The exemption rate increased 0.4 percentage points to 3.0%. Exemptions increased in 41 states, exceeding 5% in 10 states.

What are the implications for public health practice?

Exemptions >5% limit the level of achievable vaccination coverage, which increases the risk for outbreaks of vaccine-preventable diseases. Vaccination before school entry or during provisional enrollment periods could reduce exemptions resulting from barriers to vaccination during the COVID-19 pandemic.

FIGURE 1. Change in percentage* of kindergartners exempt from one or more vaccinations, by jurisdiction — United States, 2021–22 and 2022–23 school years



Seither R, et al. MMWR Morb Mortal Wkly Rep 2023;72:1217–1224. DOI: http://dx.doi.org/10.15585/mmwr.mm7245a2.

Maui is Holding a Public Health Time Bomb and Maui Wildfires Lit the Fuse

Dr. Casandra Simonson, M.D. FAAP
Pediatrics Department Chair, Community Clinic of Maui, Inc.
dba Mālama I Ke Ola Health Center
All opinions are my own.

I have been a pediatrician in Maui at the Federally Qualified Health Center, Malama I ke Ola, for almost 10 years. I take care of the most vulnerable keiki on our island; foster children, newly immigrated children, houseless children, and those with the very lowest incomes and limited resources. Tragically, I have added to this list the displaced and bereaved children, due to the August Wildfire. We lost our Lahaina clinic in the fire along with many others. My workplace mobilized and was the first to provide care in the shelters in the hours following the fire. We brought every supply and medication we could grab. "My husband is missing" said the doctor working next to me. "My nurse is missing" said the assistant on my other side. And yet they carried on dressing burns.

Prior to the fire, Maui had what could be described as "pockets" of the population with low vaccine rates. As of July 2023, of my patients 2 years old and younger, only 50% were fully vaccinated. Herd immunity required to prevent outbreaks varies from 70-95% of the population. August saw our vaccine rates drop to 46% and by December we were at 41%. Could this be because one of our clinics was physically gone, our patients displaced, and their parents' priorities focused on shelter and food? Yes, definitely. But our rates were so far from herd immunity to begin with that we had no buffer to absorb the expected effects of a natural disaster. Vaccine rates that low are an obvious set up for an outbreak. Combine this with families living in hotels or very close quarters, sometimes 14 people sleeping in a garage, and you have a bomb waiting to go off. Add the returning influx of tourists and immigrants from all over the world and you have lit the fuse.

Why do we have such low vaccine rates in Maui? Why do parents refuse vaccines in Maui? Why do so many sign the form that says their religion that prevents them from vaccinating their child when it's time to go to Kindergarten or enter 7th grade? Which religion does not allow for the miracle that is a vaccine? Why do I fear that the only thing that will change the hearts and minds of parents on Maui is a viral story on TikTok about a sick or dead child, killed by measles or chickenpox? Whose child will have to be a sacrificial lamb in order to drive parents to vaccinate their keiki?

I cannot help but feel like a failure. I took an oath to do everything I could to save and protect children. And here I can see the perfect set up for another tragedy. Our community cannot suffer any more loss. Our hearts were broken after the fire. Time is supposed to heal but I cannot get this lump out of my throat, these waves of nausea continue. I have to try something else. I started writing and reaching out to groups like the Hawaii Immunization Coalition. Studies by the American Academy of Pediatrics show that it is extremely difficult to change a parent's mind about vaccines. They have become a central issue in the culture wars and made more extreme by covid. I have always thought that Hawaii takes care of its keiki better than any other state I have worked in. I know Hawaii has robust services, legislation, advocates, and funding for keiki. I could brag to my pediatrician mainland friends how easy it is to get them insurance and medications. But for disease prevention, my patients are not being well served by their community. They are being left wide open to a minefield of deadly outbreaks.

Fear of vaccines is what seems to motivate parents to refuse them. Fear of disease is just not front and center on parent's minds anymore. How can we use education, legislation, outreach and yes, even social media to reach them? No human likes being told what to do, it can automatically trigger a defensive reaction. This is especially true in a community where colonization remains a neglected wound on collective souls. Disease from those same colonialists also devastated the population of Hawaii, especially the keiki. We cannot let that portion of history repeat itself.

