Meld je aan met de **QR-code**

Practopics

Praktische topics voor de huisarts

Of **klik op de link** in de Q&A rechtsboven.

?

Practopics

Praktische topics voor de huisarts

Paediatric RSV prevention in 25-26

What's new ?

Focus on hospitalization reduction

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ZIEKENHUIS aan de STROOM

Disclosures

Daan Van Brusselen received consultancy fees from:

- Sanofi
- Pfizer
- MSD

ZIEKENHUIS aan de STROOM

What to do?

De gynaecoloog heeft patiënte een Abrysvo-injectie gegeven in februari.

De dame bevalt in mei.

Wat doe je na de bevalling?

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RSV burden of disease

- Worldwide:
  - 33 million cases of LRTI
  - 3,6 million hospitalizations
  - 100.000 deaths (95% in LMIC !)
- Europe: 1/56 children < 1 year admitted with RSV *
- **Belgium (2018):**
  - 9.047 to 10.675 hospitalizations yearly
  - 452 (10%) – 533 (11.8%) PICU admissions
- Major **social and economic impact of RSV infection**: high direct and indirect costs
- **Most 'medically attended' cases**, including hospitalisations: **otherwise healthy** term infants
- 71% of RSV-associated **hospitalisations occur <1 year (KCE 2025)****; **25 % occurring between 6 and 12m**
- 4% of hospitalizations referred to PICU (KCE 2025)

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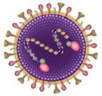
- Karron RA. RSV illness in the young and the old – the beginning of the end . NEJM 2023.
- Raes et al.Strategies to prevent severe RSV infections in infants: the Belgian expert opinion. BJP 2023.

Milestones In RSV research

No Preventative Options Available

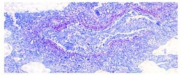
Limited Preventative Options

New Preventative Options



1957
RSV identified in humans[1]

1966-69
Formalin-inactivated RSV[1,2]



1985
Purified F protein[9]

1996
RespiGam FDA approval[1]

1998-1999
Palivizumab FDA/EMA approval[1,3]

2013
RSV preF structure/ stabilizatio
4

2022 & 2023
Nirsevimab EMA & FDA approval[5,6]

2023
RSV Pre F vaccine FDA & EMA approval[7,8]

1950s | 1960s | 1970s | 1980s | 1990s | 2000s | 2010s

FDA, Food and Drug Administration; preF, prefusion F; RSV, respiratory syncytial virus.

1. Gonik B. *Glob Health Sci Pract.* 2019;7(4):515-520. **2.** Polack FP et al. *J Exp Med.* 2002;196(6):859-865. **3.** Resch B. *Hum Vaccin Immunother*. 2017;13(9):2138-2149. **4.** McLellan JS et al. *Science.* 2013;342(6158):592-598. **5.** Nirsevimab authorization details. EMA. June 23, 2023. Accessed August 25, 2023. https://www.ema.europa.eu/en/medicines/human/EPAR/beyfortus#authorisation-details-section **6.** FDA approves new drug to prevent RSV in babies and toddlers. FDA. July 17, 2023. Accessed August 14, 2023. https://www.fda.gov/news-events/press-announcements/fda-approves-new-drug-prevent-rsv-babies-and-toddlers **7.** FDA approves first vaccine for pregnant individuals to prevent RSV in infants. FDA. August 21, 2023. Accessed August 23, 2023. https://www.fda.gov/news-events/press-announcements/fda-approves-first-vaccine-pregnant-individuals-prevent-rsv-infants. **8.** European commission approves Pfizer's ABRYSVO™ to help protect infants through maternal immunization and older adults from RSV. August 24, 2023. Accessed September 8, 2023. https://www.pfizer.com/news/press-release/press-release-detail/european-commission-approves-pfizers-abrysvotm-help-protect. 9. Walsh EE et al. *J Gen Virol* 1985;66:409-415

Young Infant: poor immunity

Innate[1,3]

Young infants rely heavily on this *(although qualitatively & quantitatively inferior)*

Adaptive[1,2]

Young infants: immaturity of B cells and T cells

Poor quality of B cells > few antibodies

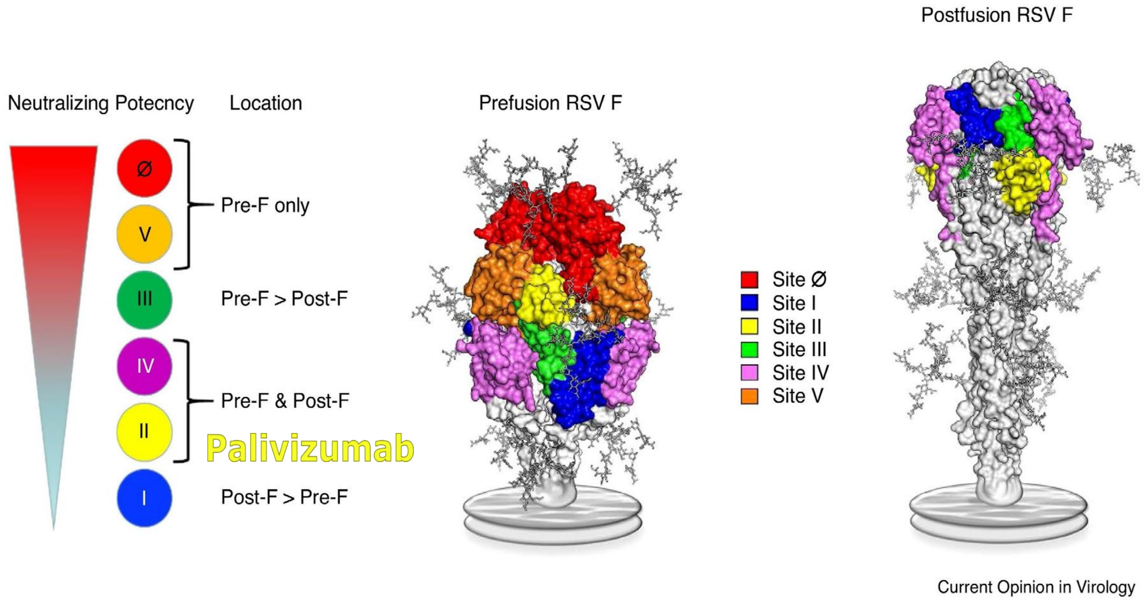
Maternally derived antibodies <u>or</u> mAb's
NECESSARY for early protection

1. *Basha S, et al. Expert Rev Clini Immun. 2014;10(9):1171-1184.*
2. *Nunez N et al. Vaccines (Basel). 2021;9(6):584.*
3. *Kollman TR et al. Protecting the newborn and young infant from infectious diseases: lessons from immune ontogeny. Immunity 2017*

All current strategies target:
RSV preF = Unstable Prefusion Form

ONLY Prefusion F can bind host cells

Antibodies specific to **prefusion form** = most effective at blocking virus infection

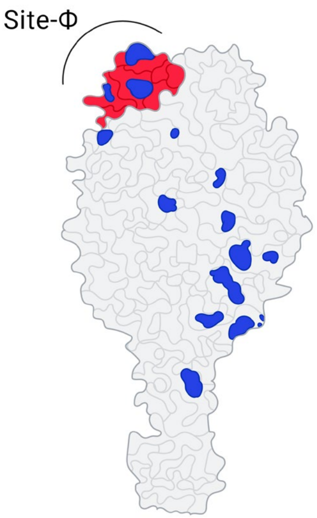


NIH = National Institutes of Health.

- McLellan JS, et al. *Science.* 2013;342(6158):592-598
- Graham BS, et.al. Current Opinion Immunology. 2015. 35:30-8; Graham BS, Current Opinion in Virology, 2017. 23:107-12; Tripp, RA, et. Al., J Virol 2018. 92(3): e01302-17

Option 1: the maternal vaccine

RSV PreF vaccine (Abrysvo ®) = Stabilized RSV Prefusion F Vaccine



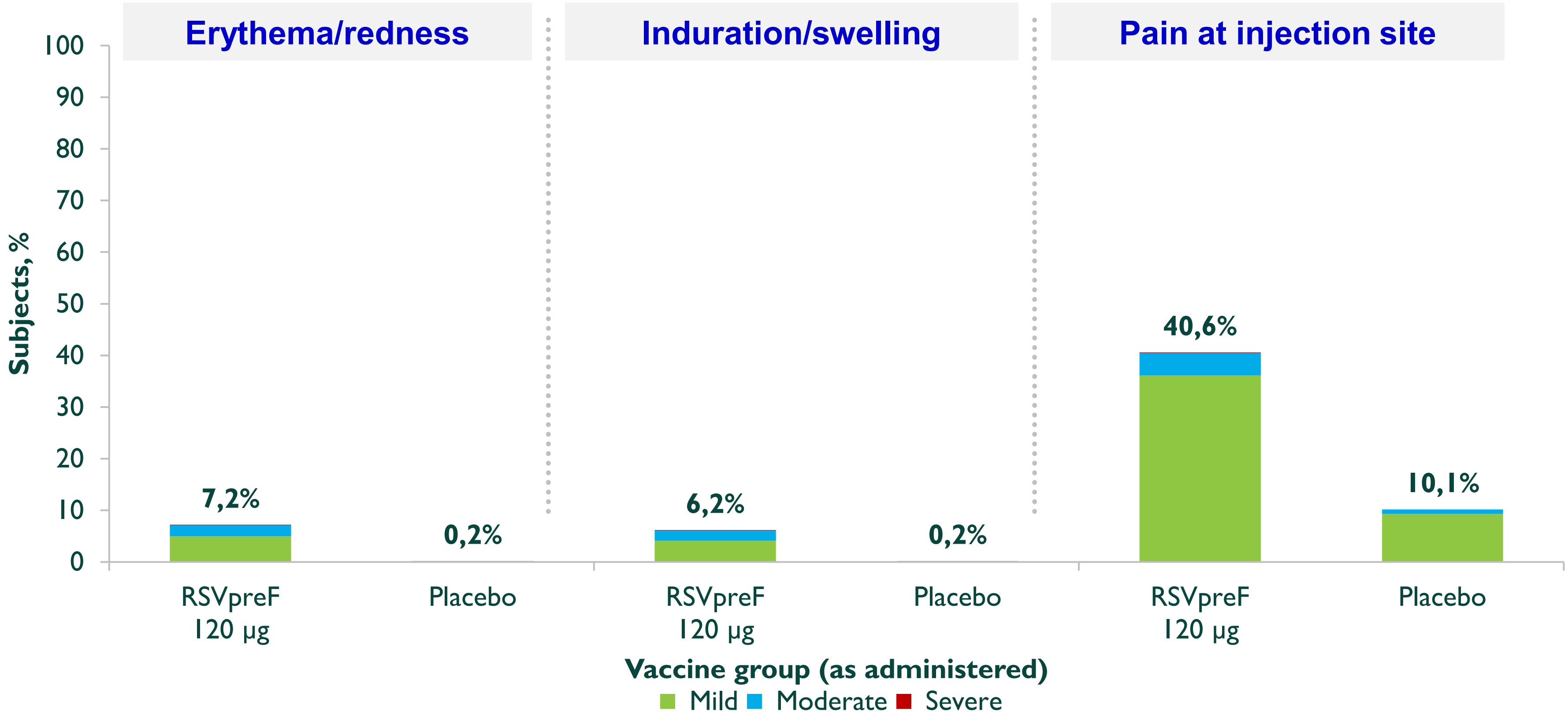
Ontario (RSV A) & Buenos Aires (RSV B)
= dominant genotypes
= basis of bivalent vaccine [3]

