Société Française de Pédiatrie

CONGRÈS des SOCIÉTÉS de PÉDIATRIE

Paris 2026 - du 10 au 12 juin

Immunisation contre le VRS
Saison 3

Robert COHEN

Une co-organisation

Prévention des infections précoces à VRS

Synagis® : Palivizumab Ac. monoclonal historique pour les nourrissons à haut risque

Beyfortus®

Nirsévimab
Anticorps monoclonal longue durée

Efficacy (IRB)
Effectiveness saison 1 (IRB)
Effrectiveness saison 1 (autres)
Effectiveness saison 2
Questions au-delà de la saison 1&2

Abrysvo®

Vaccination maternelle / anticorps monoclonal

Efficacy
Effectiveness(saison 1
Stratégies variables selon les pays

Enflonsia®

Clersovimab
Anticorps monoclonal longue durée

Efficacy (IRB)

Trois produits qui ont changé le paysage de la prévention du VRS

Questions

Diapo
R. Cohen

Les produits sont-ils tous aussi efficaces ?

Pourquoi les stratégies diffèrent-elles d'un pays à l'autre ?

Le nirsévimab protège-t-il aussi bien des autres infections à VRS que les bronchiolites ?

Quelle effectiveness au-delà d'un an ?

L'effectiveness va-t-elle se maintenir dans le temps ?

Les 3 produits sont-ils aussi efficaces ?

Diapo
R. Cohen

- On ne peut pas répondre directement à cette question
  - ✓Pas d'études prospective comparative (efficacité)
  - ✓En plus, cela pourrait changer dans le temps

- Mais ce qu'on sait c'est qu'avec le schéma vaccinal en France
  - 32-36 semaines
  - Campagne de vaccination 1er sept → 1er février

- Il n'y a aucun élément de preuve que l'Enflonsia® soit **plus ou moins efficace** que le Beyfortus®

Les données françaises disponibles, l'effectiveness observée du nirsévimab pour l'année 2024-2025 semble supérieure à celle de la vaccination maternelle dans les conditions actuelles d'utilisation.

JAMA | Original Investigation

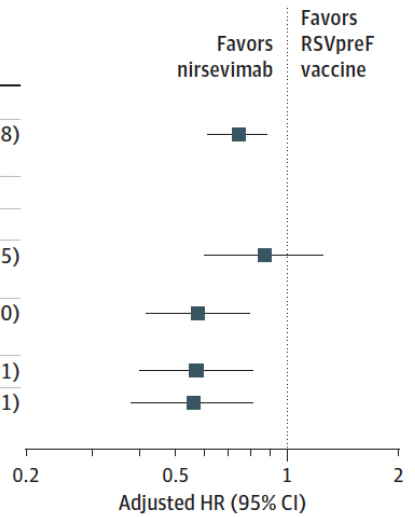
Janvier 2026

Nirsevimab vs RSVpreF Vaccine for Respiratory Syncytial Virus–Related Hospitalization in Newborns

Marie-Joelle Jabagi, PharmD, PhD; Marion Bertrand, MSc; Amélie Gabet, PhD; Epiphane Kolla, MD, PhD; Valérie Olié, PhD; Mahmoud Zureik, MD, PhD

Figure 2. Comparative Analysis for Primary Outcome of Hospitalization for Respiratory Syncytial Virus (RSV)–Associated Lower Respiratory Tract Infection and Secondary Outcomes Among Matched Infants

	No. (%)				
	Nirsevimab (n = 21 280)	RSVpreF vaccine (n = 21 280)	Between-group difference (95% CI), %	HR[a] (95% CI)	Adjusted HR[b] (95% CI)
Primary outcome					
Hospitalization for RSV-associated lower respiratory tract infection	212 (1.0)	269 (1.3)	-0.3 (-0.5 to -0.1)	0.79 (0.65 to 0.94)	0.74 (0.61 to 0.88)
Secondary outcomes					
RSV-associated lower respiratory tract infection					
With high-dependency unit admission[c]	58 (0.3)	67 (0.3)	0 (-0.1 to 0.1)	0.86 (0.61 to 1.23)	0.87 (0.60 to 1.25)
With pediatric intensive care unit admission	55 (0.3)	101 (0.5)	-0.2 (-0.3 to -0.1)	0.54 (0.39 to 0.76)	0.58 (0.42 to 0.80)
With ventilatory support	51 (0.2)	89 (0.4)	-0.2 (-0.3 to -0.1)	0.56 (0.40 to 0.79)	0.57 (0.40 to 0.81)
With oxygen therapy[d]	39 (0.2)	76 (0.4)	-0.2 (-0.3 to -0.1)	0.51 (0.34 to 0.76)	0.56 (0.38 to 0.81)



Effectiveness of nirsevimab immunisation after birth versus RSVpreF maternal vaccination in preventing RSV-related hospitalisations in infants: a population-based retrospective cohort study

Mai 2026

Zaba Valtuille, Inès Fafi*, Florentia Kaguelidou, Corinne Levy, Robert Cohen, Laurent Mandelbrot, Marta Nunes, François Angoulvant, Etienne Bizot, Stéphane Bonacorsi, André Birgy, Delphine Viriot, Aurélie Bourmaud, Léa Lenglart, Zein Assad, Manon Jaboyedoff, Jee-Seon Yang, Valérie Biran, Géraldine Poncelet, Christèle Gras-Le Guen, Loic De Pontual, Romain Basmaci*, Naïm Ouldali**

Summary

Background Maternal respiratory syncytial virus (RSV) prefusion F (RSVpreF) vaccine and nirsevimab immunisation are two products recently implemented to reduce RSV-related lower respiratory tract infection (LRTI) in infants

