Infectious disease modelling and cost-effectiveness of RSV intervention strategies

Dr. David Hodgson

World Vaccine Congress: Europe

18th October 2023

LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

RSV protection in infants in 2023

Nirsevimab (**Beyfortus**, *Sanofi*)

- Long-acting monoclonal antibody
- Given once before RSV season

74.5% (95 CI 49.6 to 87.1) against MA-LRTI

Hammit et al. 2022. NEJM

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

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

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The NEW ENGLAND JOURNAL of MEDICINE

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Bivalent Prefusion F Vaccine in Pregnancy to Prevent RSV Illness in Infants

B. Kampmann, S.A. Madhi, I. Munjal, E.A.F. Simões, B.A. Pahud, C. Llapur, J. Baker, G. Pérez Marc, D. Radley, E. Shittu, J. Glanternik, H. Snaggs, J. Baber, P. Zachariah, S.L. Barnabas, M. Fausett, T. Adam, N. Perreras, M.A. Van Houten, A. Kantele, L.-M. Huang, L.J. Bont, T. Otsuki, S.L. Vargas, J. Gullam, B. Tapiero, R.T. Stein, F.P. Polack, H.J. Zar, N.B. Staerke, M. Duron Padilla, P.C. Richmond, K. Koury, K. Schneider, E.V. Kalinina, D. Cooper, K.U. Jansen, A.S. Anderson, K.A. Swanson, W.C. Gruber, and A. Gurtman, for the MATISSE Study Group*

Kampmann et al. 2023. NEJM

RSVPreF (**ABRYSVO**, *Pfizer*)

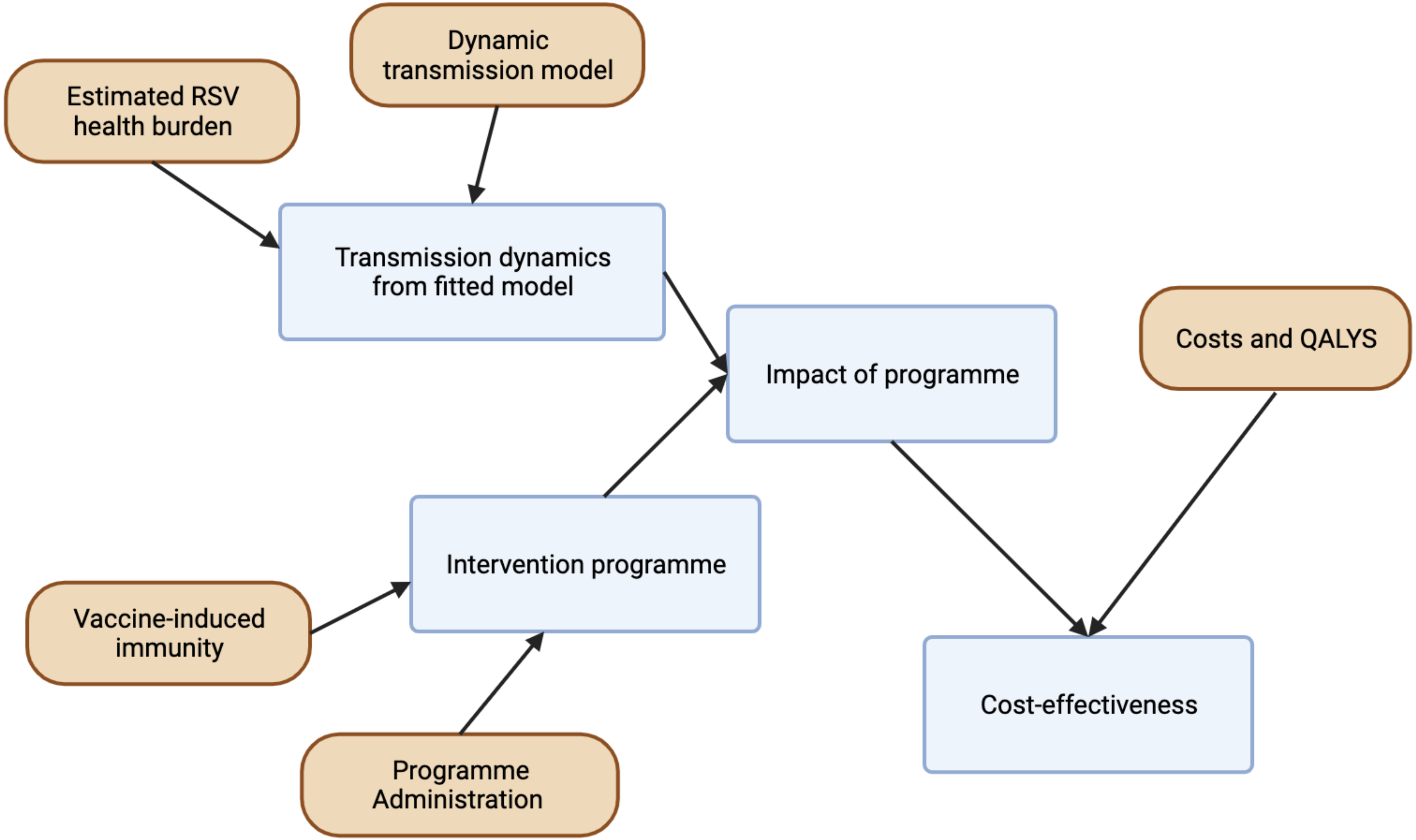
- Maternal vaccine
- Given during third trimester

69.4% 97.58% CI (44.3 to 84.1) against severe MA-LRTI

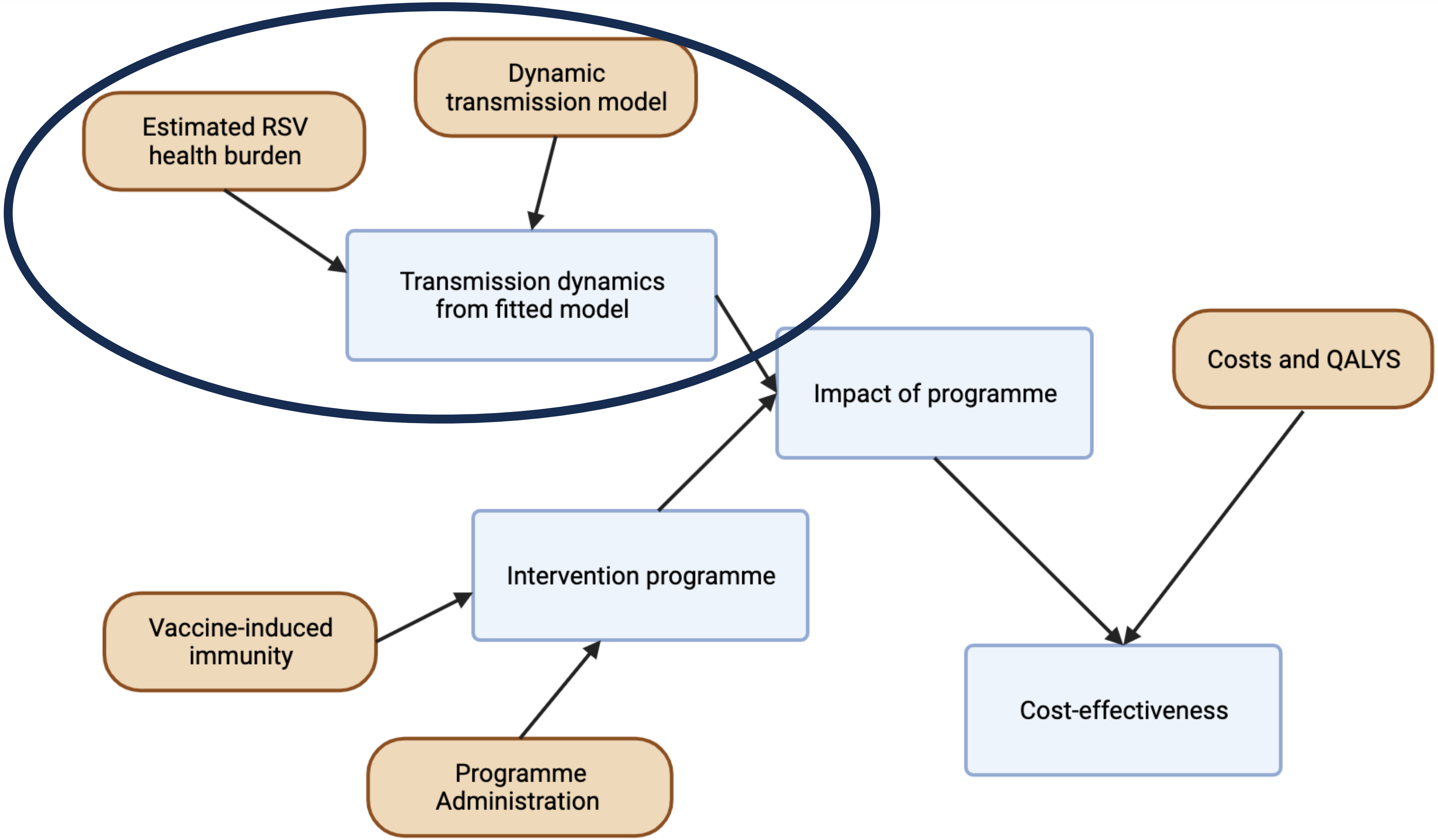
Both approved for use by FDA/EMA

Question for UK: which, if any, of these should we incorporate into the NIP?

