I-VAC Adult & Pediatric Learning Collaborative for COVID-19 Vaccination

Please use your first name and health center name when you join the session

Use the **“chat”** feature to let us know if you have a question

Please remember to **mute your microphone** unless speaking

If you can’t connect audio via computer or lose computer audio at anytime, you can call in to session at **(669) 900-6833, Meeting ID 812-8864-4528##**

I-VAC ILLINOIS VACCINATES AGAINST COVID-19

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Disclosures

- No one in a position to control the education content of the activity has any relevant financial disclosures with ineligible companies to disclose.
- What gets said here today may change based on new data and recommendations
  - Knowledge is shared more rapidly through ECHO

I-VAC ILLINOIS VACCINATES AGAINST COVID-19

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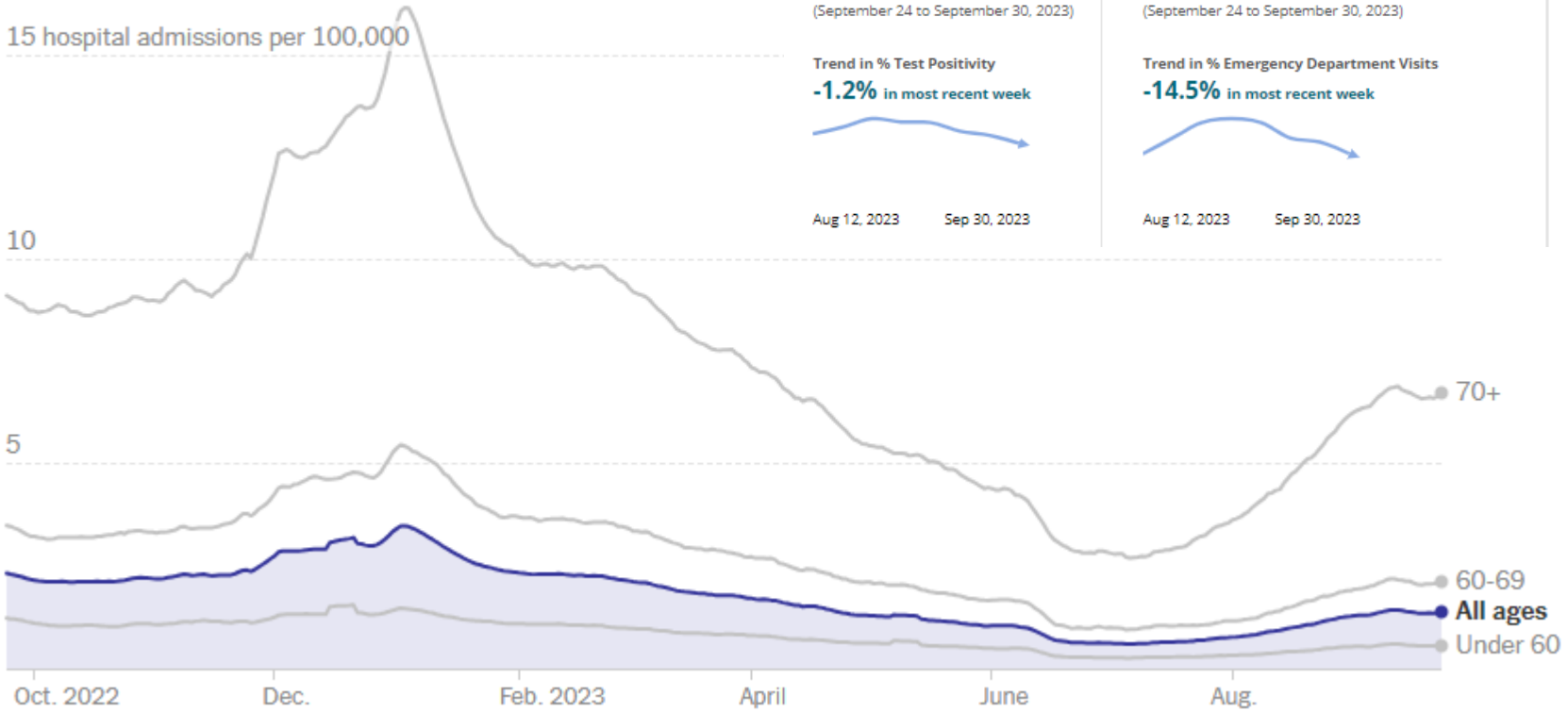
Track Covid-19 in the U.S.

Updated Oct. 9, 2023

Daily Covid hospital admissions

Avg. on Sept. 23: 4,546

14-day change: −3%



Early Indicators

Test Positivity

% Test Positivity

10.9%

(September 24 to September 30, 2023)

Trend in % Test Positivity

-1.2% in most recent week

Aug 12, 2023 Sep 30, 2023

Emergency Department Visits

% Diagnosed as COVID-19

1.6%

(September 24 to September 30, 2023)

Trend in % Emergency Department Visits

-14.5% in most recent week

Aug 12, 2023 Sep 30, 2023

Severity Indicators

Hospitalizations

Hospital Admissions

18,139

(September 24 to September 30, 2023)

Trend in Hospital Admissions

-6% in most recent week

Aug 12, 2023 Sep 30, 2023

Deaths

% of All Deaths in U.S. Due to COVID-19

2.7%

(September 24 to September 30, 2023)

