Report to the Boards of Health

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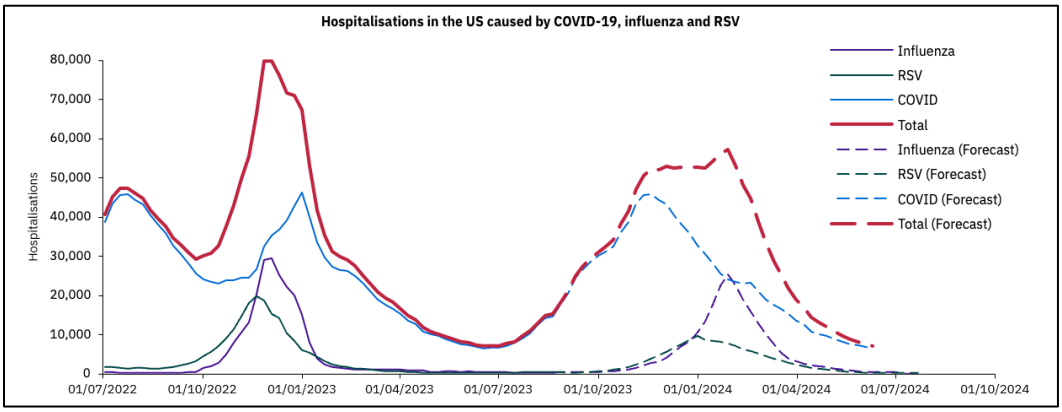
Mid-Michigan District Health Department, Wednesday, September 27, 2023
Central Michigan District Health Department, Wednesday, September 27, 2023
District Health Department 10, Friday, September 29, 2023

Immunization Update

During the winter and spring months, we typically see outbreaks of influenza, respiratory syncytial virus (RSV), and COVID-19. Below is a graph of the hospitalizations from these three viruses last year and the projections for this season.



https://www.airfinity.com/articles/tripledemic-peak-in-us-and-uk-hospitalisations-to-be-smaller-than-last-year

This is the first year we have active prevention measures for all three of these illnesses. There is an updated influenza vaccine, as is typical each fall, an updated COVID-19 vaccine, two new RSV vaccines for adults 60 years and older, and an RSV long-acting monoclonal antibody product for all infants under 8 months and some older infants and toddlers at increased risk. We will review each one.

Influenza Vaccine

Influenza, or "the flu", is a very contagious respiratory illness caused by different flu viruses. In the United States each year, millions of people get the flu, hundreds of thousands of people are hospitalized, and thousands or tens of thousands of people die. Influenza vaccines prevent flu illness, make flu illness less severe, reduce risk for hospitalization, and reduce chances of needing intensive care unit admission and duration of hospitalization. Vaccination also reduces the risk of death when infected.

Everyone ages 6 months and older should receive a flu vaccine dose each year, with few exceptions. All 2023-2024 seasonal influenza vaccines are "quadrivalent" which means they vaccinate for four (4) strains of influenza: two influenza A strains and two influenza B strains. It is best to get the flu vaccine during September or October, but the vaccine should still be given throughout the season if influenza viruses are circulating. It can be given in July and August to children who need two doses, pregnant people who are in the third trimester at that time, and others if they might not be able get it later.

Vaccine Type		Age Indication
Inactivated Influenza Quadrivalent Vaccine		6 months & older (varies per brand)
[1]Live Attenuated Influenza Quadrivalent Vaccine		2 through 49 years if healthy and not pregnant persons
[2]Cell Culture Inactivated Influenza Quadrivalent Vaccine		6 months & older
PREFERRED FOR 65 YEARS AND OLDER	[3]Recombinant Inactivated Influenza Quadrivalent Vaccine	18 years & older
	[4]High Dose- Inactivated Influenza Quadrivalent Vaccine	65 years & older
	[5]Adjuvanted Inactivated Influenza Quadrivalent Vaccine	65 years & older