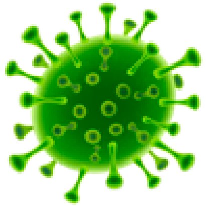
Overview of project



Overview of project



RSV issues

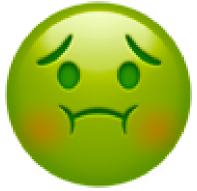


RSV is infectious

- Complex transmission patterns (indirect effects)

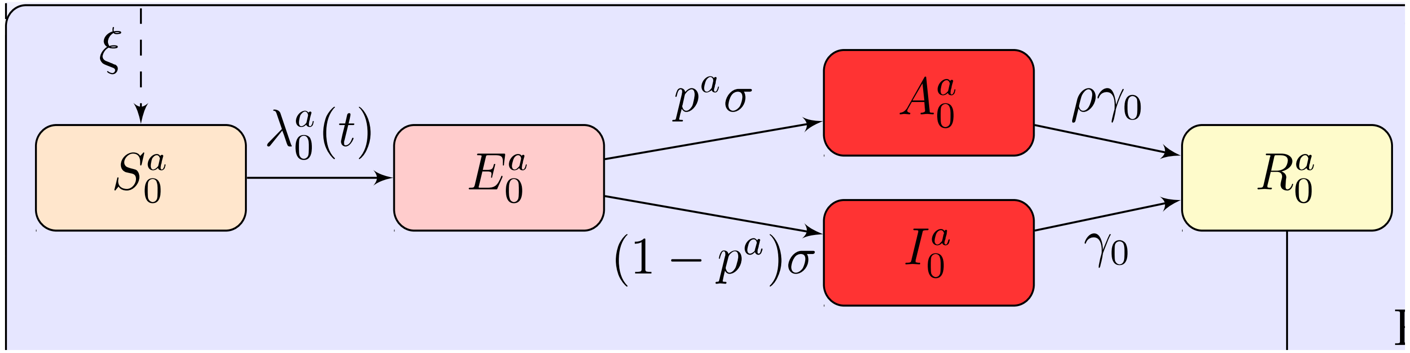
RSV has various levels of severity

- Very severe in infants/Milder in adults
- Requires different estimates for QALY



Exposure also effects duration of infection, susceptibility etc

Base model



Two infection categories, A (asymptomatic,) I (symptomatic) infection chosen as a large proportion of infections are asymptomatic in adults and there is a different in dynamics of transmission

Reinfection possible, so duration of protection from infection is temporary

Maternal protection group for newborns

Force of infection, λ(t) is seasonally forced.

Capturing age-specific factors

RSV disease severity is heterogeneous with age

Why?

Age-related reasons include immaturity of immune system; small bronchioles etc.

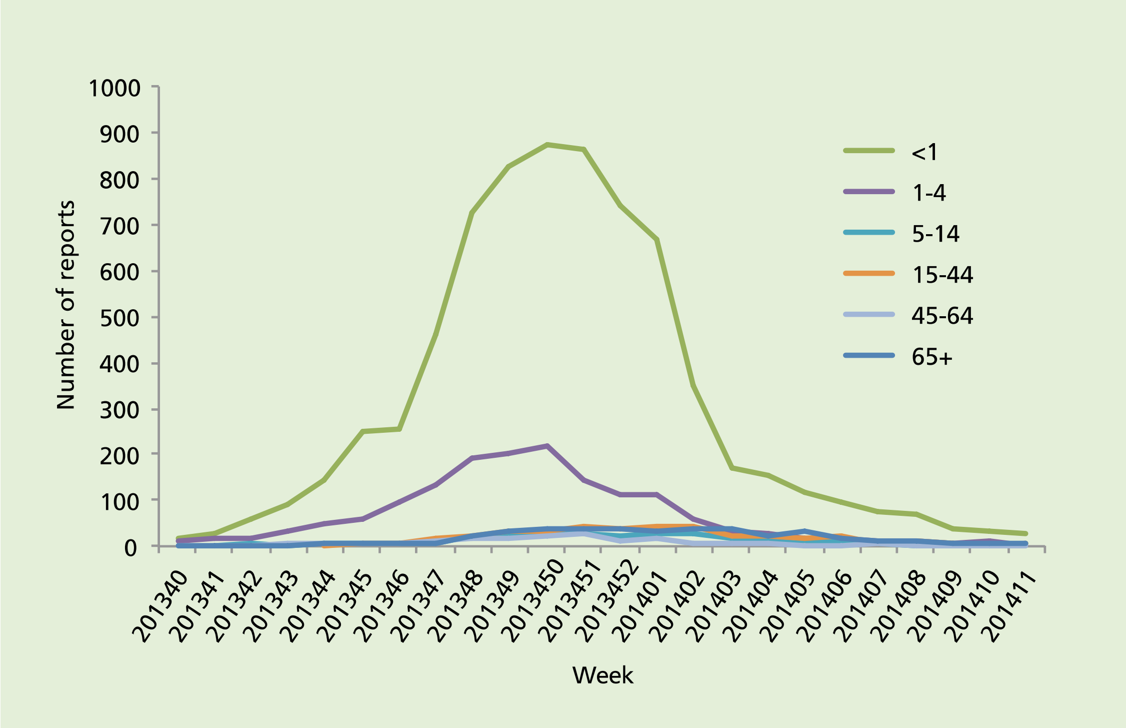
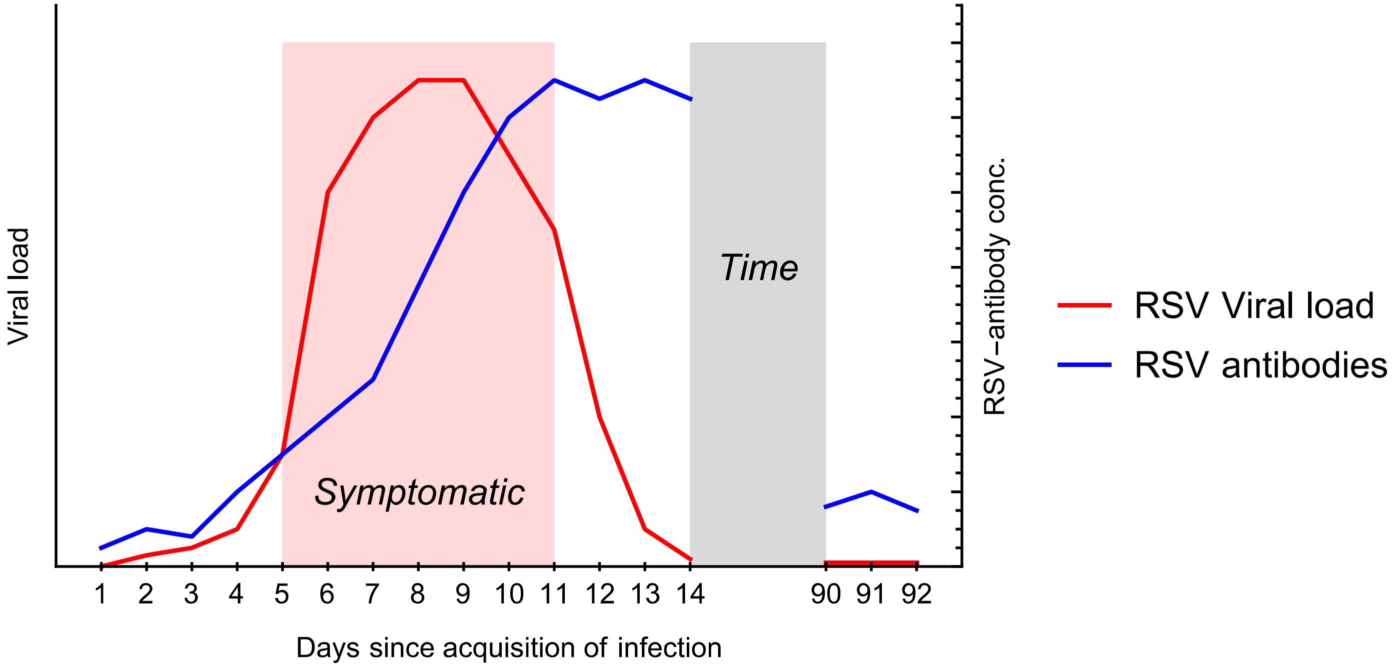