Trend in % COVID-19 Deaths

+3.8% in most recent week

Aug 12, 2023 Sep 30, 2023

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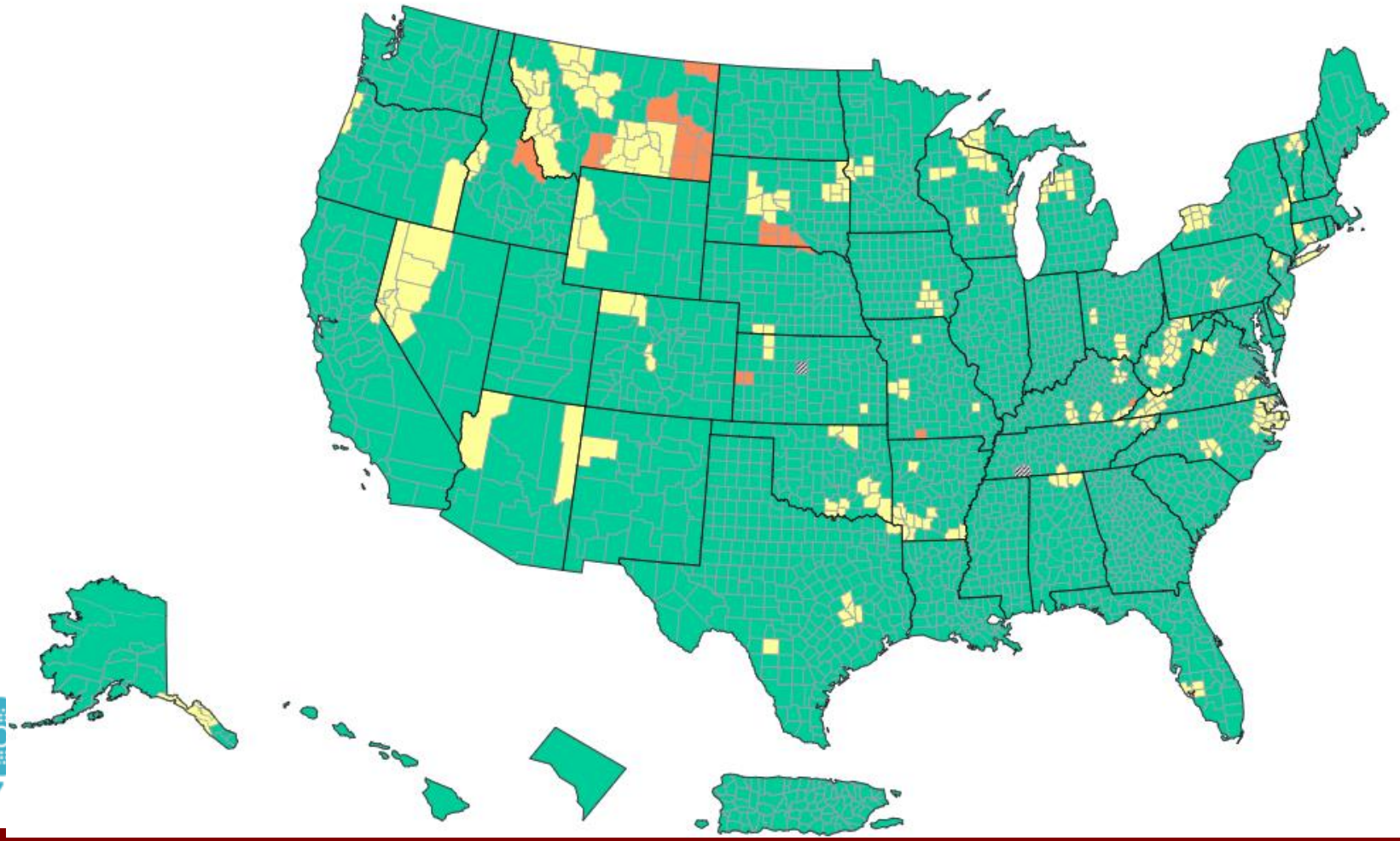
COVID-19 hospital admissions levels in U.S. by county

Based on new COVID-19 hospital admissions per 100,000 population

	Total	Percent	% Change
≥ 20.0	20	0.62%	-0.06%
10.0 - 19.9	257	7.98%	0.43%
<10.0	2942	91.39%	-0.4%

Time Period: New COVID-19 hospital admissions per 100,000 population (7-day total) are calculated using data from the MMWR week (Sun-Sat) ending September 30, 2023.

Reported COVID-19 New Hospital Admissions Rate per 100,000 Population in the Past Week, by County – United States



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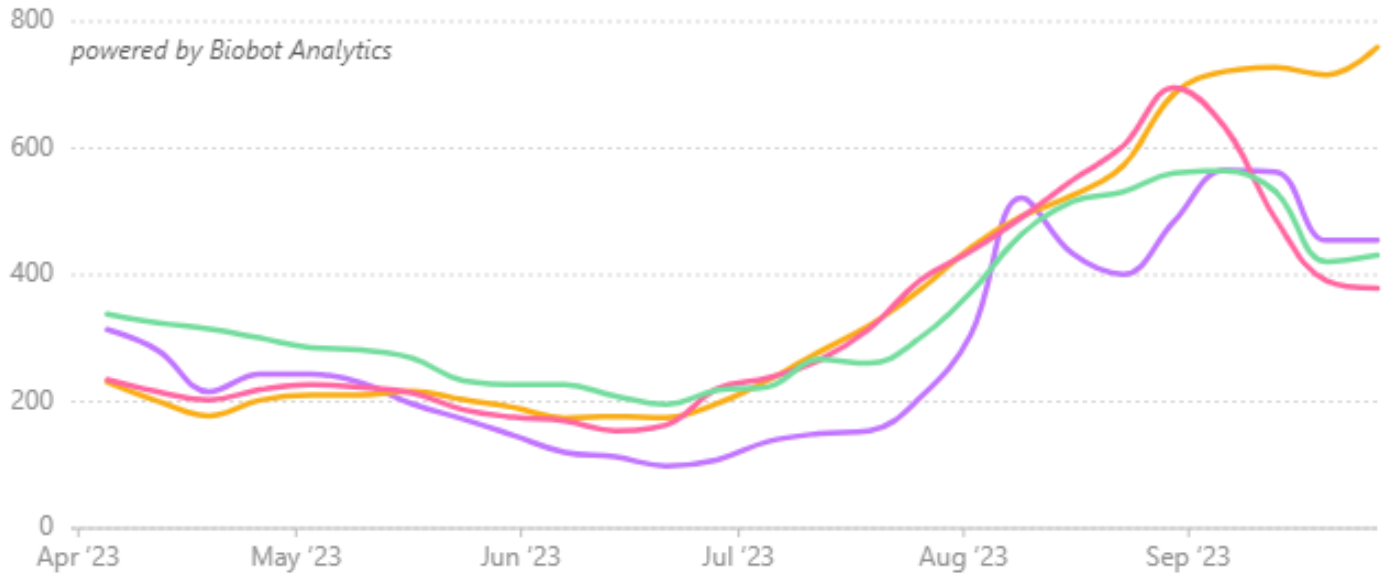
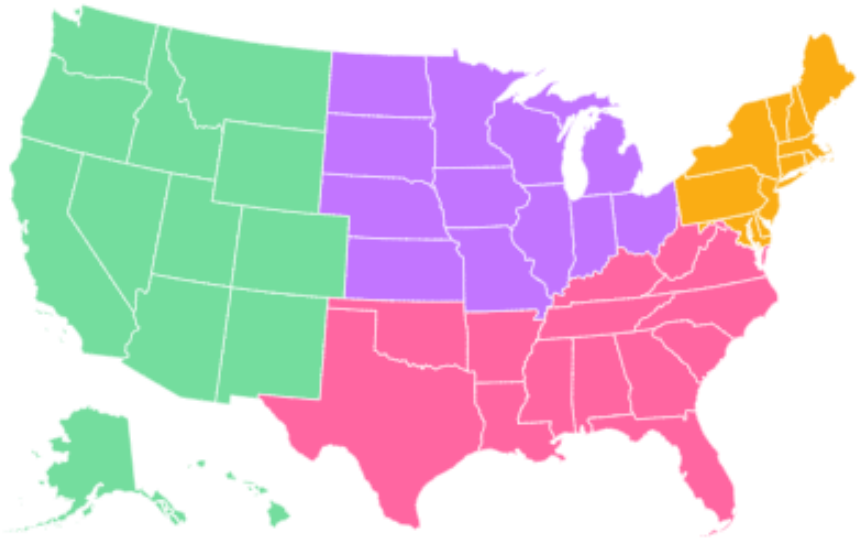
Wastewater Surveillance

Wastewater: Effective SARS-CoV-2 virus concentration (copies / mL of sewage)





Source: Wastewater data from Biobot Analytics

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Chicago's COVID-19 Risk Level is LOW

CHICAGO | COVID-19 Summary

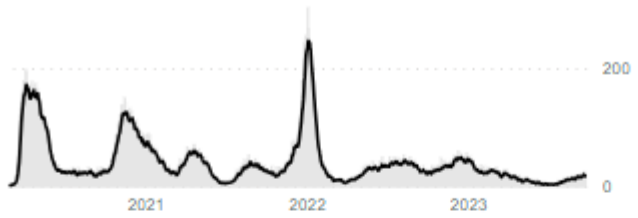
Data current as of Oct 05, 2023.
Data are updated Wednesdays at 5:30 p.m., except for City holidays.
All data are provisional and subject to change.

