RSV prevention
Why, how, who?

Marc Raes, pediatrician, Hasselt

BVN/GBN 08th June, 2022. Radisson Collection Hotel - Brussels

RSV prevention
Why, how, who?

RSV burden in children
→ rationale for prevention

- Disease-related: incidence, morbidity, mortality
- Pressure on:
  - Primary care
  - Hospitalization rates
  - PICU admissions

- Long-term consequences

- Costs: direct and indirect
  - Health care system: visits (Dr, ER), admissions, medication,…
  - Economy: leave,..

RSV epidemiology

- RSV infection accounts for 60-80 % of infact bronchiolitis cases and up to 40 % of cases of paediatric pneumonia[1]
- 70 % of infants are infected in the 1st year and 90 % by 2 years of life→ up to 40 % develop LRTI during the initial episode[2]
- A leading cause of hospitalization in infants during the winter time – most (up to 75 %) in **healthy, term infants** [3-5]
- Hospitalization rate: 1-2/100 infants < 2 mos and 0,5/100 < 2 years[2,3-5]
- Highest risk during the 1st RSV season[5]
- High burden of outpatient and ED visits as well [1,4]

1. Hall CB et al.N Engl J med 2001; 344(25):1917-1928.2.Glezen WP et al Azm J Dis Child 1986;140(6): 543-546.3.Ledare S et al. Pedaitr Infect Dis J 2002; 21(7): 629-634.4. Ariola ES et al. Pediatr Infect Dis Soc 2020; 9(5): 587-595.5. Hall CB et al. Pedaiatrics 2013; 132(2): e341-348.

Global, regional, and national disease burden estimates of acute lower respiratory infections due to respiratory syncytial virus in young children in 2015: a systematic review and modelling study

Systematic review : 1/1/1995 – 31/12/2016)
Total: N= 329 studies (79 unpublished)
Global estimate : **2015**

Children < 5 years
33.1 million RSV-ALRI episodes → 3.2 million admissions → 59.600 in-hospital deaths
Children < 6 months 1.4 million admissions → 27.300 in-hospital deaths

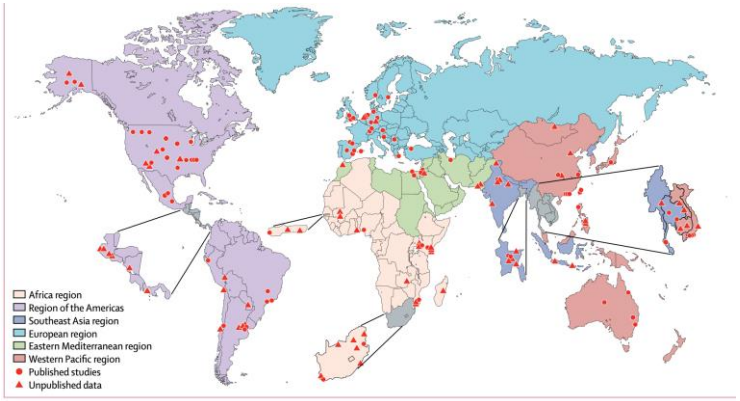


Figure 3: Location of studies reporting incidence, hospital admission, and in-hospital case fatality in children with RSV-ALRI
RSV-ALRI=RSV-associated acute lower respiratory infection.

About 45 % of all *hospitalizations* and *deaths* among children < 6 months

RSV causes 16-20 % of ALRTI deaths (99% in developing countries)

Shi T et al. Lancet 2017; 390: 946-958

Estimated Burden of Community-Onset Respiratory Syncytial Virus–Associated Hospitalizations Among Children Aged <2 Years in the United States, 2014–15

RSV surveillance (Oct 2014- April 2015) : 4 Influenza Hospitalization Surveillance Netwerk sites (FluServ-NET): California, Georgia, Minnesota, Oregon. (**4 %** US population < 2 years)

RSV-associated hospitalizations (aged<2 years) : n= 1554

- ICU: 27 %
- Mechanical ventilation: 6 %
- Deaths: n=5
- **No** underlying disease : 1047/1554 = 67 %
- Adjusted age-specific RSV hopsitalizations/100.000
  - 0-2 months: 1971
  - 3-5 months: 897
  - 6-11 months: 531
  - 12-23 months: 358

Extrapolation to US population: 49.509 – 59.867 community-onset RSV-associated hopsitalizations

Arriola CS et al. J Ped Inf Dis Soc 2020; 9(5): 587-595

Respiratory Syncytial Virus– Associated Outpatient Visits Among Children Younger Than 24 Months

Prospective, active surveillance NVSN (2004-2009: Nov – April)
3 US sites (Nashville, Rochetser, Cincinnati)

Average annual RSV infection rates children aged < 24 months

- ED: 59.6 / 1000 (peak age: 4 months - 116 / 1000)
- Pediatric practice visits: 205.7 / 1000 (peak age: 5 months – 289.2 / 1000)

Extrapolation to the US population:

- ED: 472.000
- Pediatric practice visits: 1.6 million

Lively JY et al. J Ped infect Dis Soc 2019; 8(3): 284-286

THE HEALTH SYSTEM BURDEN OF RESPIRATORY SYNCYTIAL VIRUS (RSV) IN EUROPE

The study is based on a survey conducted among HCPs (physicians in hospitals and the community, nurses, and health managers) in 20 European countries, from August 2021 to January 2022. The survey results reflect the experience and perception of healthcare professionals.
This study documents the burden and impact of RSV on hospitals and community. Specifically, it characterises the impact of RSV infection on health system performance, on care delivery and the workforce, and increased healthcare consumption due to RSV

Spain	79
United Kingdom	46
Belgium	34
Italy	29
Sweden	25
Switzerland	24
France	23
Portugal	19
Ireland	18
Romania	16
Croatia	15
Finland	14
Germany	13
Netherlands	7
Austria	5
Slovenia	3
Estonia	1
Moldova	1
Luxembourg	1
Serbia	1
Others	6

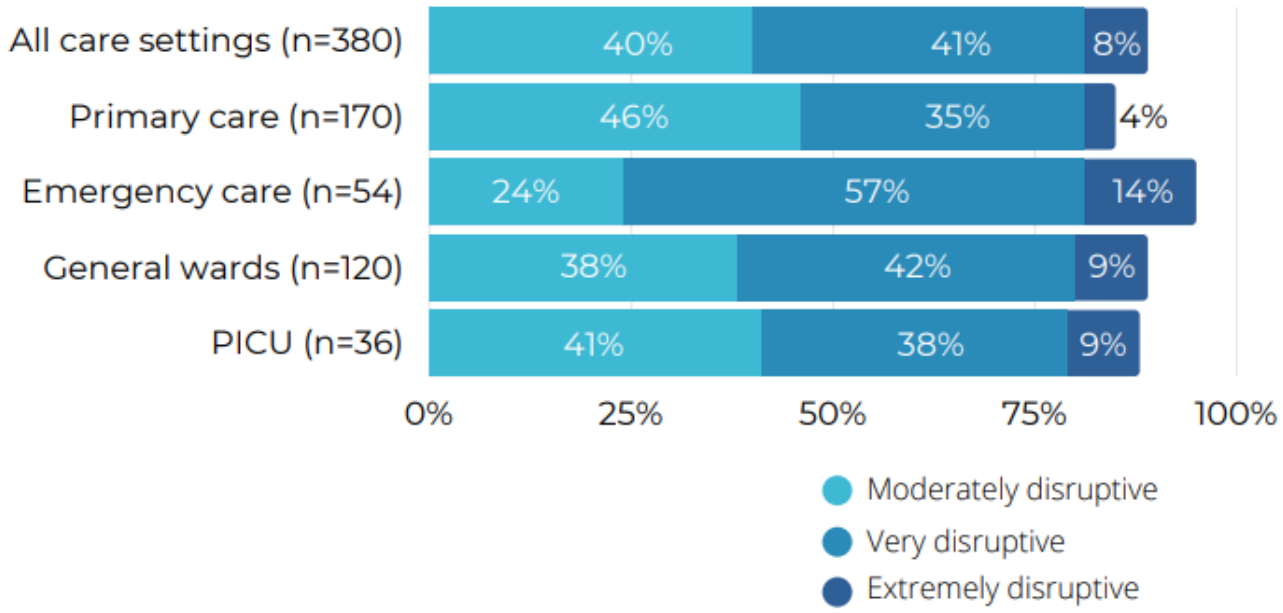
Respondents by country (n=380)

