Evidence to Recommendation Framework: Clesrovimab

Maternal/Pediatric RSV Work Group

Advisory Committee on Immunization Practices

June 25, 2025

Policy Question

- **Should clesrovimab be recommended for all infants <8 months of age born during or entering their first RSV season?**

Evidence to Recommendation (EtR) Framework

EtR Domain	Question(s)
Public Health Problem	▪ Is the problem of public health importance?
Benefits and Harms	▪ How substantial are the desirable anticipated effects? ▪ How substantial are the undesirable anticipated effects? ▪ Do the desirable effects outweigh the undesirable effects?
Values	▪ Does the target population feel the desirable effects are large relative to the undesirable effects? ▪ Is there important variability in how patients value the outcome?
Acceptability	▪ Is the intervention acceptable to key stakeholders?
Feasibility	▪ Is the intervention feasible to implement?
Resource Use	▪ Is the intervention a reasonable and efficient allocation of resources?
Equity	▪ What would be the impact of the intervention on health equity?

EtR Domain: Public Health Problem

Is RSV-associated disease among infants <8 months of age of public health importance?

RSV burden is high in children <5 years of age

Each year in the United States, RSV leads to approximately*:

~2,000,000 medical encounters[1]

58,000–80,000 hospitalizations[1,2,3]

100–300 deaths[4,5,6]

*Data on the burden of RSV disease in children under 5 are from before the 2023-2024 RSV season, when RSV prevention products became available in the US.

References: 1) Hall et al, NEJM (2009): https://doi.org/10.1056/NEJMoa0804877 2) McLaughlin et al, J Infect Dis (2022): https://doi.org/10.1093/infdis/jiaa752 3) CDC RSV-NET, unpublished data. 4) Thompson et al, JAMA (2003): https://doi.org/10.1001/jama.289.2.179 5) Matias et al, Influenza Other Respi Viruses (2014): https://doi.org/10.1111/irv.12258 6) Hansen et al, JAMA Network Open (2022): https://doi.org/10.1001/jamanetworkopen.2022.0527

RSV is the leading cause of hospitalization in infants[1]

In the absence of RSV prevention products:

- **Most infants (68%) are infected in the first year of life and nearly all (97%) by age 2 years[2]**
- **2-3% of young infants are hospitalized for RSV[3,4,5]**
  - Highest rates occur in the first months of life, and risk declines with increasing age in early childhood[3,5]
  - ~80% of hospitalized children have no underlying medical conditions[3]
  - All infants are at risk for hospitalization

References: 1) Suh et al, JID (2022): https://doi.org/10.1093/infdis/jiac120 2) Glezen et al, Arch Dis Child (1986): https://doi.org/10.1001/archpedi.1986.02140200053026 3) Hall et al, Pediatrics (2013): https://doi.org/10.1542/peds.2013-0303 4) Langley et al, PIDJ (2011): https://doi.org/10.1097/INF.0b013e3182184ae7 5) Curns et al, Pediatrics (2024): https://doi.org/10.1542/peds.2023-062574

Public Health Problem - Work Group Interpretation

- **Is RSV-associated disease among infants <8 months of age of public health importance?**

No	Probably No	Probably Yes	**Yes**	Varies	Don't know

EtR Domain: Benefits and Harms

How substantial are the desirable anticipated effects?

How substantial are the undesirable anticipated effects?

Do the desirable effects outweigh the undesirable effects?

GRADE: PICO Question

Population	All infants <8 months of age born during or entering their first RSV season
Intervention	Clesrovimab
Comparison	No immunization
Outcomes	<u>Benefits</u> Prevention of: 1. RSV-associated medically attended lower respiratory tract infection (LRTI) 2. RSV-associated LRTI with hospitalization 3. RSV-associated LRTI with intensive care unit admission 4. All-cause medically attended LRTI 5. All-cause LRTI with hospitalization <u>Harms</u> 1. Serious adverse events

Abbreviations: GRADE: Grading of Recommendations, Assessment, Development and Evaluation

Interpreting a GRADE certainty assessment

- **A certainty assessment reflects our confidence that the *true effect* lies close to the *estimated effect***
- There are 4 certainty levels:
  - **High:** We are very confident that the true effect lies close to that of the estimated effect. *Randomized controlled trial certainty starts here and can be downgraded or upgraded*[1].
  - **Moderate:** We are moderately confident that the true effect lies close to the estimated effect, but there is a possibility that it is substantially different.
  - **Low:** We have limited confidence that the true effect lies close to the estimated effect; the true effect may be substantially different from the estimated effect. *Observational certainty starts here and can be downgraded or upgraded*[1].
  - **Very low:** We have very limited confidence that the true effect lies close to the estimated effect; the true effect is likely to be substantially different from the estimated of effect.
- A certainty assessment does not reflect our confidence in the quality of the individual studies or the overall confidence in benefits and harms of the vaccine, which may be informed by additional data.

1) Evidence type may be downgraded due to risk of bias, inconsistency, indirectness, imprecision or other considerations such as publication bias and upgraded for indications of a dose-response gradient, large or very large magnitude of effect, and opposing residual confounding.
Abbreviations: GRADE: Grading of Recommendations, Assessment, Development and Evaluation

GRADE: Outcomes, importance, and data sources

Outcome	Importance[1]	Data sources
Benefits		
1. RSV-associated medically attended LRTI	Critical	Phase 2b/3 RCT[2]
2. RSV-associated LRTI with hospitalization	Critical	Phase 2b/3 RCT[2]
3. RSV-associated LRTI with ICU admission	Critical	Phase 2b/3 RCT[2]
4. All-cause medically attended LRTI	Important	Phase 2b/3 RCT[2]
5. All-cause LRTI with hospitalization	Important	Phase 2b/3 RCT[2]
Harms		
6. Serious adverse events	Important	Phase 2b/3 RCT[2]

1. Three options: Critical; Important but not critical; Not important for decision making
2. Protocol 004: *A Phase 2b/3 Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Clesrovimab in Healthy Preterm and Full-Term Infants* – described in Zar et al., Open Forum Infectious Diseases (2025): https://doi.org/10.1093/ofid/ofae631.003; Sinha, presentation to ACIP (2024): https://www.cdc.gov/acip/downloads/slides-2024-10-23-24/02-RSV-Mat-Peds-Sinha-508.pdf; and unpublished data from manufacturer