SUMMARY | CASES | CASES BY ZIP | TESTS

Learn how to use this dashboard.

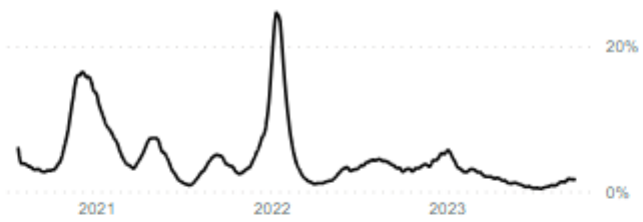
HOSPITALIZATIONS

18 ▲	17 (+5%)	54,016	0.65
Current daily avg	Prior week	Cumulative	Daily rate per 100,000



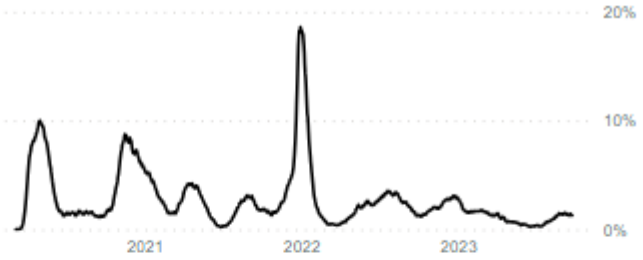
HOSPITAL BEDS IN USE

1.6% ▼	1.7%
Current daily avg	Prior Week



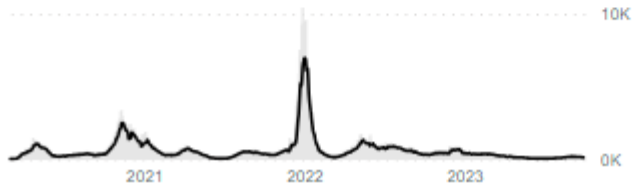
EMERGENCY ROOM VISITS

▼	1.4%
Current daily avg	Prior Week



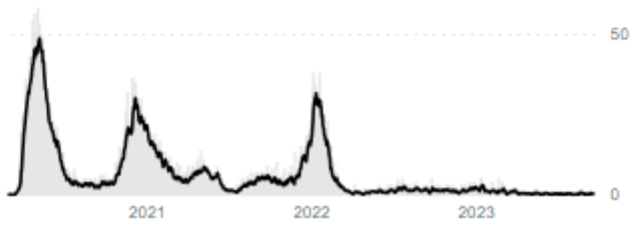
LABORATORY-CONFIRMED CASES

111 ▼	143 (-23%)	788,399	4.25
Current daily avg	Prior week	Cumulative	Daily rate per 100,000



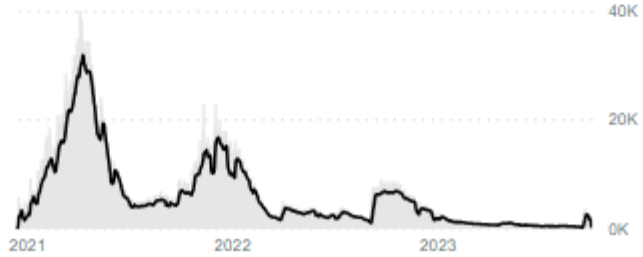
DEATHS

0.29 ↔	0.29 (0%)	8,176	0.01
Current daily avg	Prior week	Cumulative	Daily rate per 100,000



VACCINATIONS ADMINISTERED

300 ▼	5,907,645	24.3%
Current daily avg	Cumulative	People with updated booster



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AGAINST C

When's the Best Time to Get the Updated COVID Shot?

- In general, people who were recently infected with COVID-19, who should wait around 3 months until their natural immunity wears off to maximize their protection
- Waiting until right before the holidays wouldn't offer much of a benefit - new antibodies from the shot take around 3 weeks to form
- Vaccine does not become ineffective after 4 months, but rather has the best protection against mild illness for that duration
- People who are highest risk should prioritize this:
  - Older adults, pregnant people, and the immunocompromised, along with those who live with them, "because that's the goal of this vaccine, to prevent severe disease.“
- Call ahead! Not every clinic or pharmacy has the vaccine yet!

https://www.medpagetoday.com/special-reports/features/106572

Considerations for Co-Administrations

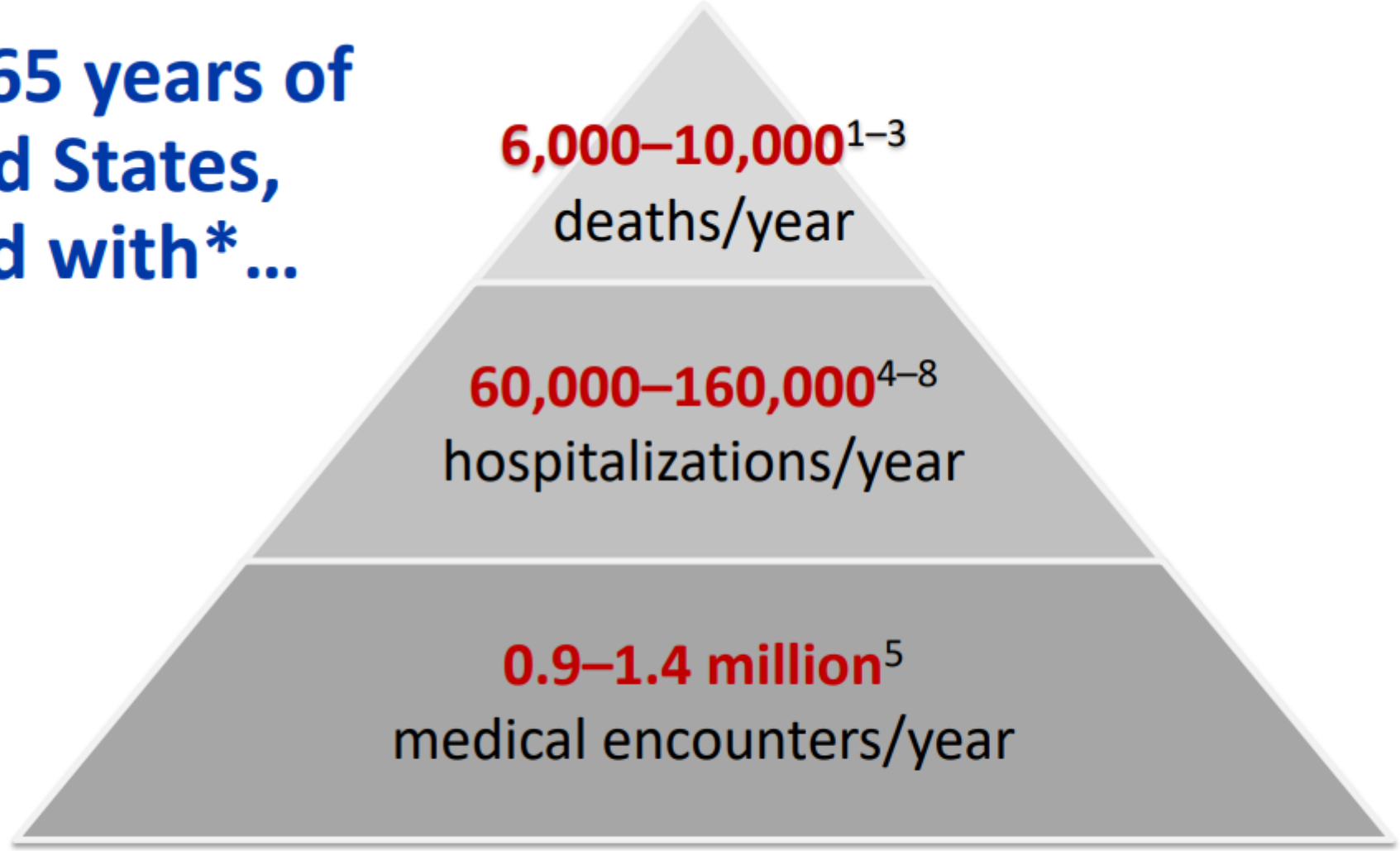
- Out that of the respiratory syncytial virus (RSV), influenza, and COVID-19 shots, "the highest priority definitely is the COVID vaccine, and people should really get that first and as soon as possible, because the strains have changed.“
- CDC guidance states that influenza, COVID-19 and RSV vaccines ***CAN all be given at the same time*** to eligible individuals
- Patients receiving multiple vaccines during the same clinic visit may be more likely to experience reactogenicity associated with vaccines, such as fever, headache and pain or swelling at the injection site(s).
- To minimize pain and discomfort associated with multiple vaccines given simultaneously, providers should, where possible, administer vaccines in different arms or at different injection sites. If patients request the same arm or same vaccine site for multiple vaccines, or if it is not feasible to deliver vaccines in different limbs, it is helpful to separate injection sites by 1 inch or more where possible, to reduce the potential for swelling and pain at injection sites.