Parents obviously treasure their children, as do I. Truly. Parents are afraid of giving them anything that could harm them. It is a survival mechanism to be skeptical. But that makes sense for new crazy products and inventions not for our tried-and-true vaccines. How can we respect a parent's wishes while fulfilling our obligation to protect the community?
We must work together. To listen and acknowledge the intense fear that comes with the intense love for a child. To explain. To facilitate. To prevent suffering.

Hepatitis Epidemic Hits Hawai‘i Harder Than Other States

BY: Sandy Harjo-Livingston
Posted: Dec 14, 2023 / 05:00 AM HST
Updated: Dec 12, 2023 / 12:28 PM HST

Link to Full Article

HONOLULU (KHON2) — Viral hepatitis C is curable. Hepatitis B is treatable. Both are preventable; so, why does Hawai‘i have such high rates of it? Did you know that Hawai‘i has higher liver cancer mortality due to hepatitis B and C than the continental United States? That’s according to the Hawai‘i Department of Health’s Viral Hepatitis Prevention Coordinator, Thaddeus Pham.

“When we look at hepatitis B, and hepatitis C specifically, we also see higher death rates of both of those compared to the continental U.S.,” explained Pham. “People who die from hepatitis in Hawai‘i, hepatitis C specifically, can die up to 20 years earlier than residents in the rest of the state.”

That’s right. There’s a 20-year difference in life expectancy between those who contract the curable hepatitis C and those who don’t have it. Pham said that his goal is give those 20 years back. And his work on the **HepFree by 2030** campaign is making strides.

He and the DOH are in the middle of developing a surveillance infrastructure that will track the spread of viral hepatitis and hopefully begin pinpointing specifics on who is contracting hepatitis and how.

Now, don’t let the word surveillance scare you. It’s not what you may think. This is a system that will allow the DOH to help those who have contracted viral hepatitis in order to get them link to care and help develop prevention strategies.

THE NUMBERS
Pham was kind enough to provide KHON2.com with some statistics on how hepatitis is impacting Hawai‘i. He pointed out that because the surveillance system is still being developed, there is still much to learn from collecting data and observation.

- Hepatitis B Mortality Rates – **DOH Report**.
  - Hawai‘i has higher rates than U.S. from 2000-2020.
    - Hawai‘i rate was 3 times higher than U.S. in 2019.
  - Within Hawai‘i, higher rates among Asian and Pacific Islander (1.2 to 1.4 times) residents, compared to state average.
- Liver Cancer Mortality Rates – **DOH Report**.
  - Hawai‘i has higher rates than U.S. from 2000-2020.
  - Hawai‘i rates increased from 2000 to 2020 with 7.96 per 100,000 to 9.41 per 100,000.
  - Rates partially driven by disparities among Asian and Pacific Islander residents.
  - Note: HBV and HCV are leading causes of liver cancer in Hawai‘i, **per journal article**.
- HCV Mortality Rates – **Journal article** and **CDC Data**.
  - HCV is associated with up to 20 year lower life expectancy compared to the rest of the state.
  - Hawai‘i is state with highest proportion of NHAPI decedents among HCV-listed deaths (2016-2017).

The spread of hepatitis C is why things like syringe exchanges are so important for prevention. You can **click here** for access to information and resources.

Pham said that the Centers for Disease Control and Prevention recommends that all adults, regardless of your perceived risk, need to be tested at least one time for both hepatitis B and C