RSV subgroup dominance can vary over time [2]

Balanced neutralizing responses against both RSV A and RSV B observed with bivalent RSV preF [1]

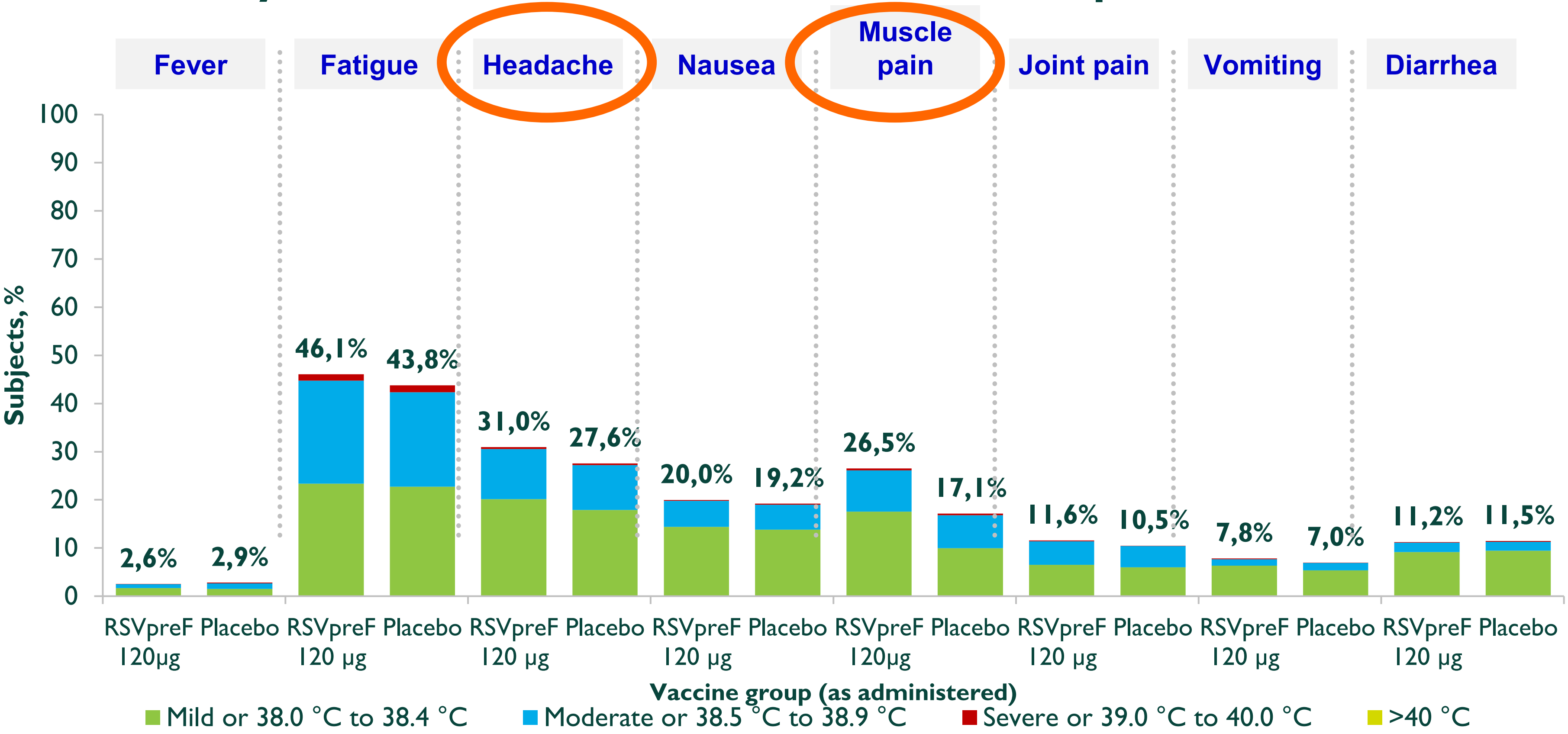
1. Crank MC, et al. *Science* 2019, 365:505-9. **2.** Nam HH et Ison MG. Semin Respir Crit Care Med 2021;42:788–799. **3.** Langedijk AC, et al. *Rev Med Virol.* 2022;32(3):e2284.

Local Reactions, by Maximum Severity, within 7 Days After Vaccination in Maternal Participants



Kampmann B, et al. *N Engl J Med*. 2023;388(16):1451-1464.

Systemic Events, by Maximum Severity, within 7 Days After Vaccination in Maternal Participants

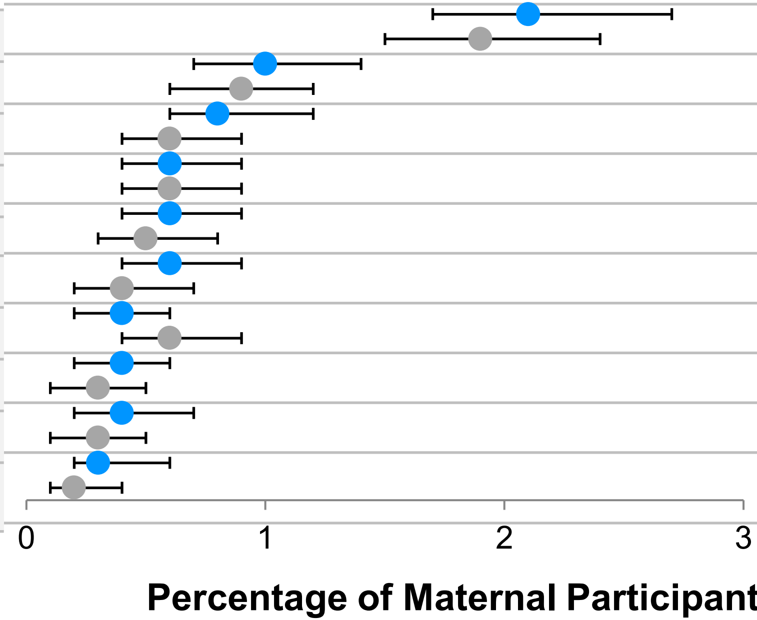


Kampmann B, et al. *N Engl J Med*. 2023;388(16):1451-1464.

Common AEs Comparable Between RSVpreF & Placebo within 1 Month After Vaccination in mothers

Percentage with Event

Pregnancy complications	RSVpreF 120 µg N=3682	Placebo N=3675
Premature delivery	2.1	1.9
Pre-eclampsia	1.0	0.9
Gestational hypertension	0.8	0.6
SARS-CoV-2 test positive	0.6	0.6
Urinary tract infection	0.6	0.5
Gestational diabetes	0.6	0.4
Anemia	0.4	0.6
Premature labor	0.4	0.3
Threatened labor	0.4	0.3
Premature rupture of membranes	0.3	0.2

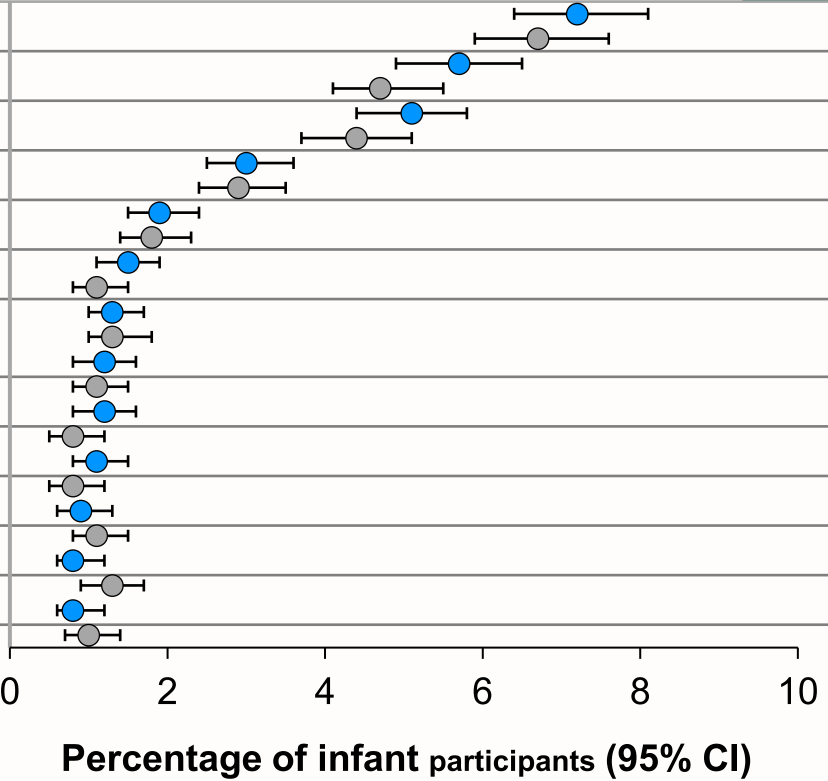


Kampmann B et al. *N Engl J Med.* 2023;388(16):1451-1464

Neonatal conditions within 1 Month After Vaccination

Neonatal conditions ≥0.8%

	Percentage with event: RSVpreF 120 µg (n=3568)	Percentage with event: Placebo (n=3558)
Jaundice neonatal	7.2	6.7
Premature baby	5.7	4.7
Low birth weight baby	5.1	4.4
Hyperbilirubinemia neonatal	3.0	2.9
Respiratory distress	1.9	1.8
Ankyloglossia congenital	1.5	1.1
Transient tachypnoea of the newborn	1.3	1.3
Hypoglycemia	1.2	1.1
Congenital nevus	1.2	0.8
Hypoglycemia neonatal	1.1	0.8
Small for dates baby	0.9	1.1
Atrial septal defect	0.8	1.3
Dermatitis diaper	0.8	1.0



