Monthly Healthcare Provider & Public Health Partner Webinar

Emerging Public Health Topics

May 11, 2023



Topics for Today

- CDC's updated COVID-19 Infection Prevention and Control Recommendations for Healthcare
- CDC's updated COVID-19 vaccine recommendations
- Tick-borne diseases (TBDs)
- RSV vaccine



CDC's Updated COVID-19 Infection Prevention and Control Recommendations for Healthcare



Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic

Updated May 8, 2023

- Reference to Transmission Metrics are removed
- Updated recommendations for use of face masks for source control, including a new <u>Appendix</u> with considerations for how/when to implement broader use of masking in healthcare settings
- Removed recommendation for admission testing in nursing homes, and leaves decision to facility discretion



CDC's Updated COVID-19 Vaccine Recommendations



Summary of CDC's Recommendations

- CDC's Interim Clinical Considerations have been updated twice in the last month ($^{\sim}$ April 22 $^{\text{nd}}$ and May 1 $^{\text{st}}$); these are transitionary recommendations
- <u>Monovalent</u> mRNA vaccines (Pfizer and Moderna) are no longer authorized/recommended for use; only use <u>bivalent</u> formulations
- Monovalent Novavax is still available and recommended
- Vaccine recommendations are complicated and based on age,
 immunocompromised status, vaccine history, and vaccine product used
- There are also recommended vs. optional vaccine recommendations
- Need to apply the guidance tables to specific patients
- Watch the CDC clinician webinar on "Updated Recommendations for COVID-19
 Vaccine Use" occurring today, May 11th from 2-3pm (or watch the recording):
 https://emergency.cdc.gov/coca/calls/2023/callinfo 051123.asp



FDA's VRBPAC Meeting June 15th

 VRBPAC is meeting in June to make recommendations on strain selection for updated vaccines that are anticipated for the 2023-2024 respiratory virus season



Tick-Borne Diseases (TBDs) in NH

Lyme disease

Anaplasmosis

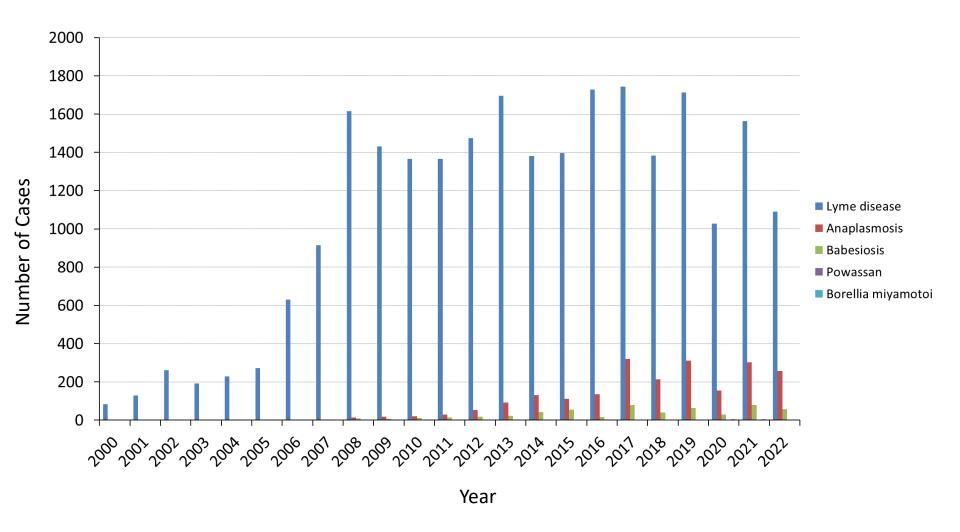
Babesiosis

Borellia miyamotoi

Powassan



Epidemiology of TBDs in New Hampshire







ORIGINAL ARTICLE

Tick bite and Lyme disease-related emergency department encounters in New Hampshire, 2010–2014