Abbreviations: GRADE: Grading of Recommendations, Assessment, Development and Evaluation | LRTI: Lower respiratory tract infection | RCT: randomized controlled trial | ICU: intensive care unit

GRADE Benefits: Efficacy estimates and concerns in certainty assessment

Outcome	Efficacy estimate[1] % (95% CI)	Concerns in certainty assessment
Benefits, through 150 days of follow-up		
1. RSV-associated medically attended LRTI	60.4 (44.1, 71.9)	Not serious (indirectness)[2]
2. RSV-associated LRTI with hospitalization	90.9 (76.2, 96.5)	Not serious (indirectness)[2]
3. RSV LRTI with ICU admission[3]	100.0 (24.0, 100.0)	Serious (imprecision)[4] Not serious (indirectness)[2]
4. All-cause medically attended LRTI	13.1 (-0.6, 24.8)	Serious (imprecision)[5] Not serious (indirectness)[2]
5. All-cause LRTI with hospitalization	49.0 (26.7, 64.5)	Not serious (indirectness)[2]

1. Estimates and 95% CI were estimated from the modified Poisson regression with robust variance method.
2. Concern for indirectness: the trial excluded infants who were palivizumab-eligible and took place during a season with disrupted seasonality due to COVID-19. This was deemed not serious.
3. Outcome was not a trial endpoint and was assessed post-hoc.
4. Serious concern for imprecision: the number of study participants did not meet optimal information size.
5. Serious concern for imprecision: the confidence interval containing estimates for which different policy decisions might be considered.

Abbreviations: GRADE: Grading of Recommendations, Assessment, Development and Evaluation | CI: confidence interval | LRTI: lower respiratory tract infection | RCT: randomized controlled trial | ICU: intensive care unit

GRADE Harms: Relative risk of serious adverse events (SAEs) and concerns in certainty assessment, days 1-365 post immunization

Outcome	Relative risk[1] (95% CI)	Concerns in certainty assessment
Harms		
Serious adverse events (SAEs)[2]	0.93 (0.77, 1.12)	Serious (imprecision)[3]

1. Relative risk was calculated as the risk of a serious adverse event in the clesrovimab arm divided by the risk of a serious adverse event in the placebo arm.
2. Adverse event resulting in death, hospitalization, significant disability, or requiring medical intervention. Serious adverse events may be related or unrelated to the study intervention.
3. Serious concern for imprecision: too few infants were included in the trial to capture rare events.

Abbreviations: GRADE: Grading of Recommendations, Assessment, Development and Evaluation | CI: confidence interval

Summary of GRADE for clesrovimab

Outcome	Importance	Design (# of studies)	Findings	Evidence type
Benefits				
1. RSV-associated medically attended LRTI	Critical	RCT (1)	Clesrovimab is effective in preventing RSV-associated medically attended LRTI	**High**
2. RSV-associated LRTI with hospitalization	Critical	RCT (1)	Clesrovimab is effective in preventing RSV-associated LRTI with hospitalization	**High**
3. RSV-associated LRTI with ICU admission	Critical	RCT (1)	Clesrovimab is effective in preventing LRTI with ICU admission	**Moderate**
4. All-cause medically attended LRTI	Important	RCT (1)	Clesrovimab is not effective in preventing all cause medically attended LRTI	**Moderate**
5. All-cause LRTI with hospitalization	Important	RCT (1)	Clesrovimab is moderately effective in preventing all cause hospitalization with LRTI	**High**
Harms				
6. Serious adverse events	Important	RCT (1)	Serious adverse events were balanced between the clesrovimab group and the placebo group	**Moderate**

Abbreviations: LRTI: Lower respiratory tract infection | RCT: randomized control trial | ICU: intensive care unit | serious adverse events

Additional benefits of clesrovimab not included in GRADE: Efficacy for RSV-associated medically-attended LRTI and hospitalization observed through 180 days

Outcome	Follow-up time: 150 days			Follow-up time: 180 days		
	Events/ Clesrovimab (n/N)	Events/ Placebo (n/N)	Efficacy estimate % (95% CI)	Events/ Clesrovimab (n/N)	Events/ Placebo (n/N)	Efficacy estimate % (95% CI)
RSV-associated medically attended LRTI	60/2398	74/1201	60.4 (44.1, 71.9)	64/2398	77/1201	59.5 (43.3, 71.1)
RSV-associated LRTI with hospitalization	5/2398	27/1201	90.9 (76.2, 96.5)	5/2398	28/1201	91.2 (77.2, 96.6)

Abbreviations: LRTI: lower respiratory tract infection | CI: confidence interval

Additional benefits of clesrovimab not included in GRADE

- *If recommended by CDC,* there will be two approved[1] and recommended[2] long-acting monoclonal antibodies for prevention of severe RSV disease in infants
- Multiple products with different binding sites are beneficial if resistance mutations develop to either product
- Multiple manufacturers in the same market allow for:
  - If one product has insufficient supply in the United States, the other product reduces the risk of a shortage.[3]
  - Competitive pricing of products may be created by market competition

1. In July 2023, the Food and Drug Administration (FDA) approved nirsevimab for the prevention of RSV–associated lower respiratory tract infection among infants and children aged <24 months. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761328s000lbl.pdf and 2. In August 2023, the Advisory Committee for Immunization Practices recommended nirsevimab infants aged <8 months born during or entering their first RSV season and for infants and children aged 8–19 months who are at increased risk of severe RSV disease entering their second RSV season. https://www.cdc.gov/mmwr/volumes/72/wr/mm7234a4.htm; 3. https://www.cdc.gov/han/2023/han00499.html

Additional harms of clesrovimab not included in GRADE: Solicited adverse events (AEs), days 1–5 post immunization

- **Injection-site and systemic reactions were comparable between the clesrovimab (29.9%) and placebo (30.9%) arms**
  - Irritability and somnolence were the most commonly reported solicited AEs
- **Mostly Grade 1 (mild) or 2 (moderate)**
  - The proportions of participants with solicited AEs of Grade 3 (severe) were low (≤0.2%) in both groups
  - No Grade 4 (potentially life-threatening) solicited AEs

Notes: Grade 1= mild; Grade 2= moderate; Grade 3=severe; Grade 4=potentially life threatening; https://www.fda.gov/media/73679/download

Additional potential harms of clesrovimab not included in GRADE: Fever*, days 1–5 post immunization

- **Rates of fever were comparable between the clesrovimab (3.7%) and placebo (4.0%) arms**

Study	Events*/Clesrovimab (n/N)	Events*/Placebo (n/N)
Protocol 004	89/2408† (3.7%)	48/1202 (4.0%)

*Fever defined as a temperature ≥ 100.4°F

† Total N=2409; 2408 had temperature data available per communication with manufacturer on March 9, 2025

Work group interpretation of benefits and harms of clesrovimab

Benefits

- Efficacious long-acting, monoclonal antibody that can prevent severe RSV disease in young infants during the duration of their first RSV season
- Second long-acting, monoclonal antibody RSV prevention product would mitigate the risk of manufacturing shortages and loss of efficacy due to mutations in the binding site.