[1] Cannot use in the following situations: Concomitant aspirin- or salicylate-containing therapy in children and adolescents; Children aged 2 through 4 years who have received a diagnosis of asthma or whose parents or caregivers report that a health care provider has told them during the preceding 12 months that their child had wheezing or asthma or whose medical record indicates a wheezing episode has occurred during the preceding 12 months; Immunocompromised due to any cause, including but not limited to immunosuppression caused by medications, congenital or acquired immunodeficiency states, HIV infection, anatomic asplenia, or functional asplenia (e.g., due to sickle cell anemia); Close contacts and caregivers of severely immunosuppressed persons who require a protected environment; Pregnancy; Persons with active communication between the cerebrospinal fluid (CSF) and the oropharynx, nasopharynx, nose, or ear or any other cranial CSF leak; Persons with cochlear implants; Receipt of influenza antiviral medication within the previous 48 hours for oseltamivir and zanamivir, previous 5 days for peramivir, and previous 17 days for baloxavir; Other underlying medical conditions that might predispose to complications after wild-type influenza infection (e.g., chronic pulmonary, cardiovascular [except isolated hypertension], renal, hepatic, neurologic, hematologic, or metabolic disorders [including diabetes mellitus])

[2] Does not contain egg protein

[3] Contains three times the amount of antigen as in the traditional influenza vaccine, made from recombinant hemagglutinin produced in an insect cell line using genetic sequences from cell-derived influenza viruses and is manufactured without the use of influenza viruses or eggs

[4] Contains four times the amount of antigen as in the traditional influenza vaccine

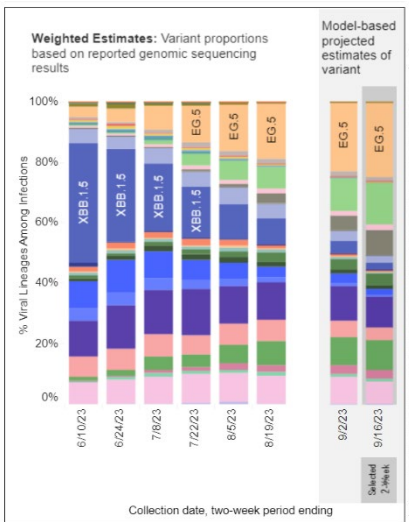
[5] Includes the adjuvant MF59C.1

There are several flu vaccines available. For those over 65 years of age and older, high

dose flu vaccine, adjuvanted flu vaccine, and recombinant flu vaccine are recommended because they stimulate the immune system better.

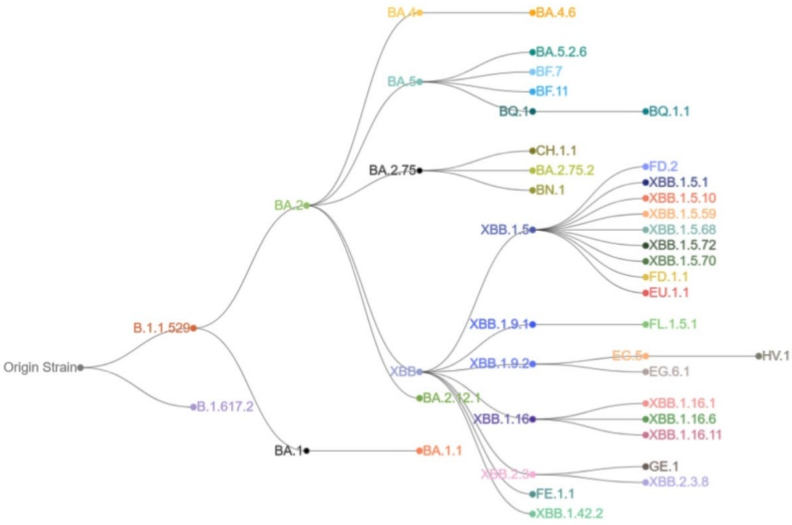
COVID-19 Vaccine

The COVID-19 virus keeps changing and our immunity, whether from vaccination or infection, wears off with time. Because of both things, we need an updated COVID-19 vaccine. There is now an updated COVID-19 vaccine available which targets one of the Omicron subvariants, XBB.1.5. The original strain of COVID-19 has been replaced by variants and is no longer spreading or causing illness. That is why we don't need to keep it in the vaccine anymore, and why we have a monovalent vaccine instead of a bivalent.