CDC Health Advisory: Influenza, COVID-19, and RSV

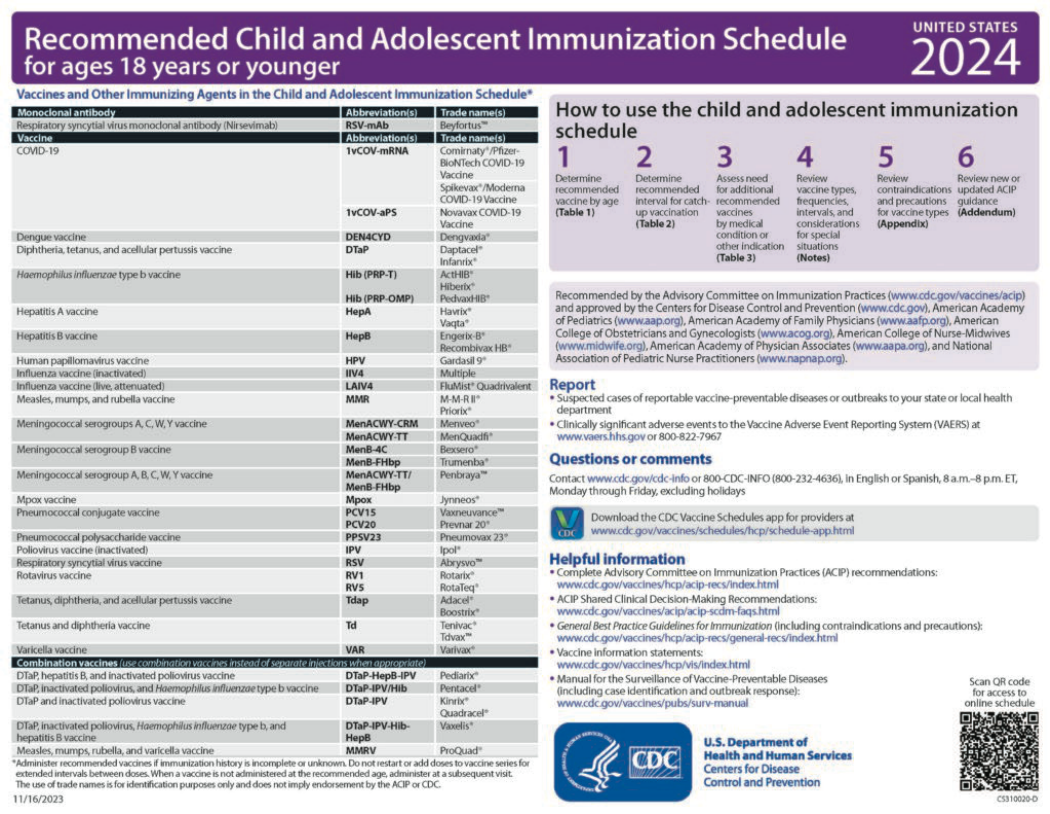
Urgent Need to Increase Immunization Coverage for Influenza, COVID-19, and RSV and Use of Authorized/ Approved Therapeutics in the Setting of Increased Respiratory Disease Activity During the 2023 – 2024 Winter Season

Distributed via the CDC Health Alert Network
December 14, 2023, 12:15 PM ET
CDCHAN-00503

Link to Full Health Alert

The Centers for Disease Control and Prevention (CDC) is issuing this Health Alert Network (HAN) Health Advisory to alert healthcare providers to low vaccination rates against influenza, COVID-19, and RSV (respiratory syncytial virus). Low vaccination rates, coupled with ongoing increases in national and international respiratory disease activity caused by multiple pathogens, including influenza viruses, SARS-CoV-2 (the virus that causes COVID-19), and RSV, could lead to more severe disease and increased healthcare capacity strain in the coming weeks. In addition, a recent increase in cases of multisystem inflammatory syndrome in children (MIS-C) following SARS-CoV-2 infection in the United States has been reported. **Healthcare providers should administer influenza, COVID-19, and RSV immunizations now to patients, if recommended. Healthcare providers should recommend antiviral medications for influenza and COVID-19 for all eligible patients, especially patients at high-risk of progression to severe disease such as older adults and people with certain underlying medical conditions**. Healthcare providers should also counsel patients about testing and other preventive measures, including covering coughs/sneezes, staying at home when sick, improving ventilation at home or work, and washing hands to protect themselves and others against respiratory diseases.

2024 Immunization Schedules



Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger — UNITED STATES 2024

Vaccines and Other Immunizing Agents in the Child and Adolescent Immunization Schedule*