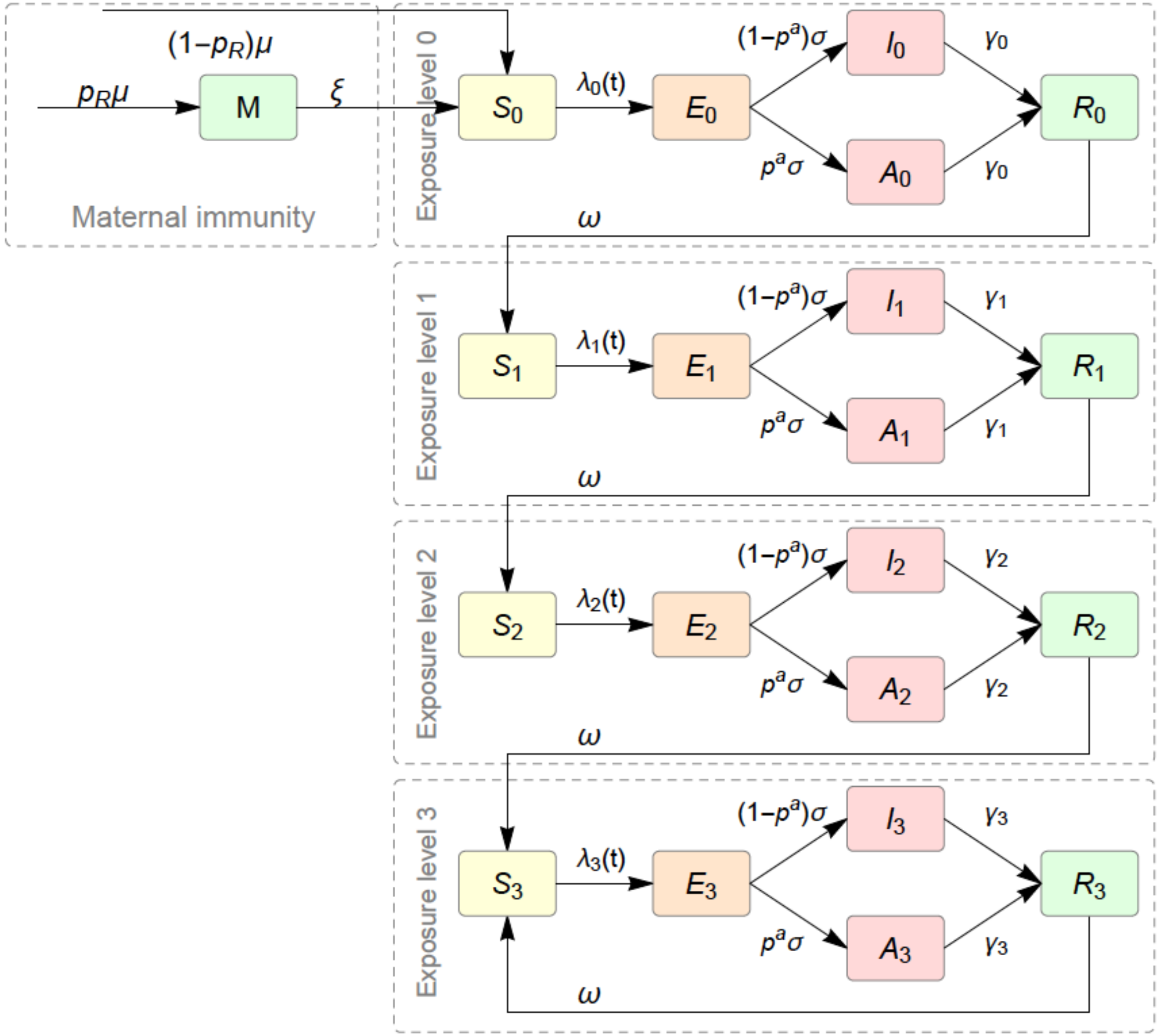
Figure: RSV incidence across ages. *[Communicable Disease Control Handbook 2005. 135-141.]*

Role of exposure

- There is a cumulative build-up of antibodies after each RSV infection
- The level of antibody build-up reduces the severity of subsequent infections
- Therefore, first infection is most severe, then future infections become milder

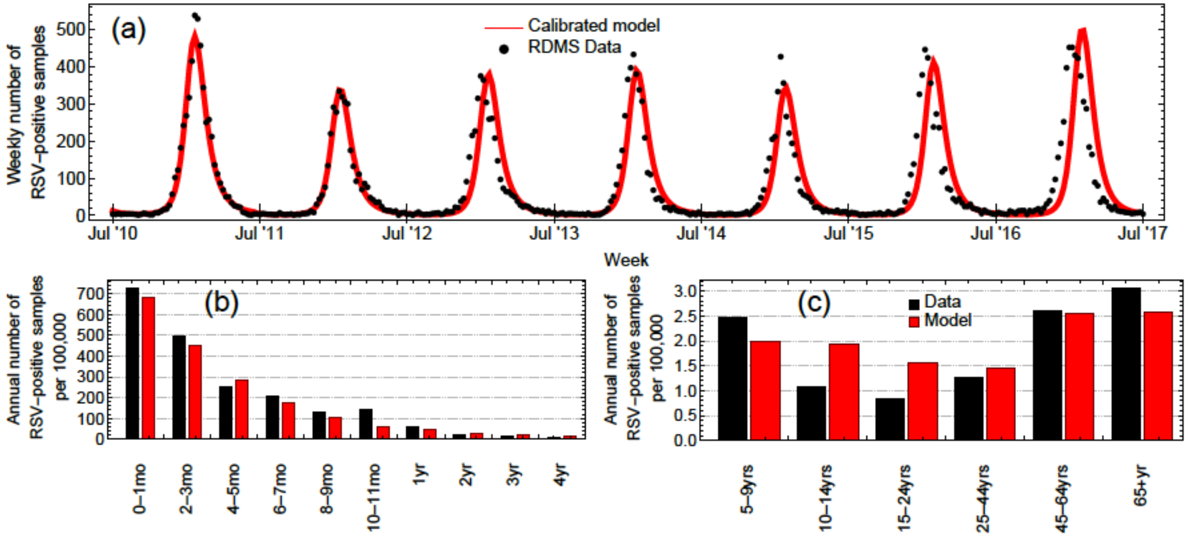


Overview of model



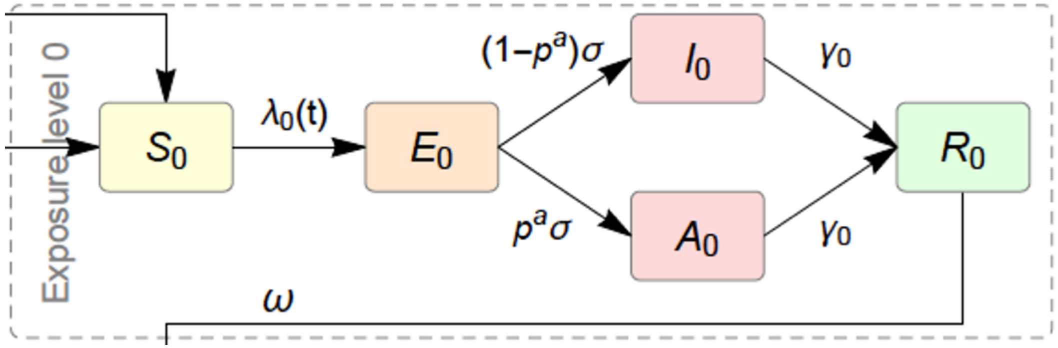
<- Full SEIR model per age group

Data we fit too:



Modelling RSV transmission

SEIRS model fitted to RDMS (RSV positive samples)