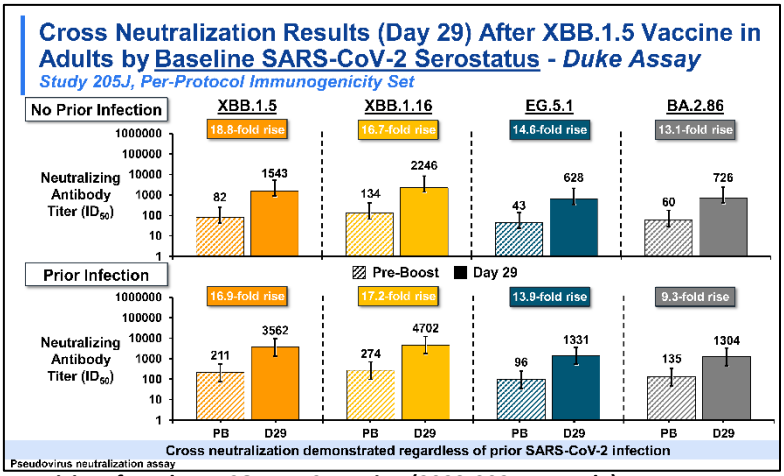
USA

WHO label	Lineage #	%Total	95%PI
Omicron	EG.5	24.5%	22.5-26.6%
	FL.1.5.1	13.7%	9.8-18.7%
	XBB.1.16	10.2%	8.6-11.9%
	XBB.1.16.6	9.9%	8.4-11.7%
	HV.1	8.4%	6.6-10.5%
	XBB.2.3	7.2%	6.2-8.5%
	XBB.1.16.1	4.1%	3.4-4.9%
	XBB.1.5.70	3.8%	2.9-4.9%
	XBB.1.16.11	3.0%	2.3-3.8%
	XBB	2.5%	2.1-2.9%
	XBB.1.5	2.2%	1.9-2.6%
	XBB.1.9.1	1.9%	1.6-2.2%
	GE.1	1.7%	1.3-2.3%
	EG.6.1	1.5%	1.0-2.1%
	XBB.1.5.72	1.2%	0.9-1.6%
	XBB.1.42.2	0.9%	0.5-1.7%
	XBB.1.9.2	0.7%	0.6-0.9%
	XBB.1.5.68	0.6%	0.4-0.9%
	XBB.1.5.10	0.6%	0.4-0.7%
	XBB.2.3.8	0.4%	0.2-0.6%
	CH.1.1	0.3%	0.2-0.4%
	FD.1.1	0.3%	0.2-0.4%
	XBB.1.5.59	0.2%	0.1-0.4%
	FE.1.1	0.2%	0.1-0.3%
	EU.1.1	0.0%	0.0-0.1%
	XBB.1.5.1	0.0%	0.0-0.0%
	BQ.1	0.0%	0.0-0.1%
	BA.2.12.1	0.0%	0.0-0.0%
	B.1.1.529	0.0%	0.0-0.0%
	BA.5	0.0%	0.0-0.0%
	FD.2	0.0%	0.0-0.0%
Other	Other*	0.1%	0.0-0.1%



It is recommended that everyone 6 months and older get an updated COVID-19 vaccine if they have not had a COVID-19 vaccine in the past 2 months or been infected with COVID-19 in the past 3 months. Novavax vaccine, which is made like the recombinant flu vaccine and some other vaccines, has not yet been approved by the FDA due to some delays but should be soon and should have the same recommendations.