Lancet Child Adolesc Health 2026

	RSVpreF maternal vaccine	Nirsevimab newborn immunisation	Odds ratio (95% CI)
Time between maternal RSVpreF vaccination and birth, weeks			
2 weeks to less than 4 weeks	60/4156 (1·44%)	31/4156 (0·76%)	0·45 (0·32–0·63)
4 weeks to less than 6 weeks	163/15 268 (1·07%)	147/15 268 (0·96%)	0·80 (0·68–0·95)
6 weeks to less than 8 weeks	130/14 842 (0·88%)	114/14 842 (0·77%)	0·80 (0·60–0·99)
8 weeks or more	50/7832 (0·64%)	58/7832 (0·74%)	1·01 (0·77–1·32)

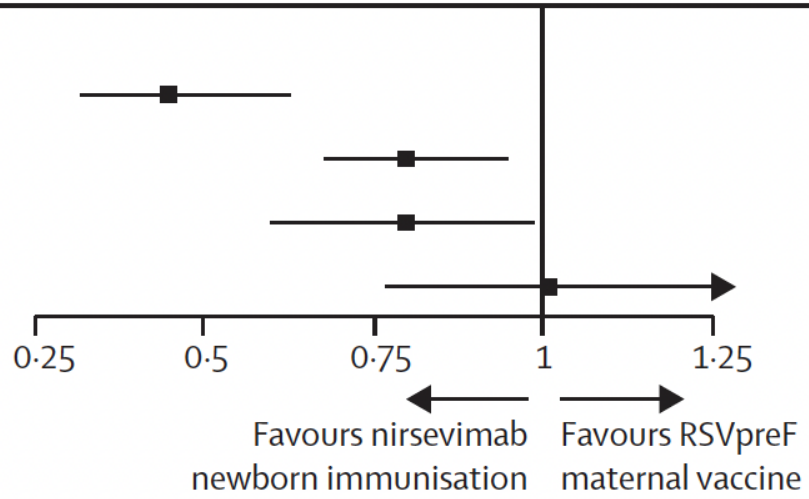


Figure 3: **Effectiveness of RSVpreF maternal vaccine versus nirsevimab newborn immunisation against RSV-related LRTI hospitalisations, according to timing of vaccination**

Effectiveness of nirsevimab immunisation after birth versus RSVpreF maternal vaccination in preventing RSV-related hospitalisations in infants: a population-based retrospective cohort study

Zaba Valtuille*, Inès Fafi*, Florentia Kaguelidou, Corinne Levy, Robert Cohen, Laurent Mandelbrot, Marta Nunes, François Angoulvant, Etienne Bizot, Stéphane Bonacorsi, André Birgy, Delphine Viriot, Aurélie Bourmaud, Léa Lenglart, Zein Assad, Manon Jaboyedoff, Jee-Seon Yang, Valérie Biran, Géraldine Poncelet, Christèle Gras-Le Guen, Loic De Pontual, Romain Basmaci*, Naïm Ouldali*

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RSV		Odds ratio (95% CI)
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2 weeks to less than 4 weeks	60	0·45 (0·32–0·63)
4 weeks to less than 6 weeks	163	0·80 (0·68–0·95)
6 weeks to less than 8 weeks	130	0·80 (0·60–0·99)
8 weeks or more	50	1·01 (0·77–1·32)

1·25

RSVpreF
nal vaccine

Ce n'est pas une surprise
les Anglais et les Australiens avaient déjà démontré une ≠ d'efficacité en f° de la date d'administration pendant la grossesse
→Ils commencent la vaccination dès 28 semaines !!

Figure 3: **Effectiveness of RSVpreF maternal vaccine versus nirsevimab newborn immunisation against RSV-related LRTI hospitalisations, according to timing of vaccination**

France 2026-27 : recommandations inchangées ?

- La recommandation française reste prudente, notamment vis-à-vis du signal possible d'accouchement prématuré.
- Terme moyen d'accouchement : environ 39 SA.
- Pour les femmes ou couples qui privilégient la vaccination maternelle : viser une vaccination dès 32 SA, voire un peu plus tôt …

Pourquoi les stratégies diffèrent-elles selon les pays ?

- Les données d'efficacité ou d'effectiveness sont connues de tous, mais elles peuvent un peu varier dans l'espace et dans le temps…

« Il n'y a pas de pire aveugle que celui qui ne veut pas voir » — surtout celui qui ne veut pas budgéter.

- Ce qui change c'est la **façon d'administrer les produits**…notamment pour la vaccination
- Le prix réel des produits reste très variable et peu transparent.
- La **durée de la saison VRS (3 m à…12 mois)**
  Chili, Argentine, Australie…des milliers de km
- Le **poids du médico-économique** (nous …)
- Les **caractéristiques du système de santé**

Effectiveness sur les autres infections liées au VRS : OMA

Données de première année

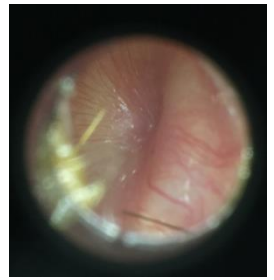
PARI — Fafi I., Clin Infect Dis, avril 2026

Chez les nourrissons < 12 mois, diminution significative du taux d'OMA pour 1 000 consultations après l'implémentation de l'immunisation VRS : −23,7 % (IC95 % −37,6 à −9,7 ; p = 0,0014).