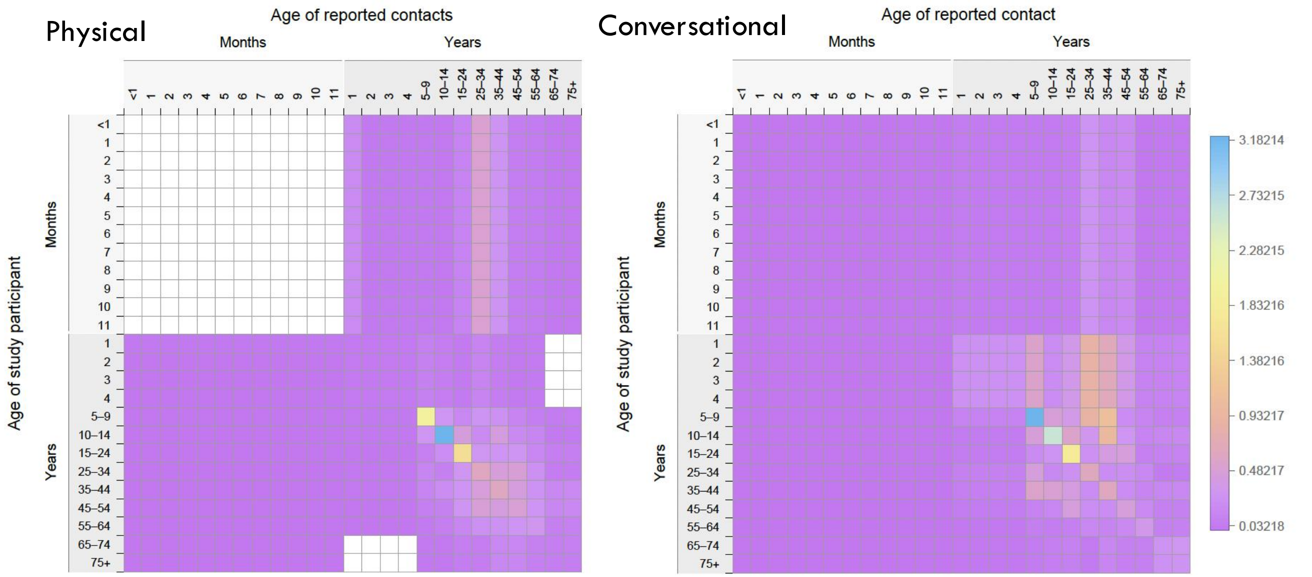


S: susceptible
E: exposure but not yet infectious
A: Infected but asymptomatic
I: Infected but symptomatic
R: Post-infection immunity (temp)

25 age groups:

Monthly up to 11 months, 1, 2, 3, 4, 5-9,
10-14, 15-24, 25-34, 35-44, 45-54, 55-64, 65-74, 75+ years

Contact matrix from POLYMOD



Risk of health outcomes

Symptomatic cases
- Taken from model

Hospital cases
- Reeves et al. 2017 *Influenza Other Respir Viruses*
- Reeves et al. 2019 *J Infect*
- **Taylor et al. 2016 *BMJ***
- Sharp et al. 2022 *Influenza Other Respir Viruses*

GP consultations
- Cromer et al. 2017 *Lancet Public Health*
- **Taylor et al. 2016 *BMJ***
- **Fleming et al. 2015 *BMC Inf Dis***

Annual burden health outcomes of RSV in England and Wales

↓

Estimated risk of health outcome per infection

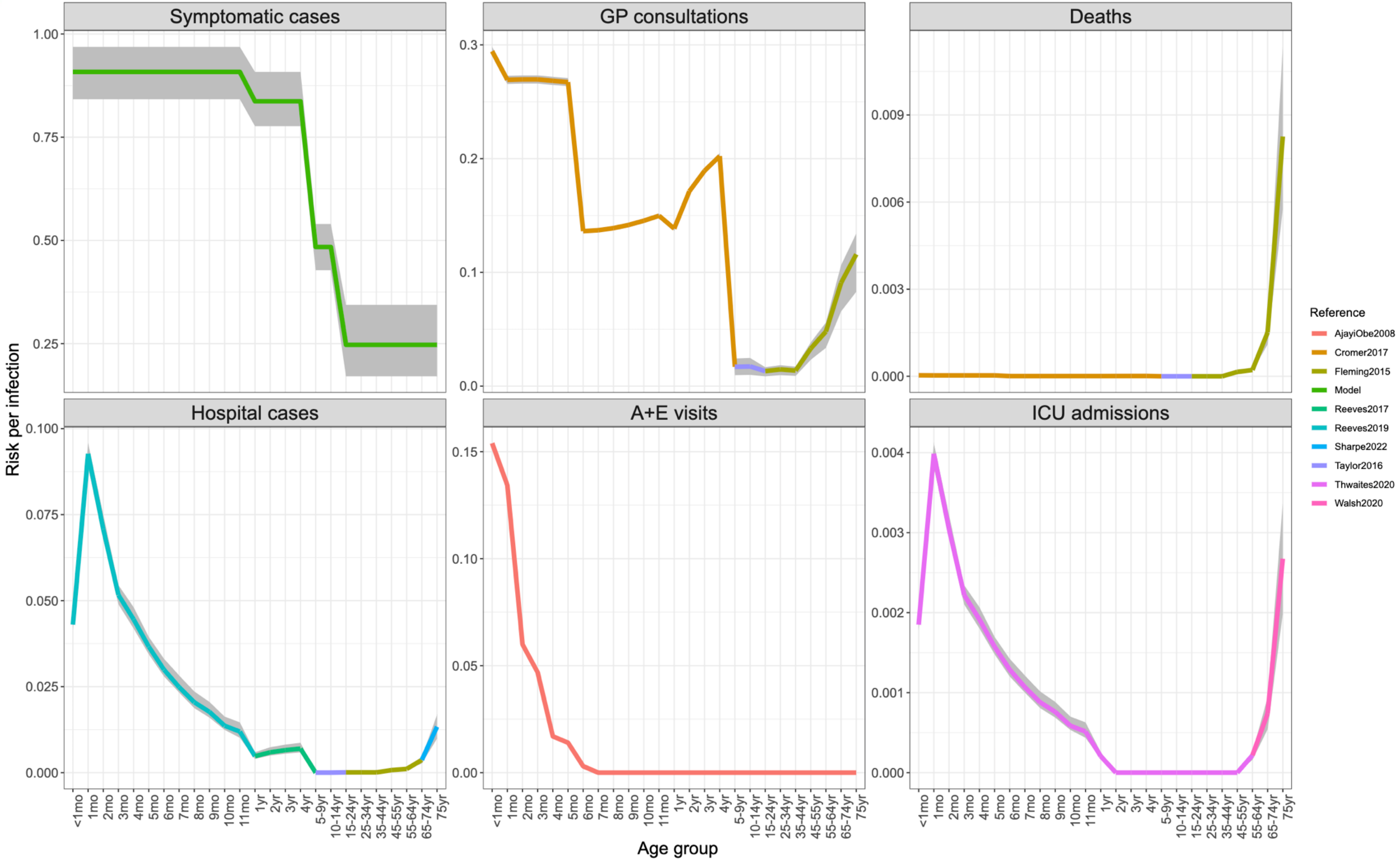
ICU
- Thwaites et al. 2020 *Eur J Pediatr*
- **Walsh et al. 2022 *Health Sci Rep***

A+E
- Ajayi-Obe et al. 2008 *Epidemiol Infect*

Deaths
- Cromer et al. 2017 *Lancet Public Health*
- **Li et al. 2023 *Infect Dis Ther***