The updated vaccines worked well last year, decreasing needs for urgent care and ER visits by 60% in children and adults. They reduced the need for hospitalization in those with COVID-19 by 65%. Benefits did decrease with time, though it is hard to sort out how much of the decrease was the effect of new variants. There is also now good and repeated evidence to show that COVID-19 vaccination, especially staying up to date on vaccination, reduces the risks and severity of long COVID. Each of the pharmaceutical companies were able to show the newest updated vaccine created increases in antibodies against the currently circulating variants, and in the case of Moderna, they included BA.2.86.



Immunogenicity of Moderna COVID-19 Vaccine (2023-2024 Formula) XBB.1.5 Monovalent Vaccine

Some question the need of COVID-19 vaccination in children. The most recent data shows that more than half of children hospitalized for COVID-19 do not have any other health problems, or co-morbidity. For kids, hospitalization rates were lower or comparable to those with the flu but once hospitalized, more kids went to the ICU for COVID-19 than for the flu. COVID-19 hospitalization rates were higher than some other vaccine-preventable diseases, such as hepatitis A, chickenpox, and invasive pneumococcal disease. There have also been concerns regarding the risks of myocarditis and pericarditis with mRNA vaccines, especially with teens and young adults. There were only 2 cases of myocarditis or pericarditis observed after over 650,000 bivalent boosters were given (or 0.31 per 100,000). This was a much smaller rate than after the primary series. It is thought this was because of the increased time between vaccine doses. The estimated rate of myocarditis with COVID-19 infections is 150 cases/100,000 individuals, or 480x higher than the rate after receiving the bivalent booster.

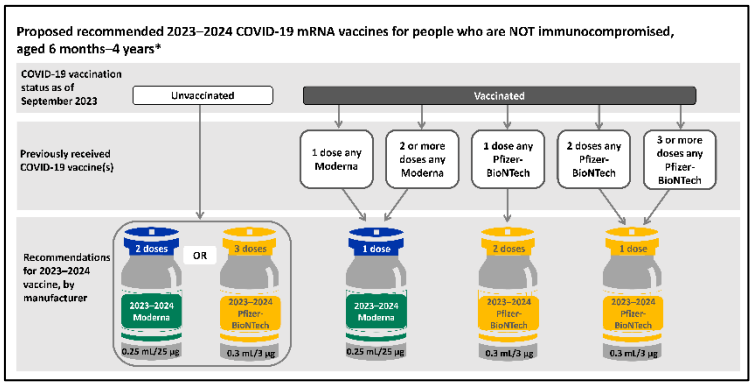
Specified Serious Adverse Events (Myocarditis/Pericarditis)

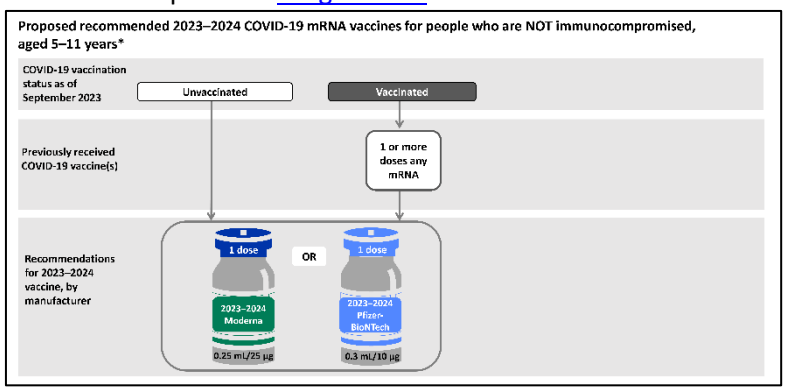
Incidence Rate of Verified Myocarditis/Pericarditis in the 0 to 7 Days After mRNA COVID-19 Vaccination among Persons Aged 12 – 39 Years by Product, Age Group, Sex.