Monoclonal antibody	Abbreviation(s)	Trade name(s)
Respiratory syncytial virus monoclonal antibody (Nirsevimab)	RSV-mAb	Beyfortus™
Vaccine	**Abbreviation(s)**	**Trade name(s)**
COVID-19	1vCOV-mRNA	Comirnaty®/Pfizer-BioNTech COVID-19 Vaccine Spikevax®/Moderna COVID-19 Vaccine
	1vCOV-aPS	Novavax COVID-19 Vaccine
Dengue vaccine	DEN4CYD	Dengvaxia®
Diphtheria, tetanus, and acellular pertussis vaccine	DTaP	Daptacel® Infanrix®
Haemophilus influenzae type b vaccine	Hib (PRP-T)	ActHIB® Hiberix®
	Hib (PRP-OMP)	PedvaxHIB®
Hepatitis A vaccine	HepA	Havrix® Vaqta®
Hepatitis B vaccine	HepB	Engerix-B® Recombivax HB®
Human papillomavirus vaccine	HPV	Gardasil 9®
Influenza vaccine (inactivated)	IIV4	Multiple
Influenza vaccine (live, attenuated)	LAIV4	FluMist® Quadrivalent
Measles, mumps, and rubella vaccine	MMR	M-M-R II® Priorix®
Meningococcal serogroups A, C, W, Y vaccine	MenACWY-CRM	Menveo®
	MenACWY-TT	MenQuadfi®
Meningococcal serogroup B vaccine	MenB-4C	Bexsero®
	MenB-FHbp	Trumenba®
Meningococcal serogroup A, B, C, W, Y vaccine	MenACWY-TT/ MenB-FHbp	Penbraya™
Mpox vaccine	Mpox	Jynneos®
Pneumococcal conjugate vaccine	PCV15	Vaxneuvance™
	PCV20	Prevnar 20®
Pneumococcal polysaccharide vaccine	PPSV23	Pneumovax 23®
Poliovirus vaccine (inactivated)	IPV	Ipol®
Respiratory syncytial virus vaccine	RSV	Abrysvo™
Rotavirus vaccine	RV1	Rotarix®
	RV5	RotaTeq®
Tetanus, diphtheria, and acellular pertussis vaccine	Tdap	Adacel® Boostrix®
Tetanus and diphtheria vaccine	Td	Tenivac® Tdvax™
Varicella vaccine	VAR	Varivax®
Combination vaccines *(use combination vaccines instead of separate injections when appropriate)*		
DTaP, hepatitis B, and inactivated poliovirus vaccine	DTaP-HepB-IPV	Pediarix®
DTaP, inactivated poliovirus, and *Haemophilus influenzae* type b vaccine	DTaP-IPV/Hib	Pentacel®
DTaP and inactivated poliovirus vaccine	DTaP-IPV	Kinrix® Quadracel®
DTaP, inactivated poliovirus, *Haemophilus influenzae* type b, and hepatitis B vaccine	DTaP-IPV-Hib-HepB	Vaxelis®
Measles, mumps, rubella, and varicella vaccine	MMRV	ProQuad®

*Administer recommended vaccines if immunization history is incomplete or unknown. Do not restart or add doses to vaccine series for extended intervals between doses. When a vaccine is not administered at the recommended age, administer at a subsequent visit. The use of trade names is for identification purposes only and does not imply endorsement by the ACIP or CDC.

11/16/2023

How to use the child and adolescent immunization schedule

1 Determine recommended vaccine by age **(Table 1)**
2 Determine recommended interval for catch-up vaccination **(Table 2)**
3 Assess need for additional recommended vaccines by medical condition or other indication **(Table 3)**
4 Review vaccine types, frequencies, intervals, and considerations for special situations **(Notes)**
5 Review contraindications and precautions for vaccine types **(Appendix)**
6 Review new or updated ACIP guidance **(Addendum)**

Recommended by the Advisory Committee on Immunization Practices (www.cdc.gov/vaccines/acip) and approved by the Centers for Disease Control and Prevention (www.cdc.gov), American Academy of Pediatrics (www.aap.org), American Academy of Family Physicians (www.aafp.org), American College of Obstetricians and Gynecologists (www.acog.org), American College of Nurse-Midwives (www.midwife.org), American Academy of Physician Associates (www.aapa.org), and National Association of Pediatric Nurse Practitioners (www.napnap.org).