THE HEALTH SYSTEM BURDEN OF RESPIRATORY SYNCYTIAL VIRUS (RSV) IN EUROPE

OVERALL IMPACT OF RSV ON HEALTH SYSTEM PERFORMANCE

Graph 1. Health systems under pressure

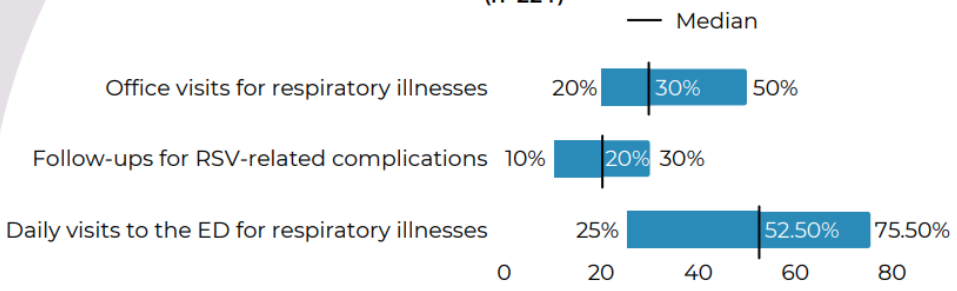
Average disruption to health system performance in peak RSV season (% of respondents)



THE HEALTH SYSTEM BURDEN OF RESPIRATORY SYNCYTIAL VIRUS (RSV) IN EUROPE

COMMUNITY/OUTPATIENT HEALTHCARE RESOURCE USE DUE TO RSV

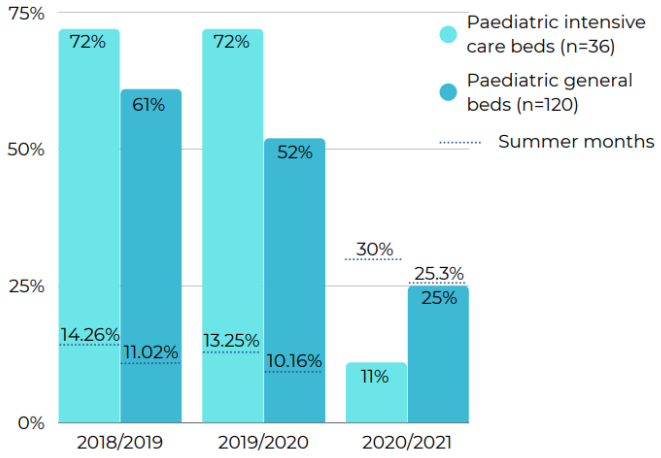
Graph 5. Increase in outpatient visits attributed to respiratory causes (%) in peak RSV season (n=224)



HOSPITAL/INPATIENT HEALTHCARE RESOURCE USE DUE TO RSV

Graph 6. Bed occupancy for respiratory patients (n=156)

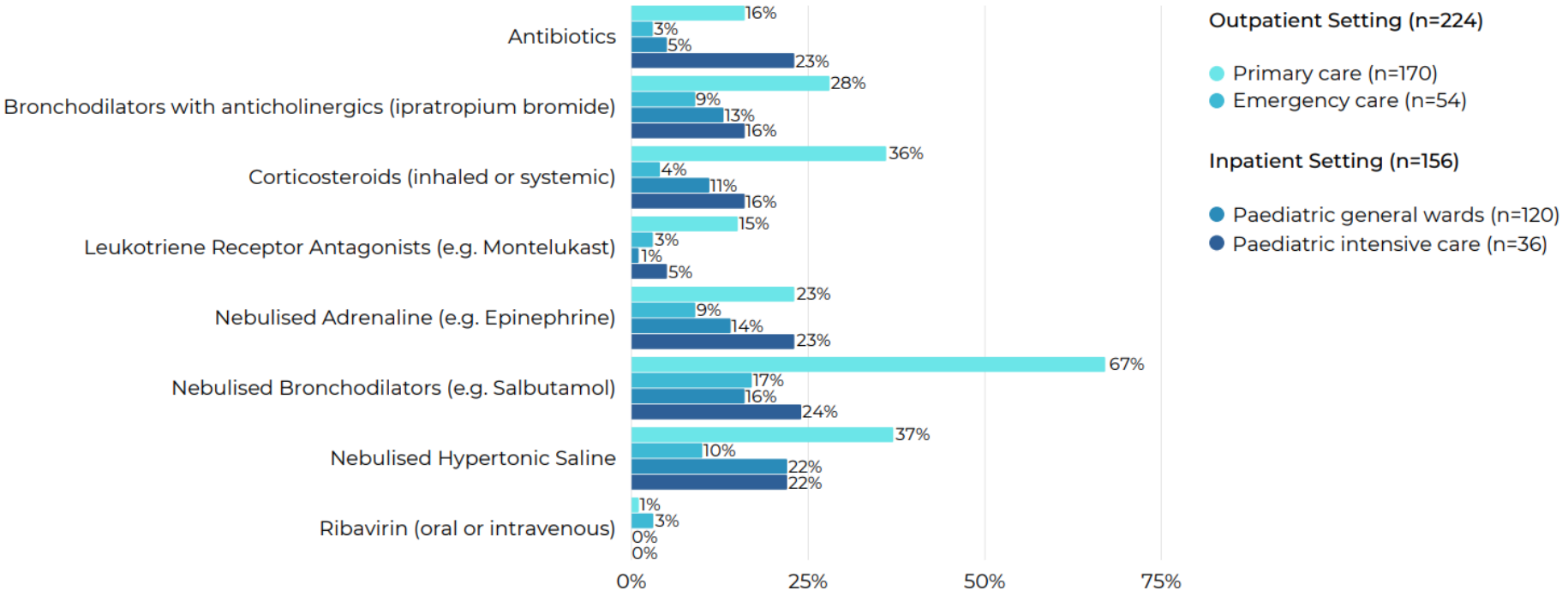
Proportion of paediatric beds occupied by respiratory patients in the peak RSV season



THE HEALTH SYSTEM BURDEN OF RESPIRATORY SYNCYTIAL VIRUS (RSV) IN EUROPE

PHARMACOLOGICAL INTERVENTIONS

Graph 7. RSV management across care settings

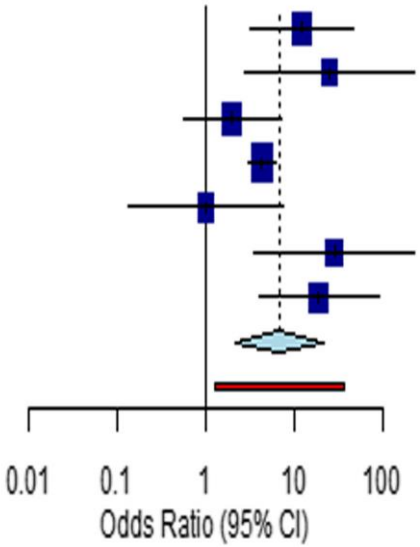


The role of respiratory syncytial virus- and rhinovirus-induced bronchiolitis in recurrent wheeze and asthma—A systematic review and meta-analysis

seven cohort studies

Source	OR (95% CI)
Schauer et al.	12.10 [3.22; 45.54]
Chung et al.	24.75 [2.69; 227.61]
Kristjansson et al.	1.99 [0.56; 7.05]
Tian M et al.	4.33 [2.98; 6.31]
Bertrand P. et al.	1.00 [0.13; 7.45]
Sigurs et al.	28.11 [3.50; 225.70]
Bont L. et al.	18.75 [3.94; 89.13]
Total	6.86 [2.20; 21.35]
Prediction interval (80%-PI)	[1.27; 37.01]

Heterogeneity: $\chi^2_6 = 14.15$ ($P = .03$), $I^2 = 58\%$



RSV-bronchiolitis and recurrent wheeze development as compared with healthy controls (OR **6.86**)