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Kampmann B et al. N Engl J Med 2023;388:1451-1464

Preterm Birth and Low Birth Weight by Income Group

	RSVpreF		Placebo	
	n/N	% (95% CI)	n/N	% (95% CI)
Preterm <37 Weeks				
All	201/3568	5.7 (4.9, 6.5)	169/3558	4.7 (4.1, 5.5)
HIC	126/2494	5.1 (4.2, 6.0)	126/2484	5.1 (4.2, 6.0)
UMIC	72/964	7.5 (5.9, 9.3)	39/961	4.1 (2.9, 5.5)
LMIC/LIC	3/110	2.7 (0.6, 7.8)	4/113	3.5 (1.0, 8.8)
Low Birth Weight ≤2500g				
All	181/3568	5.1 (4.4, 5.8)	155/3558	4.4 (3.7, 5.1)
HIC	108/2494	4.3 (3.6, 5.2)	102/2484	4.1 (3.4, 5.0)
UMIC	66/964	6.8 (5.3, 8.6)	42/961	4.4 (3.2, 5.9)
LMIC/LIC	7/110	6.4 (2.6, 12.7)	11/113	9.7 (5.0, 16.8)

HIC,High Income Countries; LIC,Low Income Countries LMIC,Lower-Middle Income Countries; UMIC,Upper Middle-Income Countries
VRBPAC https://www.fda.gov/media/168255/download

MATISSE Primary endpoint: RSV-positive MA-LRTIs

Time interval	RSVpreF 120 µg (n=3495) n	Placebo (n=3480) n	Vaccine efficacy (CI 97.58, 99.5%*)
90 days after birth	24	56	57.1% (14.7, 79.8)
120 days after birth	35	81	56.8% (31.2, 73.5)
150 days after birth	47	99	52.5% (28.7, 68.9)
180 days after birth	57	117	51.3% (29.4, 66.8)

Predefined criterium lower bound of CI >20%: NOT MET at 90 days *

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* CI = confidence interval; MA-LRTI = medically attended lower respiratory tract illness

Kampmann B et al. N Engl J Med 2023;388:1451-1464

MATISSE Primary endpoint: RSV-positive Severe MA-LRTIs

Time interval	RSVpreF 120 µg (n=3495) n	Placebo (n=3480) n	Vaccine efficacy (CI 97.58, 99.5*)
90 days after birth	6	33	81.8% (40.6, 96.3)
120 days after birth	12	46	73.9% (45.6, 88.8)
150 days after birth	16	55	70.9% (44.5, 85.9)
180 days after birth	19	62	69.4% (44.3, 84.1)

Predefined criterium: lower bound CI >20% = ok

And hospitalisation ?
Matisse study: 56,8% VE at 180d
(99% CI 10,1 – 80,7)

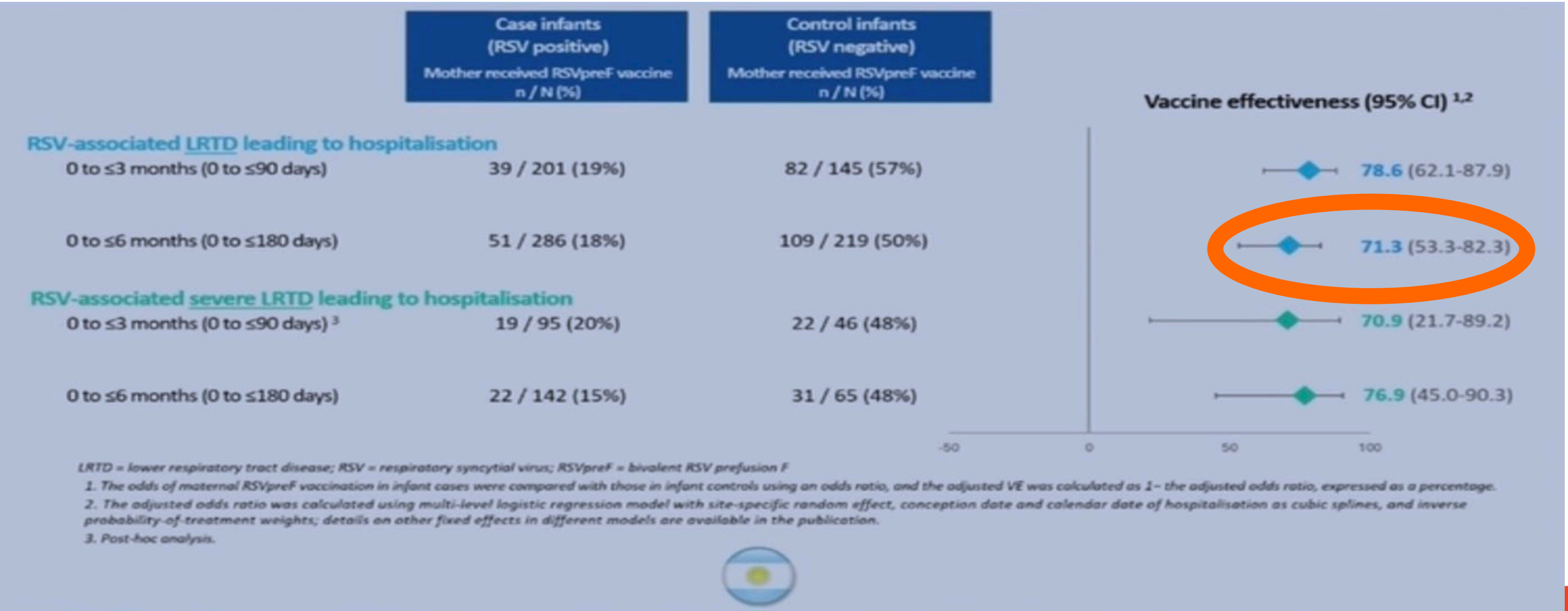
* CI = confidence interval; MA-LRTI = medically attended lower respiratory tract illness
Kampmann B et al. N Engl J Med 2023;388:1451-1464

ZIEKENHUIS aan de STROOM

What's new in 2025?
Abrysvo implementation in Argentina

BERNI Effectiveness of RSV preF in Argentina for hospitalization (Gonzalez Perez Marc, Buenos Aires, Lancet Infec Dis 2025)

- 'Test negative'* case control (= retrospective, so significant chance on confounders…)
- no difference in prematurity
- 3 RSV deaths, all from mothers who weren't vaccinated



	Case infants (RSV positive) Mother received RSVpreF vaccine n / N (%)	Control infants (RSV negative) Mother received RSVpreF vaccine n / N (%)	Vaccine effectiveness (95% CI) [1,2]
RSV-associated LRTD leading to hospitalisation			
0 to ≤3 months (0 to ≤90 days)	39 / 201 (19%)	82 / 145 (57%)	78.6 (62.1-87.9)
0 to ≤6 months (0 to ≤180 days)	51 / 286 (18%)	109 / 219 (50%)	71.3 (53.3-82.3)
RSV-associated severe LRTD leading to hospitalisation			
0 to ≤3 months (0 to ≤90 days) [3]	19 / 95 (20%)	22 / 46 (48%)	70.9 (21.7-89.2)
0 to ≤6 months (0 to ≤180 days)	22 / 142 (15%)	31 / 65 (48%)	76.9 (45.0-90.3)

LRTD = lower respiratory tract disease; RSV = respiratory syncytial virus; RSVpreF = bivalent RSV prefusion F

1. The odds of maternal RSVpreF vaccination in infant cases were compared with those in infant controls using an odds ratio, and the adjusted VE was calculated as 1– the adjusted odds ratio, expressed as a percentage.

2. The adjusted odds ratio was calculated using multi-level logistic regression model with site-specific random effect, conception date and calendar date of hospitalisation as cubic splines, and inverse probability-of-treatment weights; details on other fixed effects in different models are available in the publication.

3. Post-hoc analysis.

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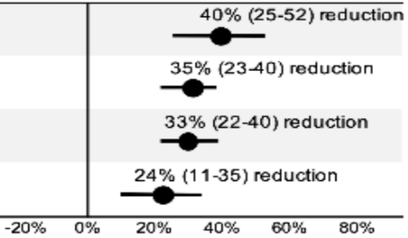
What's new in 2025?
Abrysvo implementation in Argentina

<u>BERNI Descriptive Before-And-After study</u> (Rearte A et al. Group of Gonzalez Perez Marc. ESPID 2025)

- Ecological study = compare disease frequency BEFORE and AFTER implemetation
- Risk of 'ecological fallacy'
- 'real' impact on hospitalization

Figure. Preliminary estimated impact of RSVpreF vaccination program on RSV-associated and all-cause hospitalisation outcomes, before (2023) and after (2024) implementation in Argentina

Outcome	Age (months)[a]	Incidence proportion (cases/100 hospitalisations)[b] Before RSVpreF implementation (2023)	After RSVpreF implementation (2024)	Ratio after vs. before (2024 vs. 2023)	Relative reduction	Crude difference-in-difference[c]	Impact[d] (95%CI) Favours vaccine introduction
RSV-LRTD hospitalisation	0 to ≤3	14.4	7.1	0.49	51%	0.60	40% (25-52) reduction
	>6 to ≤24	14.7	12.0	0.82	18%		
Any RSV hospitalisation	0 to ≤3	20.6	11.9	0.58	42%	0.65	35% (23-40) reduction
	>6 to ≤24	21.7	19.3	0.89	11%		
All-cause LRTD hospitalisation	0 to ≤3	32.8	21.1	0.64	[illegible]	0.67	33% (22-40) reduction
	>6 to ≤24	44.9	42.8	0.95	5%		
All-cause bronchiolitis hospitalisation	0 to ≤3	25.2	16.9	0.68	32%	0.76	24% (11-35) reduction
	>6 to ≤24	22.1	19.6	0.89	11%		



[a] Infants 0 to ≤3 months (0 to ≤90 days) represent the intervention group, with potential to be born to an RSVpreF-vaccinated mother in the 2024 season. Infants and children >6 to ≤24 months (>180 to ≤720 days) represent the control group, with no potential to be born to an RSVpreF-vaccinated mother in the 2024 season.
[b] Incidence proportions (i.e., cases/100 hospitalisations) were estimated during the RSV season from epidemiological week 14 to epidemiological week 35 (inclusive) in each calendar year. Before RSVpreF implementation period: 2023. After RSVpreF implementation period: 2024.
[c] Crude difference-in-difference calculated as the ratio of before vs. after RSVpreF implementation incidence proportions of outcomes among infants 0 to ≤3 months compared to infants and children aged >6 to ≤24 months.
[d] Impact calculated as one minus the crude difference-in-difference expressed as a percentage.