Report
- Suspected cases of reportable vaccine-preventable diseases or outbreaks to your state or local health department
- Clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov or 800-822-7967

Questions or comments
Contact www.cdc.gov/cdc-info or 800-CDC-INFO (800-232-4636), in English or Spanish, 8 a.m.–8 p.m. ET, Monday through Friday, excluding holidays

Download the CDC Vaccine Schedules app for providers at www.cdc.gov/vaccines/schedules/hcp/schedule-app.html

Helpful information
- Complete Advisory Committee on Immunization Practices (ACIP) recommendations: www.cdc.gov/vaccines/hcp/acip-recs/index.html
- ACIP Shared Clinical Decision-Making Recommendations: www.cdc.gov/vaccines/acip/acip-scdm-faqs.html
- *General Best Practice Guidelines for Immunization* (including contraindications and precautions): www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html
- Vaccine information statements: www.cdc.gov/vaccines/hcp/vis/index.html
- Manual for the Surveillance of Vaccine-Preventable Diseases (including case identification and outbreak response): www.cdc.gov/vaccines/pubs/surv-manual

Scan QR code for access to online schedule

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

CS310020-D

The 2024 immunization schedules are now available and effective immediately,

https://www.cdc.gov/vaccines/schedules/hcp/index.html

Childhood and Adolescent Immunization Schedules by Age, 2024

Adult Immunization Schedules by Age, 2024

The Hawaii Immunization Coalition (HIC) is a statewide, community-based non-profit 501(c)3 coalition of public and private organizations and concerned individuals whose mission is to promote effective strategies to ensure that all of Hawaii's families are appropriately vaccinated against vaccine-preventable diseases.

Recent FDA Approvals

August 21, 2023
FDA Approves First Vaccine for Pregnant Individuals to Prevent RSV in Infants

Full Abrysvo Press Release

The U.S. Food and Drug Administration approved Abrysvo (Respiratory Syncytial Virus Vaccine), the first vaccine approved for use in pregnant individuals to prevent lower respiratory tract disease (LRTD) and severe LRTD caused by respiratory syncytial virus (RSV) in infants from birth through 6 months of age. Abrysvo is approved for use at 32 through 36 weeks gestational age of pregnancy. Abrysvo is administered as a single dose injection into the muscle. The FDA approved Abrysvo in May for the prevention of LRTD caused by RSV in individuals 60 years of age and older.

The safety and effectiveness of Abrysvo for immunization of pregnant individuals to prevent LRTD and severe LRTD caused by RSV in infants from birth through 6 months of age was evaluated in ongoing, randomized, placebo-controlled international clinical studies.
A clinical study evaluated the effectiveness of Abrysvo to prevent LRTD and severe LRTD caused by RSV in infants born to individuals who were vaccinated during pregnancy. Among approximately 3,500 pregnant individuals who received Abrysvo, compared to approximately 3,500 pregnant individuals who received placebo, Abrysvo reduced the risk of severe LRTD by 81.8% within 90 days after birth, and 69.4% within 180 days after birth. In a subgroup of pregnant individuals who were 32 through 36 weeks gestational age, of whom approximately 1,500 received Abrysvo and 1,500 received placebo, Abrysvo reduced the risk of LRTD by 34.7%, and reduced the risk of severe LRTD by 91.1% within 90 days after birth when compared to placebo. Within 180 days after birth, Abrysvo reduced the risk of LRTD by 57.3% and by 76.5% for severe LRTD, when compared to placebo.

The safety of Abrysvo was evaluated in two studies. In one study, approximately 3,600 pregnant individuals received a single dose of Abrysvo and approximately 3,600 pregnant individuals received a placebo. In the second study, approximately 100 pregnant individuals received Abrysvo and approximately 100 pregnant individuals received placebo.

November 9, 2023
FDA Approves First Vaccine to Prevent Disease Caused by Chikungunya Virus

Full IxchiqPress Release

The U.S. Food and Drug Administration approved Ixchiq, the first chikungunya vaccine. Ixchiq is approved for individuals 18 years of age and older who are at increased risk of exposure to chikungunya virus.

The chikungunya virus is primarily transmitted to people through the bite of an infected mosquito. Chikungunya is an emerging global health threat with at least 5 million cases of chikungunya virus infection reported during the past 15 years. The highest risk of infection is in tropical and subtropical regions of Africa, Southeast Asia, and parts of the Americas where chikungunya virus-carrying mosquitos are endemic. However, chikungunya virus has spread to new geographical areas causing a rise in global prevalence of the disease.

The most common symptoms of chikungunya include fever and joint pain. Other symptoms may include a rash, headache, and muscle pain. Some individuals may experience debilitating joint pain that persists for months or even years. Treatment includes rest, fluids, and over-the-counter medications for pain and fever.