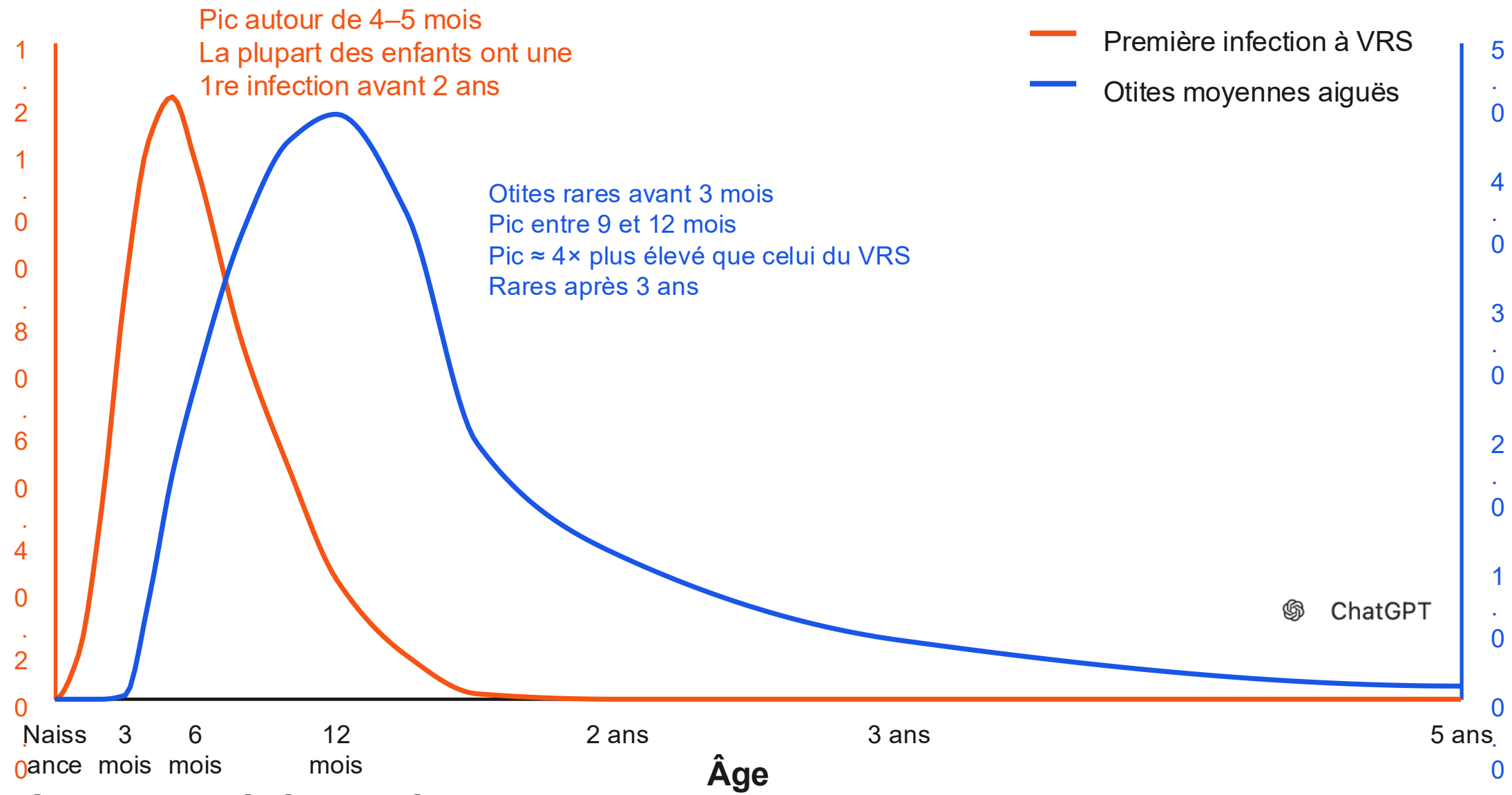
OURSIN — Lenglart L., J Pediatr, mars 2026

Effectiveness ajustée du nirsévimab estimée à 78,2 % (IC95 % 44,4–92,4) pour la prévention des OMA associées au VRS dans cet échantillon.

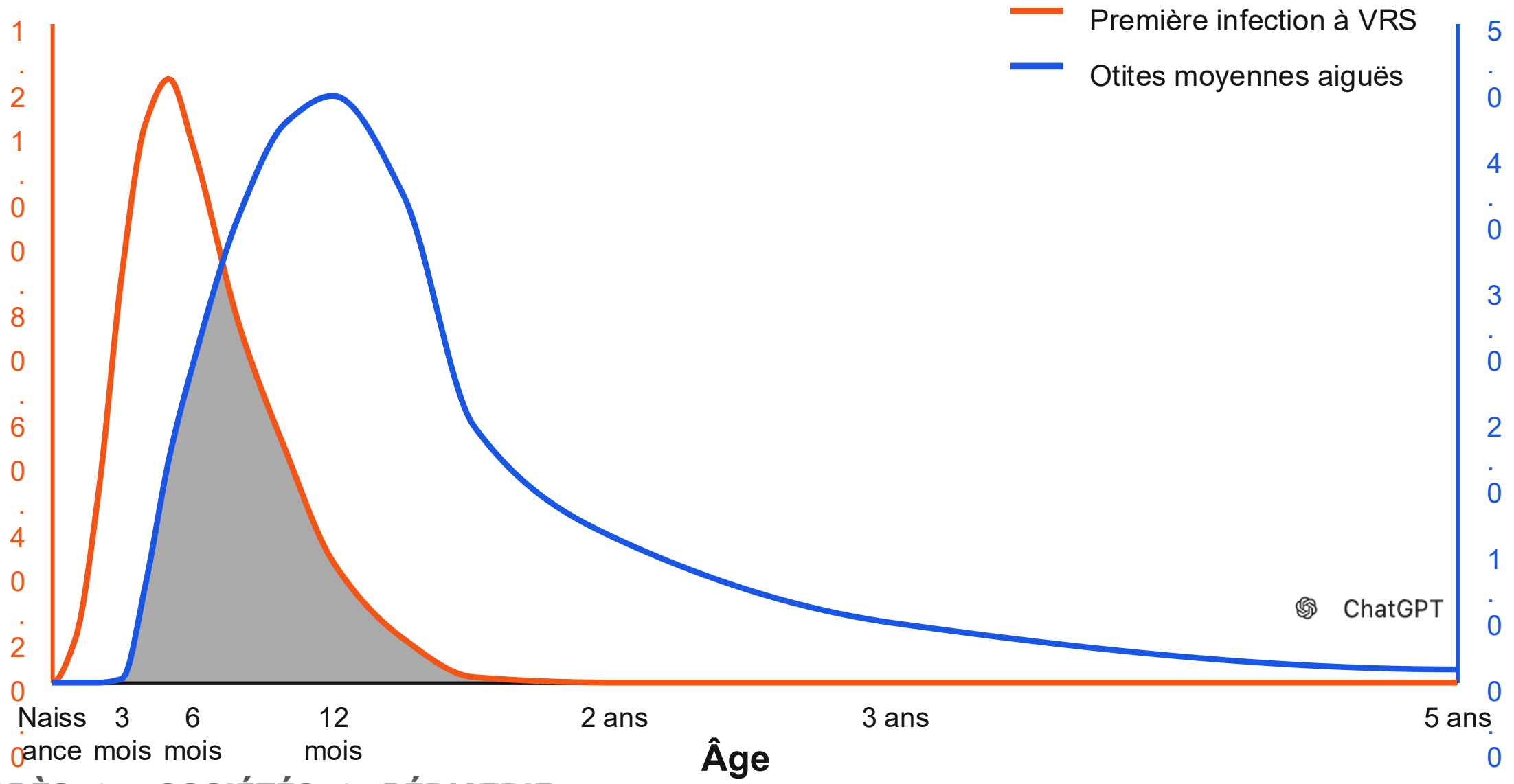
Message : le bénéfice pourrait dépasser la bronchiolite hospitalisée, notamment chez les nourrissons au pic d'incidence des OMA.