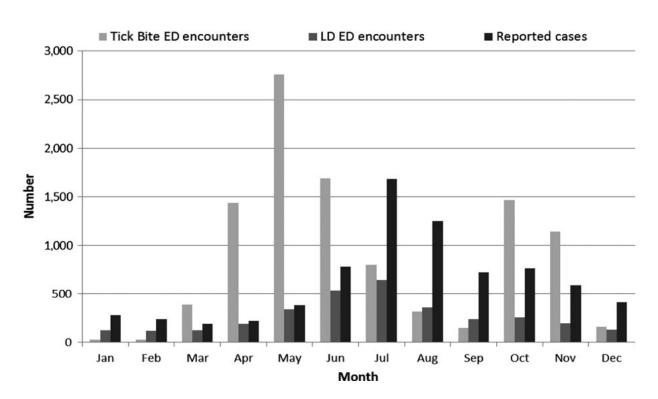
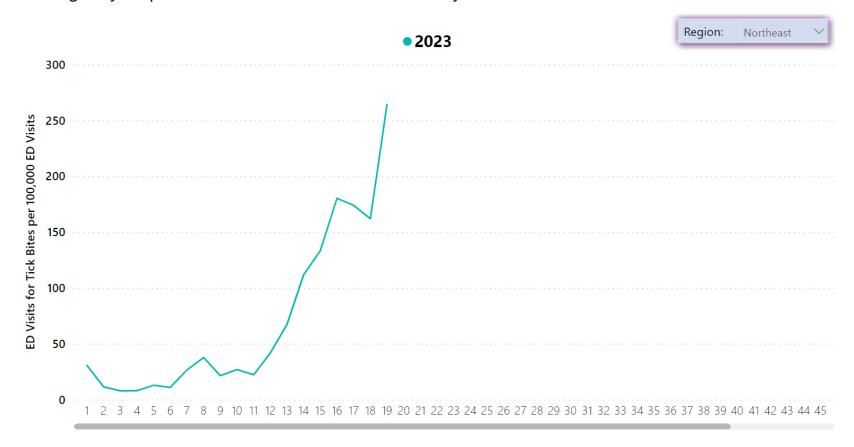


FIGURE 2 Number of tick bite-related and LD-related emergency department encounters and reported Lyme disease cases by month, New Hampshire, 2010–2014. ED: Emergency department, LD: Lyme disease.

CDC's Tick Bite Tracker

Emergency Department (ED) Visits for Tick Bites by Week, United States, 2023



Prevention of Tick Bites

- Avoid tick habitat
- Wear long sleeved clothing to cover skin
- Apply insect repellent to exposed skin
- Treat clothing with Permethrin
- Daily tick-checks (body, clothing, gear, pets)
- Shower to wash off loose ticks after coming indoors
- Place DRY clothes in the dryer on HIGH heat for 10 minutes to kill any attached ticks
- Remove attached ticks promptly (see <u>Tick</u> <u>Removal Instructions</u>)







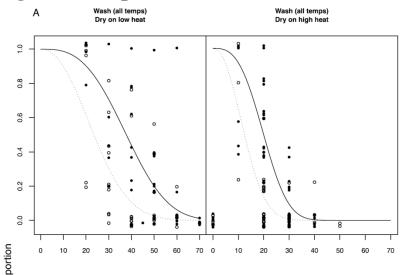


The heat is on: Killing blacklegged ticks in residential washers and

dryers to prevent tickborne diseases







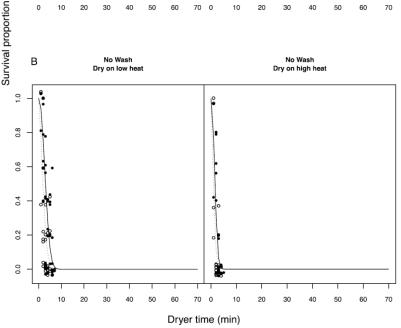


Table 1 Estimated time to kill all *I. scapularis* ticks under various washing and drying conditions. The last column shows the 95% upper bound on the time at which the model estimated a tick has only a 0.5% chance of survival.