Risks of healthcare outcomes

Risk per infection: outcome incidence/ model predicted incidence



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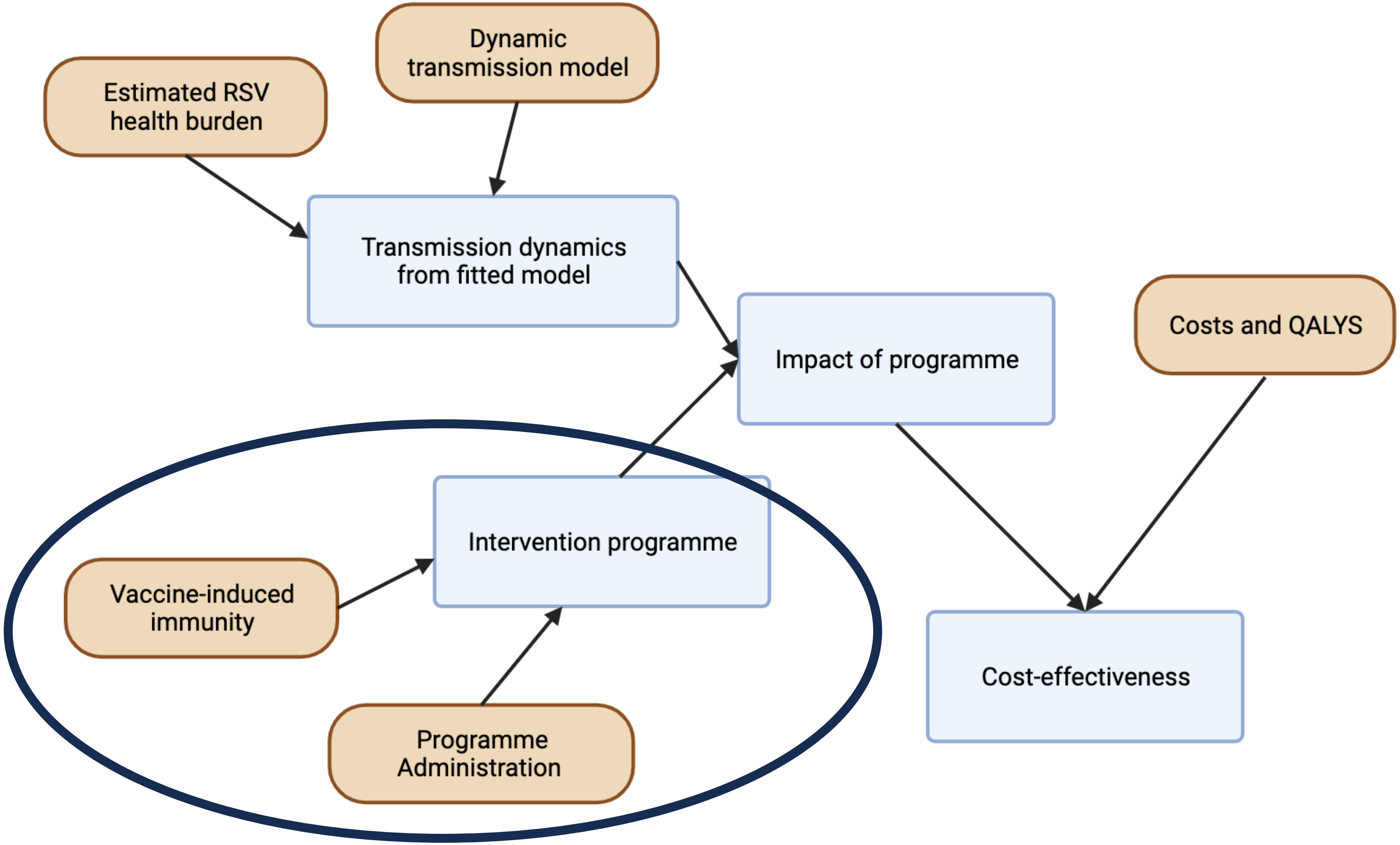
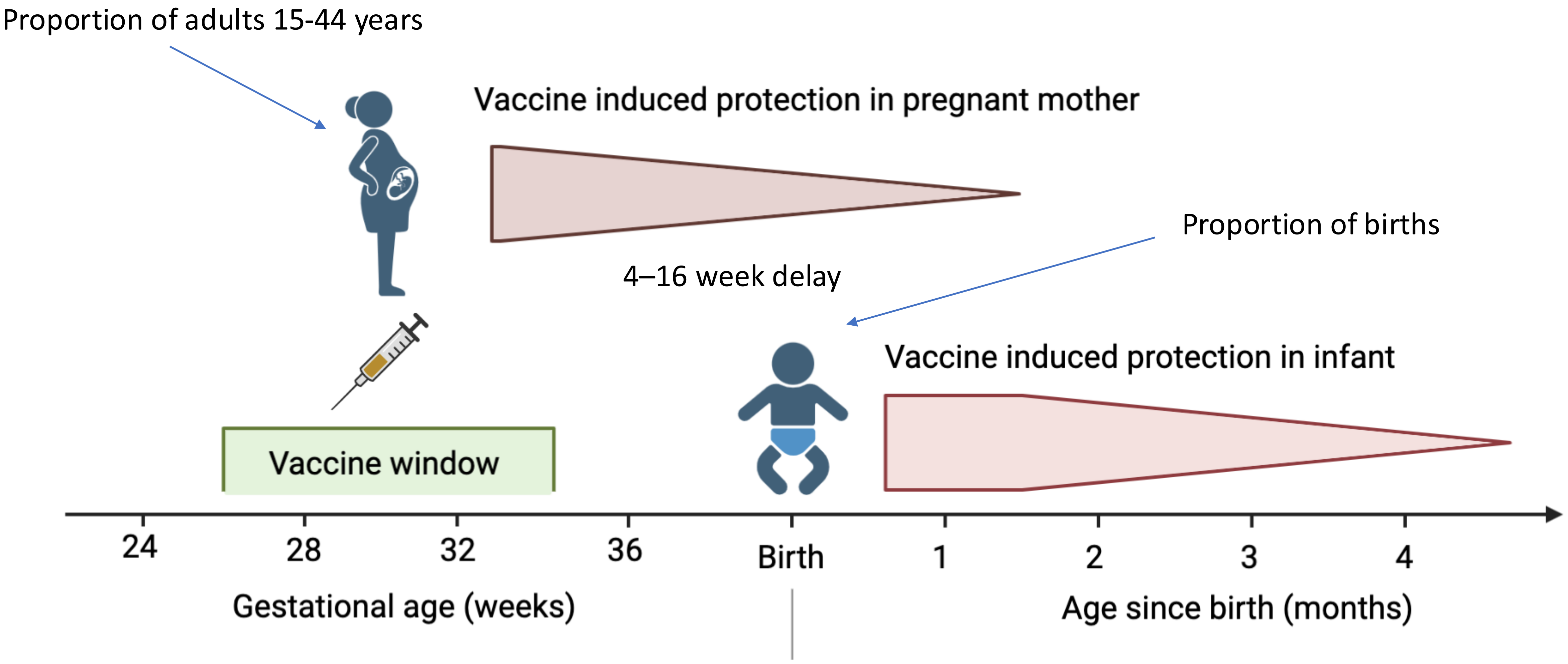
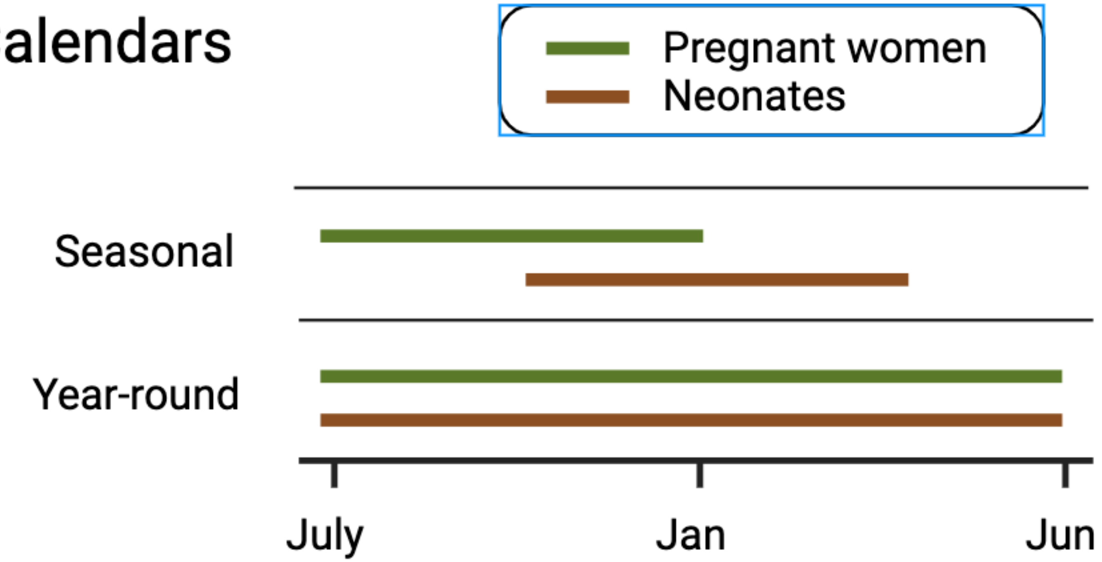


Modelling maternal vaccination (conceptually)



Modelling maternal vaccination (implementation)

Calendars



Coverage in pregnant women (%)

	Flu	Pertussis
2022/23	35.0	–
2021/22	37.9	60.0
2020/21	43.7	65.0
2019/20	43.6	73

Base assumption: **60% (50-90)**

Modelling maternal vaccination (implementation)