Fréquence selon l'âge : 1ère infection à VRS et incidence des OMA



Âge de première infection à VRS et incidence des otites moyennes aiguës



Effet sur les autres infections liées au VRS : IIP

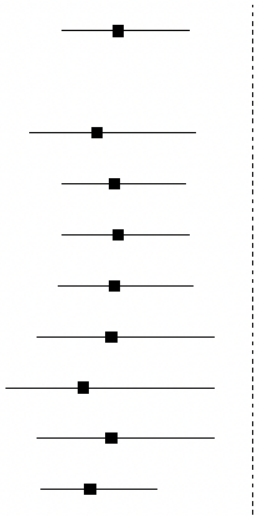
Infections invasives à pneumocoque

Étude nationale française

Effectiveness of nirsevimab immunisation on invasive pneumococcal disease in children: nationwide observational cohort study. Fafi I. et al., Lancet Infectious Diseases, juin 2026.

Figure 2. Effectiveness of nirsevimab against hospitalisation for IPD.

	Immunised with nirsevimab* *no. of IPD cases in each group/total no. (no. of IPD cases in each group/100,000)*	Non–immunised with nirsevimab*
Primary analysis***	17/119,435 (14.2/100,000)	95/408,536 (23.3/100,000)
Sensitivity analyses		
Matching immunised / non–immunised children (1:2) †	12/76,846 (15.6/100,000)	42/153,692 (27.3/100,000)
Double–robust adjustment ‡	17/119,435 (14.2/100,000)	95/408,536 (23.3/100,000)
Random intercept for region §	17/119,435 (14.2/100,000)	95/408,536 (25.0/100,000)
Removing IPD cases defined by code B953 + meningitis, bacteremia, pneumonia, osteoarticular infection or mastoiditis ¶	17/119,435 (14.2/100,000)	81/408,536 (19.8/100,000)
Average effect in the treated population ††	17/119,435 (14.2/100,000)	95/408,536 (23.3/100,000)
Propensity score matching ‡‡	17/119,434 (14.2/100,000)	53/211,811 (25.0/100,000)
Overlap–weighting §§	17/119,435 (14.2/100,000)	95/408,536 (23.3/100,000)
Trimming ¶¶	16/113,463 (14.1/100,000)	91/388,103 (23.4/100,000)



Fréquence selon l'âge : première infection à VRS et infections invasives à pneumocoque