Scenarios where spacing between vaccines could be considered

- Because administering multiple vaccines at the same visit may result in an increased likelihood of reactogenic events, providers may consider spacing vaccines out for individuals who are concerned about pain, swelling or other similar events.
- Providers may also want to consider this for individuals with a history of reactogenic events after vaccination, such as severe swelling or induration.
- Individuals who are immunocompromised may wish to consider spacing vaccines out to maximize vaccine-mediated protection and prevent intra-season waning of vaccine effectiveness.
- Providers should keep in mind that the timing of seasonal respiratory virus epidemics is difficult to predict and can vary substantially by geography. If vaccines are planned to be administered at separate visits, it will be important to schedule those visits before the start of the respiratory virus season.

RSV Vaccine

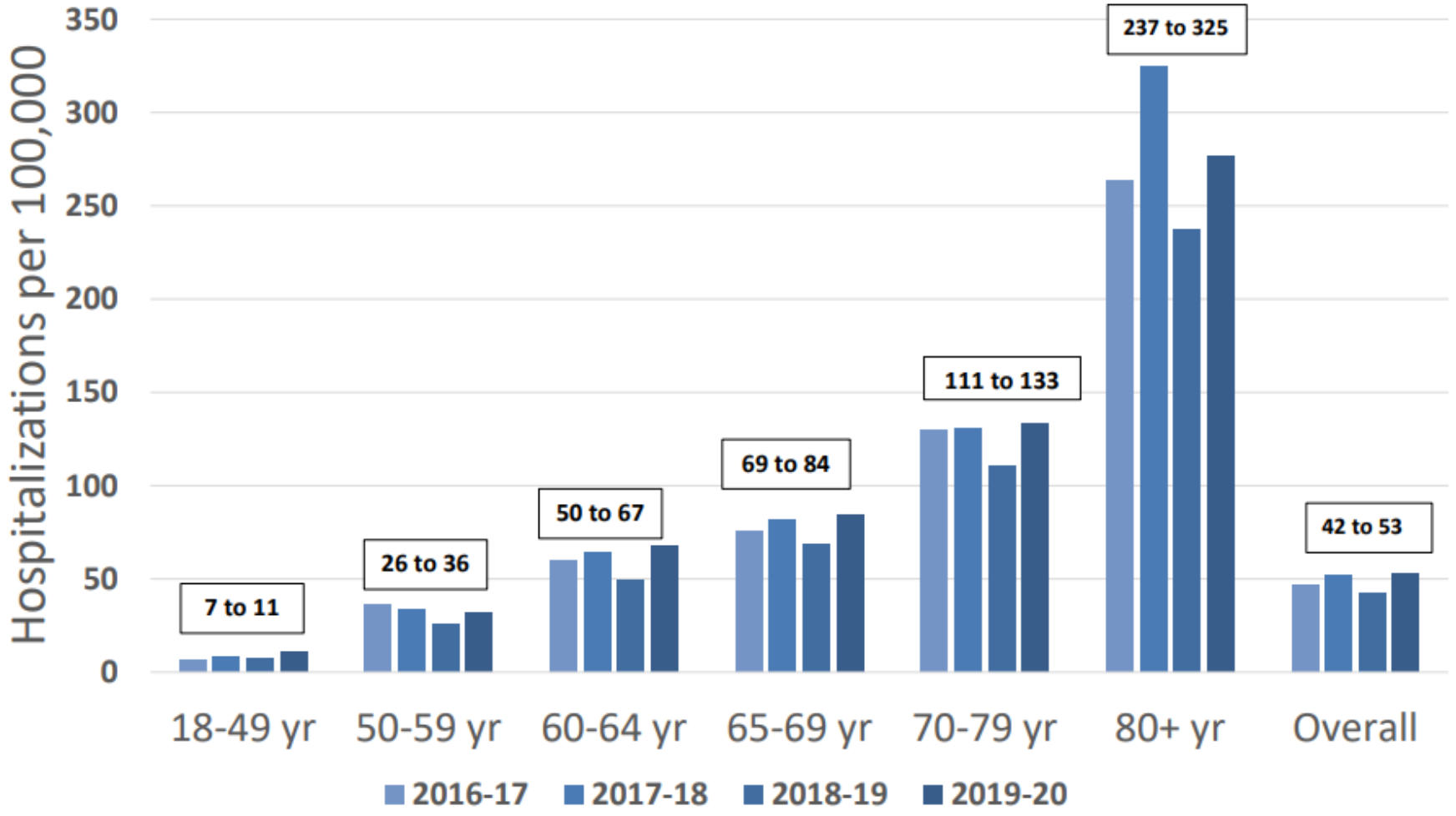
Among adults ≥65 years of age in the United States, RSV is associated with*…



*There is substantial uncertainty in burden of disease, reflected in wide ranges here.