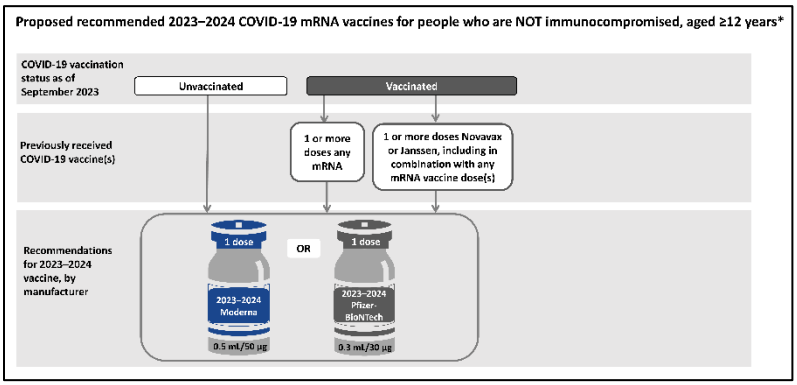
	Monovalent Booster Dose		Bivalent Booster Dose	
Age group	Cases/Doses Administered	Incidence Rate/Million Doses (95% CI)	Cases/Doses Administered	Incidence Rate/Million Doses (95% CI)
Pfizer				
Male				
12-17 y	-	-	0/55649	0.0 (0.0 – 53.8)
12-15 y	5/81613	61.3 (19.9 – 143.0)	-	-
16-17 y	9/47874	188.0 (86.0 – 356.9)	-	-
18-29 y	7/166973	41.9 (16.9 – 86.4)	1/60338	16.6 (0.4 – 92.3)
30-39 y	3/197554	15.2 (3.1 – 44.4)	0/97171	0.0 (0.0 – 30.8)
Female				
12-17 y	-	-	0/57776	0.0 (0.0 – 51.9)
12-15 y	0/84114	0.0 (0.0 – 35.6)	-	-
16-17 y	2/55004	36.4 (4.4 – 131.3)	-	-
18-29 y	1/240226	4.2 (0.1 – 23.2)	0/95162	0.0 (0.0 – 31.5)
30-39 y	1/268412	3.7 (0.1 – 20.8)	0/133305	0.0 (0.0 – 22.5)
Moderna				
Male				
18-29 y	7/109337	64.0 (25.7 – 131.9)	0/22247	0.0 (0.0 – 134.7)
30-39 y	1/149468	6.7 (0.2 – 37.3)	1/41820	23.9 (0.6 – 133.2)
Female				
18-29 y	1/156707	6.4 (0.2 – 35.6)	0/35393	0.0 (0.0 – 84.6)
30-39 y	2/191765	10.4 (1.3 – 37.7)	0/55816	0.0 (0.0 – 53.7)

Source: Goddard K, et al. Incidence of Myocarditis/Pericarditis Following mRNA COVID-19 Vaccination Among Children and Younger Adults in the United States. Ann Intern Med. 2022;175:1169-1771. **Bivalent booster data through March 11, 2023. Data unpublished.** 49

Those that are up to date on their COVID-19 vaccines and most 5years old and older will just need one dose of the updated vaccine. Some who are younger than 5 years may need additional doses. For those who are immunocompromised, talk with your health department or healthcare provider for guidance.







RSV Vaccine

Respiratory syncytial virus, or RSV, is a common respiratory virus and in most people causes cold symptoms. Most children will have RSV by the time they are 2 years old. Young infants and older adults are more likely than others to develop severe RSV and need hospitalization. Each year in the United States, RSV leads to approximately: 2.1 million healthcare visits for children younger than 5 years; 58,000-80,000 hospitalizations for children younger than 5 years old and 60,000-160,000 hospitalizations for adults 65 years and older, and; 100–300 deaths in children younger than 5 years old and 6,000-10,000 deaths among adults 65 years and older.