Makinioti H et al. Paed All Immunol 2022: 13741

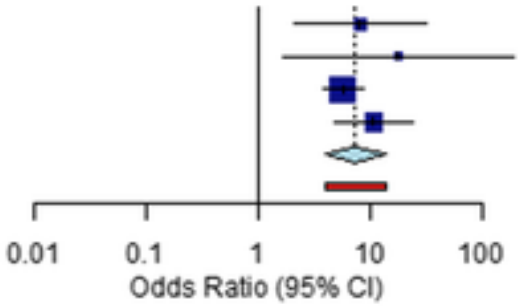
Jessa Ziekenhuis

The role of respiratory syncytial virus- and rhinovirus-induced bronchiolitis in recurrent wheeze and asthma—A systematic review and meta-analysis

four cohort studies

Source	OR (95% CI)
Sigurs et al	7.93 [2.06; 30.46]
Yamada Y. et al	17.33 [1.63; 184.36]
Zomer-Kooiker et al	5.56 [3.66; 8.44]
Cassimos et al.	10.51 [4.63; 23.82]
Total	7.21 [3.92; 13.28]
Prediction interval (80%-PI)	[3.92; 13.26]

Heterogeneity: $\chi^2_3 = 2.60$ ($P = .46$), $I^2 = 0\%$



RSV-bronchiolitis and asthma development as compared with healthy controls (OR **7.21**)

Makinioti H et al. Paed All Immunol 2022: 13741

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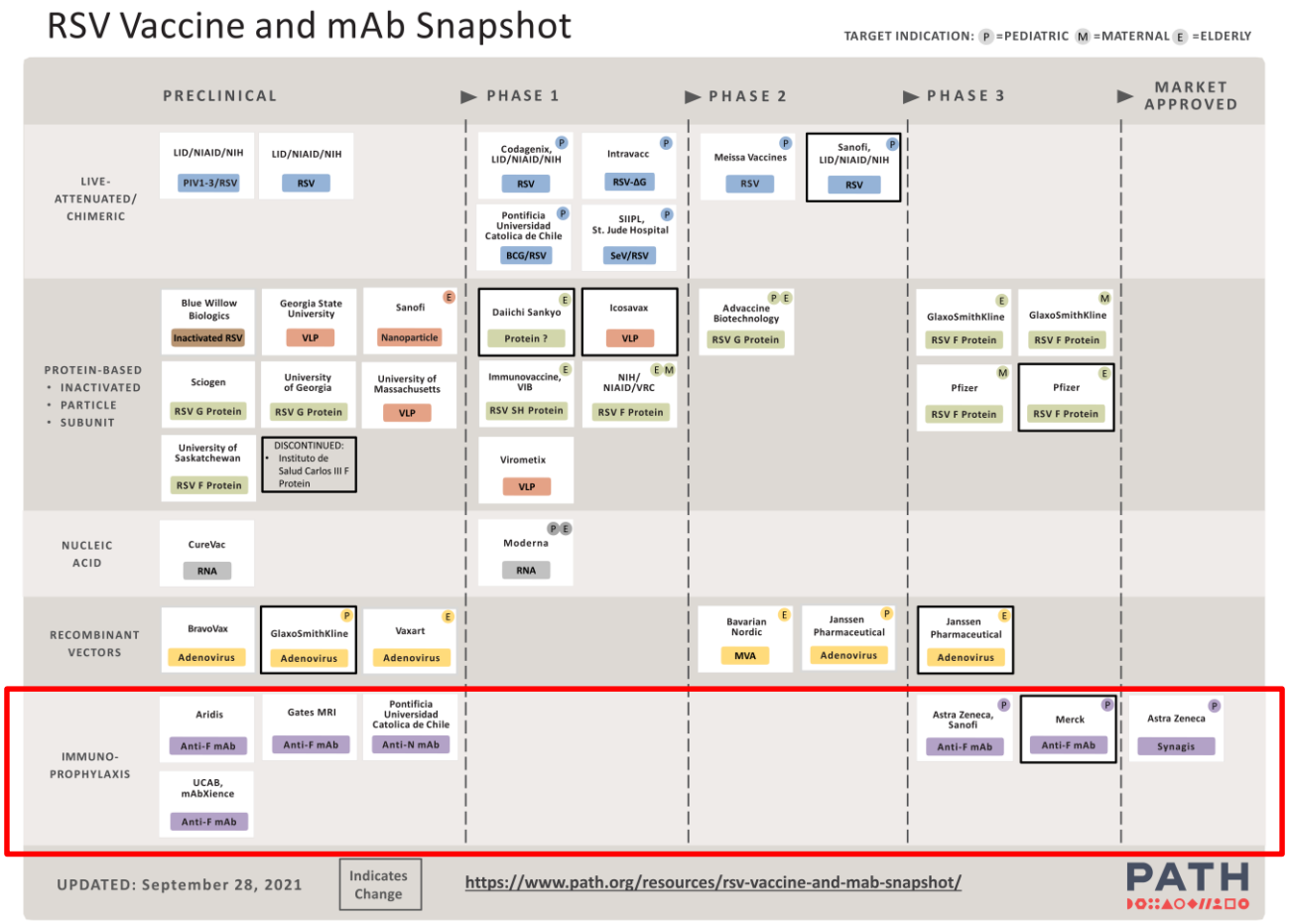
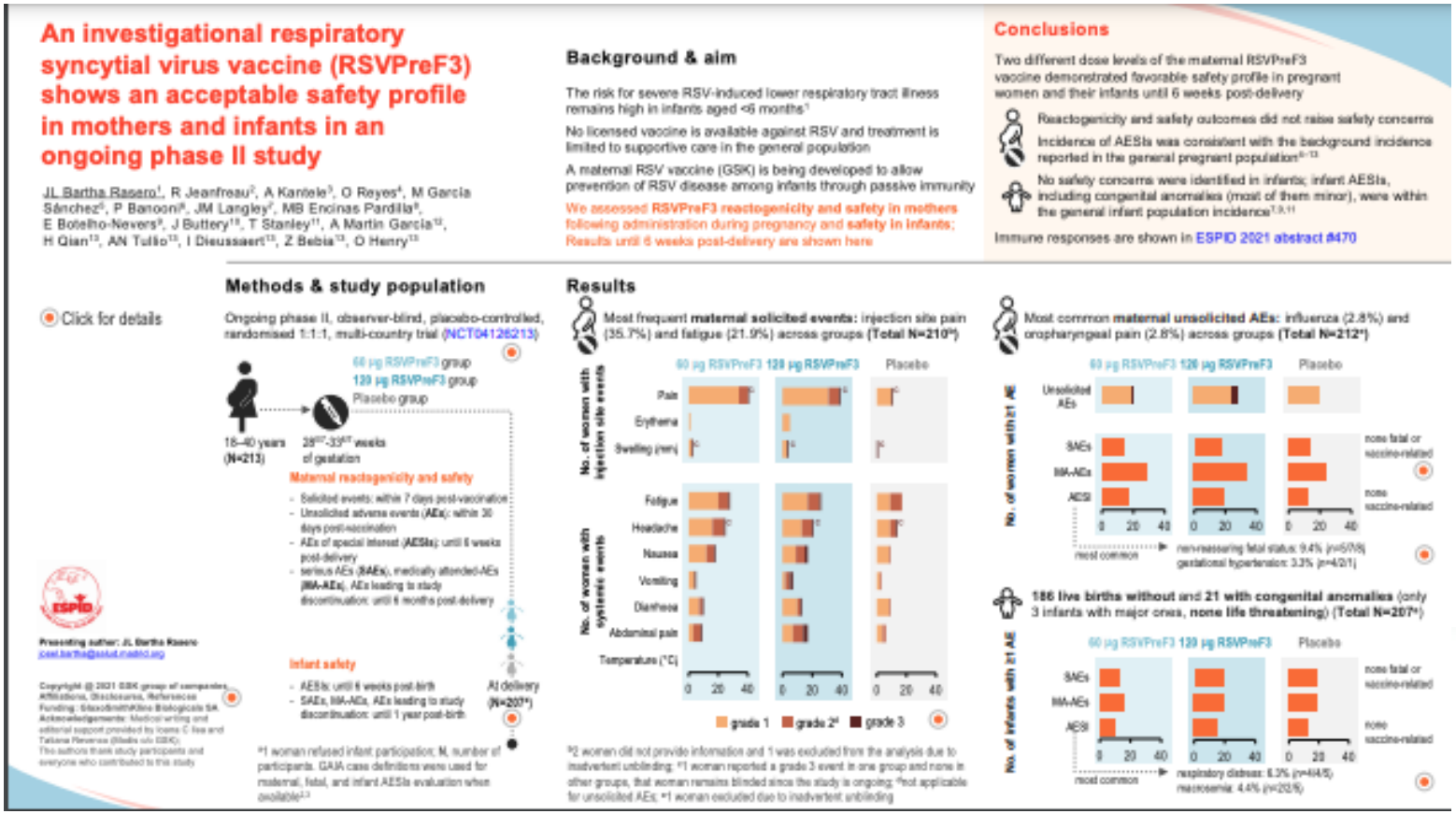
RSV prevention
Why, how, who?