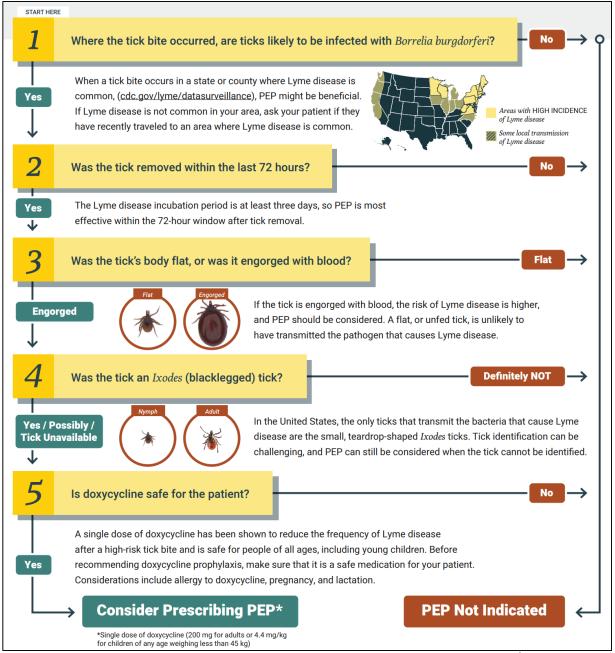
Wash	Drying temperature	Tick life stage	Time to kill all ticks in trials (minutes)	Estimated 95% upper bound on time to kill all ticks (minutes)
Yes	Low	Nymph	70	85
Yes	Low	Adult	70	96
Yes	High	Nymph	50	45 ^a
Yes	High	Adult	41	55
No	Low	Nymph	6	10
No	Low	Adult	7	11
No	High	Nymph	4	6
No	High	Adult	4	6

Lyme Disease Prophylaxis After a Tick Bite

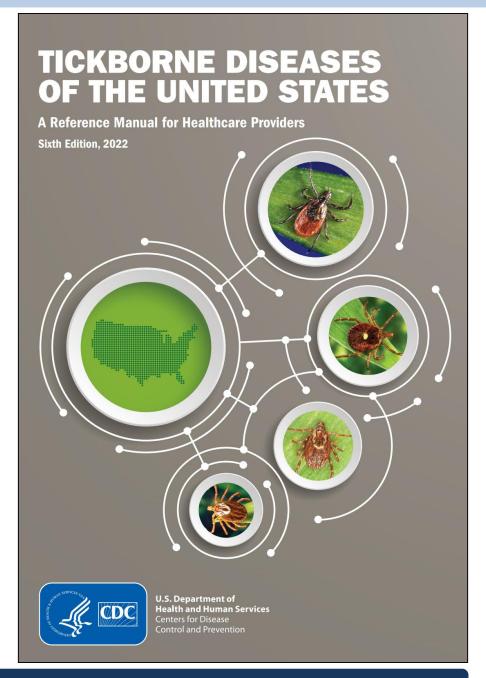
Feed time (hours) 0 24 48 72 96



Age Category	Drug	Dosage	Maximum	Duration	
Adults	Doxycycline	200 mg orally	N/A	Once	
Children weighing less than 45 kg	Doxycycline	4.4 mg/kg orally	200 mg	Once	