Harms

- Favorable safety profile with no observed increase in serious adverse events, local or systemic reactions, including fever
- Rare serious adverse events unlikely to be detected in a trial due to sample size

Benefits and Harms

- **How substantial are the <u>desirable</u> anticipated effects?**
  - How substantial are the anticipated effects for each main outcome for which there is a desirable effect?

Minimal	Small	Moderate	**Large**	Varies	Don't know

Benefits and Harms

- **How substantial are the <u>undesirable</u> anticipated effects?**
  - How substantial are the anticipated effects for each main outcome for which there is an undesirable effect?

Minimal	**Small**	**Moderate**	**Large**	**Varies**	**Don't know**

Benefits and Harms

- **Do the desirable effects outweigh the undesirable effects?**

Favors intervention (clesrovimab)
Probably favors the intervention (clesrovimab)
Probably favors the comparison (no immunization)
Favors the comparison (no immunization)
Unclear

EtR Domain: Values

Do parents and caregivers feel that the desirable effects of clesrovimab are large relative to the undesirable effects?

Is there important uncertainty about, or variability in, how much parents and caregivers value the prevention of severe RSV disease?

RSV risk perceptions and knowledge among pregnant women in the U.S. (n=523), December 2022-January 2023

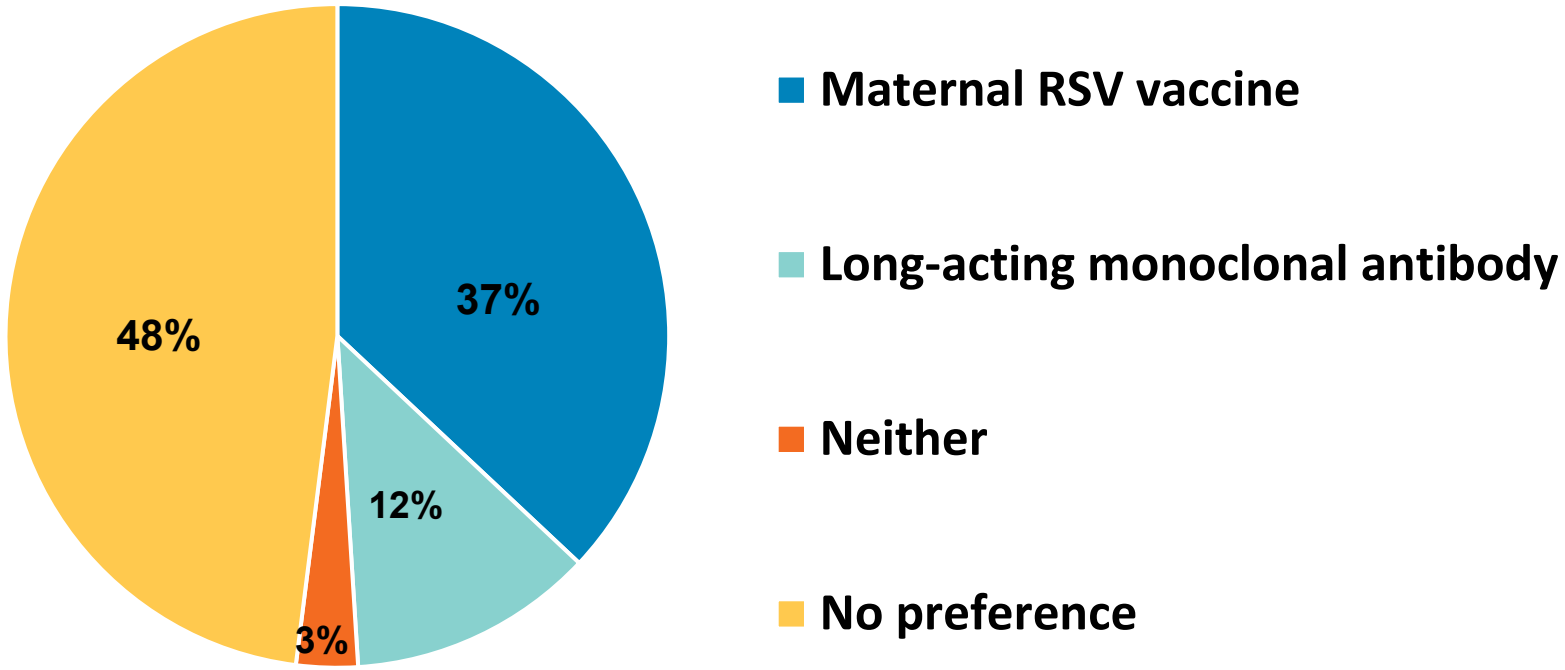
In a nationwide, online survey of women who were pregnant or < 12 months postpartum:

- 31% of respondents reported knowing a baby who had been hospitalized for RSV
- 40% of respondents believed that their own baby would be moderately or severely ill if infected with RSV
- 69% of respondents were worried their baby would need to be hospitalized if infected with RSV

Reference: Gidengil et al, Open Forum Infect Dis. (2023): https://doi.org/10.1093/ofid/ofad500.1467