- (Covid – "XX" : NPI) / Vaccines / monoclonals

RSV prevention: vaccines & monoclonals



RSV prevention : vaccines



An investigational respiratory syncytial virus vaccine (RSVPreF3) shows an acceptable safety profile in mothers and infants in an ongoing phase II study

JL Bartha Rasero[1], R Jeanfreau[2], A Kantele[3], O Reyes[4], M García Sánchez[5], P Banooni[6], JM Langley[7], MB Encinas Pardilla[8], E Botelho-Nevers[9], J Buttery[10], T Stanley[11], A Martin García[12], H Qian[13], AN Tullio[13], I Dieussaert[13], Z Belia[13], O Henry[13]

Background & aim

The risk for severe RSV-induced lower respiratory tract illness remains high in infants aged <6 months[1]

No licensed vaccine is available against RSV and treatment is limited to supportive care in the general population

A maternal RSV vaccine (GSK) is being developed to allow prevention of RSV disease among infants through passive immunity

We assessed RSVPreF3 reactogenicity and safety in mothers following administration during pregnancy and safety in infants; Results until 6 weeks post-delivery are shown here

Conclusions

Two different dose levels of the maternal RSVPreF3 vaccine demonstrated favorable safety profile in pregnant women and their infants until 6 weeks post-delivery

Reactogenicity and safety outcomes did not raise safety concerns

Incidence of AESIs was consistent with the background incidence reported in the general pregnant population[6–13]

No safety concerns were identified in infants; infant AESIs, including congenital anomalies (most of them minor), were within the general infant population incidence[7,9,11]

Immune responses are shown in ESPID 2021 abstract #470

Methods & study population

Click for details

Ongoing phase II, observer-blind, placebo-controlled, randomised 1:1:1, multi-country trial (NCT04126213)

60 µg RSVPreF3 group
120 µg RSVPreF3 group
Placebo group

18–40 years (N=213)

28[0]–35[6] weeks of gestation

Maternal reactogenicity and safety

- Solicited events: within 7 days post-vaccination
- Unsolicited adverse events (AEs): within 30 days post-vaccination
- AEs of special interest (AESIs): until 6 weeks post-delivery
- serious AEs (SAEs), medically attended-AEs (MA-AEs), AEs leading to study discontinuation: until 6 months post-delivery

Infant safety

- AESIs: until 6 weeks post-birth
- SAEs, MA-AEs, AEs leading to study discontinuation: until 1 year post-birth

At delivery (N=207*)

*1 woman refused infant participation; N, number of participants. GAIA case definitions were used for maternal, fetal, and infant AESIs evaluation when available[13]

Results

Most frequent **maternal solicited events:** injection site pain (35.7%) and fatigue (21.9%) across groups **(Total N=210*)**

Most common **maternal unsolicited AEs:** influenza (2.8%) and oropharyngeal pain (2.8%) across groups **(Total N=212*)**

186 live births without and 21 with congenital anomalies (only 3 infants with major ones, **none life threatening**) **(Total N=207*)**

[a]2 woman did not provide information and 1 was excluded from the analysis due to inadvertent unblinding; *1 woman reported a grade 3 event in one group and none in other groups, that woman remains blinded since the study is ongoing; [b]not applicable for unsolicited AEs; *1 woman excluded due to inadvertent unblinding

Presenting author: JL Bartha Rasero
jose.bartha@salud.madrid.org

Jessa Ziekenhuis

ESPID 2021

RSV prevention : vaccines

pharmaphorum™
bringing healthcare together

GSK's halts RSV vaccine trials in pregnant women after pause

Phil Taylor

February 28, 2022

Shares in the company were down almost 2% after the decision was announced to stop the phase 3 GRACE trial and two other studies involving pregnant women.

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RSV prevention: monoclonals

- Palivizumab (Medimmune)
- Nirsevimab (Medimmune/Astra-Zeneca/Sanofi-Pasteur)
- MK-1654 (MSD)

Palivizumab: reimbursement criteria in Belgium : children at risk

- Children born **at less than 28 weeks of gestation** and younger than 12 months of age at the onset of the RSV season
- Children born **between 28 and 35 weeks of gestation**, who needed ventilation for at least 48 hours in NICU and less than 6 months of age at the onset of the RSV season
- Children **less than 2 years of age and requiring chronic O2 treatment for BPD** within the last 6 months
- Children **less than 2 years of age and with haemodynamically significant congenital heart disease**
- NB: Children must have been **admitted in a NICU**

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RSV prevention: monoclonals

The NEW ENGLAND JOURNAL of MEDICINE

Griffin P et al N Engl J Med **2020** 383; 5: 415-425

Single-Dose Nirsevimab for Prevention of RSV in Preterm Infants

Phase 2b

Hammit LL et al N Engl J Med **2022**; 386(9) 837-846

Nirsevimab for Prevention of RSV in Healthy Late-Preterm and Term Infants

Phase 3

Domachowske et al N Engl J Med **2022** 386(9)

Safety of Nirsevimab for RSV in Infants with Heart or Lung Disease or Prematurity

Phase 2b + 3

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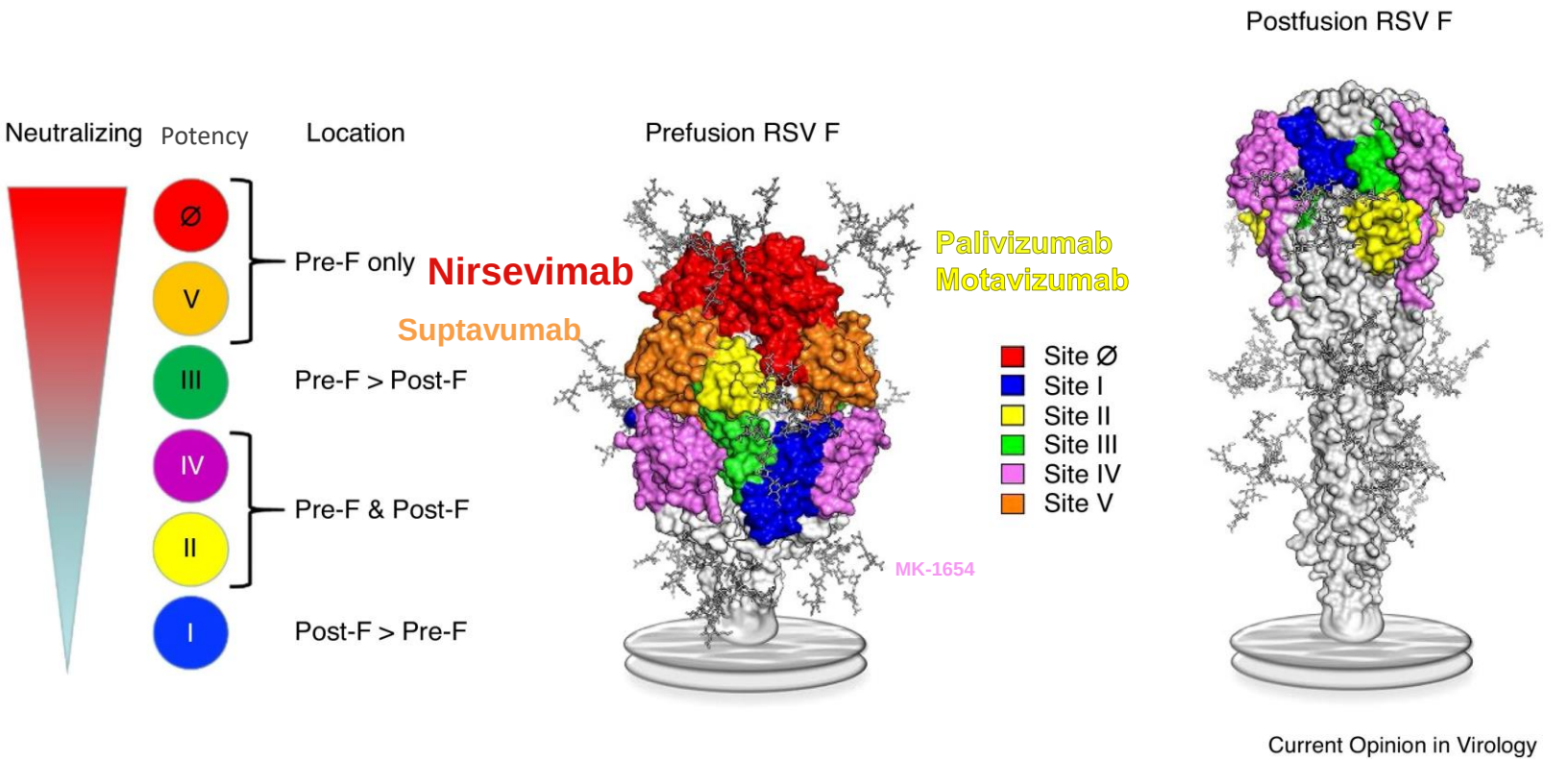
Target site for RSV mABs : F(usion) protein