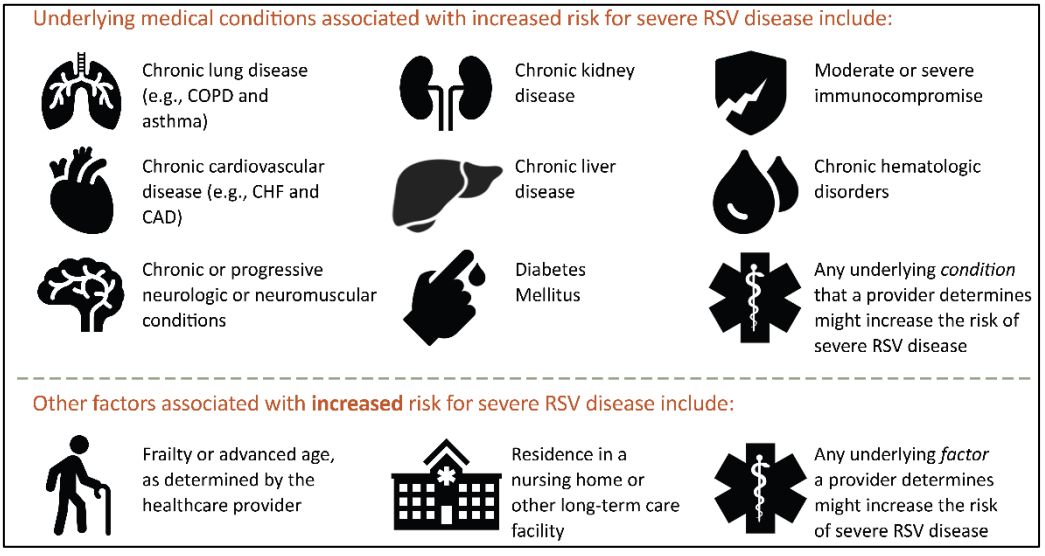
There are two new vaccines available that can be given starting at age 60 to prevent RSV, Arexvy (GSK) and Abrysvo (Pfizer), Abrysvo is also FDA approved for use in late pregnancy but still awaiting more input from the Advisory Committee on Immunization Practices (ACIP) as to the safest way to use it. When given later in pregnancy, antibodies pass to the baby providing around 6 months of protection after birth. However, there is some discussion regarding how much protection is provided, and concerns about side effects.

Both vaccines are recombinant protein subunit vaccines. Arexvy, (from GSK) uses an adjuvant (called AS01E) which is an ingredient that helps vaccines create a stronger and longer immune responses. Because they activate the immune system so well, vaccines with adjuvants tend to cause more short-term side effects like injection site redness, swelling, pain, as well as headache, muscle aches, and fatigue. Abrysvo (from Pfizer) has no adjuvant but does target one extra area of the same protein. In reality, it is expected that this will not add much to the protection it provides, but the vaccine does have fewer side effects since it has no adjuvant.

The recommendation is to give a single dose of either RSV vaccine as early as the vaccine supply becomes available and prior to the onset of RSV season (if possible) using *shared clinical decision making* between patient and healthcare provider. There are currently no recommendations for boosters but may change in future as more long-term evidence is available. In initial trials these vaccines reduced the need to seek healthcare and the risks of bronchitis and pneumonia from RSV by over 80%. They were studied over 2 RSV seasons.