Coadministration of RSVpreF With Other Vaccines
esp. tetanus, diphtheria and acellular pertussis vaccine (Tdap) [1,2]

No safety concerns when RSVPreF co-administered with Tdap in healthy **non-pregnant** women.

- **Immune responses** to RSV A, RSV B, **diphtheria and tetanus** on co-administration: **non-inferior** to those after separate administration.

- Immune response to **pertussis lower on co-administration** compared to separate administration. ***Clinical relevance ??***

A minimum interval of two weeks is recommended between administration of RSV PreF and Tdap

No available data on coadministration of the RSVpreF with other vaccines **in pregnant individuals**.

Tdap, = tetanus, diphtheria and acellular pertussis vaccine

Peterson JT, et al. *J Infect Dis*. 2022;225(12):2077-2086. 2 Abrysvo (Respiratory Syncitial Virus Vaccine) Summary of Product Characteristics https://www.ema.Europa.eu/en/medicines

Acceptability of another vaccine in pregnancy
= unknown

Tabel 3: Vaccinatiegraad in Vlaanderen van recent bevallen moeders (bevallingsdatum 1/12/2020-14/02/2021) voor de aanbevolen vaccins tijdens de zwangerschap en voor cocoonvaccinatie bij de partner, uitgedrukt in procenten (met 95% betrouwbaarheidsinterval), Vlaanderen 2020

	vaccinatiegraad (95%BI)
kinkhoest[a]	85,0 (81,8-88,1)
griep[a]	62,3 (58,3-66,2)
kinkhoestvaccinatie tijdens de laatste 10 jaar[b]	71,2 (67,0-75,4)

a N=612 (recent bevallen moeders

b N= 594 (partners)

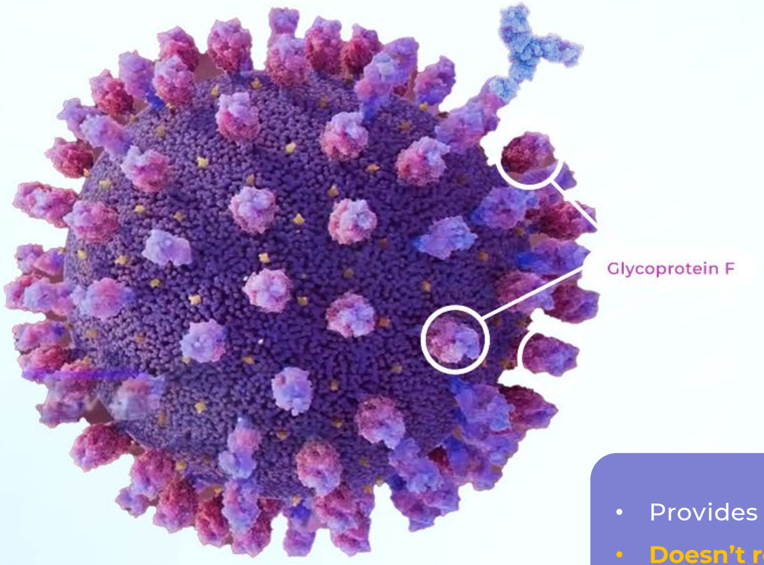
Willen Laura et al. Vaccinatiegraad in Vlaanderen 2020.

Option 2: monoclonal antibodies

Nirsevimab - Beyfortus ®

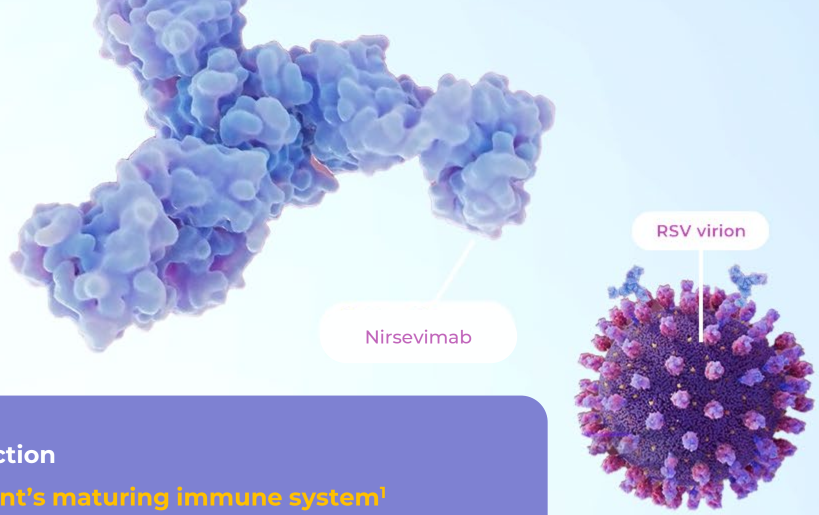
= direct, long-acting antibody[1]

- **Monoclonal antibody (mAb): attaches to PREFUSION conformation of RSV F protein**[1]
- **Inhibits RSV virus entry** into the cells[1]



Modified with **triple amino acid substitution (YTE) in the Fc region to extend half-life**[1]

> makes it LONG ACTING:
min. 5 months of protection against RSV LRTI*,[1]



- Provides **DIRECT protection**
- **Doesn't rely on the infant's maturing immune system**[1]

LRTD, lower respiratory tract disease; **mAb,** monoclonal antibody
Footnotes: * Based on clinical and pharmacokinetic data.[1]

References: 1. Beyfortus®. EU Summary of Product Characteristics (SmPC). [

Adverse effects of Nirsevimab
= uncommon

Adverse reactions reported in 2,966 term and pre-term infants (GA ≥29 weeks)

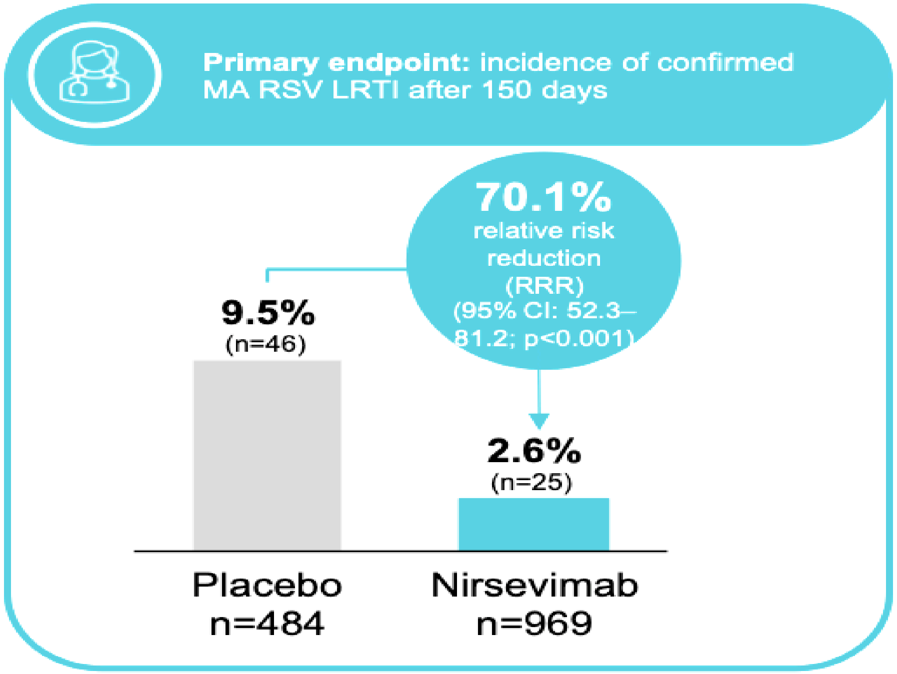
System Organ Class	Preferred term	Frequency
Skin and subcutaneous tissue disorders	Rash **(0,7%)**	Uncommon
General disorders and administration site conditions	Injection site reaction **(0,3%)**	Uncommon
	Pyrexia **(0,5%)**	Uncommon

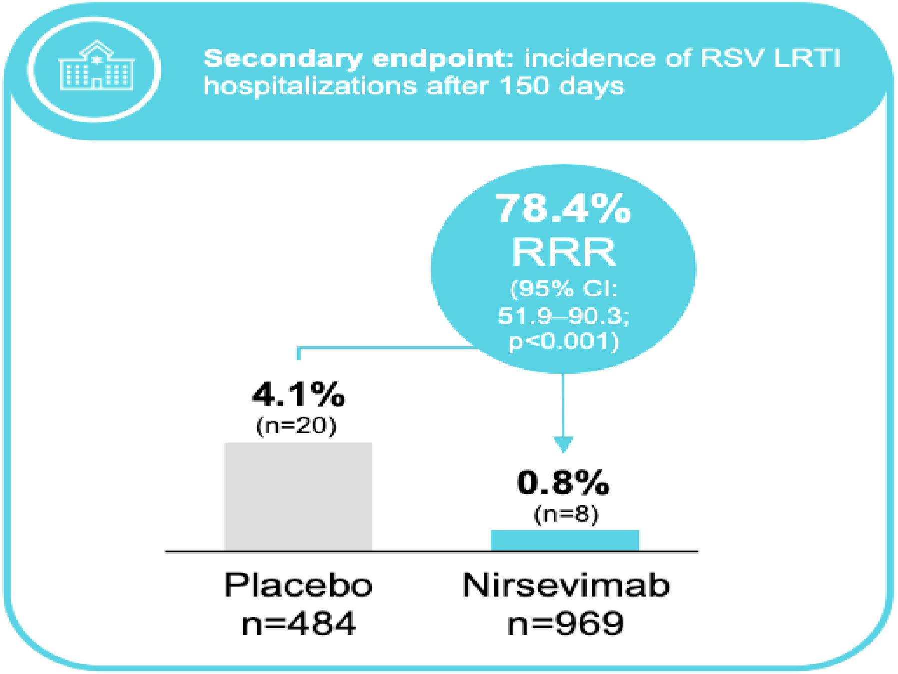
GA, gestational age.

References: 1.. Beyfortus®. EU Summary of Product Characteristics (SmPC).

How effective is Nirsevimab ?
Phase 2b study: ‘proof of concept’ & efficacy GA 29-35w

Phase 2b





Adapted from Griffin MP et al.[1]

LRTI, lower respiratory tract infection; **MA,** medically attended;; **RRR**, relative risk reduction.