General Diagnostic Principles

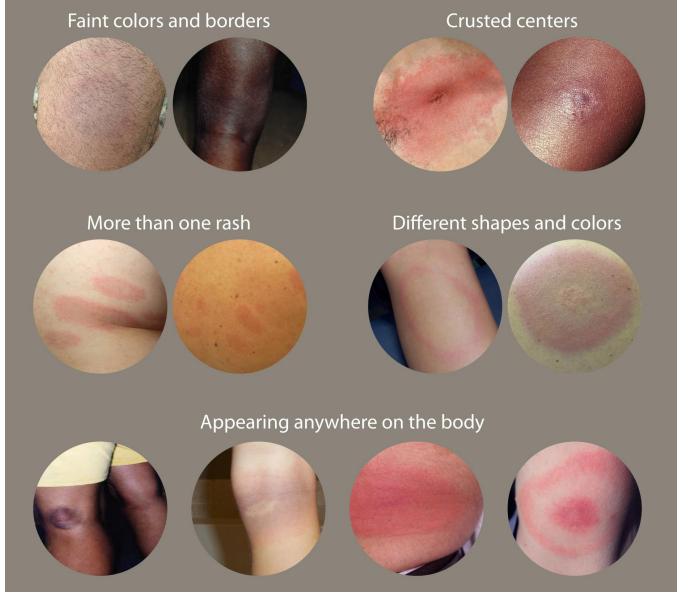
- PCR testing (when recommended and available) is generally most useful in the very early stage of illness (i.e., first week)
- Serology (antibody-based) testing is often negative during the early acute presentation, and becomes positive weeks after infection
- If you suspect early infection and initial antibody tests are negative, rechecking serology 4-6 weeks after suspected infection is often recommended to look for seroconversion ("acute and convalescent" serology)
- Antibody tests can remain positive for years after an infection:
 - Repeat antibody testing should NOT be used as a marker for treatment response
 - It might be difficult to know if positive antibody tests are the result of recent or past (and cleared) infection



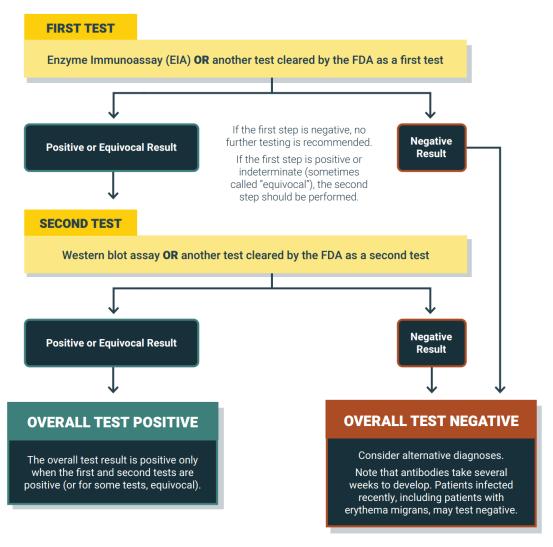
Overview of TBD Diagnosis & Treatment

Disease	Organism	Diagnosis (check with your clinical lab to see what testing options are available)	Outpatient Oral Antimicrobial Therapy (refer to guidelines)
Lyme	Borrelia burgdorferia	 Erythma migrans (EM) rash is diagnostic Serology: two-step serologic testing; IgM considered only if signs/symptoms present for less than 30 days 	 Doxycycline Amoxicillin Cefuroxime (Specific therapy dependent on stage/type of infection)
Anaplasmosis	Anaplasma phagocytophilum	 PCR (first week of illness) Serology: 4-fold rise in IgG-specific antibody 	• Doxycycline
Babesiosis	Babesia spp.	 Peripheral blood smear PCR Serology: total immunoglobulin or IgG-specific titer (supportive) 	 Azithromycin + Atovaquone (preferred) Clindamycin + Quinine (alternate)
Hard Tick Relapsing Fever	Borrelia miyamotoi	PCRSerology	DoxycyclineAmoxicillin
Powassan	Powassan virus	 Serology: IgM antibodies in serum or CSF; confirmation with PRNT neutralization antibody test PCR (can help confirm infection) 	• None

Different Forms of EM Rash in Lyme Disease



Lyme Disease Diagnosis: Two-Step Testing



CDC recommends using only FDA-cleared assays performed in CLIA-certified laboratories. Some laboratories, including some with CLIA-certification, offer laboratory-developed tests that are not FDA-cleared. CDC recommends against using these tests as there is less assurance regarding their clinical accuracy.