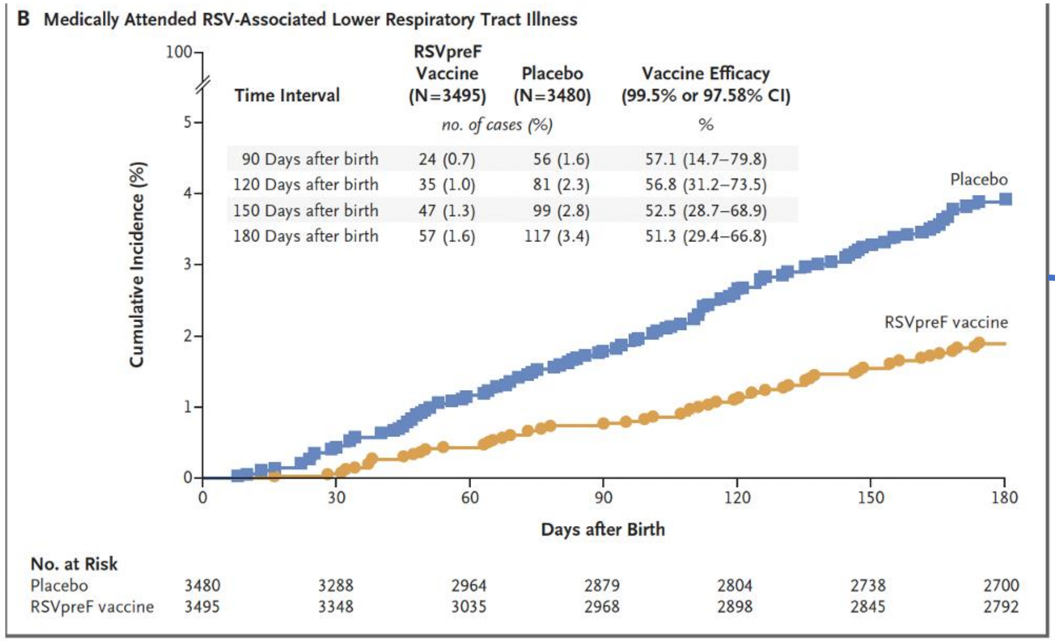
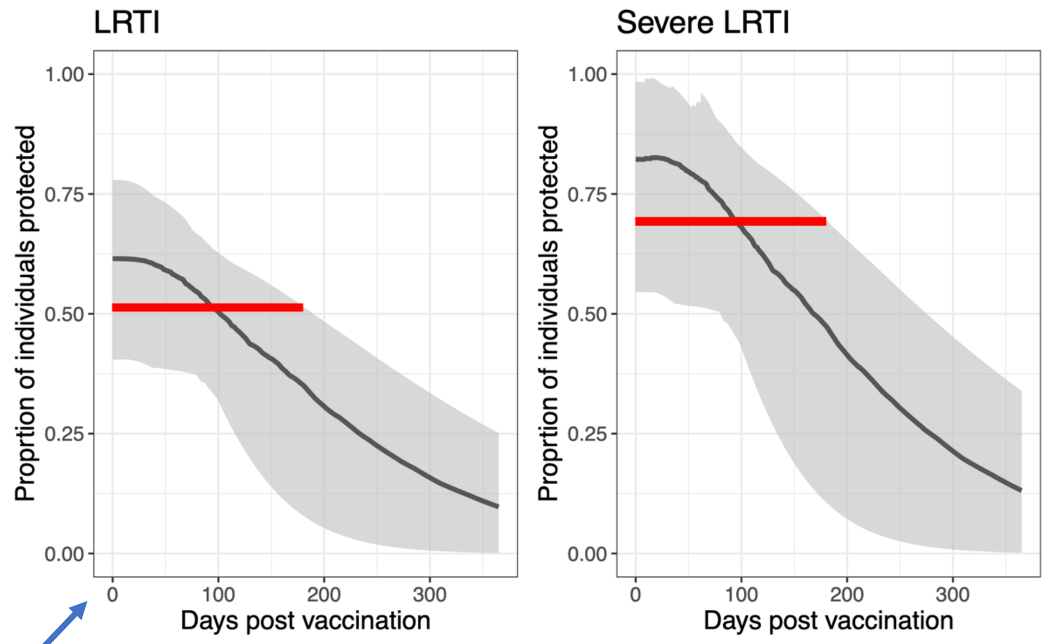


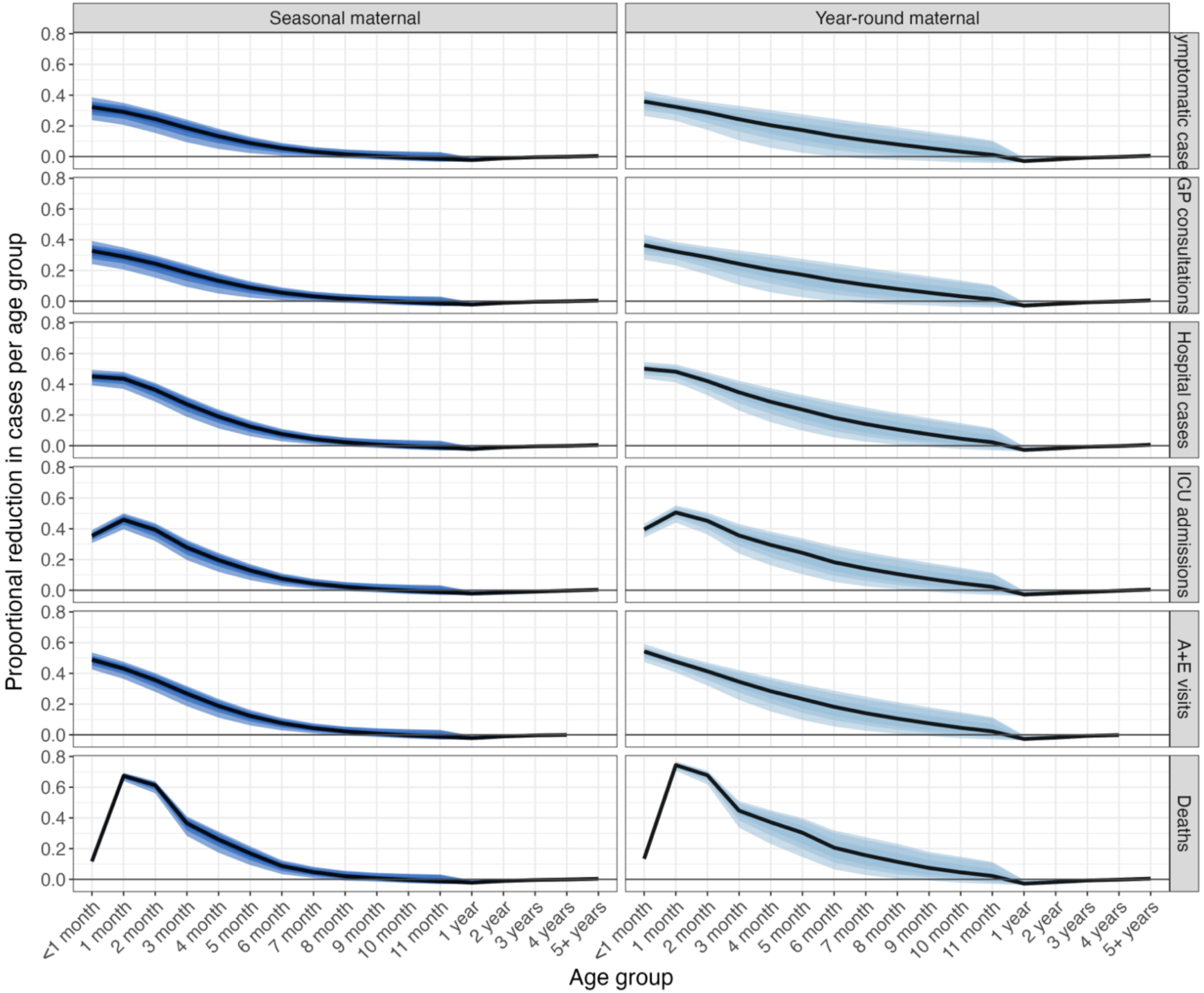
Figure 4. Figure 1b, taken from [Kampmann2023]. The Kaplan-Meier plots show the efficacy of RSVPreF3 vaccine in preventing Medically Attended RSV-Associated Lower Respiratory Tract Illness in infants.



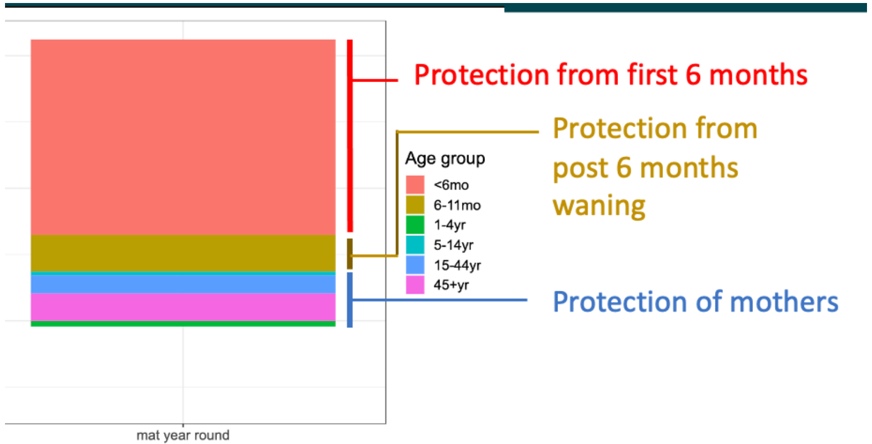
0.093 (95% 0.001–0.237) of infants still have protection 365 days after vaccination.