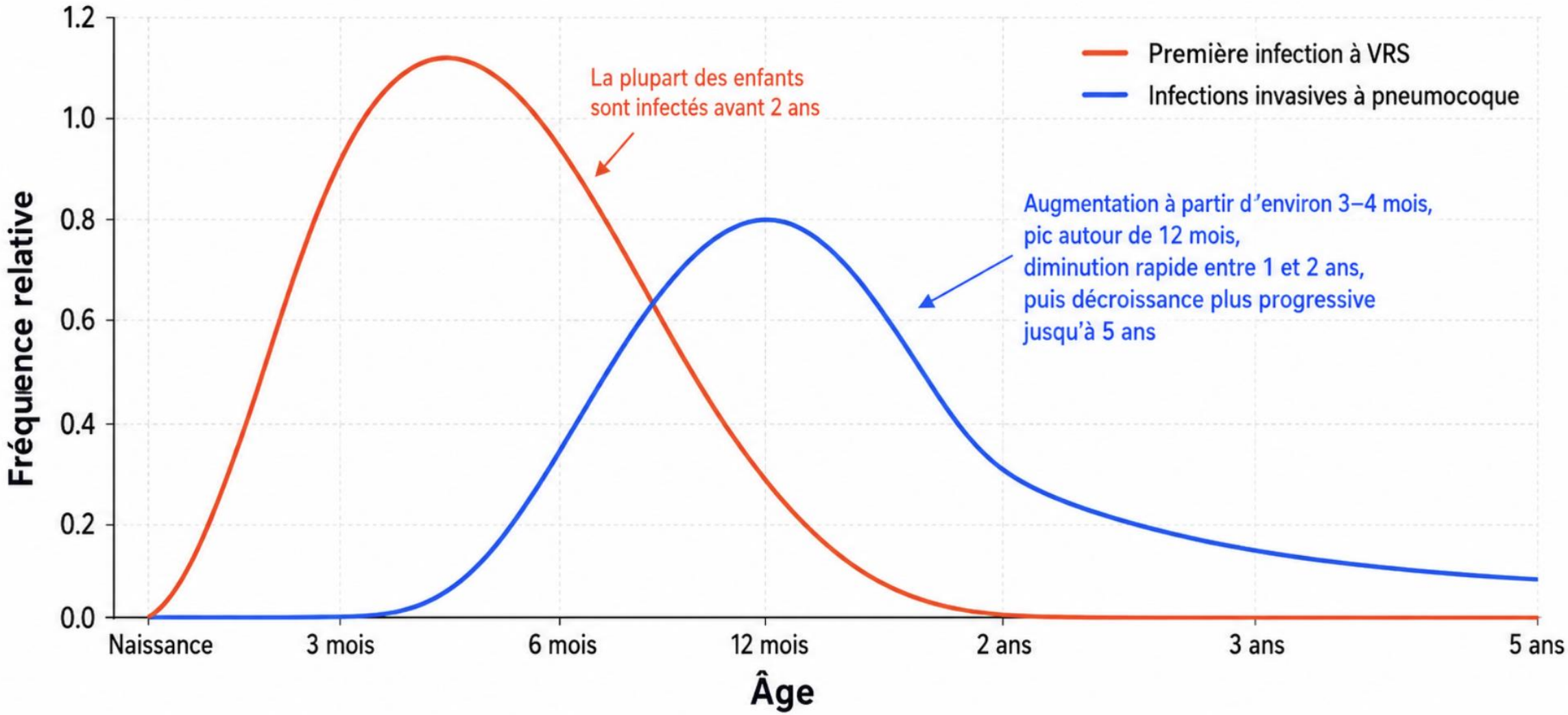
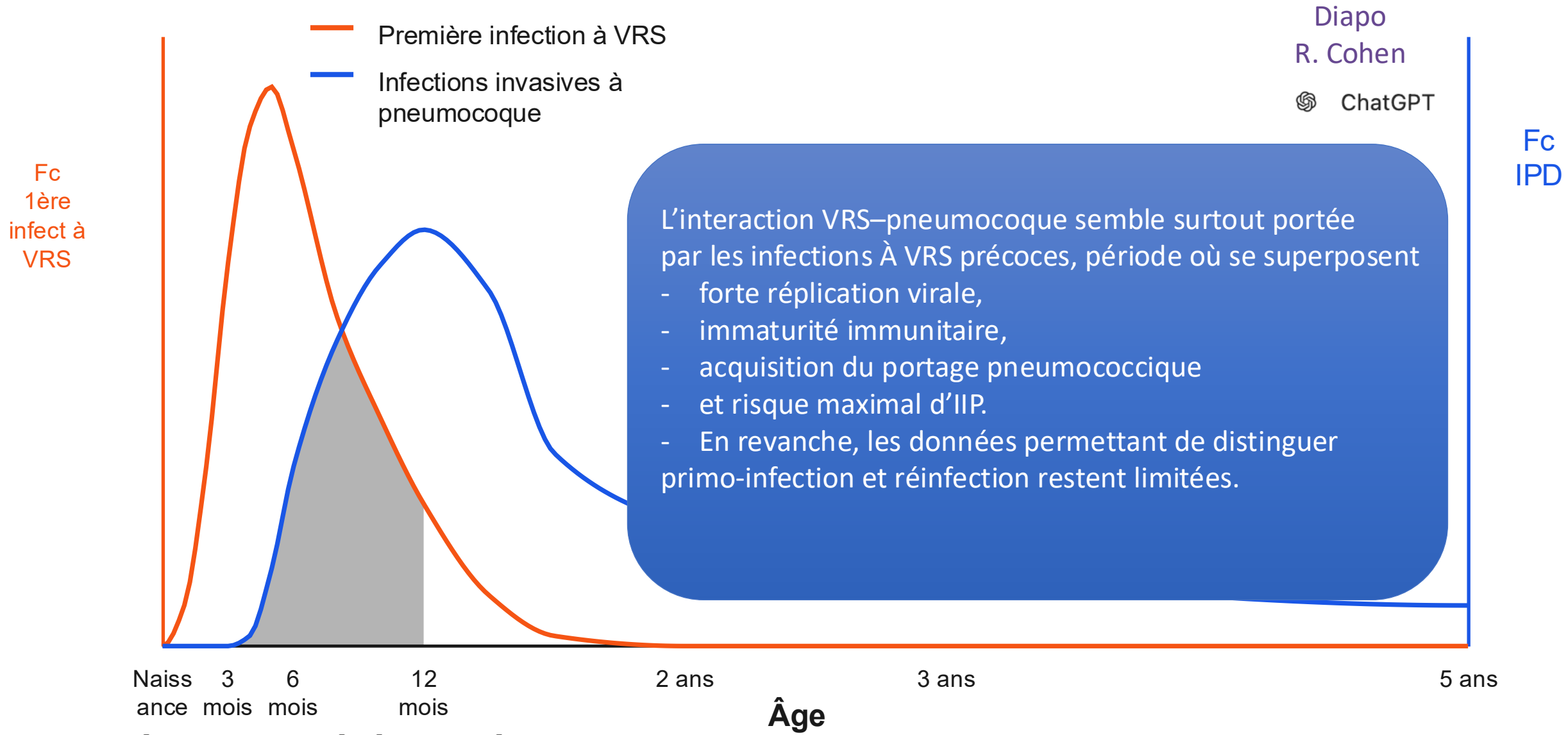


Schéma illustratif des distributions d'âge, à visée pédagogique.