Parents do not have a clear preference among RSV immunization products

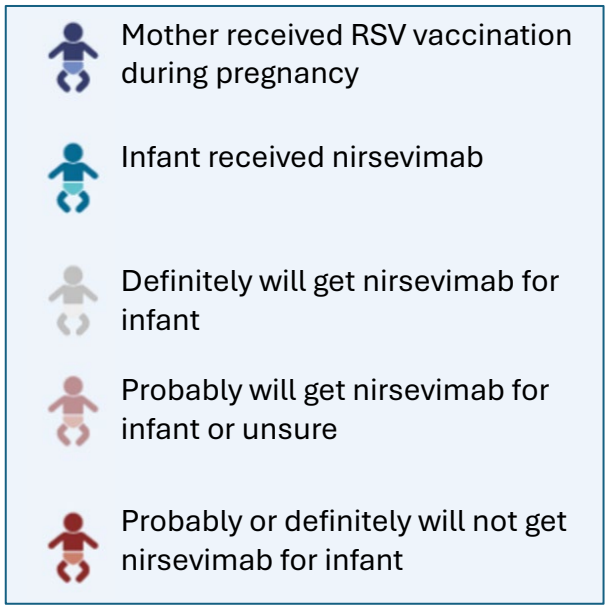
Parental preference for RSV immunization products if both were available, safe and effective among adults aged 18-49 years with children, CASCADIA Study, Oregon and Washington, U.S., April-May 2023 (n=1082)



Source: Kuntz et al. Attitudes about Respiratory Syncytial Virus (RSV) Vaccination during Pregnancy, and Infant Monoclonal Antibodies for RSV, 2024

50% of women 18-49 years who have an infant <8 months received a long-acting monoclonal antibody

Infant protection against RSV by maternal RSV vaccination* or receipt of nirsevimab†, and intent‡ for nirsevimab receipt by women aged 18–49 years who have an infant <8 months during the RSV season (born since April 1, 2024), February 2025, United States

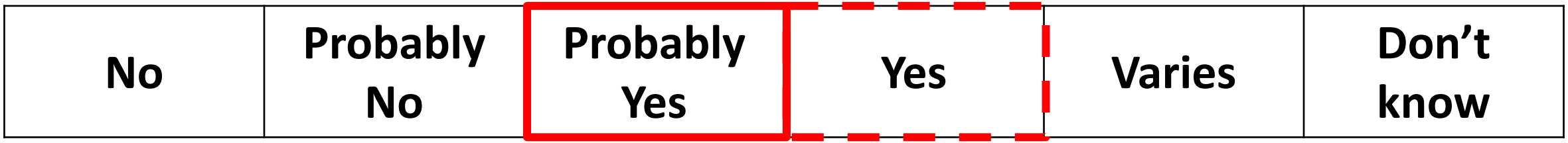


*Receipt of RSV vaccination during pregnancy was assessed by the NIS–ACM questionnaire among women 18–49 years who reported having an infant born since October 1, 2024. For infants born April 1, 2024, through September 30, 2024, maternal RSV vaccination was not assessed, and these infants were assumed to be protected against RSV only if infant was reported to have received nirsevimab. The estimates of receipt of RSV vaccination during pregnancy for infants born since April 1, 2024 are not an assessment of maternal RSV vaccination coverage among pregnant women eligible for vaccination as shown with the Vaccine Safety Datalink, as they are based on all infants eligible for nirsevimab or maternal vaccination rather than eligible pregnancies
†Estimates of nirsevimab receipt by infants born since April 1, 2024, include those who were born shortly before or are entering their first RSV season and do not account for the mother's RSV vaccination status during pregnancy
‡Intent for nirsevimab receipt is assessed among infants who had not received nirsevimab and whose mother did not receive RSV vaccination during pregnancy. Estimates of nirsevimab intent among women interviewed in August and September 2024 included all women who reported having an infant <8 months, and could include infants born in February and March 2024.

Data Source: National Immunization Survey – Adult COVID Module https://www.cdc.gov/rsvvaxview/dashboard/nirsevimab-coverage-infants.html

Values

- **Do parents and caregivers feel that the desirable effects of clesrovimab are large relative to the undesirable effects?**

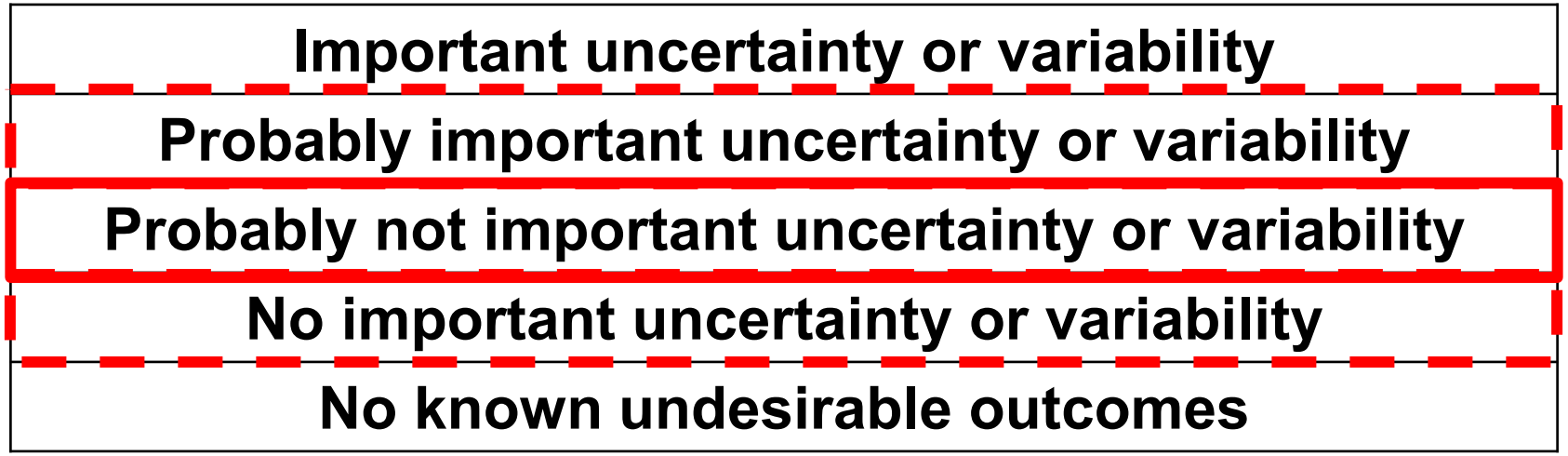


Majority opinion

Minority opinion

Values

- **Is there important uncertainty about, or variability in, how much parents and caregivers value the prevention of severe RSV disease?**