1. Thompson et al, JAMA (2003): https://doi.org/10.1001/jama.289.2.179
2. Matias et al, Influenza Other Respi Viruses (2014): https://doi.org/10.1111/irv.12258
3. Hansen et al, JAMA Network Open (2022): https://doi.org/10.1001/jamanetworkopen.2022.0527
4. Widmer et al, JAMA Network Open (2012): https://doi.org/10.1093/infdis/jis309
5. McLaughlin et al, Open Forum Infect Dis (2022): https://doi.org/10.1093/ofid/ofac300
6. Zheng et al, Pneumonia (2022): https://doi.org/10.1186/s41479-022-00098-x
7. Branche et al, Clinical Infect Dis (2022): https://doi.org/10.1093/cid/ciab595
8. CDC RSV-NET data 2016–2020 (unpublished)

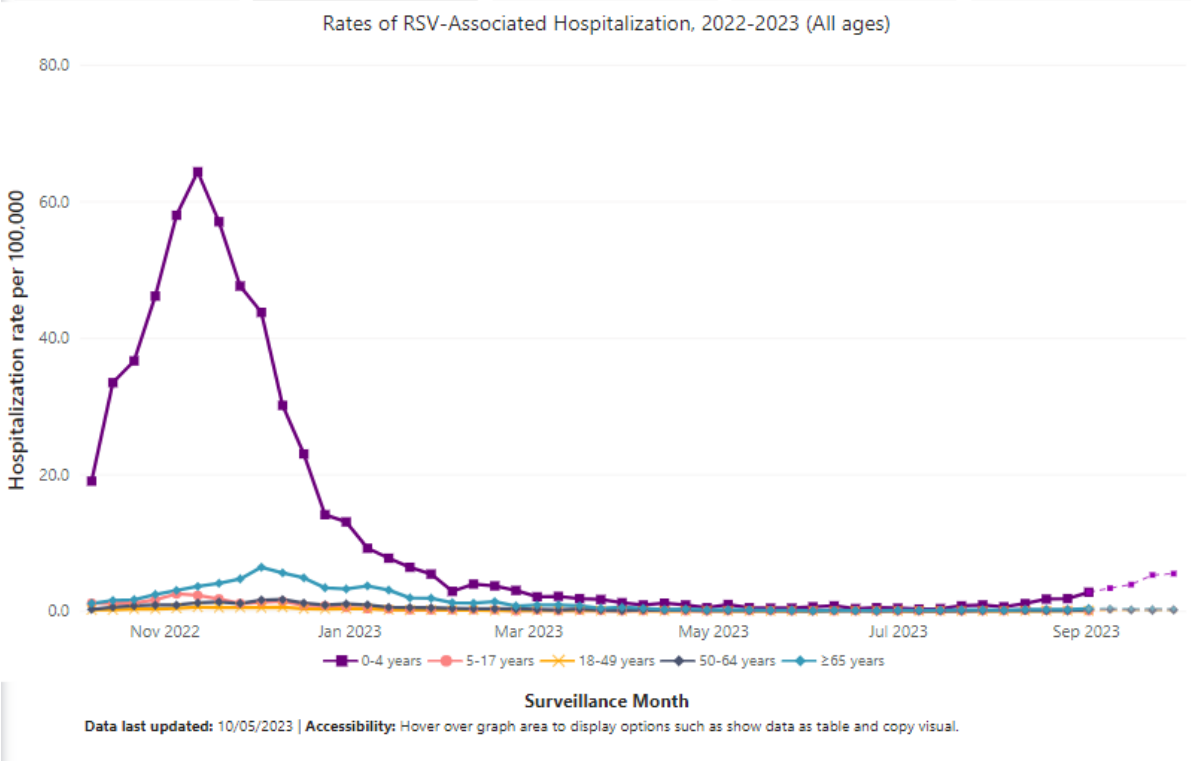
RSV-associated hospitalization rates by adult age group, RSV-NET 2016–2020

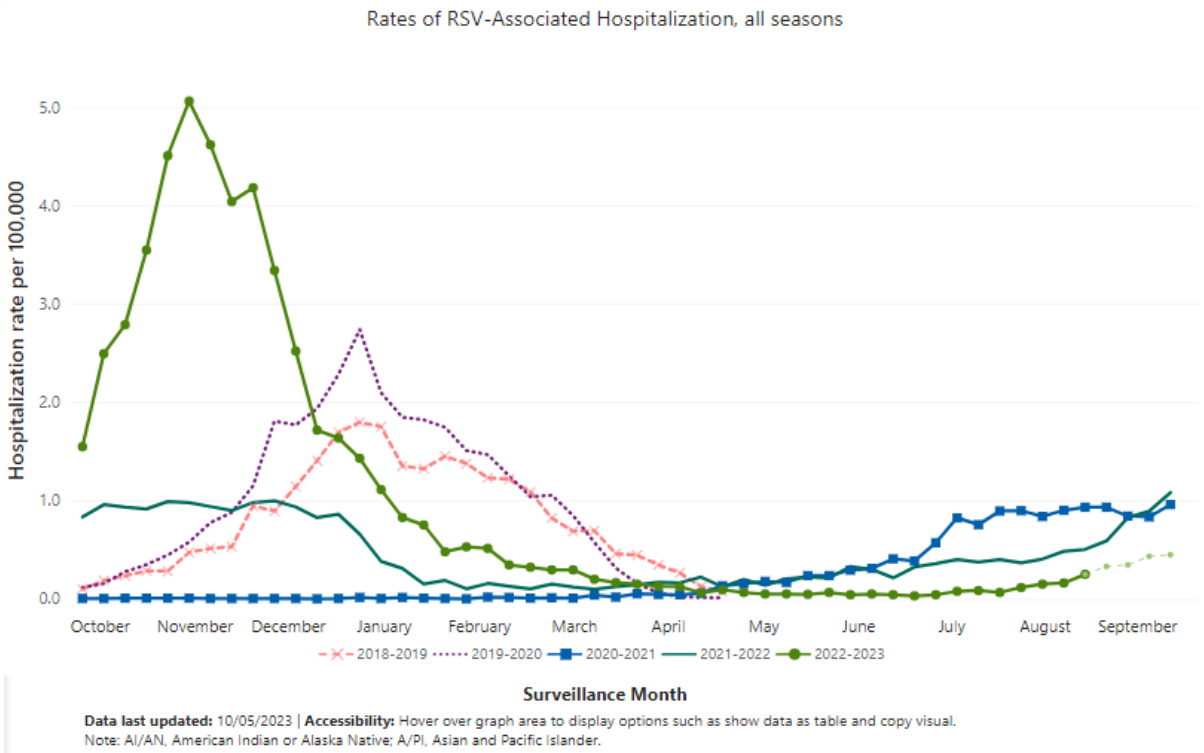


RSV-NET: unpublished data; https://www.cdc.gov/rsv/research/rsv-net/overview-methods.html.
Rates are adjusted for the frequency of RSV testing during recent prior seasons and the sensitivity of RSV diagnostic tests..