Ixchiq is administered as a single dose by injection into the muscle. It contains a live, weakened version of the chikungunya virus and may cause symptoms in the vaccine recipient similar to those experienced by people who have chikungunya disease.

The safety of Ixchiq was evaluated in two clinical studies conducted in North America in which about 3,500 participants 18 years of age and older received a dose of the vaccine with one study including about 1,000 participants who received a placebo. The most commonly reported side effects by vaccine recipients were headache, fatigue, muscle pain, joint pain, fever, nausea and tenderness at the injection site.

October 25 & 26, 2023 ACIP Updates for Flu

Safety of quadrivalent recombinant influenza vaccine in pregnant women and their infants.

Pregnant women were evaluated as a subset of a post-licensure study within Kaiser Permanente Northern California during the 2018-19 & 2019-20 influenza seasons.

Primary objective: Evaluation safety of quadrivalent recombinant influenza vaccine (RIV4) compared with standard dose quadrivalent (SD-IIV4) in pregnant women and their offspring.

- Pregnancy outcomes: Spontaneous abortion, preterm labor, stillbirth/fetal death, congenital anomalies, eclampsia, placental abruption.
- Birth outcomes: Preterm birth, low birthweight, small for gestational age.
- Neonatal outcomes: Infant death, congenital anomalies, failure to thrive.

Results

- 15,000 pregnant women received RIV4 to 33,800 receiving SD-IIV4.
- Pregnancy outcomes: No statistically significant difference in outcomes when comparing RIV4 to SD-IIV4.
- Birth/infant outcomes: No statistically significant difference in outcomes when comparing RIV4 to SD-IIV4.

Safety of simultaneous vs sequential administration of mRNA COVID-19 and quadrivalent inactivated influenza (IIV4) vaccines.

Prospective, randomized, placebo-controlled, observer blind study in non-pregnant persons ≥5 years if receiving primary two-dose mRNA COVID-19 vaccine series or ≥12 years if receiving a booster mRNA COVID-19 vaccine & intending to receive a quadrivalent influenza vaccine (IIV4).

Primary objective: compare proportion of participants with moderate or more severe fever, chills, myalgia, or arthralgia in the simultaneous arm (both vaccines given Visit 1, Day 1) vs sequential administration arm (influenza vaccine given Visit 2, one to two weeks after visit 1) within 7 days of either or both visits.

Results

- There were 169 individuals in the simultaneous arm to 166 individuals in the sequential arm with over 86% of the overall population aged 18 to <65 years of age.
- The proportion of a reactogenicity event following Visit 1 and/or Visit 2 was not statistically different between the simultaneous (25.60%) and sequential arms (31.33%). Difference -0.0563 [-0.1517,0.0404].

Safety of simultaneous vaccination with zoster vaccine recombinant (RZV) and quadrivalent adjuvanted inactivated influenza vaccine (aIIV4).

Prospective, randomized, observer blinded study in individuals ≥65 years old randomized 1:1 to receive either RZV + aIIV4 or RZV + high-dose influenza quadrivalent vaccine (HD-IIV4).

Primary objective: Compare proportion of individuals with at least one severe (Grade 3) solicited local or systemic reactogenicity event after RZV dose 1 between groups.

Results

- In the modified intent-to-treat population there were 130 individuals in the RZV + aIIV4 group to 136 in the RZV + HD-IIV4 group.
- The difference in proportion of at least one Grade 3 reactogenicity event was not statistically significant following dose 1 of RZV between the aIIV4 group (11.54%) and HD-IIV4 group (12.50%). Difference -0.0096 [-0.0894,0.0710].
- There were no significant differences in proportion of moderate/severe local or systemic reactogenicity events between groups.
- Few participants had SAEs, with clinical conditions as expected in a population of older adults; no statistically significant difference in frequency of SAEs was observed between administration of RZV and either aIIV4 or HD-IIV4.

October 25 & 26, 2023 ACIP Updates for Flu, *Continued*

Update on COVID-19 influenza vaccine safety.