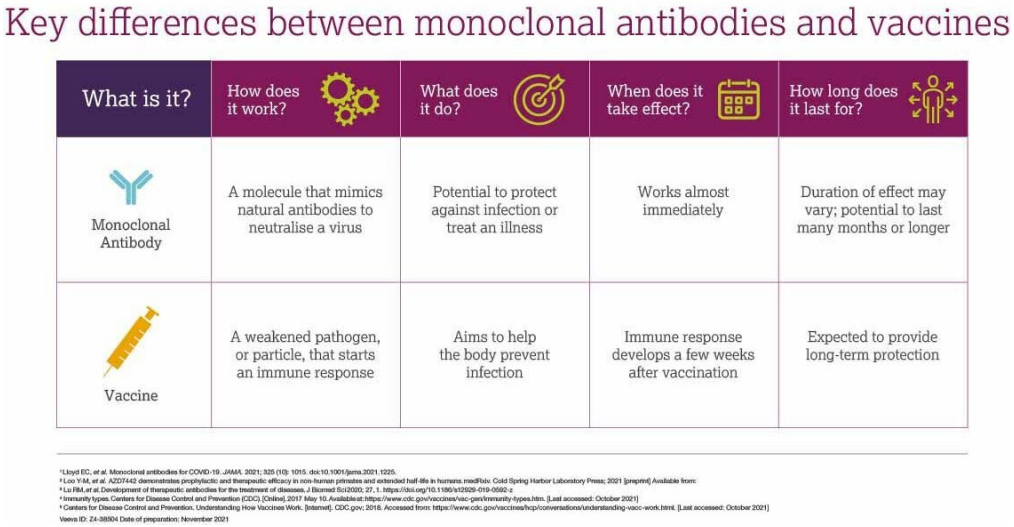
The decision was made to not recommend these vaccines to all adults at this time until we know how well it prevents hospitalizations and deaths and how well it works over the long run. In addition, in the studies of over 50,000 people for both vaccines combined, there were 5 cases of inflammatory neurologic conditions (Guillain-Barré syndrome [GBS] and acute disseminated encephalomyelitis [ADEM]) and one case of worsening of an already existing motor-sensory polyneuropathy. Some of these cases happened in parts of the trial that had no placebo arm, making it more difficult interpret their relation to the vaccine. There was also a higher number of participants in the vaccine groups than the control groups that reported atrial fibrillation. A total of 20 in the vaccine group versus 8 in the control group reported an onset of atrial fibrillation within 30 days after vaccination. With such a small number of cases, we can't know if these issues are really related to the vaccine or just chance. With more information from additional trials and post-marketing surveillance, it should become clearer if there is any true concern as well as the full benefits from the vaccine and recommendations may change.

At this time the vaccine is targeted at those adults with the highest risks from RSV infections, as illustrated to the right.



RSV Monoclonal Antibody

Nirsevimab (Bayfortus from Sanofi and AstraZeneca) is a new long-acting monoclonal antibody available for RSV. It is labeled as a medication by the FDA and is considered an immunization rather than a vaccination. It is recommended for infants up to 8 months who are born during or entering their first RSV season and for infants and children aged 8 to 19 months who are at increased risk for severe RSV disease and are entering their second RSV season. Those at increased risk for severe disease include children with complicated chronic lung disease of prematurity; children with severe immunocompromise; children with complicated cystic fibrosis, and; American Indian or Alaska Native children. The protection lasts 4-6 months and in clinical trials it reduced the risk of hospitalization and healthcare visits by around 80%. It is very safe and has a very rare risk of allergic reactions but otherwise no major side effects.



Key differences between monoclonal antibodies and vaccines

What is it?	How does it work?	What does it do?	When does it take effect?	How long does it last for?
Monoclonal Antibody	A molecule that mimics natural antibodies to neutralise a virus	Potential to protect against infection or treat an illness	Works almost immediately	Duration of effect may vary; potential to last many months or longer
Vaccine	A weakened pathogen, or particle, that starts an immune response	Aims to help the body prevent infection	Immune response develops a few weeks after vaccination	Expected to provide long-term protection