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RSV Vaccine



New (First) RSV Vaccines

RSV is a highly contagious ARI of all ages

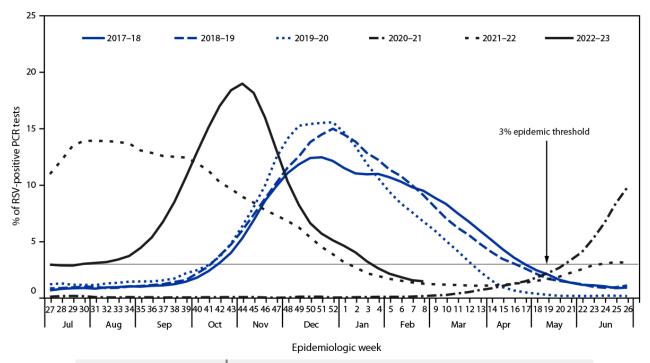
- Circulates fall, peaks winter
- Causes LRTD, including life-threatening pneumonia and bronchiolitis
- CDC estimates 60-160k hospitalizations for older adults with 6-10k deaths each year
- No antiviral treatment

Pfizer Abrysvo and GSK Arexvy

Seasonality of Respiratory Syncytial Virus — United States, 2017-2023

Weekly / April 7, 2023 / 72(14);355-361

FIGURE 1. Percentage* of polymerase chain reaction test results positive for respiratory syncytial virus, by epidemiologic week — National Respiratory and Enteric Virus Surveillance System, United States, July 2017–February 2023



What is already known about this topic?

In the United States, the timing of seasonal respiratory syncytial virus (RSV) epidemics (October–April) was disrupted during the COVID-19 pandemic.

What is added by this report?

RSV circulation was historically low during 2020–21 and began earlier and continued longer during 2021–22 than during prepandemic seasons. The 2022–23 season started later than the 2021–22 season but earlier than prepandemic seasons, suggesting a return toward prepandemic seasonality.

What are the implications for public health practice?

Ongoing monitoring of RSV seasonality can guide the timing of immunoprophylaxis and evaluation of new immunization products. Although an eventual return to prepandemic RSV seasonality is expected, clinicians should be aware that off-season RSV circulation might continue.



Pfizer RSVPreF (Abrysvo)

- Bivalent recombinant subunit vaccine with antigens against two RSV subgroups, A and B
- Single IM dose 120ug
- Placebo-controlled trial >34k participants
 - 2 primary end points VE against seasonal RSVassociated LRTD with <u>></u> 2 or <u>></u> 3 signs or symptoms
 - Secondary end point VE against RSV-associated ARI
- 66.7% VE against RSV with >2 symptoms (11 vs 33)
 - 85.7% VE against RSV \geq 3 symptoms (2 vs 14)

RESEARCH SUMMARY

Efficacy and Safety of a Bivalent RSV Prefusion F Vaccine in Older Adults

Walsh EE et al. DOI: 10.1056/NEJMoa2213836

CLINICAL PROBLEM

Respiratory syncytial virus (RSV) infection causes substantial illness in older adults, yet no RSV vaccine is currently approved by the Food and Drug Administration. Previously, an RSV challenge study showed that the investigational bivalent RSV prefusion F protein–based (RSVpref) vaccine (containing stabilized prefusion F glycoproteins from the two major cocirculating antigenic subgroups, RSV A and RSV B) had high efficacy against symptomatic RSV infection in healthy adults who were 18 to 50 years of age, but its efficacy in older adults is unknown.

CLINICAL TRIAL

Design: An ongoing, phase 3, multinational, doubleblind, randomized, placebo-controlled trial evaluated the efficacy and safety of RSVpreF vaccine in adults ≥60 years of age during a single RSV season.

Intervention: 34,284 participants received one intramuscular 120-µg dose of RSVpreF vaccine (containing 60 µg each of RSV A and RSV B antigens) or placebo. The two primary end points were vaccine efficacy against RSV-associated lower respiratory tract illness with either ≥2 signs or symptoms or ≥3 signs or symptoms in the first RSV season (starting on day 15 after the injection).