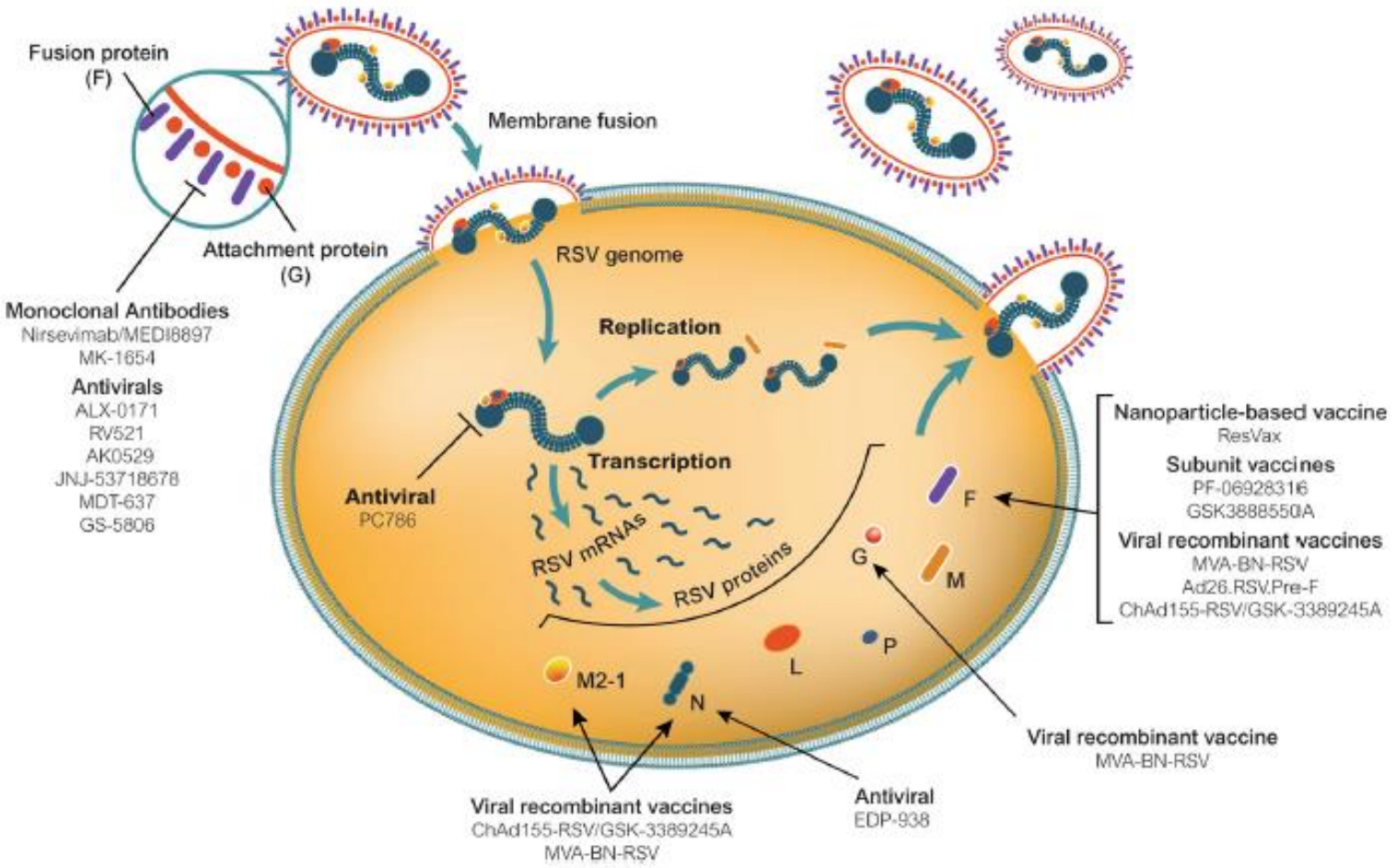
Slide credit: Fiona Havers

RSV Epidemiology





https://www.cdc.gov/rsv/research/rsv-net/dashboard.html



- After infection, more than 90% of neutralizing antibodies are directed against the F protein, which exists in both prefusion and postfusion conformations.
- The epitopes on the F protein that are most sensitive to neutralization are hidden in the postfusion state, which posed challenges to the development of both a monoclonal antibody and a vaccine.

RSV Vaccines for Older Adults

- There are two RSV vaccines licensed for use in adults aged 60 years and older in the United States:
  - RSVPreF3 (**Arexvy**, *GSK*)
  - RSVpreF (**Abrysvo**, *Pfizer*)
- CDC recommends that adults 60 years of age and older may receive a single dose of RSV vaccine using shared clinical decision-making
- Persons aged 60 years and older who are at highest risk for severe RSV disease and who might be most likely to benefit from vaccination include those with chronic medical conditions such as:
  - Cardiopulmonary disease, Kidney disorders, Liver disorders, Neurologic or neuromuscular conditions, Hematologic disorders, Diabetes mellitus, and Moderate or severe immune compromise (either attributable to a medical condition or receipt of immunosuppressive medications or treatment);
  - Persons who are frail, advanced age, reside in nursing homes or other long-term care facilities, persons with other underlying conditions or factors that the provider determines might increase the risk for severe respiratory disease.

The Vaccines

- **Pfizer bivalent RSVpreF vaccine** (ABRYSVO) is a sterile solution for intramuscular injection. The vaccine is supplied as a vial of Lyophilized Antigen Component that is reconstituted at the time of use with a Sterile Water Diluent Component.
- The RSV preF A and RSV preF B recombinant proteins are expressed in genetically engineered Chinese Hamster Ovary cell lines grown in suspension culture using chemically-defined media, without antibiotics or animal-derived components. The recombinant proteins are purified through a series of column chromatography and filtration steps followed by formulation, filling into vials, and lyophilization.
- After reconstitution, each dose is approximately 0.5 mL.

- **GSK adjuvanted RSVpreF3 vaccine** (AREXVY) consists of a recombinant RSV F protein antigen (based on the RSV-A subtype), stabilized in the prefusion conformation (preF), and $AS01_E$ adjuvant. The AS01 adjuvant system is the same used in GSK's recombinant zoster vaccine (RZV, Shingrix), but at a lower dose.
- The vaccine is supplied as a single-dose vial of 120 µg of lyophilized preF antigen component to be reconstituted with the accompanying vial of $AS01_E$ adjuvant suspension component.
- A single dose after reconstitution is 0.5 mL.

Vaccine Efficacy and Safety: GSK

- 1 ongoing randomized, double-blind, placebo-controlled phase 3 clinical trial conducted in 17 countries and including 24,973 immunocompetent participants aged ≥60 years randomized 1:1 to receive 1 dose of vaccine or saline placebo
- Severe reactogenicity events (grade 3 solicited local or systemic reactions after vaccination) occurred in 3.8% of the intervention group participants, compared with 0.9% of the control group The frequency of serious adverse events (SAEs) across both trials was similar in the intervention (4.4%) & control (4.3%)
- Inflammatory neurologic events were reported in 3 of 17,922 participants within 42 days; 1 case of GBS and 2 of ADEM

TABLE 1. Efficacy of 1 dose of GSK respiratory syncytial virus RSVpreF3 vaccine against respiratory syncytial virus–associated disease among adults aged ≥60 years — multiple countries, 2021–2023

Return

Efficacy evaluation period	Vaccine efficacy against outcome*	
	RSV-associated LRTD†	RSV-associated medically attended LRTD§
Season 1¶	82.6 (57.9–94.1)**	87.5 (58.9–97.6)††
Season 2§§	56.1 (28.2–74.4)††	—¶¶
Combined seasons 1 and 2 (interim)***	74.5 (60.0–84.5)†††	77.5 (57.9–89.0)††

¶¶ Interim analysis underpowered to estimate efficacy

https://www.cdc.gov/mmwr/volumes/72/wr/mm7229a4.htm#T1_down

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Number needed to vaccinate (NNV): GSK RSVpreF3

- Derived from cost effectiveness analysis performed by U. Michigan
- Time horizon: one year

Number of vaccinations required to prevent…	Adults aged ≥65 years	Adults aged ≥60 years
1 RSV outpatient visit[a]	84 vaccinations	90 vaccinations
1 RSV hospitalization[b]	1,097 vaccinations	1,348 vaccinations
1 RSV death[c]	21,442 vaccinations	27,284 vaccinations

[a] Incidence rates of RSV illness requiring outpatient visit taken from McLaughlin et al, OFID (2022) (unadjusted for RSV under-detection by NP swab RT-PCR). Vaccine efficacy (VE) against this outcome assumed to be equal to that against medically attended acute respiratory illness (ARI) caused by RSV (GSK AReSVi-006 trial, unpublished).
[b] Incidence rates of RSV hospitalization taken from RSV-NET 2015–2019 (unpublished). VE against RSV-associated hospitalization assumed to be equal to that against medically attended lower respiratory tract disease (LRTD) caused by RSV (GSK AReSVi-006 trial, unpublished).
[c] Probability of in-hospital death among adults hospitalized for RSV taken from RSV-NET 2015–2019 (unpublished). VE against RSV-associated death assumed to be equal to that against medically attended lower respiratory tract disease (LRTD) caused by RSV (GSK AReSVi-006 trial, unpublished).