Fréquence selon l'âge : première infection à VRS et infections invasives à pneumocoque



Effectiveness > 1 an
Nirse-gal (année 2)

Effectiveness > 1 an
Nirse-gal Hôpital (année 2)

nirse-gal

RODEO Taming RSV

Results

Table 1: Estimations of RR and NNI for different first primary healthcare endpoints, by different timeframes and groups

	Infants' first RSV season - 2023–24 (October 2, 2023 - April 14, 2024)					Second RSV season – 2024-25 (September 30, 2024–April 13, 2025)				
Acute bronchitis/bronchiolitis										
Cohort	**Observed**	**Expected**	**Averted**	**NNI**	**RR (95% CI)**	**Observed**	**Expected**	**Averted**	**NNI**	**RR (95% CI)**
Seasonal	432	631	199	32	-31.4 (–42.3, -18.4)	1,254	1,058	-196	-31	18.6 (3.2, 36.2)
Catch-up	1,352	1,917	565	12	-29.4 (–42.1, 14)	717	491	-226	-27	46.3 (30.0, 64.6)
Combined	1,784	2,577	793	16	**-30.8 (-41.9, -17.5)**	1,971	1,535	-436	-28	**28.5 (14.4, 44.3)**
Wheezing/asthma										
Seasonal	616	838	222	28	-26.5 (–36.5, -14.9)	1,447	1,198	-249	-24	20.7 (7.4, 35.7)
Catch-up	1,651	2,262	611	11	-27.1 (–39.6,-11.9)	845	593	-252	-24	42.5 (27.4, 59.4)

Relative change in first RSV season (n = 12,492 infants):

- *Primary care for LRTI:* ***-33.4%***
- *Acute bronchitis/bronchiolitis:* ***-30.8%***
- *Wheezing/asthma:* ***-27.7%***

Effectiveness > 1 an
Nirse-gal Hôpital (année 2)

nirse-gal

ESPID

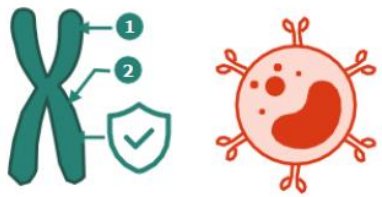
RODEO Taming RSV

Potential Mechanisms of Nirsevimab Second-Season Benefit

Preventing severe RSV disease in the first season reshapes the child's long-term respiratory health trajectory.

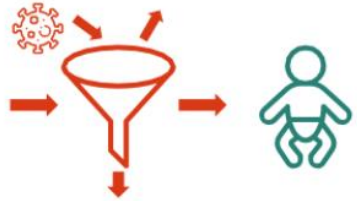
The Lung-Sparing Hypothesis

Preventing severe LRTI during critical alveolar growth preserves pulmonary reserve and structural integrity for the second season



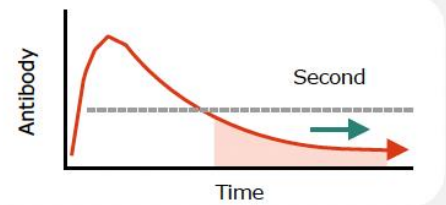
Epigenetic and Immune Imprinting

Prophylaxis avoids severity-driven DNA methylation and "trained immunity" that would eventually reprogram the



Selective Protection of High-Risk Endotypes

Nirsevimab removes the "first hit" in biologically susceptible infants who are most likely to require second-season

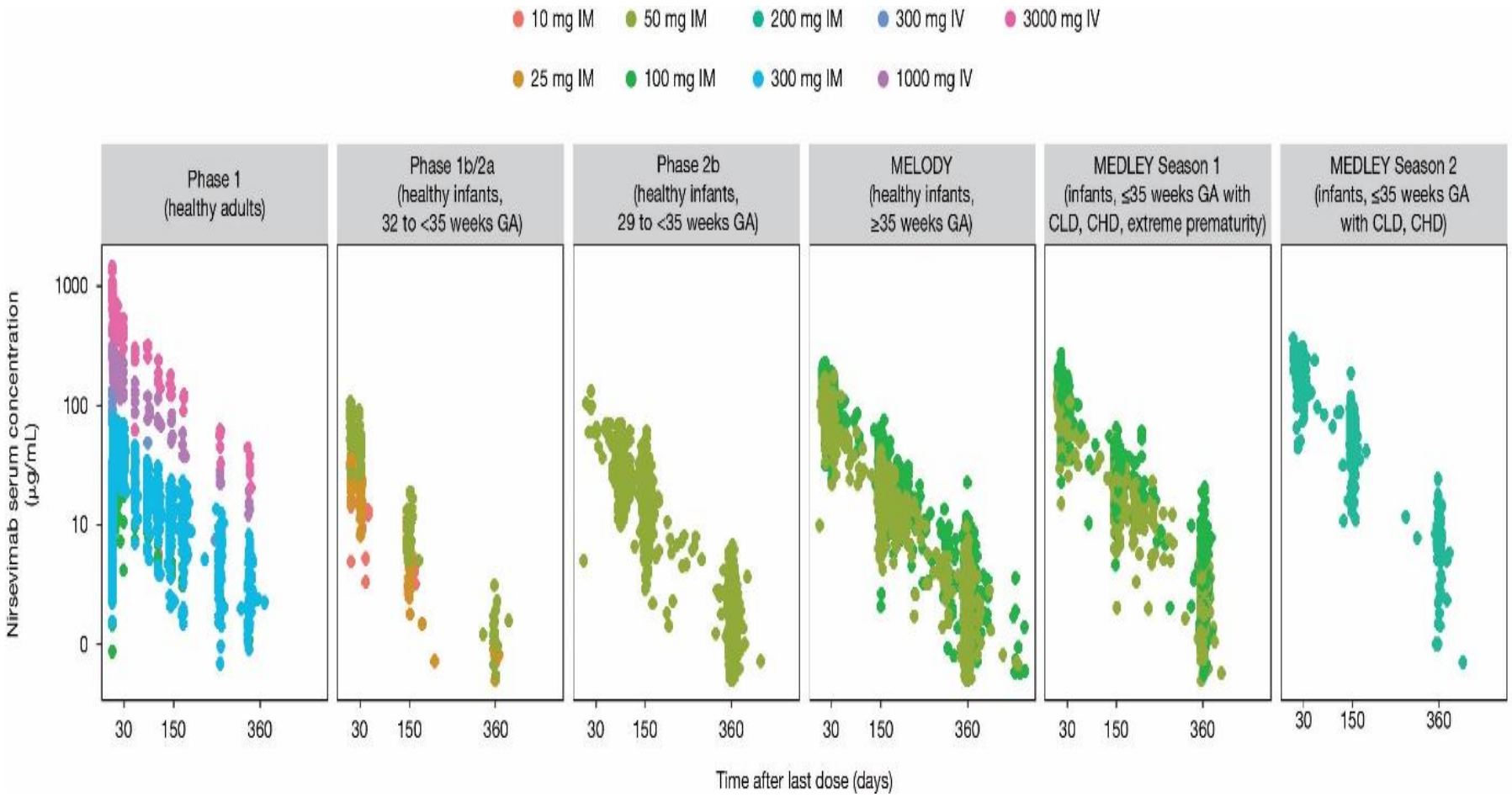


Residual Pharmacokinetic "Tail"