Graham BS, 2017. Current Opinion in Virology, 23:107–112

The NEW ENGLAND JOURNAL of MEDICINE

Single-Dose Nirsevimab for Prevention of RSV in Preterm Infants

A phase 2b randomized, double-blind, placebo-controlled study to evaluate the safety and efficacy of nirsevimab, a monoclonal antibody with an extended half-life against respiratory syncytial virus, in healthy preterm infants

Phase 2b

Study population

- 1453 Preterm infants 29 – 35 weeks gestational age entering their first RSV season who did not meet AAP or other national/local guidelines to receive palivizumab (Synagis®)

- **Primary endpoint**
  - Incidence of **medically attended LRTI** (inpatient and outpatient) caused by RT-PCR confirmed RSV for 150 days after dosing
- **Secondary and exploratory endpoints**
  - Incidence of **hospitalization** due to RT-PCR-confirmed RSV for 150 days after dosing
  - Safety
  - Pharmacokinetics
  - Anti-drug antibodies
  - Healthcare resource utilization and caregiver burden assessment

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Griffin P et al N Engl J Med **2020** 383; 5: 415-425

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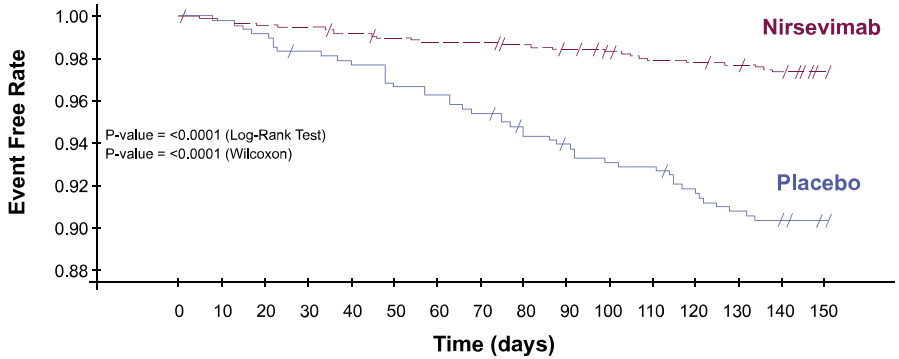
Single-Dose Nirsevimab for Prevention of RSV in Preterm Infants

Kaplan-Meier plot for time to first medically attended RSV LRTI

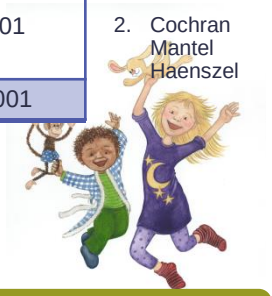


Phase 2b

		Placebo N=484	Nirsevimab N=969	Relative risk reduction (95% CI)	P-value
Medically attended RSV LRTI	**Observed events**	**46 (9.5%)**	**25 (2.6%)**	**70.1%** (52.3%, 81.2%)	<0.0001
	Subjects requiring imputation (Poisson)	11 (2.3%)	24 (2.5%)		
	CMH	46 (9.5%)	25 (2.6%)	**72.9%** (56.5%, 83.1%)	<0.0001
RSV LRTI hospitalization	**Observed events**	**20 (4.1%)**	**8 (0.8%)**	**78.4%** (51.9%, 90.3%)	0.0001
	Subjects requiring imputation (Poisson)	11 (2.3%)	24 (2.5%)		
	CMH	20 (4.1%)	8 (0.8%)	**80.0%** (55.0%, 91.1%)	<0.0001

Statistical models:

1. Poisson regression with imputation of missing data
2. Cochran Mantel Haenszel



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The NEW ENGLAND JOURNAL of MEDICINE

Nirsevimab for Prevention of RSV in Healthy Late-Preterm and Term Infants

STUDY CONDUCT

STUDY DESIGN	PARTICIPANTS	INTERVENTIONS	LOCATION AND SEASON
A Phase III, randomized (Nirsevimab:placebo = 2:1), multicenter study NCT03979313	**1490 Healthy infants enrolled** Gestational age ≥35 weeks 0 days; ≤1 year of age; entering their first RSV season	**Nirsevimab (N=994)** (50 mg if <5 kg or 100 mg if ≥5 kg) Versus **Placebo** (N=496)	**Northern hemisphere** (20 countries,150 sites, followed through the 2019/20 RSV season) **Southern hemisphere** (10 sites in South Africa followed through the expected 2020 season)

The baseline characteristics in the two groups were well-balanced

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Hammit LL et al N Engl J Med **2022**; 386(9) 837-846

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Nirsevimab for Prevention of RSV in Healthy Late-Preterm and Term Infants

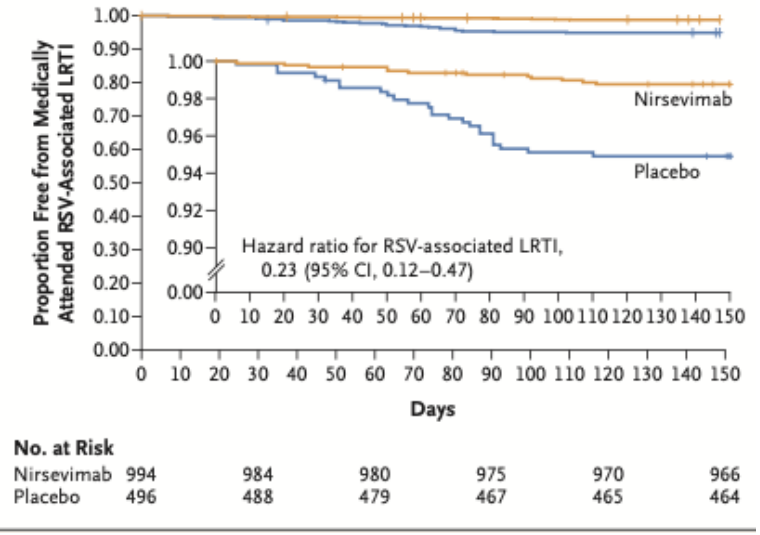

Table 3. Outcomes through 150 Days after the Injection.*

Outcome	Nirsevimab (N=686)	Placebo (N=342)	Efficacy (95% CI)†	Cases Averted per 1000 Infants Treated (95% CI)‡	Number Needed to Treat (95% CI)§
	no. (%)				
Medically attended RSV-associated lower respiratory tract infection on any test result¶	17 (2.5)	37 (10.8)	77.0 (59.8 to 86.8)	83.4 (62.0 to 105.0)	12 (10 to 17)
Medically attended RSV-associated lower respiratory tract infection on central test result¶	15 (2.2)	33 (9.6)	77.2 (58.7 to 87.5)	74.7 (53.0 to 95.0)	14 (11 to 19)
Medically attended lower respiratory tract infection of any cause¶	60 (8.7)	62 (18.1)	51.5 (32.6 to 65.2)	93.6 (63.0 to 124.0)	11 (9 to 16)
Hospitalization for any respiratory illness due to RSV on any test result	9 (1.3)	11 (3.2)	59.0 (2.1 to 82.9)	19.0 (5.5 to 32.0)	53 (32 to 182)
Hospitalization for any respiratory illness due to RSV on central test result	7 (1.0)	9 (2.6)	61.1 (−3.7 to 85.4)	16.1 (4.5 to 28.0)	62 (36 to 223)
Hospitalization for any respiratory illness of any cause	16 (2.3)	14 (4.1)	42.8 (−15.8 to 71.7)	17.7 (2.0 to 33.0)	57 (31 to 500)