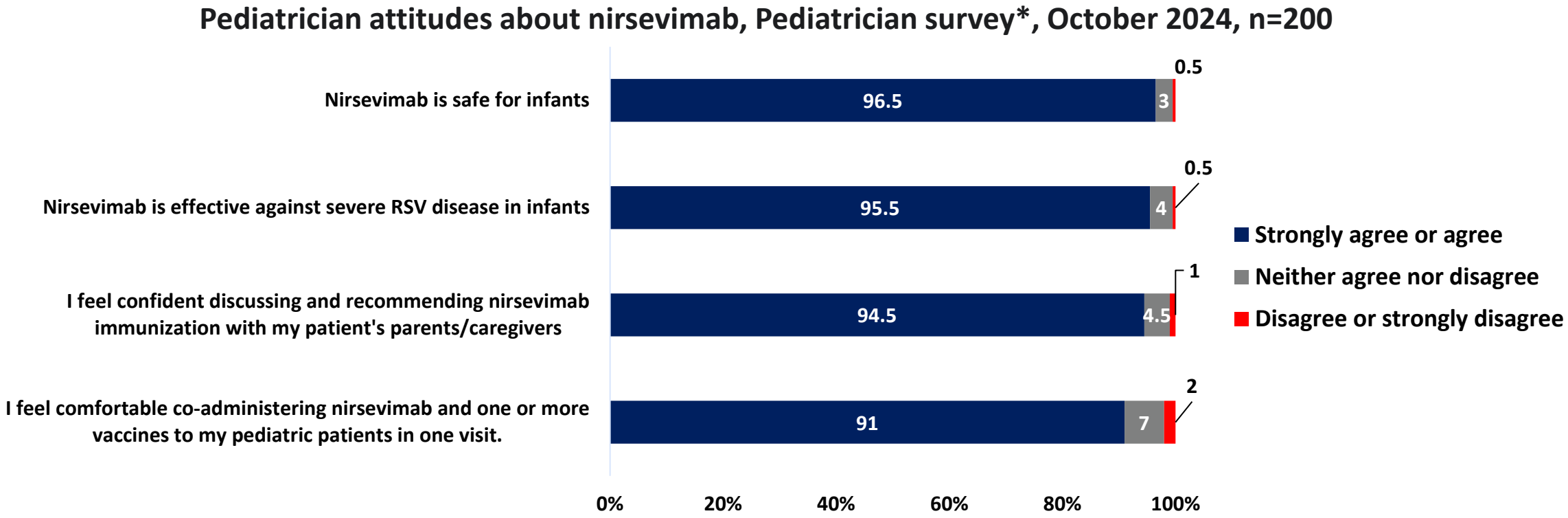
Majority opinion

Minority opinion

EtR Domain: Acceptability

Is clesrovimab acceptable to key stakeholders?

Pediatrician attitudes regarding long-acting monoclonal antibody



- **77% of pediatricians reported that their practice had ever offered nirsevimab**
- **The majority of pediatricians agreed that nirsevimab is safe for infants and effective against severe disease in infants**

*Porter Novelli View Points Health Care Practitioner survey was conducted from October 2-10, 2024, among 200 U.S. pediatricians who reported offering at least some routine pediatric vaccines to patients

Reference: Kang et al, CDC (2024); https://www.cdc.gov/rsvvaxview/publications/rsv-immunization-survey-2024.html

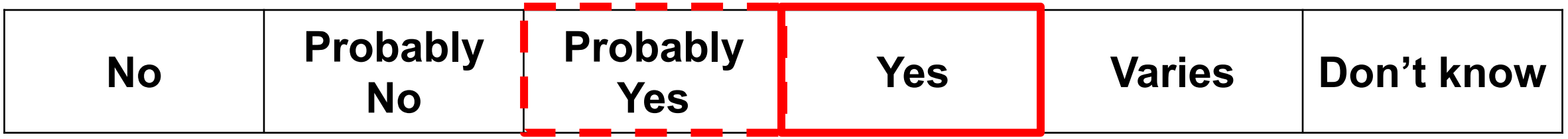
RSV prevention through long-acting, monoclonal antibodies endorsed by national organizations

- **Nirsevimab is recommended by**
  - American Academy of Pediatrics[1]
  - American Academy of Family Physicians[2]
  - National Foundation for Infectious Diseases[3]

1) https://publications.aap.org/redbook/resources/25379/AAP-Recommendations-for-the-Prevention-of-RSV?autologincheck=redirected
2) https://www.aafp.org/news/health-of-the-public/rsv-antibody-aafp-approval.html
3) https://www.nfid.org/resource/contagious-chronicles-updated-recommendations-for-respiratory-season/

Acceptability

- **Is clesrovimab acceptable to key stakeholders?**



Majority opinion

Minority opinion

EtR Domain: Feasibility

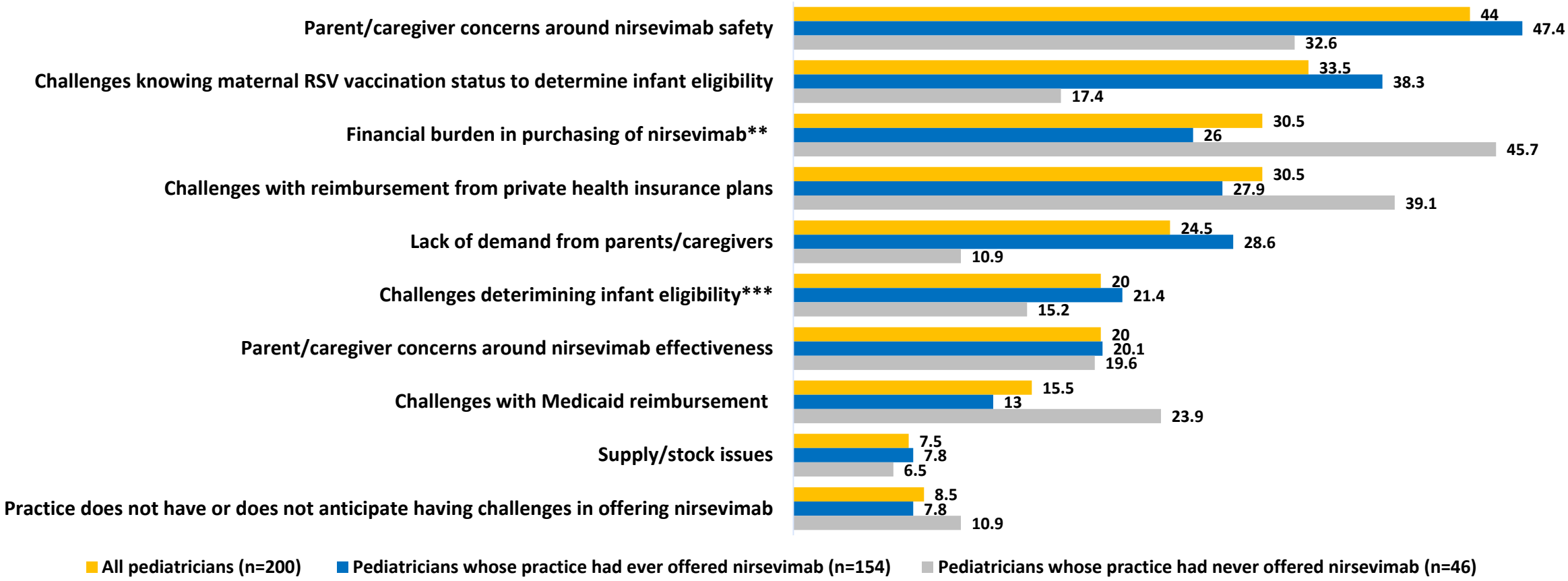
Is clesrovimab feasible to implement among all infants <8 months of age born during or entering their first RSV season?