Gradual antibody decay and heterogeneous dosing timing provide a non-negligible protective bridge into the early

Variations inter-individuelles de pharmacocinétique

Nirsevimab Serum Concentration Versus Time, by Trial and Season[a]



Effectiveness > 1 an
Nirse-gal Ambulatoire (année 2)

nirse-gal

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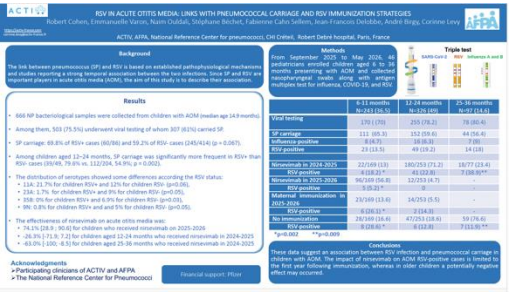
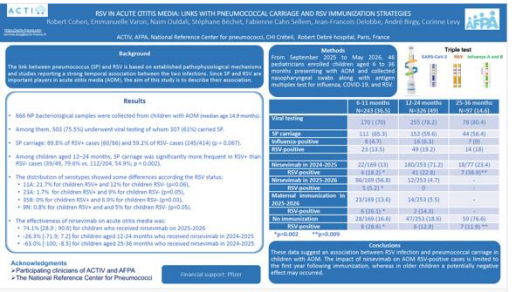


Effectiveness > 1 an

Etude Flore nasopharyngée : OMA, VRS/pneumo

- 666 NP bacteriological samples were collected from children with AOM (median age 14.9 months).
- Among them, 503 (75.5%) underwent viral testing of whom 307 (61%) carried SP.
- SP carriage: 69.8% of RSV+ cases (60/86) and 59.2% of RSV- cases (245/414) (p = 0.067).
- Among children aged 12–24 months, SP carriage was significantly more frequent in RSV+ than RSV- cases (39/49, 79.6% vs. 112/204, 54.9%; p = 0.002).

	6-11 months N=243 (36.5)	12-24 months N=326 (49)	25-36 months N=97 (14.6)
Viral testing	170 ((70)	255 (78.2)	78 (80.4)
SP carriage	111 (65.3)	152 (59.6)	44 (56.4)
Influenza-positive	8 (4.7)	16 (6.3)	7 (9)
RSV-positive	23 (13.5)	49 (19.2)	14 (18)



Effectiveness > 1 an

Etude Flore nasopharyngée : OMA, VRS/pneumo

- The effectiveness of nirsevimab on acute otitis media was:
  - 74.1% [28.9 ; 90.6] for children who received nirsevimab on 2025-2026
  - -26.3% [-71.9; 7.2] for children aged 12-24 months who received nirsevimab in 2024-2025
  - -63.0% [-100; -8.5] for children aged 25-36 months who received nirsevimab in 2024-2025

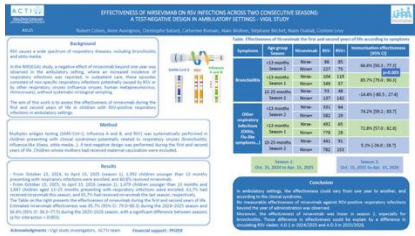
- The distribution of serotypes showed some differences according the RSV status:
  - 11A: 21.7% for children RSV+ and 12% for children RSV- (p=0.06),
  - 23A: 1.7% for children RSV+ and 9% for children RSV- (p=0.05),
  - 35B: 0% for children RSV+ and 6.9% for children RSV- (p=0.03),
  - 9N: 0.8% for children RSV+ and and 5% for children RSV- (p=0.05).

Effectiveness > 1 an

VIGIL : VRS toutes pathologies ambulatoires

Table. Effectiveness of Nirsevimab the first and second years of life according to symptoms

Symptoms	Age group Season	Nirsevimab	RSV-	RSV+	Immunisation effectiveness [95% CI]
Bronchiolites	<13 months Season 1	Nirse-	104	119	85.7% [79.0 ; 90.3]
		Nirse+	349	57	
	13-25 months Season 2	Nirse-	53	48	-14.4% [-80.5 ; 27.4]
		Nirse+	137	142	
Autres infections à VRS	<13 months Season 1	Nirse-	492	65	72.8% [57.0 ; 82.8]
		Nirse+	778	28	
	13-25 months Season 2	Nirse-	441	91	5.2% [-26.0 ; 28.7]
		Nirse+	782	153	



EFFECTIVENESS OF NIRSEVIMAB ON RSV INFECTIONS ACROSS TWO CONSECUTIVE SEASONS:
A TEST-NEGATIVE DESIGN IN AMBULATORY SETTINGS - VIGIL STUDY

Robert Cohen, Anne Auvrignon, Christophe Batard, Catherine Romain, Alain Wollner, Stéphane Béchet, Naïm Ouldali, Corinne Levy