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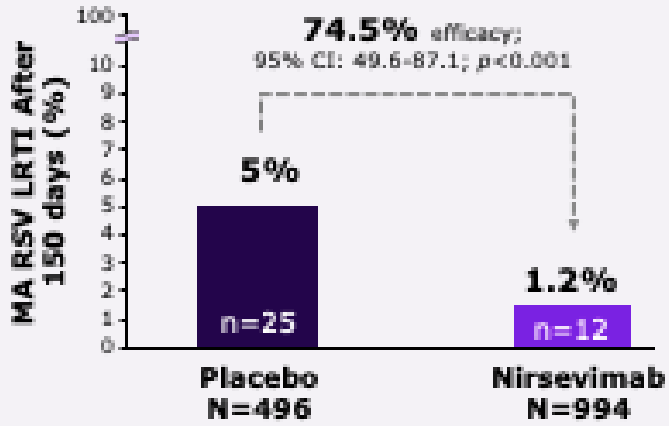
Nirsevimab for Prevention of RSV in Healthy Late-Preterm and Term Infants

EFFICACY



PRIMARY ENDPOINT

The incidence of **MA RSV-associated LRTI** was:

- 1.2% in the nirsevimab group
- 5.0% in the placebo group

Efficacy of nirsevimab of **74.5% (95% CI 49.6, 87.1; $p<0.001$), meeting the primary endpoint**

SECONDARY ENDPOINT

The incidence of **RSV-associated hospitalization due to MA LRTI** was:

- 0.6% in the nirsevimab group
- 1.6% in the placebo group

Efficacy of nirsevimab of **62.1% (95% CI – 8.6, 86.8; $p=0.07$)**

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The NEW ENGLAND JOURNAL of MEDICINE

Nirsevimab for Prevention of RSV in Healthy Late-Preterm and Term Infants

SAFETY

SAFETY

- Safety events were balanced between the treatment groups
- Three deaths occurred through day 361 (all in nirsevimab recipients on or after day 140)
- None of the serious adverse events (SAEs), including deaths, were considered by investigators to be related to the investigational product
- A single adverse event (AE) of special interest was a grade 3 generalized macular rash without any systemic features, which required no treatment and resolved; the investigator considered this event to be related to nirsevimab

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CORRESPONDENCE

Safety of Nirsevimab for RSV in Infants with Heart or Lung Disease or Prematurity

Table 1. Adverse Events Occurring during Treatment through 360 Days after Administration of the First Dose of Nirsevimab in the As-Treated Population.*

Event	Preterm Cohort		CHD–CLD Cohort	
	Palivizumab (N=206)	Nirsevimab (N=406)	Palivizumab (N=98)	Nirsevimab (N=208)
	number of infants (percent)			
≥1 Adverse event	134 (65.0)	268 (66.0)	72 (73.5)	148 (71.2)
≥1 Treatment-related adverse event	4 (1.9)	6 (1.5)	2 (2.0)	4 (1.9)
≥1 Adverse event of grade ≥3 severity†	7 (3.4)	14 (3.4)	13 (13.3)	30 (14.4)
≥1 Treatment-related adverse event of grade ≥3 severity†	0	0	0	0
Any adverse event with outcome of death (grade 5 severity)†	0	2 (0.5)	1 (1.0)	3 (1.4)
≥1 Serious adverse event‡	11 (5.3)	28 (6.9)	20 (20.4)	40 (19.2)
≥1 Serious adverse event, grade ≥3 adverse event, or both†	11 (5.3)	28 (6.9)	21 (21.4)	45 (21.6)
≥1 Treatment-related serious adverse event	0	0	0	0
≥1 Adverse event of special interest§	0	1 (0.2)	0	1 (0.5)
≥1 Covid-19–related adverse event¶	1 (0.5)	8 (2.0)	1 (1.0)	2 (1.0)

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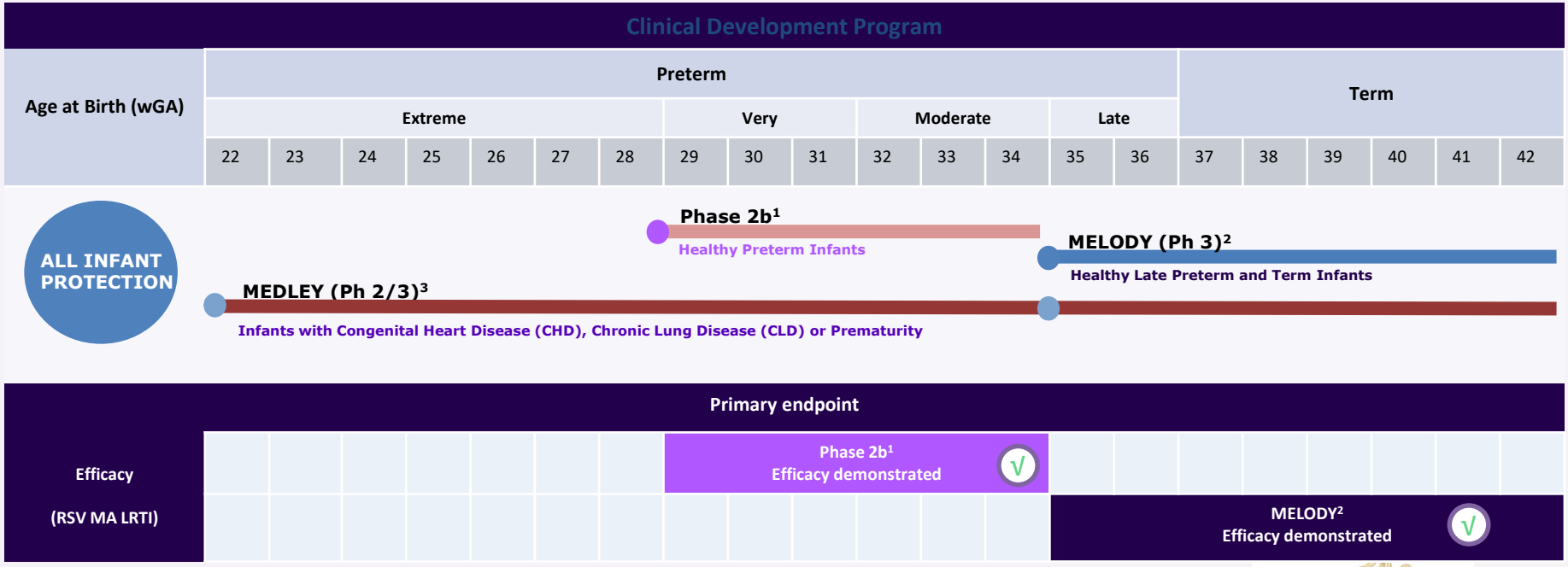
Domachowske et al. N Engl J Med 2022; 386(9)

Paradigma shift:

Nirsevimab to Protect All Infants from RSV ???