Implementation and access

- The Vaccines for Children (VFC) program is a federally-funded program that provides immunizations at no cost to children who might not otherwise be immunized because of inability to pay.[1]
  - If ACIP votes to include clesrovimab in VFC, it will be the second monoclonal antibody to be included in the VFC program.
- Implementation **pros and cons:**
  - Pro: Clesrovimab is a single dose regardless of weight
  - Con: Stocking clesrovimab may be challenging for providers who also need to stock nirsevimab for high-risk children 8 through 19 months entering their second RSV season and prefer to stock a **single** RSV monoclonal antibody

1. CDC. Vaccines for Children. https://www.cdc.gov/vaccines-for-children/about/index.html

Frequency of main challenges* pediatricians reported or anticipated in offering long-acting monoclonal antibody, Pediatrician survey, October 2024 (n=200)



*Respondents were instructed to select up to 3 response categories

** Private stock of nirsevimab for practices participating in the VFC (Vaccines for Children) program

*** Challenges knowing whether infant received nirsevimab at a birthing hospital

Kang et al, https://www.cdc.gov/rsvvaxview/publications/rsv-immunization-survey-2024.html

Feasibility

- **Is clesrovimab feasible to implement among all infants <8 months of age born during or entering their first RSV season?**

No	Probably No	Probably Yes	Yes	Varies	Don't know

Majority opinion

Minority opinion

EtR Domain: Resource Use

Is clesrovimab a reasonable and efficient allocation of resources?

RSV-associated outcomes averted: 50% coverage with clesrovimab among an annual US birth cohort[1]

Comparison	Outpatient Visits Averted	ED Visits Averted	Hospital Admissions Averted	ICU Admissions Averted	Deaths Averted	QALYs Gained
Clesrovimab[2] vs. no RSV immunizations for most infants[3]	121,022	43,480	20,198	4,444	20	3,413

1. Estimates provided by an updated UM-CDC model, where updates included VE and cost/dose. Original model and methods described here: Hutton et al, Pediatrics (2024): https://doi.org/10.1542/peds.2024-066461
2. Clesrovimab has 50% coverage, and includes 50% palivizumab use for eligible high-risk babies that do not get clesrovimab
3. "No RSV immunizations for most infants" means the only RSV immunization is palivizumab for eligible high-risk infants

Abbreviations: ED: emergency department | ICU: intensive care unit | QALY: quality adjusted life year

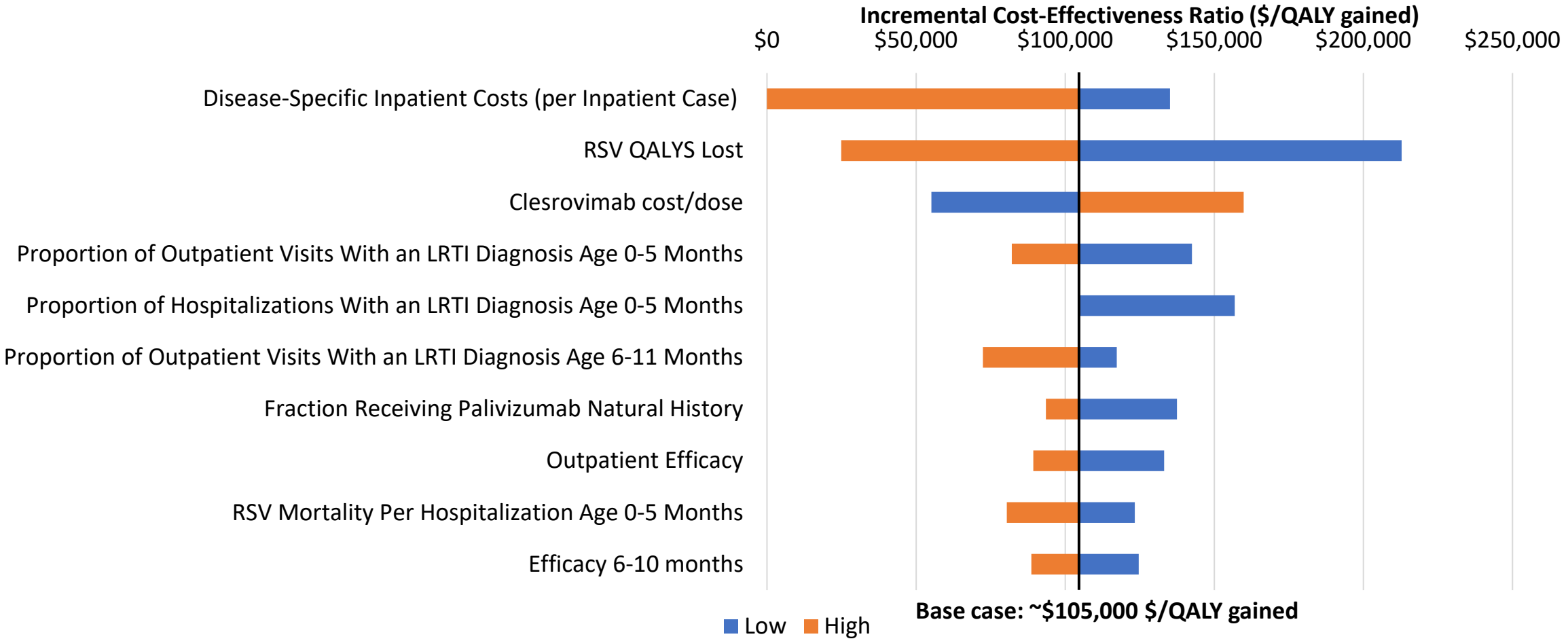
Incremental cost effectiveness ratios (ICERs): 50% coverage with clesrovimab among an annual US birth cohort[1]