Vaccine Efficacy and Safety: Pfizer

- Data from one ongoing, randomized, double-blind, placebo-controlled phase 3 clinical trial conducted in seven countries and including **36,862** immunocompetent participants aged ≥60 years randomized 1:1 to receive 1 dose of vaccine or placebo containing the same buffer ingredients as the vaccine but without active component
- Severe reactogenicity events (grade 3 or higher local or systemic reactions) occurred in 1.0% of the intervention group participants, compared with 0.7% of the control group participants (pooled RR = 1.43; 95% CI = 0.85–2.39). The frequency of SAEs across both trials was similar in the intervention (4.3%) and control (4.1%)
- A higher number of participants in the intervention group than in the control group reported atrial fibrillation as an unsolicited event within the 30 days after injection (intervention = 10 events [<0.1%]; control = four events [<0.1%], of which seven were SAEs [intervention = four; control = three]). Among participants who reported atrial fibrillation, a medical history of atrial fibrillation was reported by six of 10 Pfizer vaccine recipients and two of four placebo recipients
- Inflammatory neurologic events were reported in three of 20,255 participants within 42 days ; 1 case of GBS, 1 case of Miller Fisher syndrome and one case undifferentiated motor-sensory axonal polyneuropathy with worsening of preexisting symptoms

TABLE 3. Efficacy of 1 dose of Pfizer respiratory syncytial virus RSVpreF vaccine against respiratory syncytial virus–associated disease among adults aged ≥60 years — multiple countries, 2021–2023

Return

Efficacy evaluation period	Vaccine efficacy against outcome, % (95% CI)*	
	RSV-associated LRTD†	RSV-associated medically attended LRTD§
Season 1¶	88.9 (53.6–98.7)	84.6 (32.0–98.3)
Season 2 (interim)**	78.6 (23.2–96.1)	—††
Combined seasons 1 and 2 (interim)§§	84.4 (59.6–95.2)	81.0 (43.5–95.2)

†† Interim analysis underpowered to estimate efficacy

https://www.cdc.gov/mmwr/volumes/72/wr/mm7229a4.htm#T1_down

I-VAC ILLINOIS VACCINATES AGAINST COVID-19

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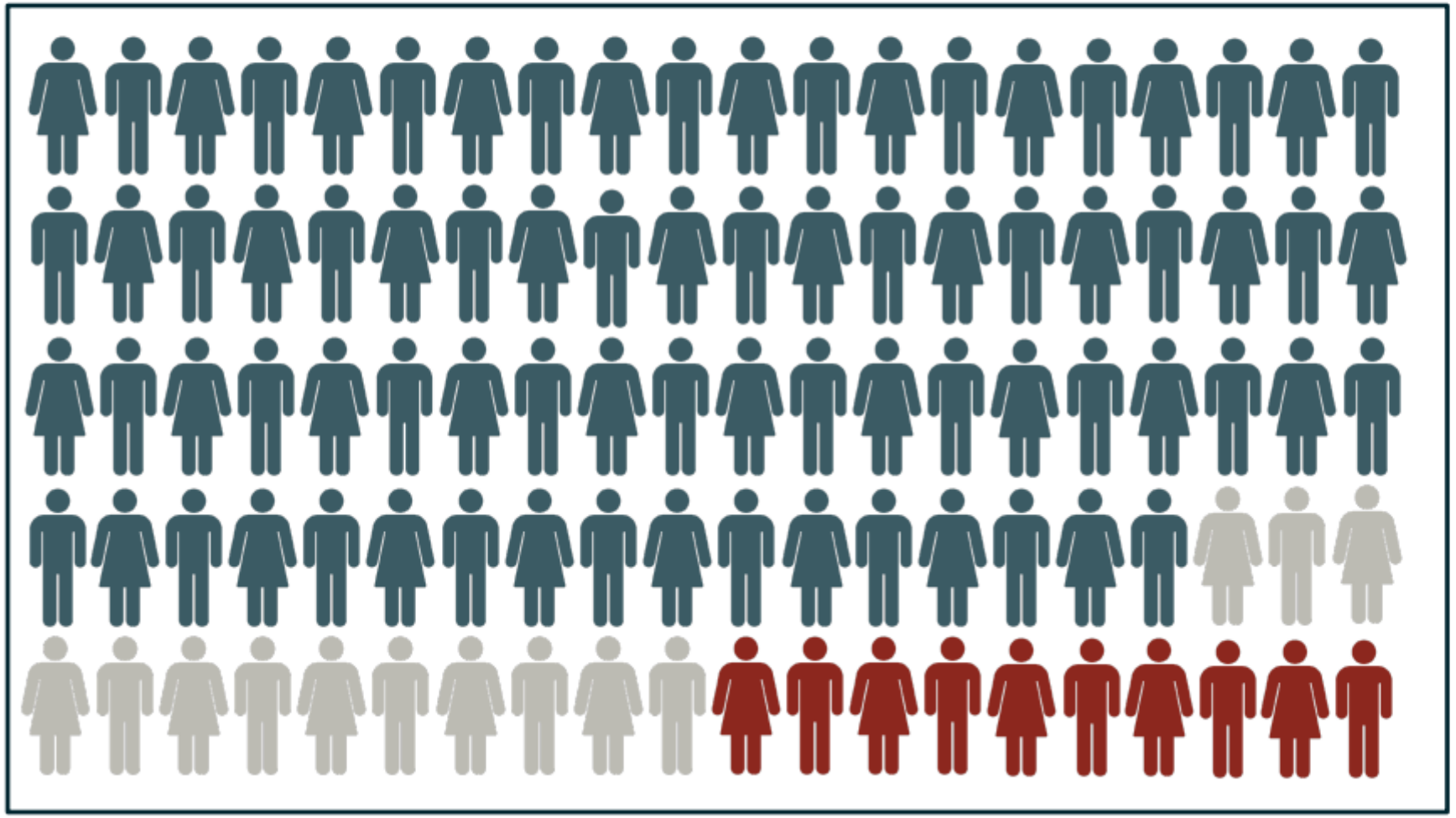
Number needed to vaccinate (NNV): Pfizer RSVpreF

- Derived from cost effectiveness analysis performed by U. Michigan
- Time horizon: one year

Number of vaccinations required to prevent…	Adults aged ≥65 years	Adults aged ≥60 years
1 RSV outpatient visit[a]	95 vaccinations	103 vaccinations
1 RSV hospitalization[b]	1,275 vaccinations	1,567 vaccinations
1 RSV death[c]	24,927 vaccinations	31,717 vaccinations