References: 1. Griffin MPS et al. N Engl J Med 2020;383(5): 415–425. 2. Beyfortus®. EU Summary of Product Characteristics (SmPC).

How effective is Nirsevimab ?

Post-hoc analysis of MELODY: GA >35w, not eligible to palivizumab

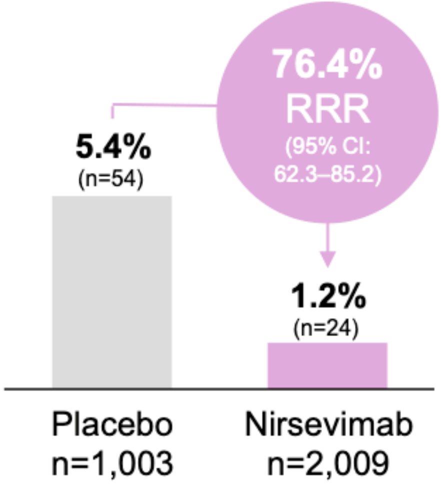
Phase 3 – all subjects (exploratory analysis)

Enrollment was paused during the peak of the COVID-19 pandemic, but was continued from April 2021

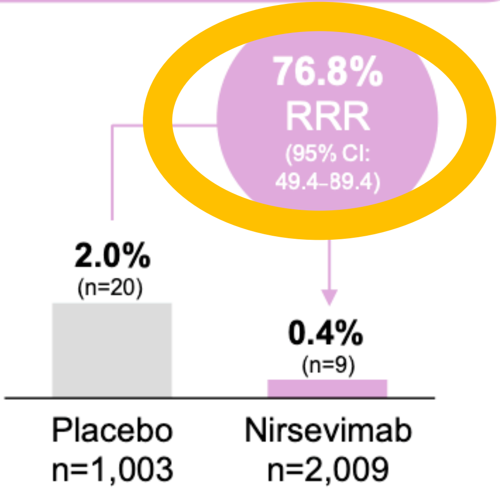
Overall, **3,012 infants have been randomized** to receive nirsevimab (n=2,009) or placebo (n=1,003)

Treatment-related adverse events were reported in **1.3% of infants receiving nirsevimab** vs. 1.5% of infants receiving placebo

Primary endpoint: incidence of confirmed MA RSV LRTI after 150 days



Secondary endpoint: incidence of RSV LRTI hospitalizations after 150 days



Adapted from Muller WJ et al. 2023.[1]

LRTI, lower respiratory tract infection; **MA,** medically attended;; **RRR**, relative risk reduction.

References: 1. Muller WJ et al. N Engl J Med 2023; 388(16): 1533–1534. 2. Beyfortus®. EU Summary of Product Characteristics (SmPC)..

How effective is Nirsevimab ?
Pooled analysis of Phase 2b and MELODY

Infants <5 kg from the phase 2b study and all infants from the primary cohort of the MELODY study (N=2,350)

79.5% RRR in MA RSV LRTI after 150 days vs. placebo (95% CI: 65.9–87.0; p<0.0001)	**77.3% RRR** in MA RSV LRTI requiring hospitalization after 150 days vs. placebo (95% CI: 50.3–89.7; p=0.0002)**
Nirsevimab 1.2% (n=19/1,564) vs. placebo 6.5% (n=51/786)	Nirsevimab 0.6% (n=9/1,564) vs. placebo 2.7% (n=21/786)

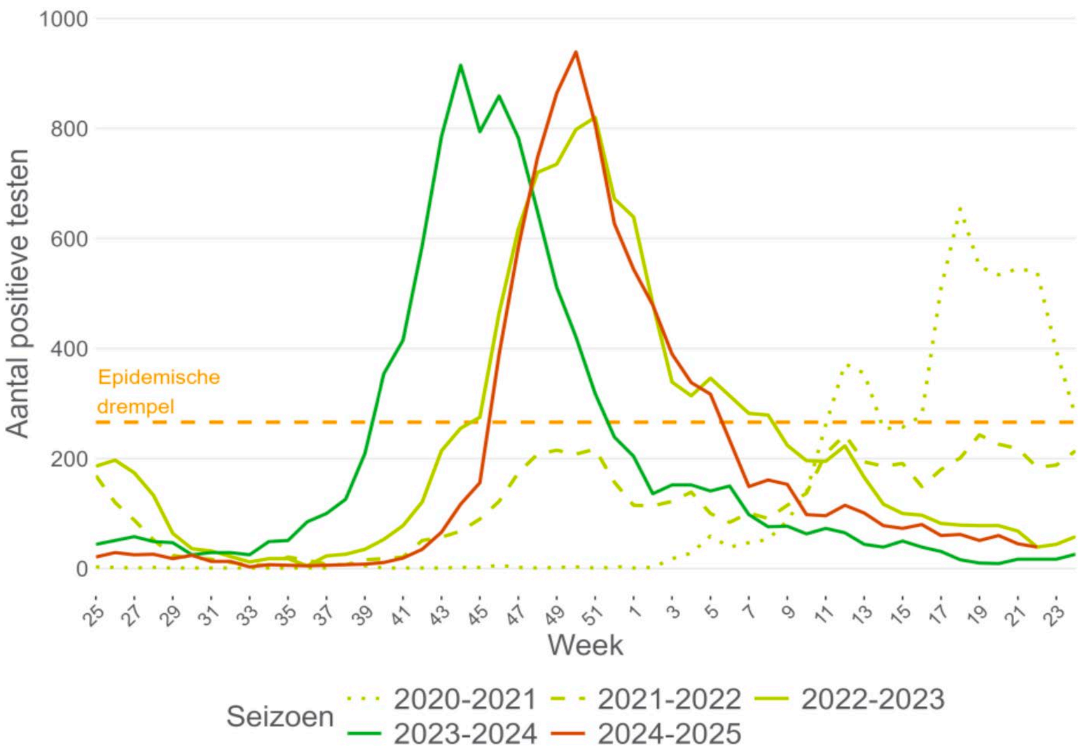
The proportion of pre-term infants included in this analysis was higher than in the general population†,1

LRTI, lower respiratory tract infection; **MA,** medically attended;; **RRR**, relative risk reduction.

References: 1. Simoes EAF et al. Lancet Child Adolesc Health 2023; 7(3): 180–189. 2. Muller WJ et al. N Engl J Med 2023; 388(16): 1533–1534. Protocol.

'Real world postlicensure effectiveness': the case of Belgium

sciensano



pediatrische RSV-infecties in België in 2024-2025:

Een analyse van de routine sentinel-surveillancegegevens van Sciensano

11 juli 2025

'Real world postlicensure effectiveness': the case of Belgium

sciensano

Statuut	SARI opname RSV neg	SARI opname RSV pos	EI (95% CI)
Niet geïmmuniseerd	67	138	Ref.
Geïmmuniseerd	164	44	85.63% (75-91.74)

Tabel 1 • Schatting van de werkzaamheid van nirsevimab bij kinderen geregistreerd in het netwerk van peilziekenhuizen en die in aanmerking komen voor terugbetaling, gebaseerd op het resultaat van de RSV-test.

pediatrische RSV-infecties in België in 2024-2025:

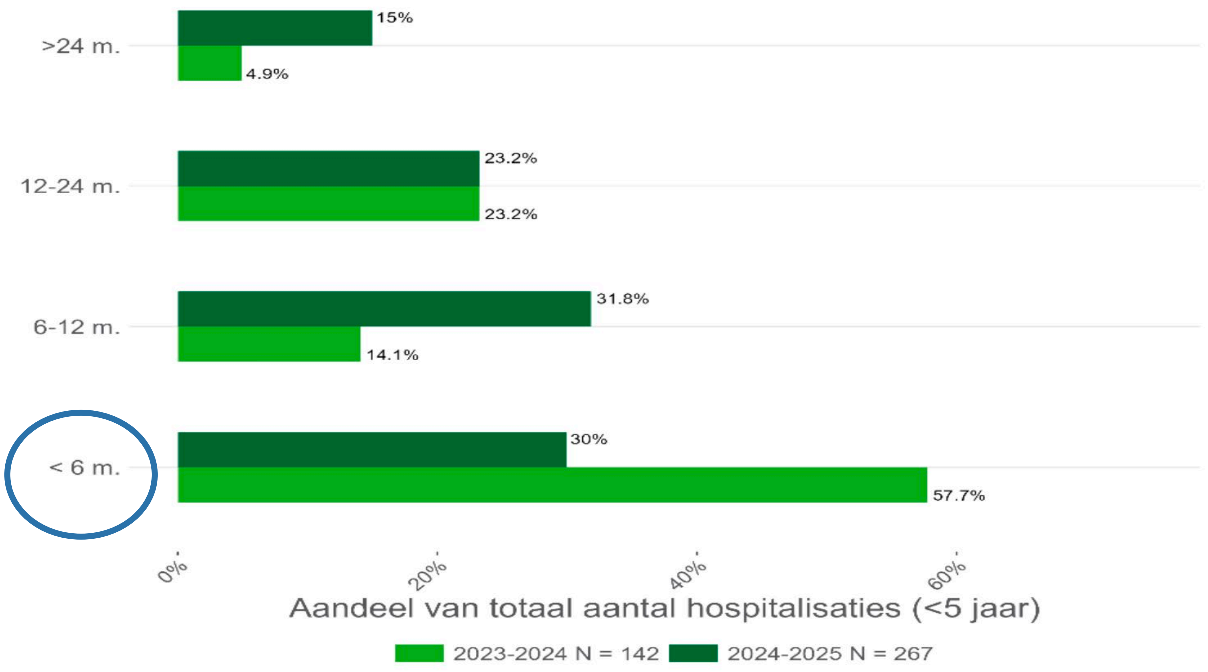
Een analyse van de routine sentinel-surveillancegegevens van Sciensano

11 juli 2025

Statuut	SARI hosp. RSV neg.	SARI hosp. RSV pos	EI (95% CI)
Niet geïmmuniseerd	67	138	Ref.
Meer dan 90 dagen geïmmuniseerd	25	2	86,27% (29-97,34)
60 tot 90 dagen geïmmuniseerd	44	9	88,61% (72,09-95,36)
30 tot 60 dagen geïmmuniseerd	54	19	86,01% (72,06-93)
Maximum 30 dagen geïmmuniseerd	41	14	81,88% (59,1-91,97)

Tabel 2 • Werkzaamheid van immunisatie in functie van de tijd tussen immunisatie en ziekenhuisopname.