Comparison	$/Outpatient Visit Averted	$/ED Visit Averted	$/Hospital Admission Averted	$/ICU Admission Averted	$/Death Averted	$/QALY Gained
Clesrovimab[2] vs. no RSV immunizations for most infants[3]	2,948	8,207	17,666	80,300	17,666,032	104,543

1. Estimates provided by an updated UM-CDC model, where updates included vaccine efficacy, vaccine efficacy waning trajectory, and cost/dose. Original model and methods described here: Hutton et al, Pediatrics (2024): https://doi.org/10.1542/peds.2024-066461
2. Clesrovimab has 50% coverage, and includes 50% palivizumab use for eligible high-risk babies that do not get clesrovimab
3. "No RSV immunizations for most infants" means the only RSV immunization is palivizumab for eligible high-risk infants

Abbreviations: ED: emergency department | ICU: intensive care unit | QALY: quality adjusted life year

One-way sensitivity analysis: 50% coverage with clesrovimab among an annual US birth cohort[1]



1. Estimates provided by an updated UM-CDC model, where updates included VE and cost/dose. Original model and methods described here: Hutton et al, Pediatrics (2024): https://doi.org/10.1542/peds.2024-066461

Abbreviations: QALY: quality adjusted life year | LRTI: lower respiratory tract infection

Resource Use

- **Is clesrovimab use among infants under 8 months of age born during or entering their first RSV season a reasonable and efficient allocation of resources with an estimated cost of $458 on average ($365 VFC / $560 other) per dose?**

No	Probably No	Probably Yes	Yes	Varies	Don't know

Majority opinion

Minority opinion

Abbreviations: VFC: Vaccines for Children

EtR Summary

Work group considerations and interpretation

- **Phase 2b/3 trial demonstrated high efficacy for prevention of severe RSV disease through 150 days**
- **Serious adverse events appeared balanced between the clesrovimab and placebo arms; however, rare adverse events are unlikely to be detected in a trial of this size**
- **Work group discussion also highlighted:**
  - Clesrovimab has demonstrated a shorter half-life than nirsevimab (44 days[1] vs 71 days[2]) though efficacy against severe RSV appeared sustained through 150 days
  - Clesrovimab and nirsevimab trial outcomes had different definitions, making direct comparisons in efficacy challenging

References 1) FDA prescribing information for clesrovimab: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/761432s000lbl.pdf 2) FDA prescribing information for Nirsevimab: ihttps://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761328s000lbl.pdf

Work group considerations and interpretation, continued

- **The work group highlighted the benefits of multiple long-acting RSV antibody products and multiple manufacturers, including:**
  - If RSV develops resistance to one product or one product has insufficient supply, another is available
  - Potential for decrease in price
- **The leading cause of hospitalization in infants (RSV) can be prevented through immunization. However, for RSV immunizations to have public health impact, they must be administered early:**
  - For infants born outside the RSV season, high uptake prior to season onset is critical
  - For infants born during the RSV season, administration should be within the first week of life - *ideally during the birth hospitalization*

Evidence to Recommendations Framework
Summary

- What is the balance between the desirable effects relative to the undesirable effects?

Balance of consequences	Undesirable consequences *clearly outweigh* desirable consequences in most settings	Undesirable consequences *probably outweigh* desirable consequences in most settings	The balance between desirable and undesirable consequences is *closely balanced* or *uncertain*	Desirable consequences *probably outweigh* undesirable consequences in most settings	Desirable consequences *clearly outweigh* undesirable consequences in most settings	There is insufficient evidence to determine the balance of consequences

Evidence to Recommendations Framework
Summary

- Should clesrovimab be recommended for all infants <8 months of age born during or entering their first RSV season?

Type of recommendation	We do not recommend the intervention	We recommend the intervention for individuals based on shared clinical decision-making	We recommend the intervention