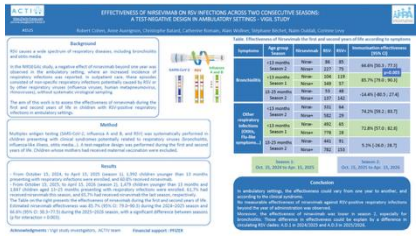
Effectiveness > 1 an

VIGIL : VRS toutes pathologies ambulatoires

Table. Effectiveness of Nirsevimab (1ère annné) 2024-25 vs 2025-26

Symptoms	Age group Season	Nirsevimab	RSV-	RSV+	Immunisation effectiveness [95% CI]
Bronchiolitis	<13 months Season 2	Nirse-	86	85	66.6% [50.3 ; 77.5]
		Nirse+	227	75	
	<13 months Season 1	Nirse-	104	119	85.7% [79.0 ; 90.3]
		Nirse+	349	57	
Other respiratory infections (Otitis, Flu-like symptoms…)	<13 months Season 2	Nirse-	331	64	74.2% [59.2 ; 83.7]
		Nirse+	582	29	
	<13 months Season 1	Nirse-	492	65	72.8% [57.0 ; 82.8]
		Nirse+	778	28	

p=0.003



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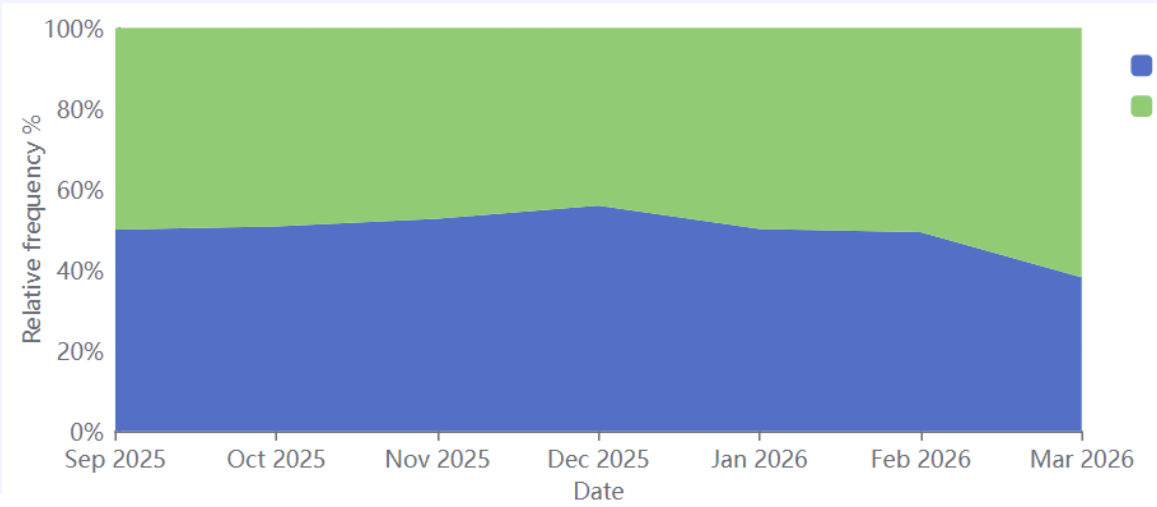
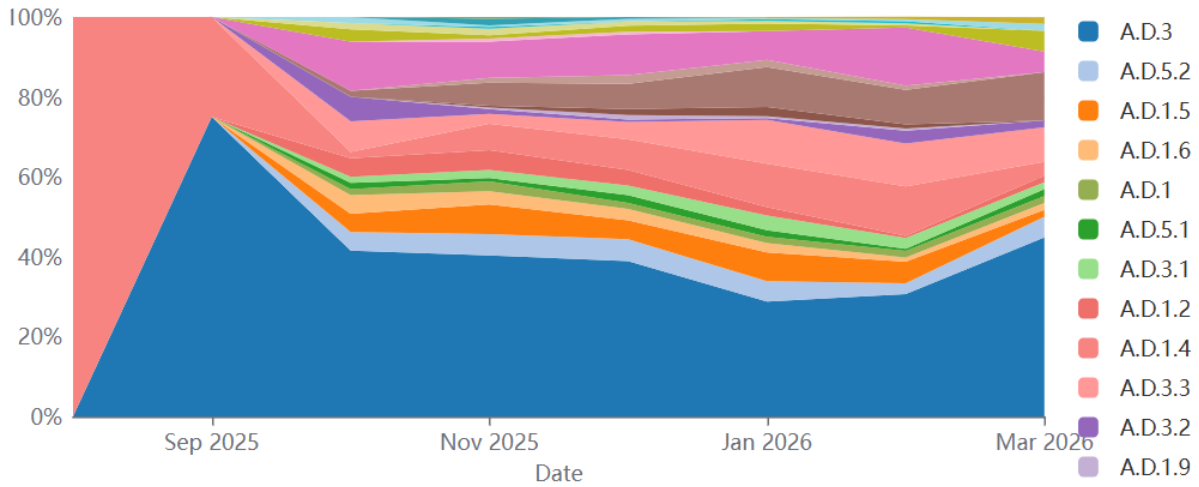
Robert Cohen, Anne Auvrignon, Christophe Batard, Catherine Romain, Alain Wollner, Stéphane Béchet, Naïm Ouldali, Corinne Levy

Circulation des clades de VRS (CNR)





Risque d'échec d'immunisation avec clade A.D.3 > aux autres ?

GISAID

Take-home messages

- Nous disposons désormais de 3 produits et 2 stratégies efficaces contre les infections précoces à VRS.
- L'objectif prioritaire reste la prévention des bronchiolites hospitalisées, en particulier en réanimation, pendant les premiers mois de vie.
- Un bénéfice sur les bronchiolites ambulatoires et d'autres infections liées au VRS est plausible, doit être confirmée dans le temps.
- Pour la vaccination maternelle, l'enjeu est de vacciner tôt dans la fenêtre recommandée : idéalement 32–33 SA (un peu plus tôt ?
- La surveillance doit rester continue : épidémiologie, virologie, effectiveness, échecs d'immunisation et impact sur les infections bactériennes.