‘Real world postlicensure effectiveness’: the case of Belgium



- <6m: 52% minder hospitalisaties
- In totaal 34 à 45% minder <5j = 4000 hospitalisaties vermeden

pediatrische RSV-infecties in België in 2024-2025:

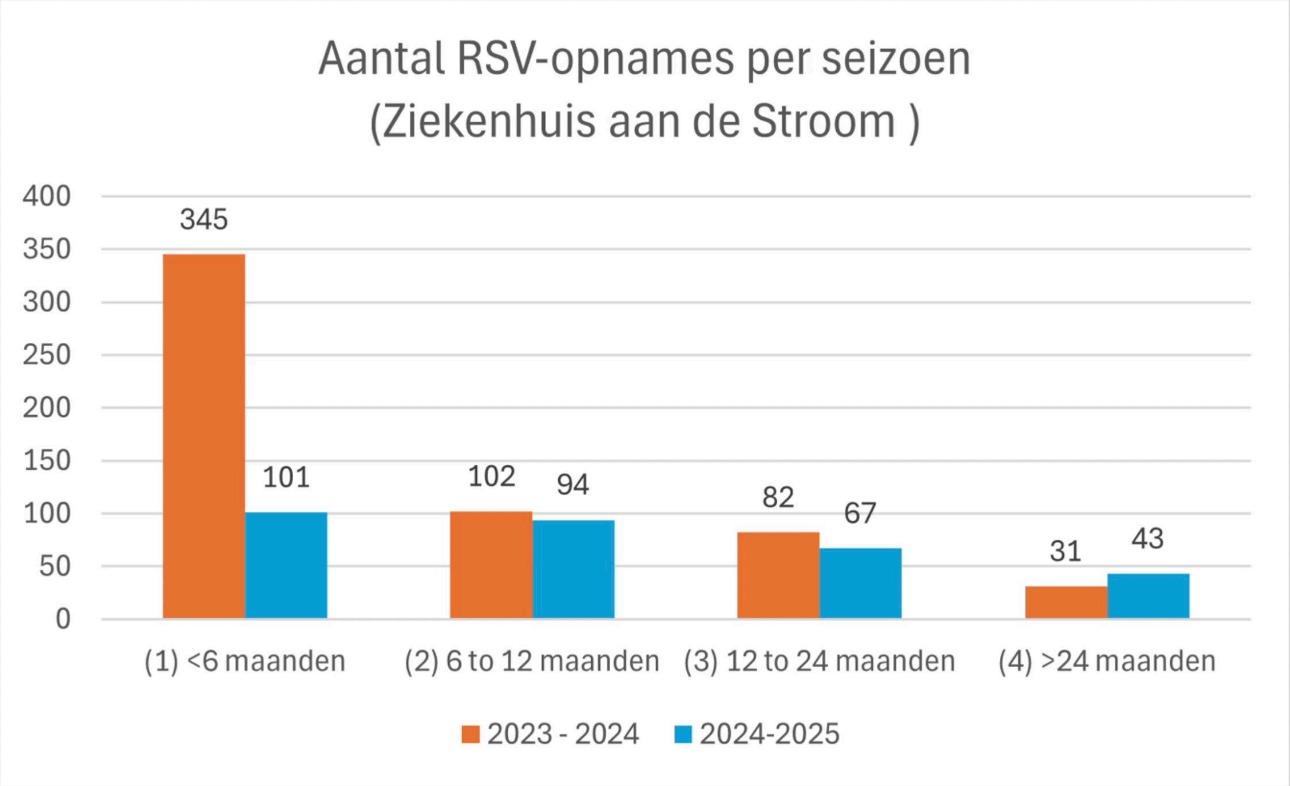
Een analyse van de routine sentinel-surveillancegegevens van Sciensano

11 juli 2025

Met **huidige immunisatiegraad:** 62-74%

> Indien 90%:
nog 10 à 15% extra hospitalisaties vermijdbaar = 1500 hospitalisaties

ZAS cijfers



- **<6m:**
  71% minder hospitalisaties

- **In totaal 46% minder**
  = 255 hospitalisaties vermeden

ZIEKENHUIS aan de STROOM

What to do in 25-26 ???

KCE rapport

ZIEKENHUIS aan de STROOM

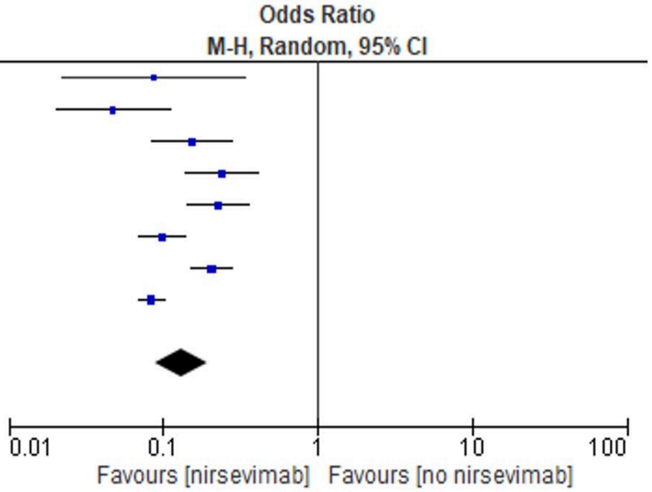
KCE meta-analysis nirsevimab

Figure 6 – Effectiveness of nirsevimab against hospitalisation for RSV LRTI (studies with follow-up > 120 days)

Study or Subgroup	nirsevimab Events	nirsevimab Total	no nirsevimab Events	no nirsevimab Total	Weight	Odds Ratio M-H, Random, 95% CI
Lefferts 2024	3	29	20	35	5.5%	0.09 [0.02, 0.34]
Moline 2024	6	73	525	802	9.4%	0.05 [0.02, 0.11]
Lenglart 2025	26	225	36	78	12.1%	0.15 [0.08, 0.28]
Mallah 2024	50	13320	18	1156	12.8%	0.24 [0.14, 0.41]
Carbajal 2024	22	723	170	1391	13.8%	0.23 [0.14, 0.35]
Coma 2024	52	23127	76	3398	14.9%	0.10 [0.07, 0.14]
Jeziorski 2024	102	230	609	766	15.3%	0.21 [0.15, 0.28]
Barbas del Buey 2024	133	29684	376	7383	16.3%	0.08 [0.07, 0.10]
Total (95% CI)		**67411**		**15009**	**100.0%**	**0.13 [0.09, 0.19]**
Total events	394		1830			

Heterogeneity: $Tau^2 = 0.23$; $Chi^2 = 43.88$, df = 7 ($P < 0.00001$); $I^2 = 84\%$

Test for overall effect: Z = 10.19 ($P < 0.00001$)



87% VE for FU >120d

(99% CI 81 – 91)

KCE meta-analysis maternal vaccine

Secondary outcome: RSV-related hospitalisation, % (n) – efficacy (95%CI):

- Within 90 days: 0.3 (10) vs 0.9 (33) – 69.7% (37.1-86.7)
- Within 120 days: 0.4 (15) vs 1.1 (39) – 61.5% (28.6-80.3)
- Within 150 days: 0.5 (18) vs 1.2 (42) – 57.1% (23.9-76.8)
- Within 180 days: 0.6 (21) vs 1.3 (47) – 55.3% (23.8-74.6)

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KCE cost-effectiveness report 2025

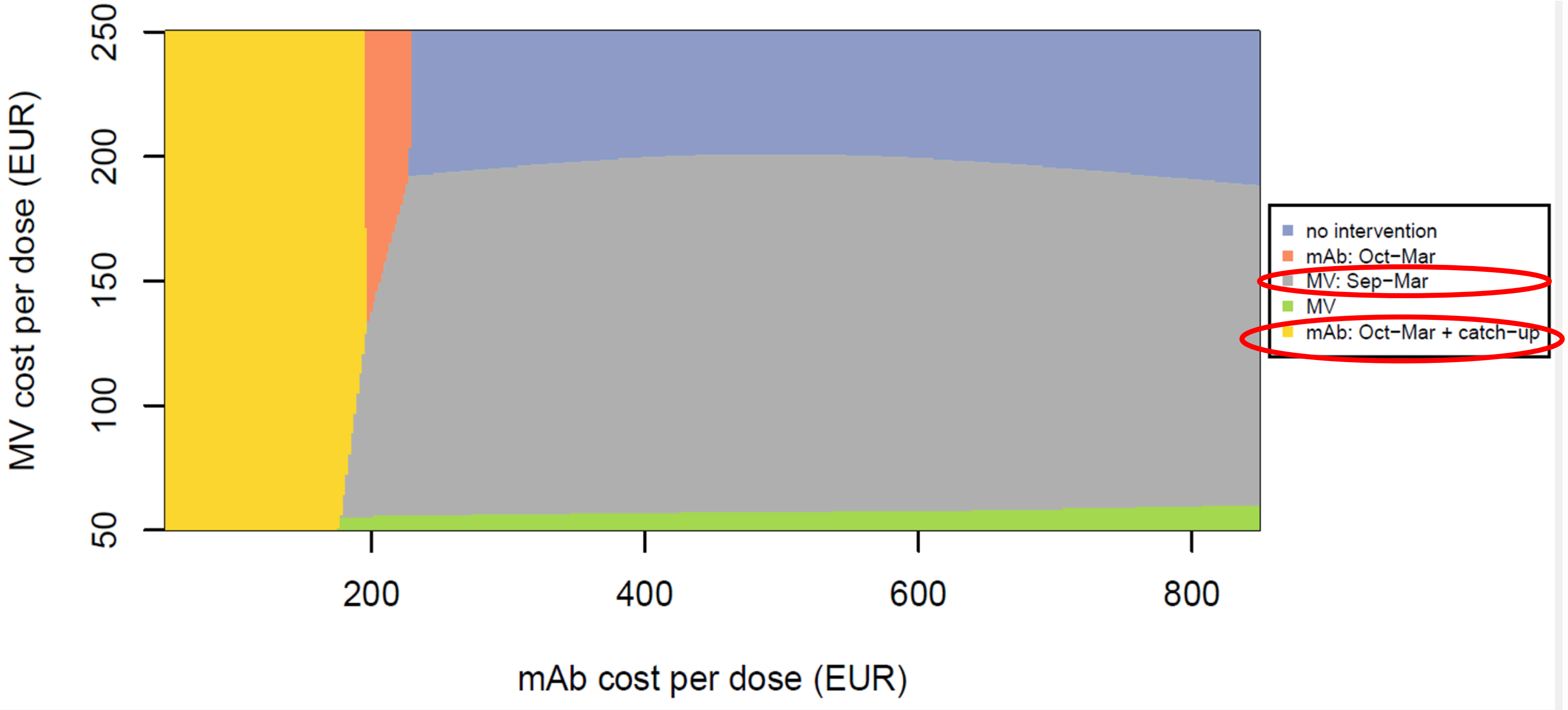
Five immunisation strategies were evaluated:

- Year-round single-dose maternal vaccine (MV) during pregnancy
- Year-round single-dose nirsevimab (mAb) at birth
- Seasonal maternal vaccine during pregnancy for infants with due delivery date in September to March (MV: Sep-Mar)
- Seasonal nirsevimab given at birth for infants born during the RSV season from October to March (mAb: Oct-Mar)
- Seasonal nirsevimab (as described above) plus a catch-up program in September for infants (≤6 months) born outside of the RSV season from April to September (mAb: Oct-Mar + catch-up)

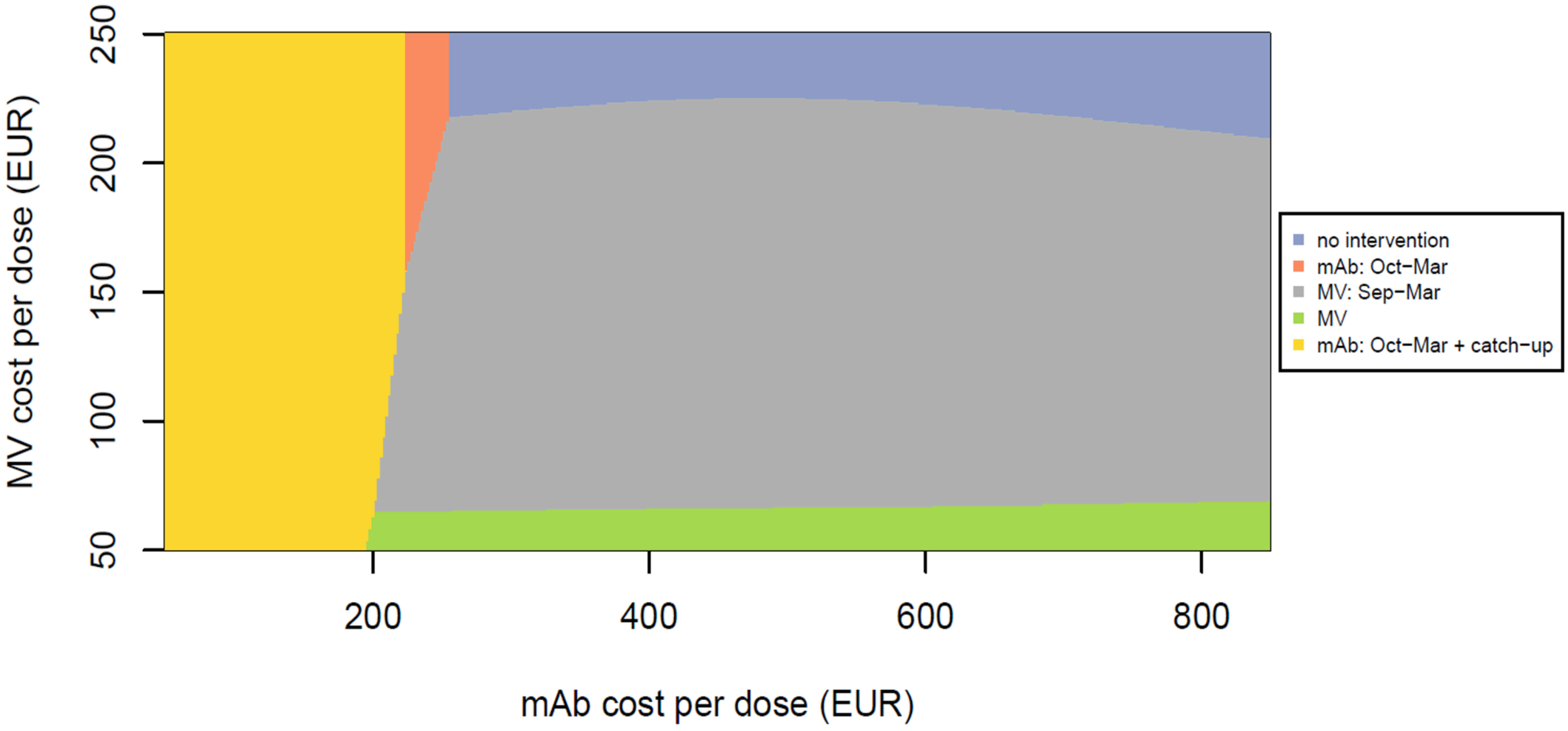
- **Assumed uptake: 40% for MV and 90% for mAb***
- **Seasonal mAb + catch-up strategy:**
  most effective strategy, avoiding:
  - 54% of the total RSV episodes in infants (<1y)
  - 63% of the hospitalisations
  - 65% of the ICU admissions and nearly 2 deaths (75% avoided)
- **ICERs per QALY (at list prices) with 'willingness to pay' of 35.000 euro per ICER:**
  - seasonal maternal vaccination per QALY: 30.013 euro (with current list price !) *
  - no other strategies would be cost-effective at current list prices**
- If MV costs <€170 to <€215 per dose and mAb costs >€200 to >€250 per dose, then seasonal MV would be preferred.
- If mAb costs <€150 to <€200 per dose, the seasonal mAb plus catch-up strategy would be preferred, regardless of the costs of MV

ZIEKENHUIS aan de STROOM

Willingness to pay 35.000 per QALY gained



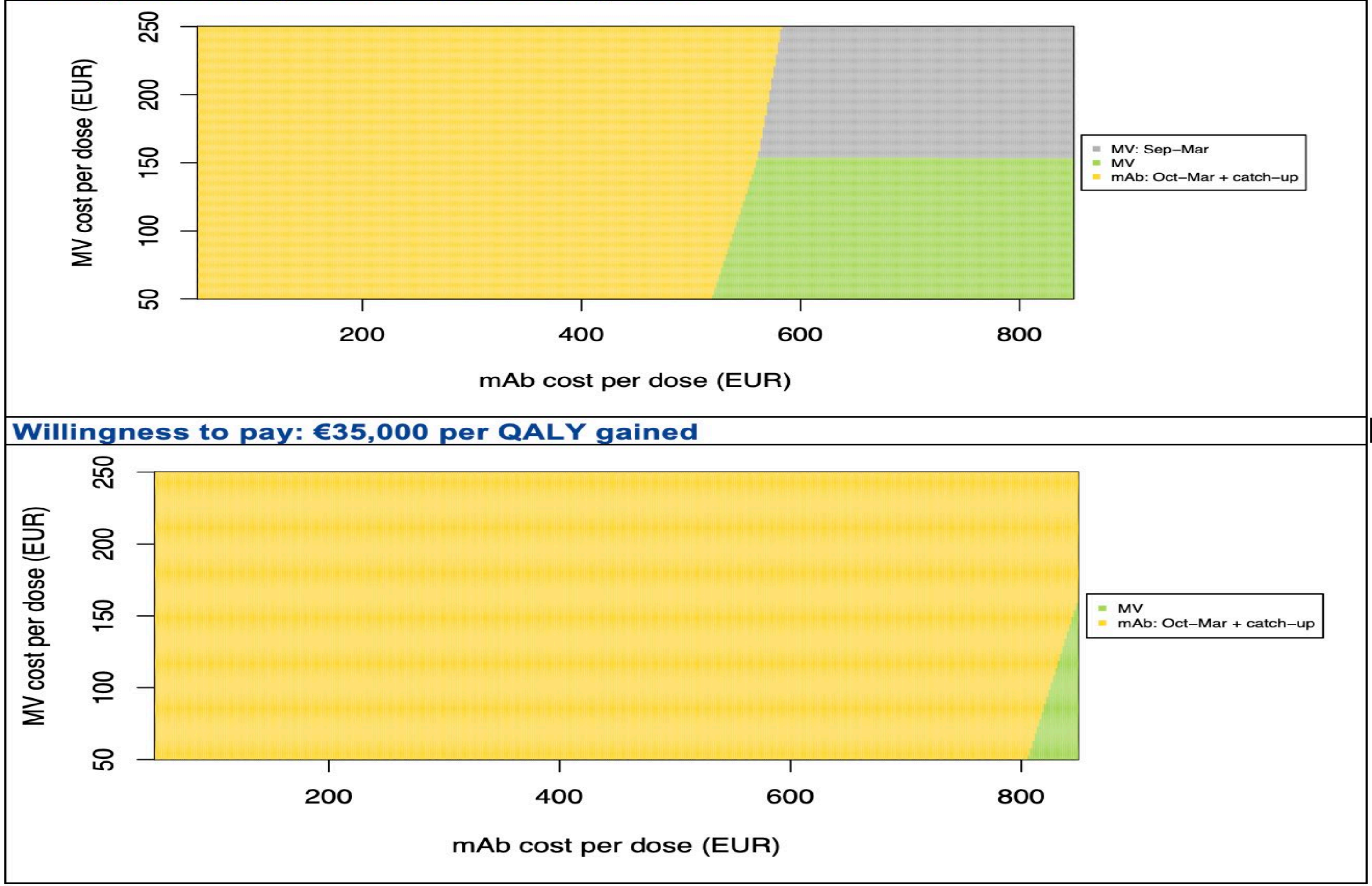
Willingness to pay 50.000 per QALY gained



Inclusion of recurrent wheezing and asthma up to 3 years

Willingness to pay: €20,000 per QALY gained

Willingness to pay: €35,000 per QALY gained



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What to do?

Een premature baby van 27w PML werd geboren op 10 feb 2025. Hij had nood aan CPAP en 3 weken Optiflow.

Op 17 feb 2025 kreeg deze baby Beyfortus.

Wat doe je dit seizoen?

How to give Nirsevimab ? 1x

Can be administered concomitantly with childhood vaccines.[†,1]

2nd season: 200mg

Footnotes: * In the EU, the recommended dose is a single dose of 50 mg administered intramuscularly for infants with body weight <5 kg and a single dose of 100 mg administered intramuscularly for infants with body weight ≥5 kg.[1] ** The gluteal muscle should not be used routinely as an injection site because of the risk of damage to the sciatic nerve.[1] † There is limited experience of Beyfortus® co-administration with vaccines. In clinical trials, when Beyfortus® was given with routine childhood vaccines, the safety and reactogenicity profile of the co-administered regimen was similar to childhood vaccines given alone. Beyfortus® should not be mixed with any vaccine in the same syringe or vial. When administered concomitantly with injectable vaccines, they should be given with separate syringes and at different injection sites.[1]

References: 1. Beyfortus®. EU Summary of Product Characteristics (SmPC).