RESULTS

Efficacy: The RSVpreF vaccine was effective in preventing RSV-associated lower respiratory tract illness with ≥2 or ≥3 signs or symptoms.

Safety: Local reactions were more common with RSVpreF vaccine than with placebo within 7 days after injection; incidences of systemic events were similar in the two groups. Incidences of adverse events through 1 month after injection were also similar in the two groups.

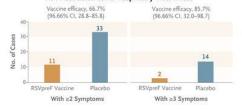
LIMITATIONS AND REMAINING QUESTIONS

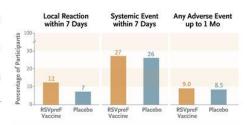
- Immunocompromised persons were excluded from the trial.
- · Given the sample size, additional safety data are needed.
- The current prespecified interim analysis was limited to one RSV season; future analyses may assess whether vaccine efficacy persists beyond one season.

Links: Full Article | NEJM Quick Take | Editorial



RSV-Associated Lower Respiratory Tract Illness





CONCLUSIONS

In adults ≥60 years of age, one dose of RSVpreF vaccine prevented RSV-associated symptomatic lower respiratory tract illness, with no apparent safety concerns, during a single RSV season.



GSK RSVPreF3 (Arexvy)

- Monovalent recombinant subunit vaccine with glycoprotein antigen against RSV subgroup A
- Single IM dose 120ug with 50ug of same (but less) adjuvant in Shingrix
- 2 studies 2500 participants
- 1 main placebo-controlled trial 25k participants in
 17 countries through 3 RSV seasons. First season:
 - 82.6% VE against LRTD, 94.1% against severe disease
 - Protection against both RSV A and B
 - 93.8% in age-group 70–79yrs

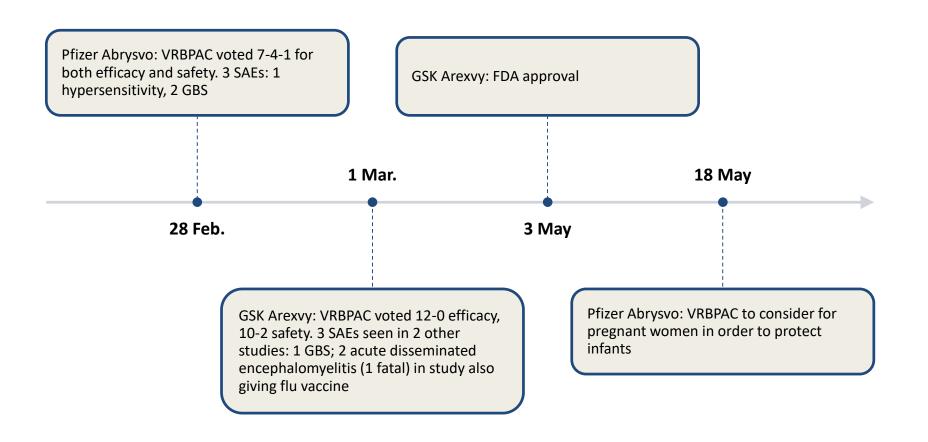
Figure 1. Vaccine efficacy against first episodes of RSV-confirmed LRTD and RSV-confirmed ARI (modified exposed set)