Health outcome	Efficacy e_d (point-estimate, 180 days)	Disease protection proportion (f_d)
Infection	51.3%	0
Symptomatic	51.3%	0
GP consultations	51.3%	0
A + E attendances	69.4%	0.35
Hospital admission	69.4%	0.35
ICU admissions	69.4%	0.35
Death	69.4%	0.35

Impact of MV programmes

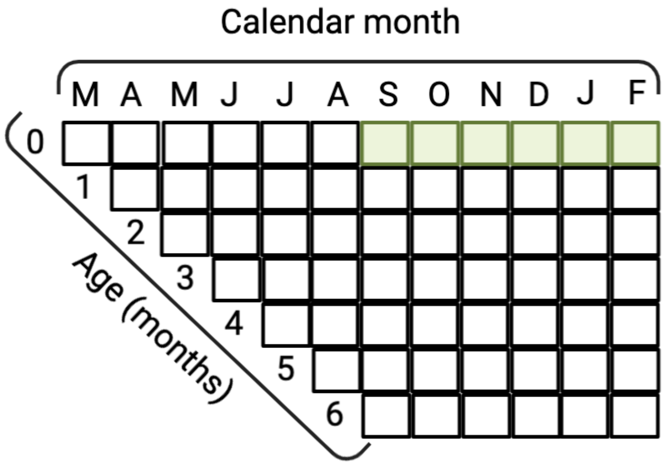


Metric	Annual number of cases averted seasonal (mean, 95% CrI)	Annual number of cases averted year-round (mean, 95% CrI)
Symptomatic	64,079 (39,999-91,887)	94,754 (44,705-152,103)
GP cons.	15,225 (10,324-20,700)	20,705 (11,261-31,570)
A + E visit	11,307 (8,508-14,257)	16,284 (10,300-22,663)
Hospital cases	5,162 (4,154-5,979)	6,587 (4,939-8,092)
ICU admissions	264 (220-303)	333 (252-408)
Deaths	13 (11-15)	15 (11-20)

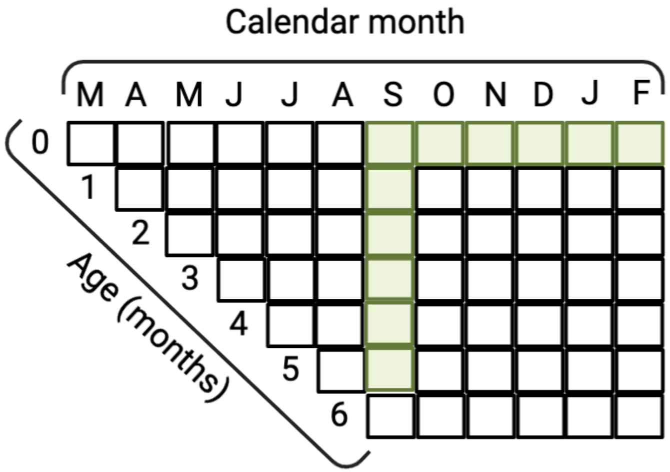


Modelling monoclonal antibodies (implementation)

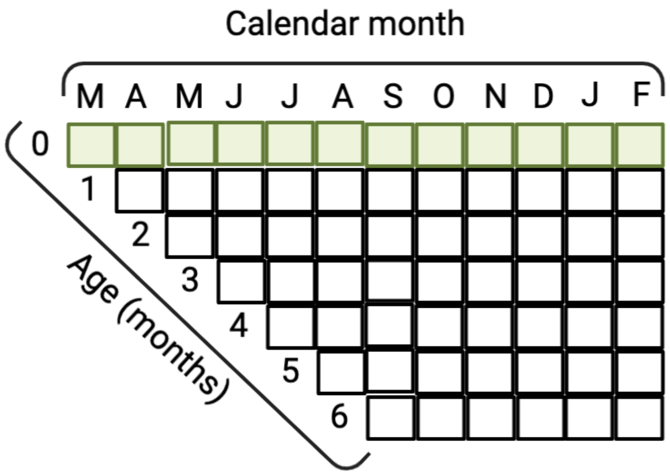
SEASONAL



SEASONAL + ANNUAL CATCH-UP



YEAR ROUND



Coverage: 90% (*as Vitamin K*) (**range: 70–90**)

Modelling la-mAB (implementation)

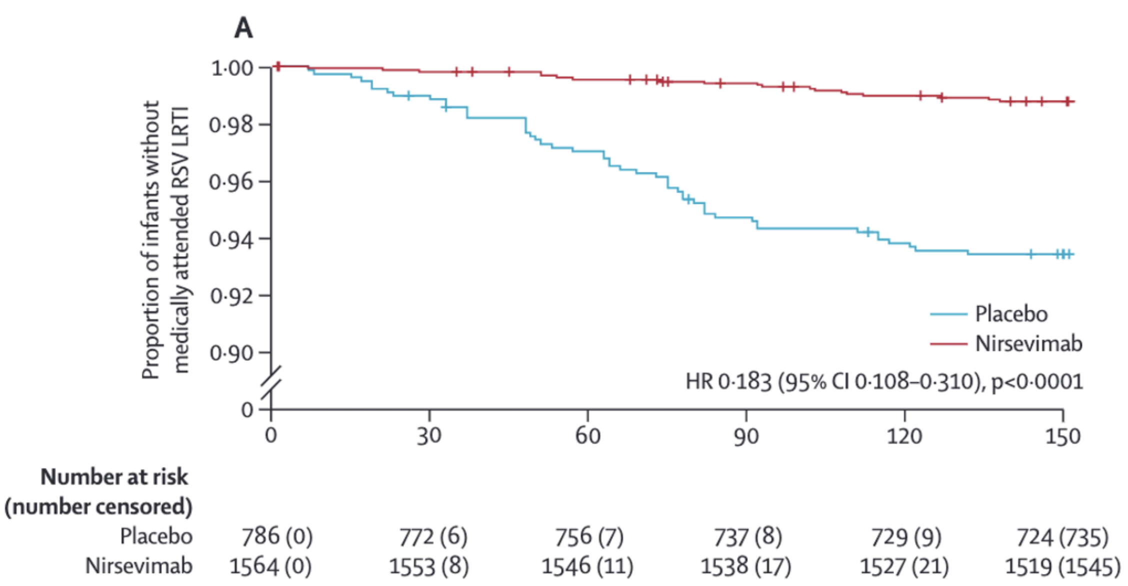
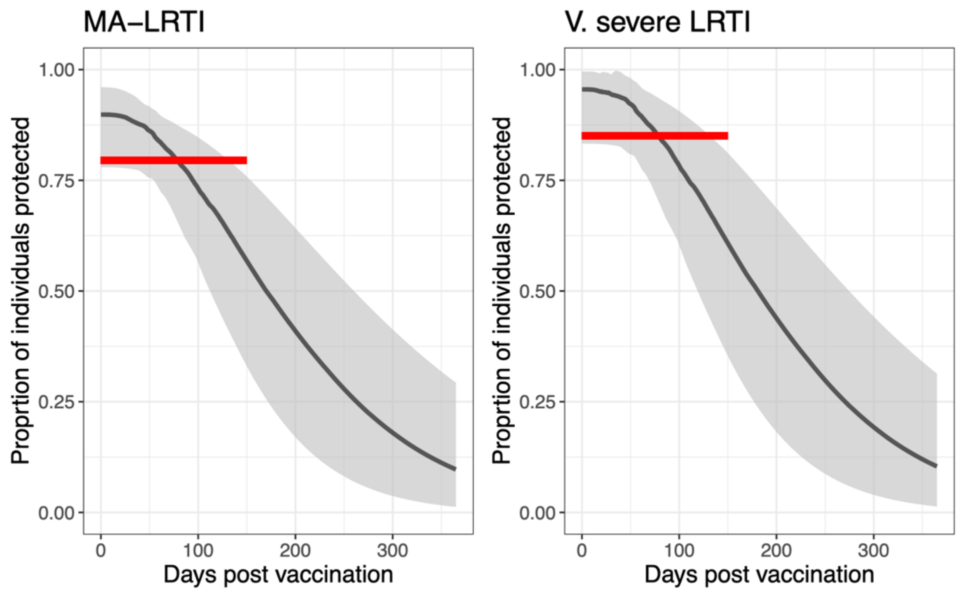