RSV preventie 2025: nieuwigheden

- **Kinderen geboren vanaf september 2025:** mag al op materniteit vanaf 1 september

- **Catch-up** (geboren vanaf 19/2): start 1e of 2e week september? Verschilt per regio en ziekenhuis.
Mag dit jaar ook 'in begin van seizoen', i.e. tot eind oktober.

- Catch-up te voorzien door huisartsen / kinderartsen (NIET kind en Gezin)
Kind en gezin gaat wel sensibiliseren (campagnes/flyers….).

- Einde seizoen wordt terug dynamisch bepaald door surveillance (Sciensano en overheid)

- Geen leveringsproblemen verwacht

- Als **Abrysvo** wordt toegediend (PML 28-36w): ENKEL met **verwachte geboorte sept - eind januari** ('expert advice' VVOG)

- Sans-papiers/Fedasil: verwijzing naar medical requisitorium (terugbetaling mogelijk via 'medisch requisitorium'
ALTIJD EERST AANVRAGEN VOORALEER TOEDIENEN: https://www.fedasil.be/en/form/webform-11190)
(bij problemen lien.bruggeman@fedasil.be contacteren): WACHTEN NIET NODIG ALS ALS ALLES IN ORDE

- OCMW 'dringende medische zorg': via sociale dienst (contact via OCMW Plein: isabel.jacobs@antwerpen.be):
WEL WACHTEN OP BESLISSING

ZAS

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Klassieke twee paragrafen blijven bestaan (via klassieke hfst IV) Risicogroepen in 2e seizoen via nieuwe paragraaf sinds 2025.

1. Preterme kinderen <36w (via gekende paragraaf 12820**100)**
2. Terme kinderen (via gekende paragraaf 12820**200)**

3. Kinderen die hartoperatie ondergaan hebben met CP bypass en daarom 2e dosis nodig hebben
EN kwetsbare kinderen die in hun TWEEDE SEIZOEN een extra dosis nodig hebben onafhankelijk van maternele vaccinatie:
(via NIEUWE paragraaf 12820**300**): 200mg

HOE ZIJN RISICOGROEPEN OMSCHREVEN ?

* Bij kinderen die een hartoperatie ondergaan met cardiopulmonale bypass waarbij zodra de persoon stabiel is na de operatie een extra dosis (50mg of 100mg tijdens het eerste RSV seizoen afhankelijk van het lichaamsgewicht of 200mg tijdens het tweede RSV seizoen) (voor kinderen <2j in 2e seizoen) toegediend kan worden om adequate nirsevimab-serumspiegels te garanderen.

* bij kinderen tot 24 maanden oud die kwetsbaar blijven voor ernstige RSV-ziekte tijdens hun **tweede RSV-seizoen met:**

- **Chronische longziekte ten gevolge van prematuriteit** die medische ondersteuning nodig had (chronische corticosteroïdentherapie, diuretische therapie of extra zuurstof) op een willekeurig moment **tijdens de periode van 6 maanden voor het begin van het tweede RSV-seizoen**
- **Hemodynamisch significante aangeboren hartziekte**
- **Immuungecompromiteerde** toestand
- Syndroom van **Down**
- **Cystische fibrose**
- **Neuromusculaire** aandoening
- Aangeboren **luchtwegafwijkingen**

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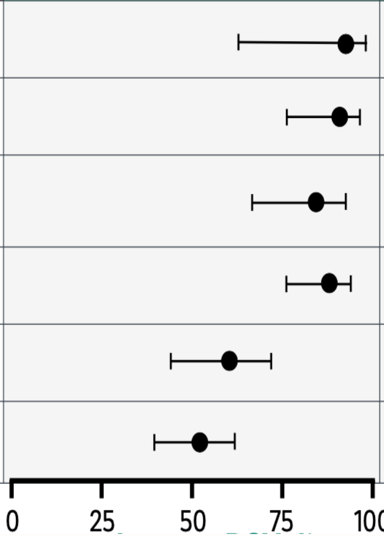
New kid on the block = Clesrovimab

Increasing Disease Severity

RSV-associated Endpoint	Endpoint Designation	Efficacy through 5 months (150 days): Clesrovimab (n=2,398) # of Cases	Placebo (n=1,201) # of Cases	Observed Efficacy %, (95% CI)[a]	Pre-Specified Hypothesis
Severe MALRI	Tertiary	2	12	91.7 (62.9, 98.1)	
LRI Hospitalization	Tertiary	5	27	90.9 (76.2, 96.5)	
Hospitalization	Secondary	9	28	84.2 (66.6, 92.6)	*P*<0.001
MALRI requiring ≥2 Indicators of LRI/Severity[b]	Post-Hoc	10	41	88.0 (76.1, 94.0)	
MALRI requiring ≥1 Indicator of LRI/Severity	Primary	60	74	60.4 (44.1, 71.9)	*P*<0.001
Acute Respiratory Infection (ARI)	Tertiary	148	148	52.0 (39.5, 61.9)	



Zar HJ, Simoes EAF, Madhi SA et al. A Phase 2b/3 Study to Evaluate the Efficacy and Safety of an Investigational Respiratory Syncytial Virus (RSV) Antibody, Clesrovimab, in Healthy Preterm and Full-Term Infants.
Oral Presentation.
Infectious Diseases Society of America (IDSA) 2024

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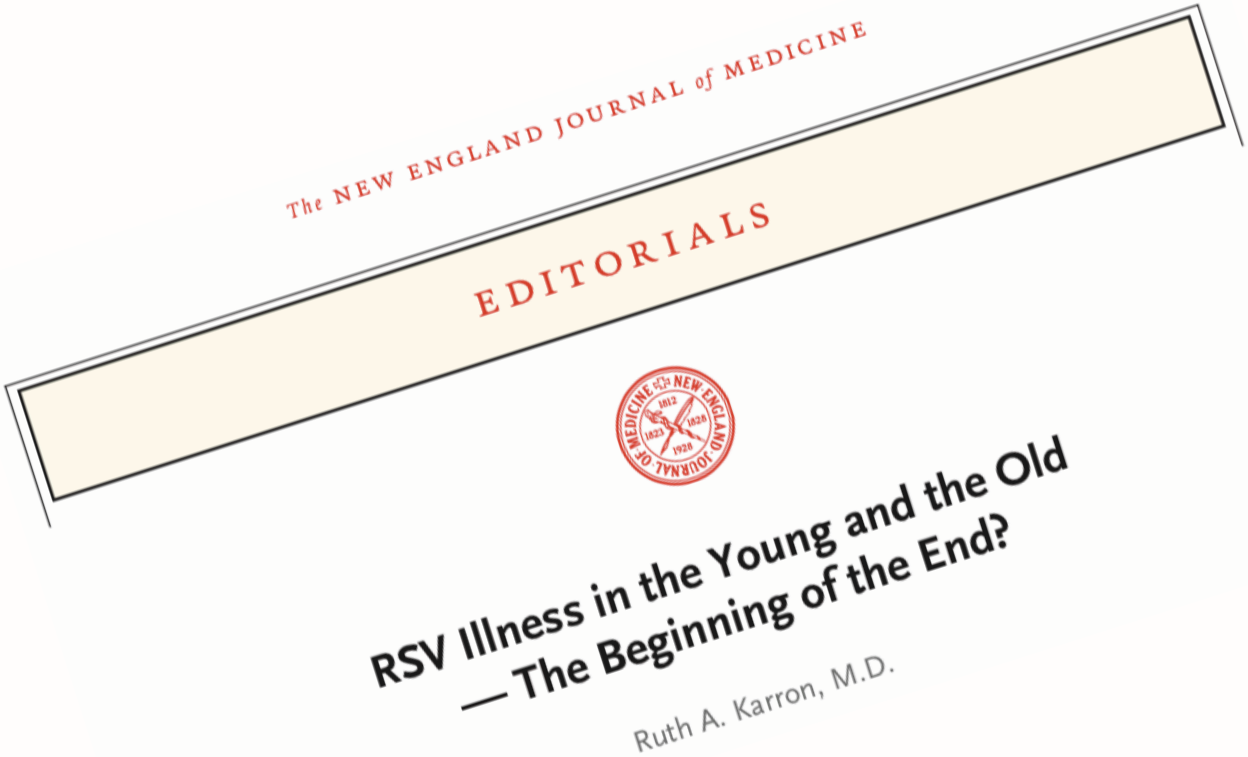
BELGIUM 25 - 26	Beyfortus®	Abrysvo®
For whom?	➢ <36 w or >36 weeks (So: ALL) ➢ **Babies** born from **unvaccinated mothers** ➢ Babies born from **vaccinated** mothers **BUT** : - Within 2 weeks following vaccination - Vaccinated January – March - Undergoing cardiopulmonary surgery or exchange transfusion in neonatal period (loss of maternal antibodies)	**Pregnant women: expected to deliver between September to January** **(expert opinion VVOG)**
Contra-indication?	No	- Immunocompromised patients - Risk of impaired transplacental transfer of antibodies (HIV…) Also: **CI like for other vaccines:** (i.e. febrile illness, allergy to a component of the product…)
When?	➢ **At the maternity ward (or after birth) if born Sept – End of season** ➢ **For premature newborns**: 48 h before NICU discharge during season ➢ **Catch up in Sept - Oct for infants born AFTER Feb 18th** at the 'beginning of the season' (sept 1st – end of october)	**Between 28 et 36 weeks of gestation**
Dose?	50 mg IM if < 5 kg 100 mg IM if ≥ 5 kg 200 mg IM if at risk in second season and <2y	One dose 0.5 ml IM
Co-administration?	Possible with other recommended vaccines	- Possible with flu vaccine - **15 days apart from Tdap vaccine**


The NEW ENGLAND JOURNAL of MEDICINE

EDITORIALS

RSV Illness in the Young and the Old — The Beginning of the End?

Ruth A. Karron, M.D.

Equity ?!

Universiteit Antwerpen

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Volg ons op **zas.be** en

ZIEKENHUIS aan de STROOM

Bevestig via de **QR-code je deelname**

Practopics

Praktische topics voor de huisarts

Of **klik op de link** in de Q&A rechtsboven.