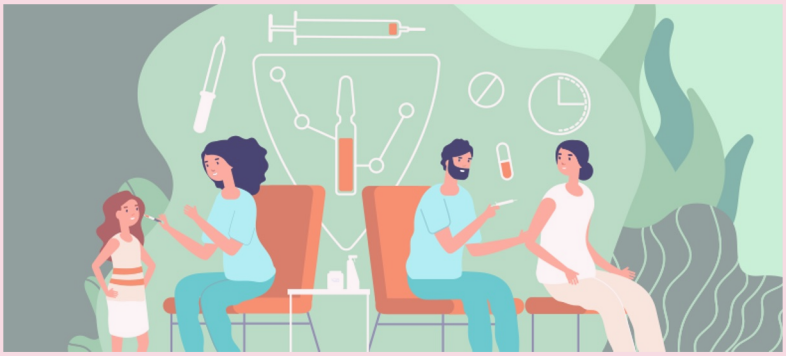
Available data do not provide clear and consistent evidence of a safety problem for ischemic stroke with bivalent mRNA COVID-19 vaccines when given alone or concomitantly with influenza vaccines or when influenza vaccine is given alone (not with COVID-19 vaccines).

Effectiveness of maternal influenza vaccination against influenza-associated hospitalizations & ED visits in infants <6 months of age.

Retrospective test-negative study to evaluate effectiveness of maternal influenza (MI) vaccination in infants <6 months of age compared to control infants with non-influenza respiratory illness from 2016-17 to 2019-2020.

Results

- 3,764 infants included in analysis with 53% born to vaccinated mothers.
- 223 case-infants tested positive to influenza, of which 42% were born to vaccinated mothers.
- Overall, point estimates of MI vaccine effectiveness against influenza hospitalizations and ED visits were 34% [12,50] for all infants and 53% [30, 68] for infants <3 months of age.
- Timing of influenza vaccination demonstrated increased VE for mothers immunized in third trimester (52% [30,68]) vs first or second trimester (17% [-15,40]).



Update on influenza B/Yamagata surveillance.

Since March 2020, through WHO's Global Influenza Surveillance and Response System (GISRS) and collaborating centers, there have been zero confirmed circulating B/Yamagata lineage viruses.

Those reported as B/Yamagata were determined to be incorrectly lineage reports, negative for influenza or B/Yamagata component of live-attenuated influenza vaccine (LAIV)

Absence of confirmed detection of naturally occurring B/Yamagata lineage viruses is indicative of very low risk of infection by B/Yamagata lineage viruses.

The WHO influenza vaccine composition advisory committee states that inclusion of a B/Yamagata antigen component of influenza vaccines is no longer warranted and should be excluded as soon as practically possible.
WHO cites theoretical reintroduction of B/Yamagata lineage viruses due to manufacture and use of vaccines as support for this decision.

Pregnancy outcomes with ccIIV4 results of a post-marketing study.

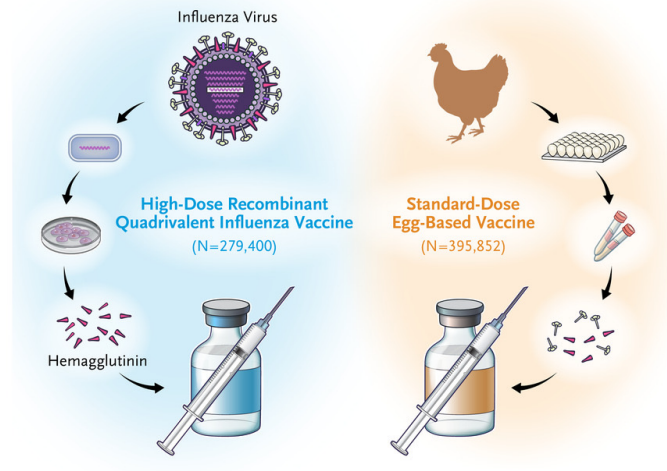
Prospective, observational safety study with pregnant women immunized with ccIIV4 during the 2017-18 through 2019-20 influenza seasons.
Primary objective: Evaluate specific pregnancy and fetus/infant outcomes.