Positive Results from Studies



MAT-GLB-2200707 (V1.0) | March 2022

1. Griffin MP et al.
N Engl J Med 2020;383:415-25

2. Hammitt LL et al.
N Engl J Med 2022;386:837-46.

3.Domachowske JB, et al.
N Engl J Med 2022; 386:892-894

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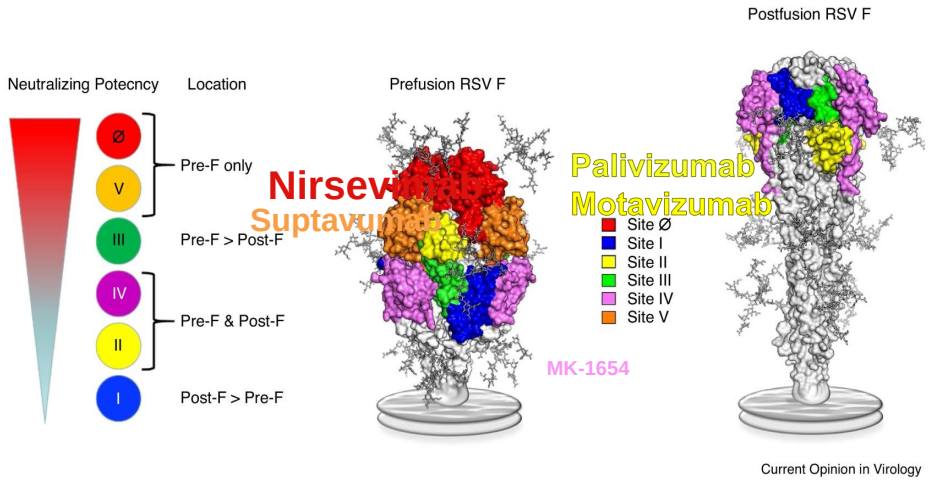

MK-1654: Clinical Development Overview

Trial	Patient Population	Interventions	Primary Endpoint
MK-1654-004 (NCT04767373) *Phase IIb/III*	Healthy pre-term and full-term infants	Single IM dose MK-1654 or placebo	Percentage of participants with RSV-associated MALRI, Percentage of participants with solicited (S)AEs
MK-1654-007 (NCT04938830) *Phase III*	Infants and Children at Increased Risk for Severe RSV Disease	IM injection with MK-1654 or palivizumab	Participants with solicited (S)AEs, Percentage of participants with RSV-associated MALRI,

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RSV prevention

Why, how, who/when?

- Risk population
- All infants?
- Seasonality

RSV prevention: target population

- Risk infants (palivizumab)
- All “young” infants
- (Elderly)

→ Seasonality

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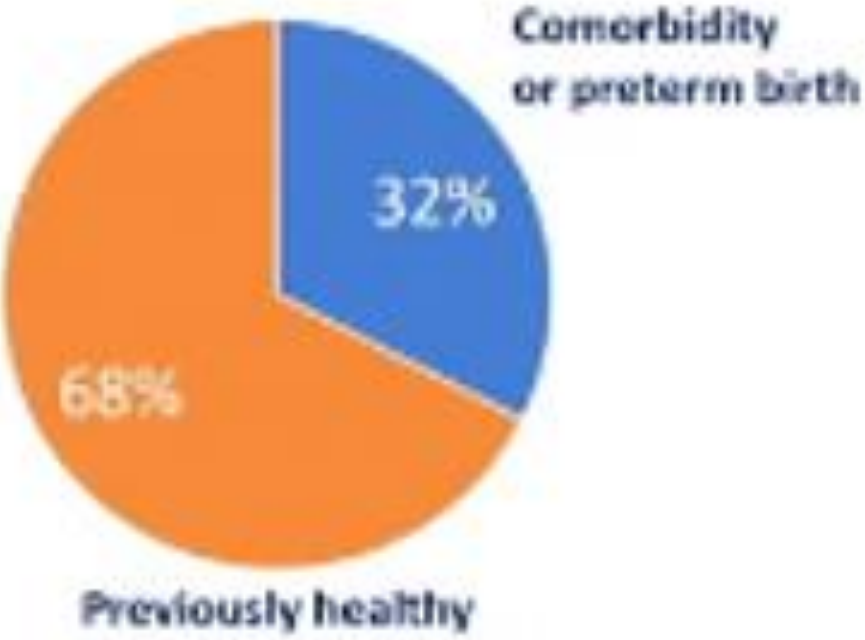
RSV epidemiology

- RSV infection accounts for 60-80 % of infact bronchiolitis cases and up to 40 % of cases of paediatric pneumonia[1]
- 70 % of infants are infected in the 1st year and 90 % by 2 years of life→ up to 40 % develop LRTI during the initial episode[2]
- A leading cause of hospitalization in infants during the winter time – most (up to 75 %) in **healthy, term infants** [3-5]
- Hospitalization rate: 1-2/100 infants < 2 mos and 0,5/100 < 2 years[2,3-5]
- Highest risk during the 1st RSV season[5]
- High burden of outpatient and ED visits as well [1,4]

1. Hall CB et al.N Engl J med 2001; 344(25):1917-1928.2.Glezen WP et al Azm J Dis Child 1986;140(6): 543-546.3.Ledare S et al. Pedaitr Infect Dis J 2002; 21(7): 629-634.4. Ariola ES et al. Pediatr Infect Dis Soc 2020; 9(5): 587-595.5. Hall CB et al. Pedaiatrics 2013; 132(2): e341-348.

Estimated Burden of Community-Onset Respiratory Syncytial Virus–Associated Hospitalizations Among Children Aged <2 Years in the United States, 2014–15

No underlying condition or born premature: **68 %**



Arriola CS et al. J Ped Inf Dis Soc 2020; 9(5): 587-595

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RSV: peak of incidence – Italy

63 % below age 3 months of age
- 1.4 % (9/624) very early pre-terms (< 28 weeks)
- 6.7 % (42/624) pre-terms (< 34 weeks)
- 5 % (31/624) other risk factors

→ **88.3 %** were NOT eligilble for prophylaxis
(because healthy and not premature)

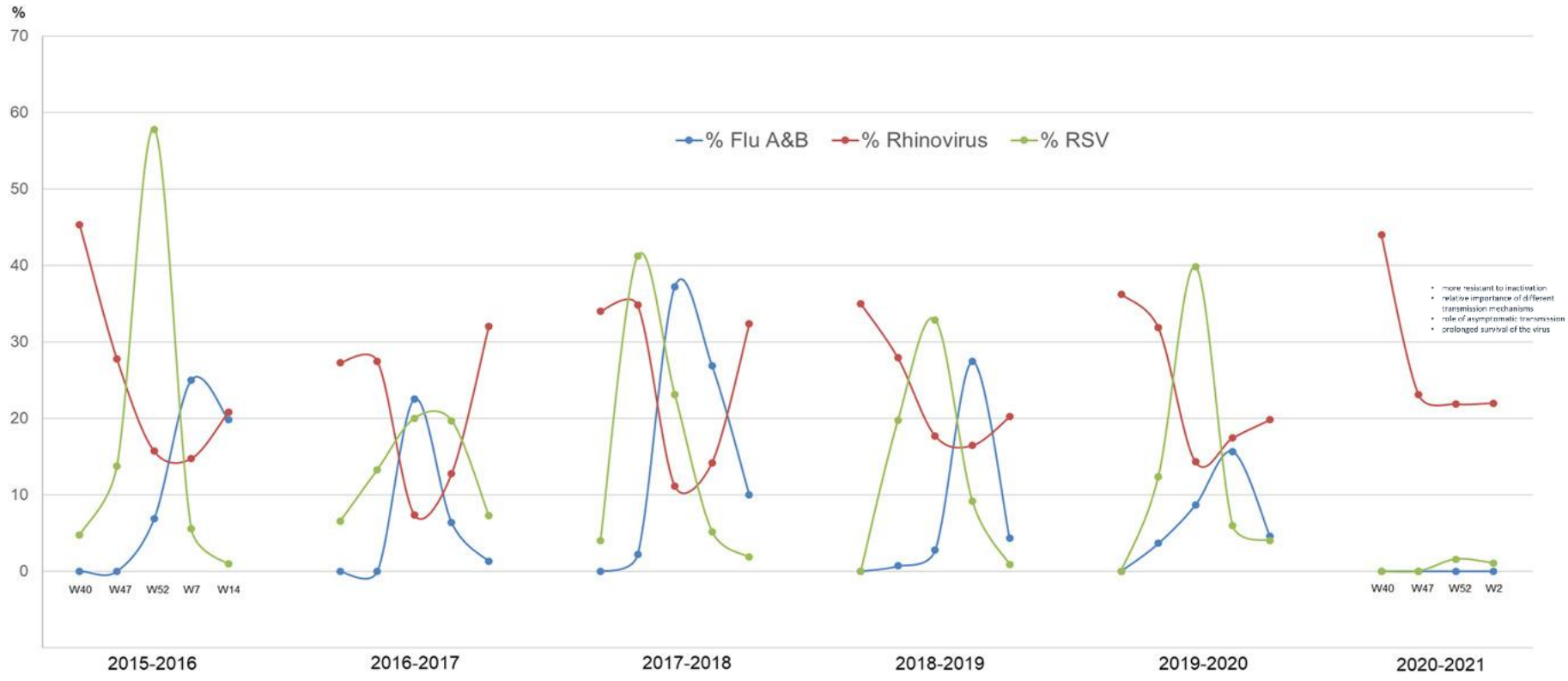
Azzari C National Meeting Italian Society Family Pediatricians, Baveno, 2021
Azzari C ESPID 2022

RSV prevention

Why, how, who/when?