	RSVPreF3 OA			Placebo							
	N	n	T (p-yr) (n/T n/1000 p-yr)	N	n	T (p-yr)	n/T (n/1000 p-yr)		Vaccine efficacy (%)	p-value
RSV-confirmed LRT	D									82.6	
Overall	12466	7	6865.9	1.0	12494	40	6857.3	5.8		94.	<0.0001*
Severe	12466	1	6867.9	0.1	12494	17	6867.7	2.5			0.0001°
By subtype										84.6	
RSV-A	12466	2	6867.4	0.3	12494	13	6868.9	1.9			0.0074°
RSV-B	12466	5	6866.7	0.7	12494	26	6862.3	3.8		80.9	0.0002°
By age										84.4	
≥70 yr	5503	3	3015.0	1.0	5515	19	3020.9	6.3		33.8	0.0008°
≥80 yr	1016	2	551.4	3.6	1028	3	559.3	5.4	477.7	81.0	0.9931°
60-69 yr	6963	4	3850.8	1.0	6979	21	3836.4	5.5		93.	0.0009°
70-79 yr	4487	1	2463.6	0.4	4487	16	2461.6	6.5		0	0.0003°
By baseline comor	bidities										
Low/medium risk ^b	8235	4	4495.8	0.9	8367	23	4560.6	5.0		82.4 82.9	0.0004°
High risk ^b	4231	3	2370.0	1.3	4127	17	2296.6	7.4			0.0021°
No comorbidity of interest ^c	7529	6	4094.1	1.5	7633	22	4148.1	5.3		72.5	0.0040°
≥1 comorbidity of interest ^c	4937	1	2771.8	0.4	4861	18	2709.1	6.6		94.	6 - <0.0001°
By frailty									14.9		
Frail	189	1	95.8	10.4	177	1	92.9	10.8	6638.7	92.9	1.0000°
Pre-frail	4792	1	2577.6	0.4	4778	14	2545.3	5.5		80.0	0.0009°
Fit	7464	5	4182.7	1.2	7519	25	4208.5	5.9			0.0003°
RSV-confirmed ARI	1									71.7	
Overall	12466	27	6858.7	3.9	12494	95	6837.8	13.9		<u>—ö—</u>	<0.0001°
By RSV subtype	12466	0	COCE 2	1.2	12404	22	C0C2 2	4.7		71.9	0.000.40
RSV-A RSV-B	12466 12466	9 18	6865.2 6861.7	1.3 2.6	12494 12494	32	6862.3 6849.4	4.7 8.9		70.6	0.0004° <0.0001°
V2A-B	12400	19	0801./	2.0	12494	DI	0849.4	6.5	,		<0.0001
									0 2	0 40 60 80	100

Cases reported up to the efficacy data lock point of 11 April 2022. **N**, number of participants in the modified exposed set; **n**, number of participants with ≥1 RSV-confirmed LRTD (identified by the adjudication committee) or ≥1 RSV-confirmed ARI; **T**, sum of follow-up time (from day 15 post-vaccination until first occurrence of the event, data lock point or drop-out); **p-yr**, person-years; **n/T**, incidence rate of participants reporting at least one event. Error bars represent 96.95% confidence intervals (CI) for primary objective (RSV-confirmed LRTD, overall) and 95% CI for other endpoints. *Two-sided exact p-value conditional to number of cases comparing incidence rates; *Two-sided exact nominal p-value conditional to number of cases comparing incidence rates; *Two-sided exact nominal p-value conditional to number of cases comparing incidence rates; *Two-sided exact nominal p-value conditional to number of cases comparing incidence rates; *Two-sided exact nominal p-value conditional to number of cases comparing incidence rates; *Two-sided exact nominal p-value conditional to number of cases comparing incidence rates; *Two-sided exact nominal p-value conditional to number of cases comparing incidence rates; *Two-sided exact nominal p-value conditional to number of cases comparing incidence rates; *Two-sided exact nominal p-value conditional to number of cases comparing incidence rates; *Two-sided exact p-value conditional to number of cases comparing incidence rates; *Two-sided exact p-value conditional to number of cases comparing incidence rates; *Two-sided exact p-value conditional to number of cases comparing incidence rates; *Two-sided exact p-value conditional to number of cases comparing incidence rates and the properties of cases comparing objective (RSV-confirmed ARI) and the properties

Toward Approved RSV Vaccine(s)

VRBPAC > FDA > ACIP > CDC



Q&A



Next Webinar is June 8th

- We will continue these webinars on a monthly cadence (2nd Thursday of each month from 12-1pm)
- Future Topics:
 - Mpox update
 - Long-COVID
 - RSV vaccine update