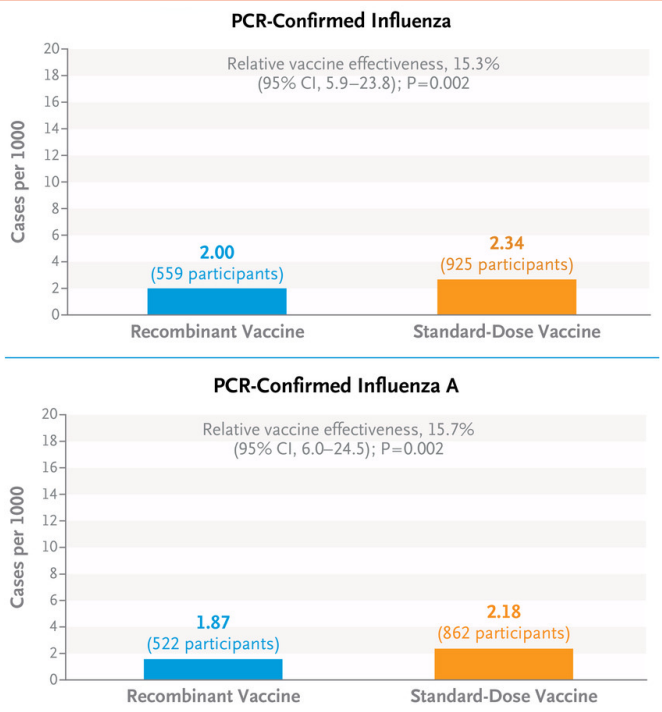
- Pregnancy outcomes: Live birth, stillbirth, spontaneous abortion, elective termination.
- Events of interest: Preterm birth, low birth weight, major congenital malformation.

Results

- 665 individuals included in the primary analysis population.
- Pregnancy outcomes: 99.1% of births were live, with no stillbirths. There were 4 cases of spontaneous abortion and 1 elective termination.
  - 2% of births were preterm.
  - 8% of births to newborns with low birthweight.
  - 9% births with major congenital malformations.
- No safety concerns were identified when data was reviewed by an independent committee of experts.

New Influenza Vaccine Study





A new influenza vaccine study was recently published in New England Journal of Medicine on December 14, 2023, and is titled "Recombinant or standard-dose influenza vaccine in adults under 65 years of age." Below you will find a summary of the study. To access the publication, please click here: Hsiao A, Klein N et al. NEJM 2023 Dec 14; 389:2245-2255.

Primary Objective: To assess the relative vaccine effectiveness (rVE) of recombinant influenza vaccine (RIV4) compared with standard-dose inactivated influenza vaccine (SD-IIV4) against polymerase chain reaction (PCR)- confirmed influenza in adults aged 50-64 years.

Secondary Objectives: rVE of RIV4 compared with SD-IIV4 against PCR-confirmed influenza A, PCR-confirmed influenza B, hospitalization for PCR-confirmed influenza, hospitalization for community-acquired pneumonia, and hospitalization for cardiorespiratory events in adults aged 50-64 years.

Methods: Cluster-randomized observational study that included 259 medical clinics and 21 hospitals within Kaiser Permanente Northern California (KPNC). Three influenza seasons were planned to be evaluated, however, data from the third season (2020-2021) was excluded due to limited circulating influenza. Thus, two seasons were included in the analysis (2018-2019 and 2019-2020).

Participants: Among 1,630,328 adults aged 18-64 years in the analysis, a total of 675,252 older adults aged 50-64 years were included in the study: 279,400 individuals were vaccinated with RIV4; 395,852 individuals were vaccinated with SD-IIV4.

Results: Overall rVE for RIV4 versus SD-IIV4 against PCR-confirmed influenza in adults aged 50-64 years was 15.3% (95% CI, 5.9 to 23.8; P=0.002). Recombinant vaccine may confer more protection than standard-dose vaccines against hospitalization outcomes. Additional secondary endpoint results can be found in the publication link above.

Strength: The two study vaccine formulations were alternated in weekly intervals of time at each facility, which allowed for balance of covariates of interest as designed.

Limitations: Compliance with weekly assigned vaccine schedule varied occasionally due to logistical constraints in this real-world setting. The COVID-19 pandemic impacted influenza circulation in 2020-2021, limiting the data to 2 influenza seasons. The primary outcome did not include infections in persons who did not undergo PCR testing, which limits its generalizability. Limited power to detect a clinically meaningful benefit of RIV4 as compared with SD-IIV4 with respect to less frequent outcomes, such as hospitalization for PCR-confirmed influenza. Although KPNC has a diverse population, it may not be representative of other populations in the United States.