- Risk population
- All infants?
- Seasonality

COVID-19 pandemic period, where are the seasonal viruses?



Schematic winter distribution (% of positive samples) for Flu A and B viruses, respiratory syncytial viruses, and rhinoviruses, from 2015–2016 to 2020–2021. The prevalences were reported at Weeks 40, 47, 52, 7, and 14 (except for winter 2020–2021 in which the fourth and last date corresponds to the second week of 2021)

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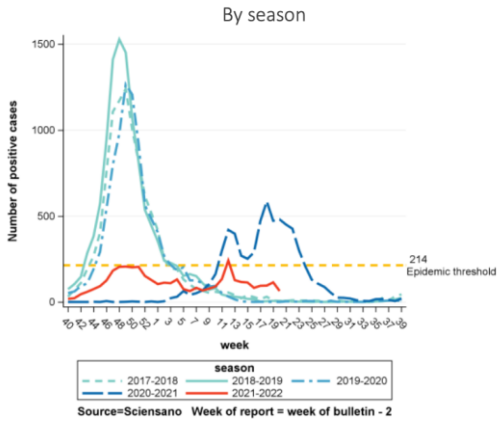
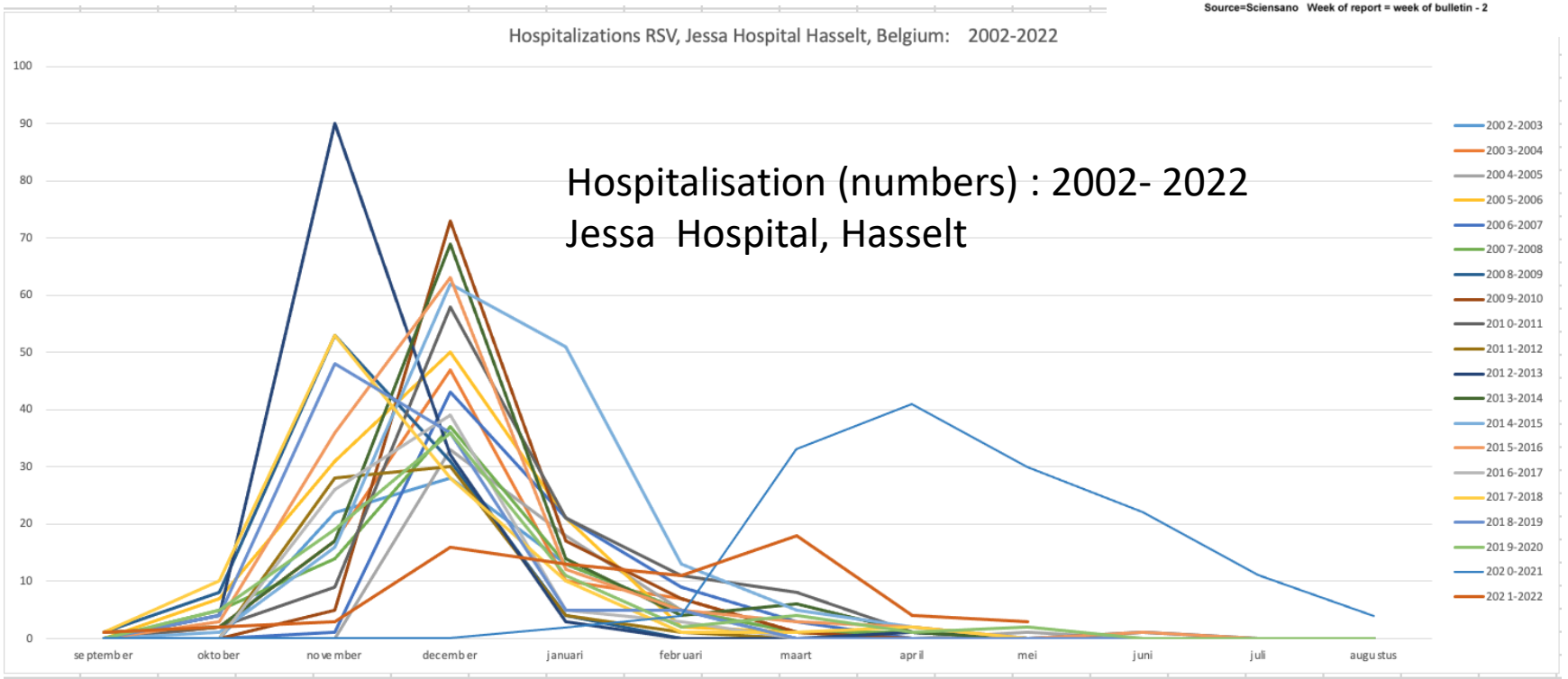
Mansuy JM et al J Med Virol 2021; 93(7): 4097-4098

RSV seasonality





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RSV prevention

Type	Target population and main characteristics
Maternal vaccines	Vaccination of pregnant women to protect neonates through transplacental transfer of maternal antibodies
	Protection of the neonate from birth
	Duration equivalent to the life of maternal antibodies (i.e., 2–4 months)
	Can immunize only infants born just before and during RSV epidemic season, and that have been born at term
mAbs with extended half-life	Neonates and infants
	Immediate onset of protection
	Duration of up to 5 months, throughout the RSV season
	Can immunize all children, at birth if born during the RSV season and by appointment if born before the season
Pediatric vaccines	Children, early infancy
	No protection during the first months of life
	Durable protection (years) throughout childhood

mAb monoclonal antibody, *RSV* respiratory syncytial virus

RSV prevention: challenges

- Maternal vaccination (couverage)
- Infant vaccination
- mABs (duration of protection)
- Implementation
  - Who: high-risks <-> all “young” infants
  - When - timing : season – all year round
  - Where: maternity ward, K&G/ONE, practioners
- Surveillance: Belgian data
- Cost-benefit

Combination?

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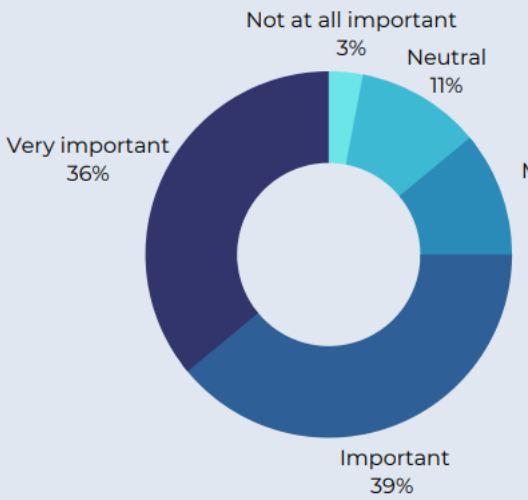
THE HEALTH SYSTEM BURDEN OF RESPIRATORY SYNCYTIAL VIRUS (RSV) IN EUROPE

PREPARE FOR ACCESS TO IMMUNISATION

Graph 8. Importance of immunisation (n=380)

Importance of access to immunisation to reduce the RSV health system burden (percentage of respondents)



75%
HCPs rank access to immunisation as important or very important to reduce the RSV health system burden.

THE HEALTH SYSTEM BURDEN OF RESPIRATORY SYNCYTIAL VIRUS (RSV) IN EUROPE

KEY RECOMMENDATIONS

- Broaden understanding/awareness (community, careggivers, HCP)
- Maintain infection control measures (NPI,…)
- Improve/expand diagnostic capabilities (POCT)
- Standardise the management of RSV infections
- Prepare for acces to immunization