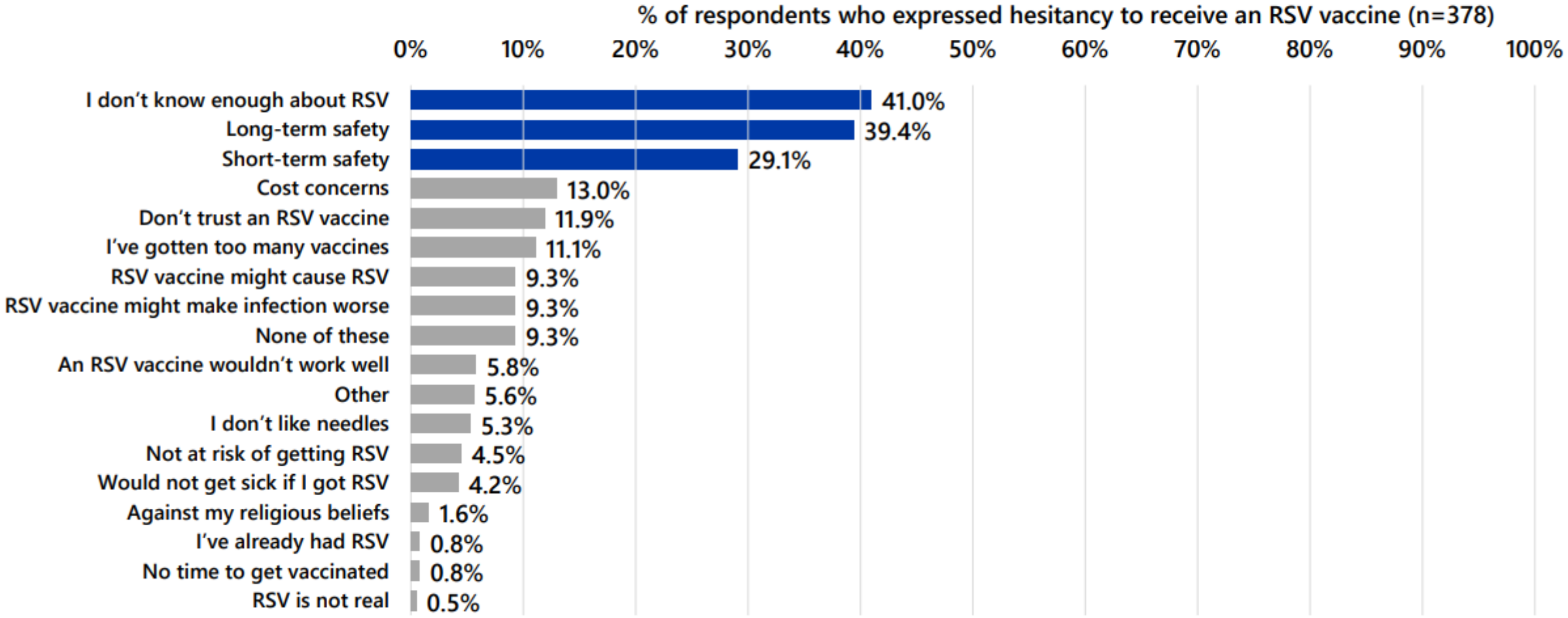
[a] Incidence rates of RSV illness requiring outpatient visit taken from McLaughlin et al, OFID (2022) (unadjusted for RSV under-detection by NP swab RT-PCR). Vaccine efficacy (VE) against this outcome assumed to be equal to that against medically attended acute respiratory illness (ARI) caused by RSV (Pfizer RENOIR trial, unpublished).
[b] Incidence rates of RSV hospitalization taken from RSV-NET 2015–2019 (unpublished). VE against RSV-associated hospitalization assumed to be equal to that against medically attended lower respiratory tract illness (LRTI) with ≥3 symptoms, caused by RSV (Pfizer RENOIR trial, unpublished).
[c] Probability of in-hospital death among adults hospitalized for RSV taken from RSV-NET 2015–2019 (unpublished). VE against RSV-associated death assumed to be equal to that against medically attended lower respiratory tract illness (LRTI) with ≥3 symptoms, caused by RSV (Pfizer RENOIR trial, unpublished).

77% said they ‘definitely’ or ‘probably’ would get an RSV vaccine if it were recommended by **a healthcare provider**



CDC and University of Iowa/RAND survey, unpublished

Lack of RSV knowledge and **safety concerns** were among the top reasons for not wanting an RSV vaccine



CDC and University of Iowa/RAND survey, unpublished

Storage and Handling

RSVPreF3 (Arexvy, GSK)

- Supplied in two vials that must be reconstituted prior to administration. One vial is a lyophilized antigen component and the second is a liquid diluent adjuvant suspension. You MUST use the diluent provided by the manufacturer.
- Store vaccine and diluent refrigerated between 2°C and 8°C (36°F and 46°F).
- Store these in their original package and keep them together in the refrigerator to optimize organization.
- Never freeze the vaccine or diluent.
- Protect the vial from light.
- Immediately administer the vaccine; you should prepare the vaccine only when ready for use.

RSVpreF (Abrysvo, Pfizer)

- Supplied in a kit with three components: a vial of Lyophilized Antigen Component (a sterile white powder), a prefilled syringe containing Sterile Water Diluent Component, and a vial adapter.
- Store vaccine and diluent refrigerated between 2°C and 8°C (36°F and 46°F).
    - Store these components in their original package and keep them together in the refrigerator to optimize organization.
- Never freeze the vaccine or diluent.
- Immediately administer the vaccine; you should prepare the vaccine only when ready for use. If you do not immediately administer the vaccine Store the reconstituted vaccine ONLY at room temperature [15°C to 30°C (59°F to 86°F)]. Do NOT refrigerate. This is very different than other reconstituted vaccines. Typically, storage after reconstitution is refrigerated storage only or refrigerated or room temperature storage. For this vaccine, do NOT put it back in the refrigerator.

https://www.cdc.gov/vaccines/vpd/rsv/hcp/older-adults.html#:~:text=RSVPreF3%20(Arexvy%2C%20GSK)%20consists,but%20at%20a%20lower%20dose.

Specific considerations for RSV vaccines for older adults

- RSV vaccines for older adults are covered under Medicare Part D, whereas influenza and COVID-19 vaccines are covered under Medicare Part B.
- Depending on the clinic environment and insurance status of the patient, the patient may be required to go to a different location (e.g., a pharmacy) to receive RSV vaccination under Medicare Part D.
- This could result in RSV vaccination occurring on a different day than influenza and COVID-19 vaccination even when same-day administration of multiple vaccines is intended or planned.
- Currently, the RSV vaccine series consists of a single dose. Studies are ongoing to determine whether older adults might benefit from receiving additional RSV vaccines in the future. So far, RSV vaccines appear to provide some protection for at least two RSV seasons.

Questions?

Upcoming Special RSV-focused Sessions:

Oct. 24th – RSV in Pediatric Populations (led by Drs. Daniel Johnson & Steve Schrantz)
Nov. 7th – RSV in Pregnant Populations (led by Drs. Ed Linn & Steve Schrantz)

For any questions, email us at pgower@peds.bsd.uchicago.edu

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