[1]Lloyd EC, et al. Monoclonal antibodies for COVID-19. JAMA. 2021; 325 (10): 1015. doi:10.1001/jama.2021.1225.
[2] Loo Y-M, et al. AZD7442 demonstrates prophylactic and therapeutic efficacy in non-human primates and extended half-life in humans. medRxiv. Cold Spring Harbor Laboratory Press; 2021 [preprint] Available from:
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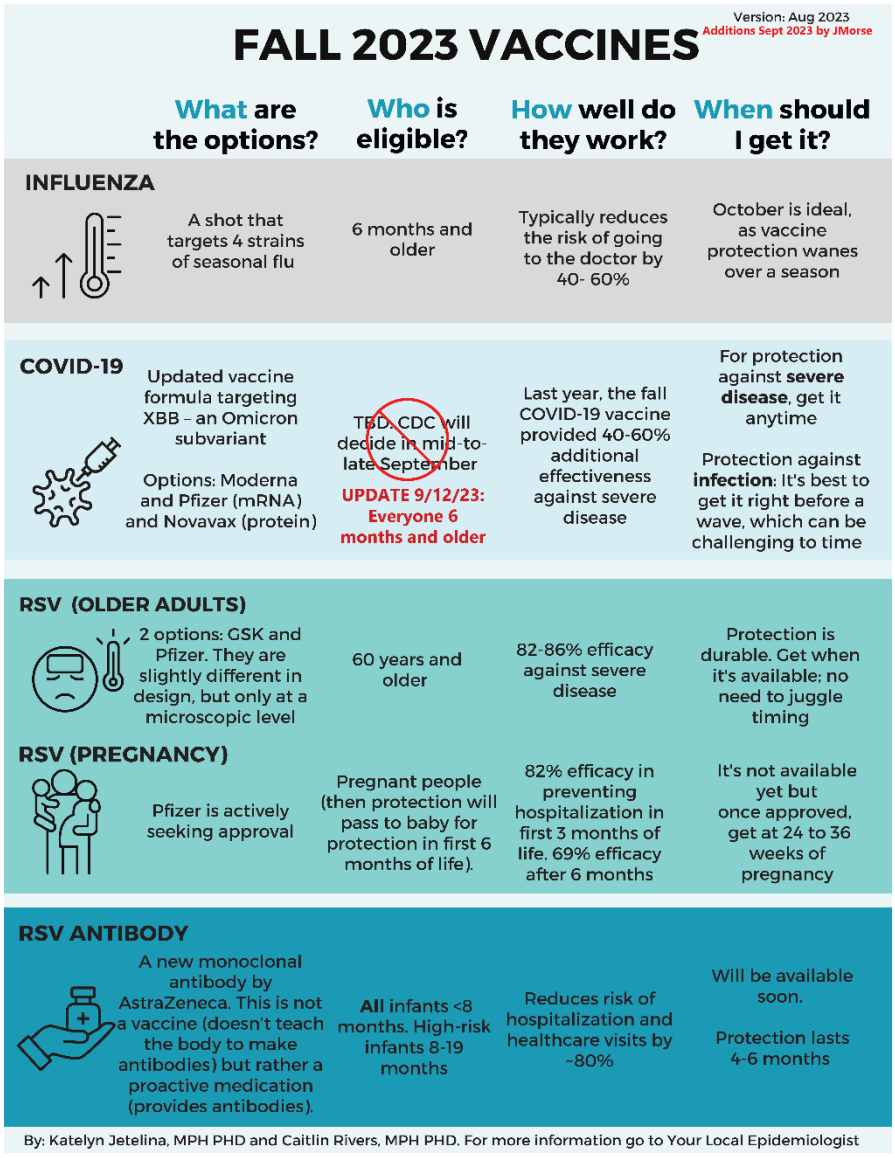
Veeva ID: Z4-38504 Date of preparation: November 2021



Recommendations:

1. While most colds and flus and minor, illness with COVID-19, influenza, and RSV can cause missed work and school, serious illness, hospitalization, and death especially in those at highest risk. Vaccination and immunization are our best tools to reduce these risks.
2. Help be a vaccination champion. Excellent toolkits available at https://www.voicesforvaccines.org/toolkits/ including Vaccine Hesitancy Toolkit: Introduction, Family Advocacy Toolkit: Introduction, and New Parent Toolkit: Congratulations!
3. Read real life stories of what these illnesses can do at: https://www.familiesfightingflu.org/family-stories/, https://www.nfid.org/resources/real-stories-real-people/?_disease=rsv, and https://covidsurvivorsforchange.org/survivor-stories/

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