Acknowledgements

Maternal/Pediatric RSV Work Group

Coronavirus and Other Respiratory Viruses Division

Immunization Services Division

RSV-NET

NIS-ACM

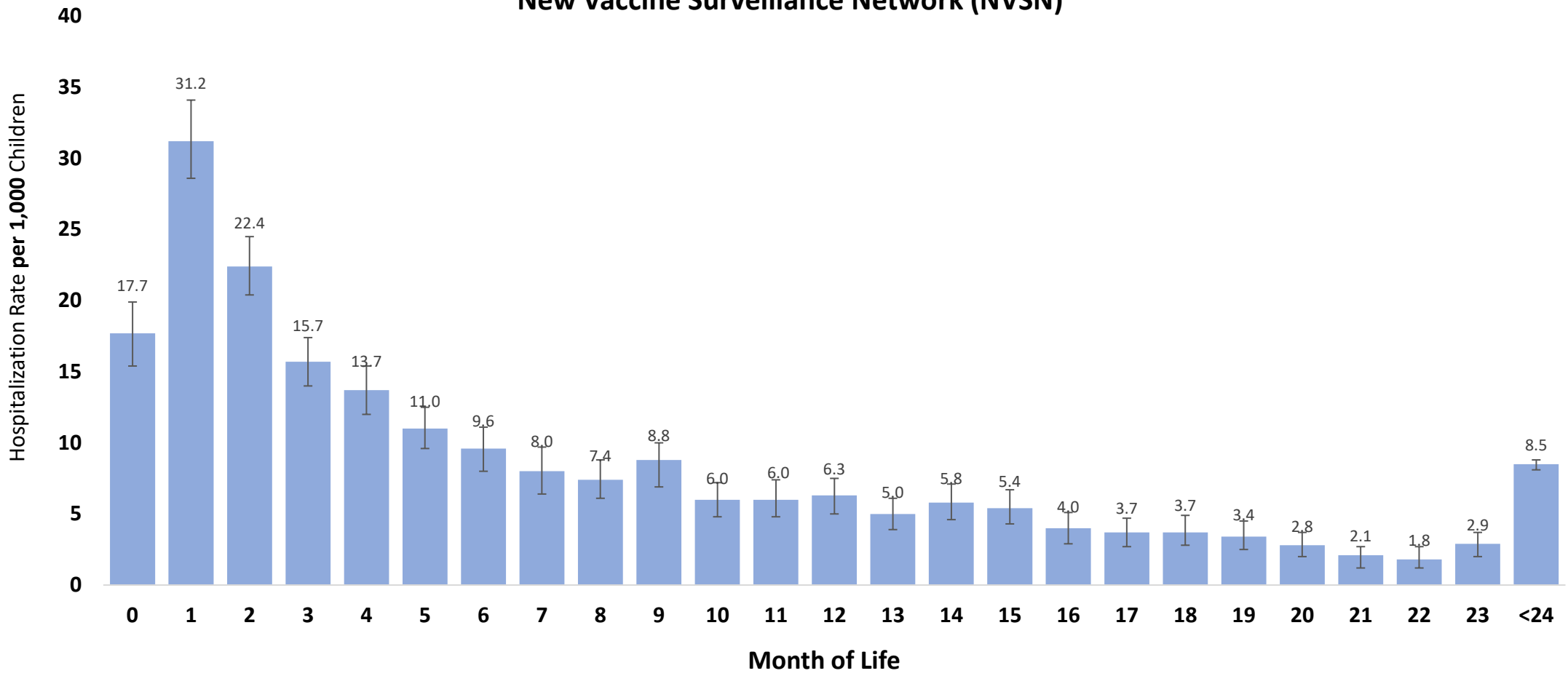
For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

Back-up

RSV-associated hospitalization rates are highest in infants less than 8 months

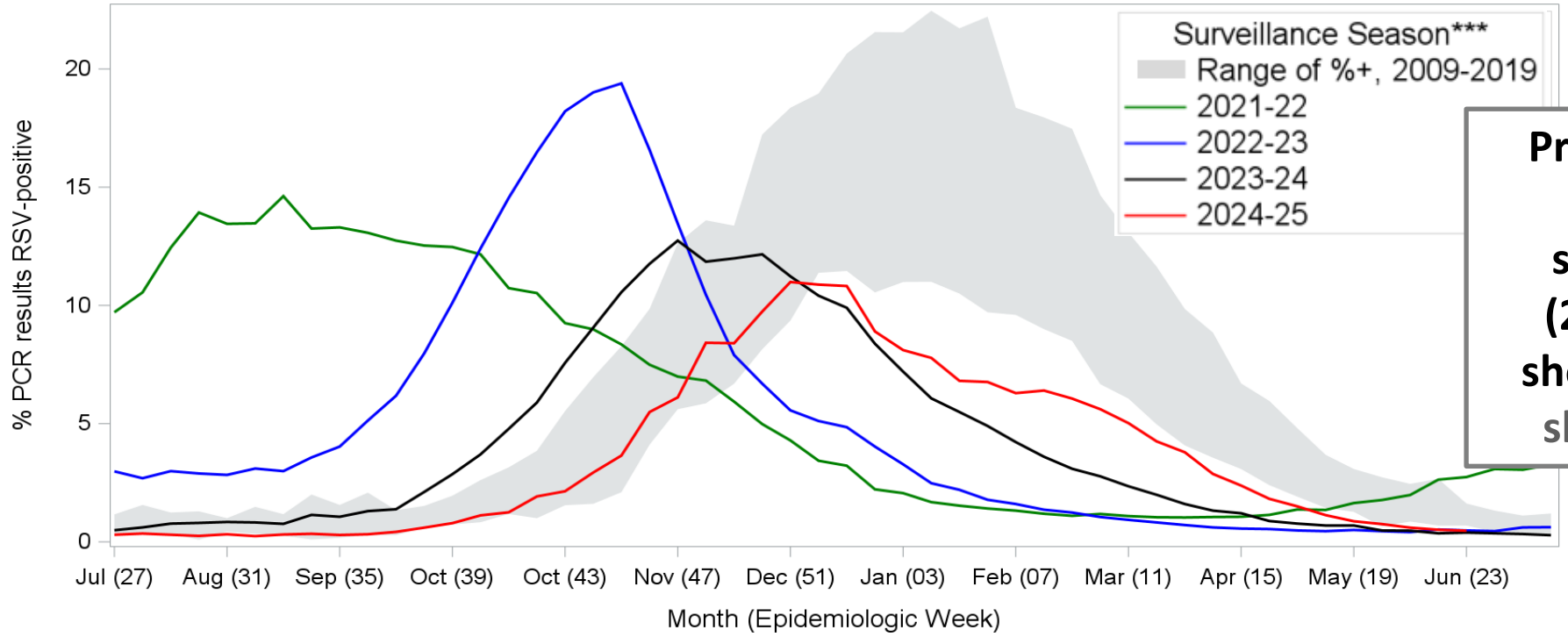
Rate of RSV-associated hospitalization by month of life among children age <2 years, December 2016–September 2020, New Vaccine Surveillance Network (NVSN)



Reference: Curns et al, Pediatrics (2024): https://doi.org/10.1542/peds.2023-062574

2024–2025 RSV seasonality has returned to pre-pandemic trends

Percentage* of polymerase chain reaction (PCR) test results positive for respiratory syncytial virus (RSV), by epidemiologic week — National Respiratory and Enteric Virus Surveillance System, United States, July 2009–June 2025**



Pre-COVID-19 pandemic seasonality (2009-2019) shown by grey shaded area

Notes: Report was last updated on 6/17/2025.
*All results presented are from polymerase chain reaction (PCR) tests, which represent >90% of the diagnostic tests reported to NREVSS. The last three weeks of data in 2024-25 may be less complete. NREVSS is an abbreviation for the National Respiratory and Enteric Virus Surveillance System. For more information on NREVSS, please visit National Respiratory and Enteric Virus Surveillance System | CDC.
**Respiratory syncytial virus types A and B are not shown separately in this report.
***The NREVSS surveillance season runs from the first week in July through June of the following year.
Abbreviations: %+: percent positive