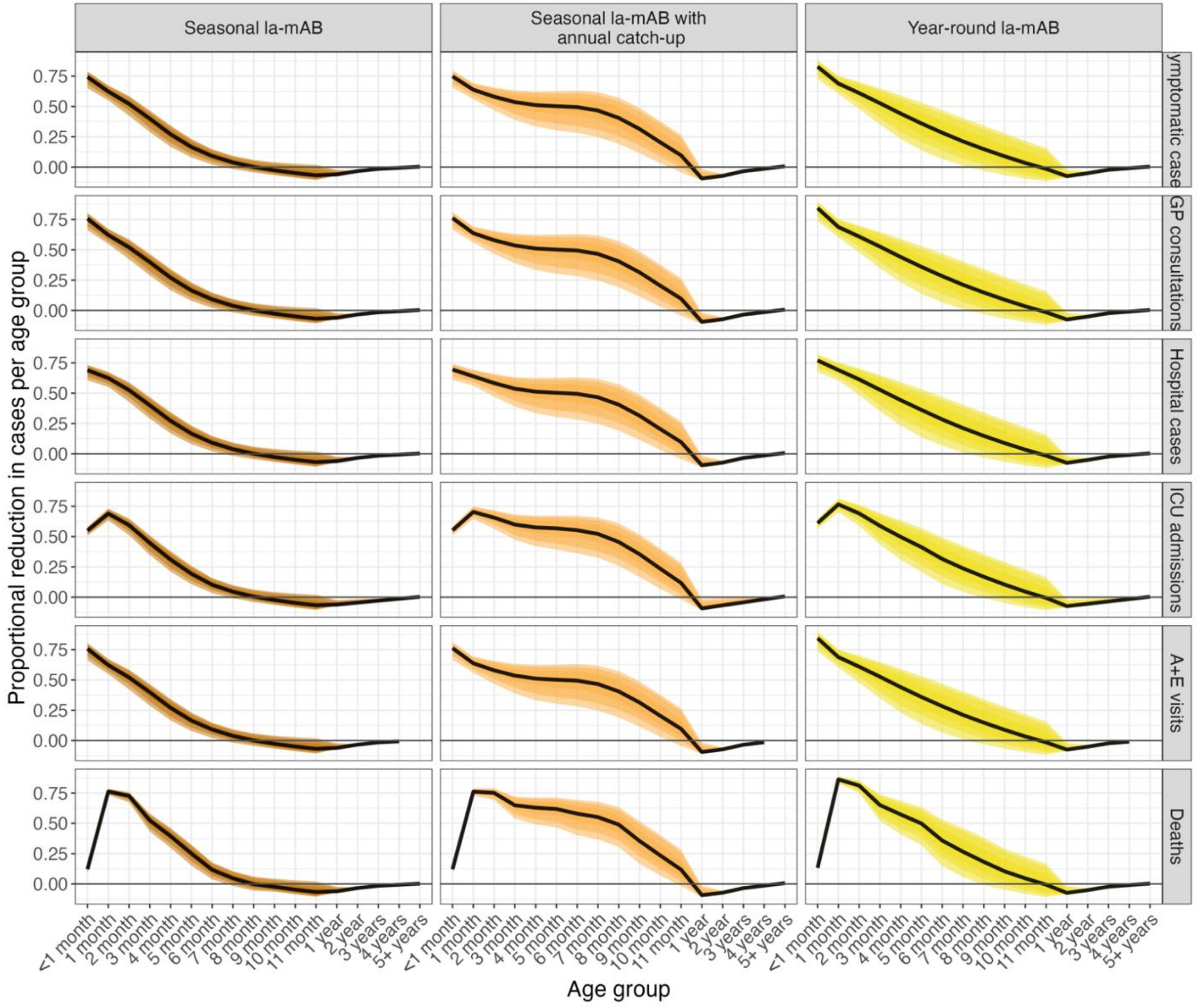
Figure 7. Figure 1A, taken from [Simoes2023]. The Kaplan-Meier plots show the efficacy of Nirsevimab in preventing Medically Attended RSV-Associated Lower Respiratory Tract Illness in infants.



0.148 (95% 0.015–0.338) of infants still have protection 365 days after vaccination.

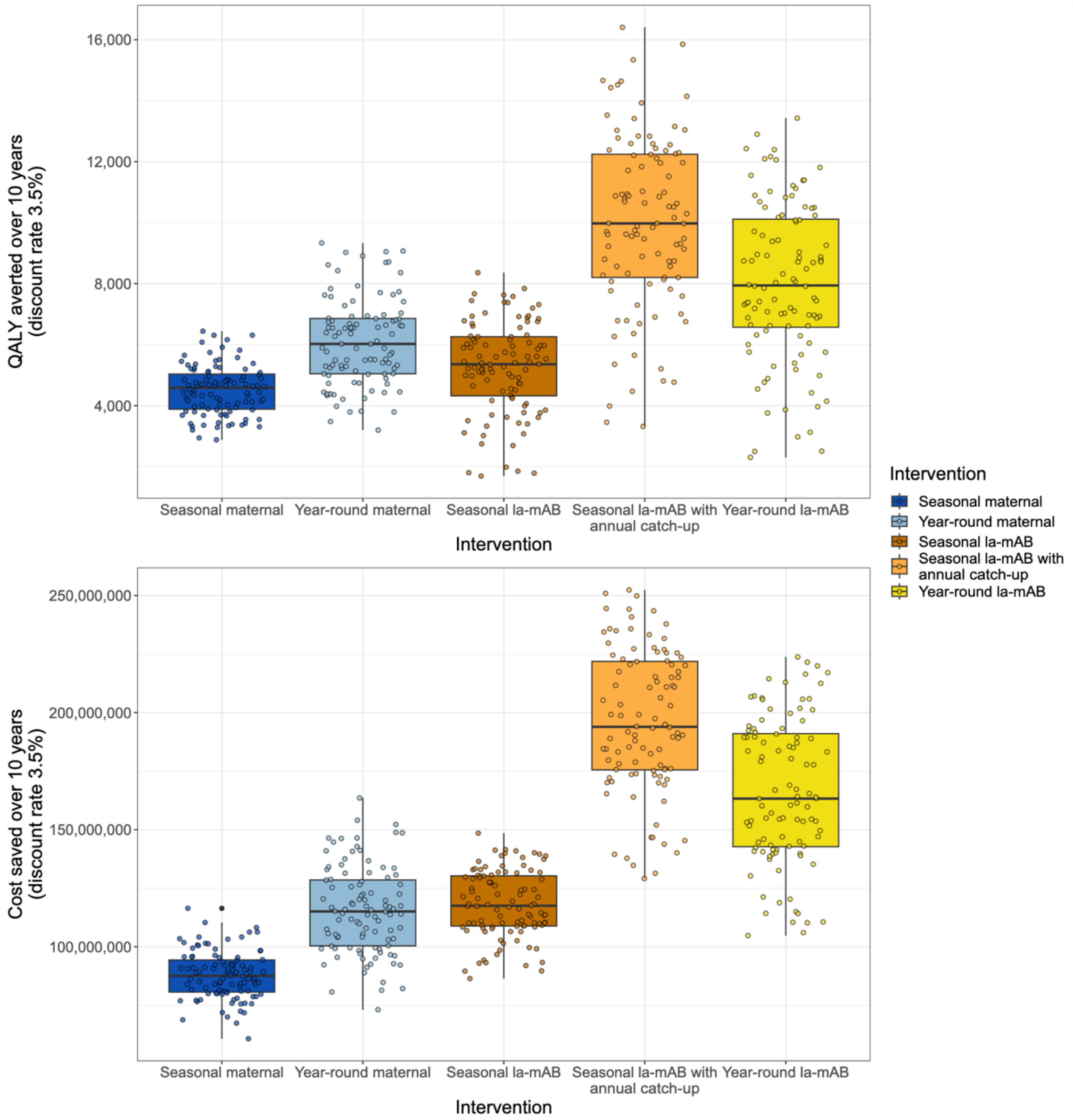
Health outcome	Efficacy e_d (point-estimate, 180 days)	Disease protection proportion (f_d)
Infection	79.5%	0
Symptomatic	79.5%	0
GP consultations	79.5%	0
A + E attendances	79.5%	0
Hospital admission	79.5%	0
ICU admissions	86.0%	0.08
Death	86.0%	0.08

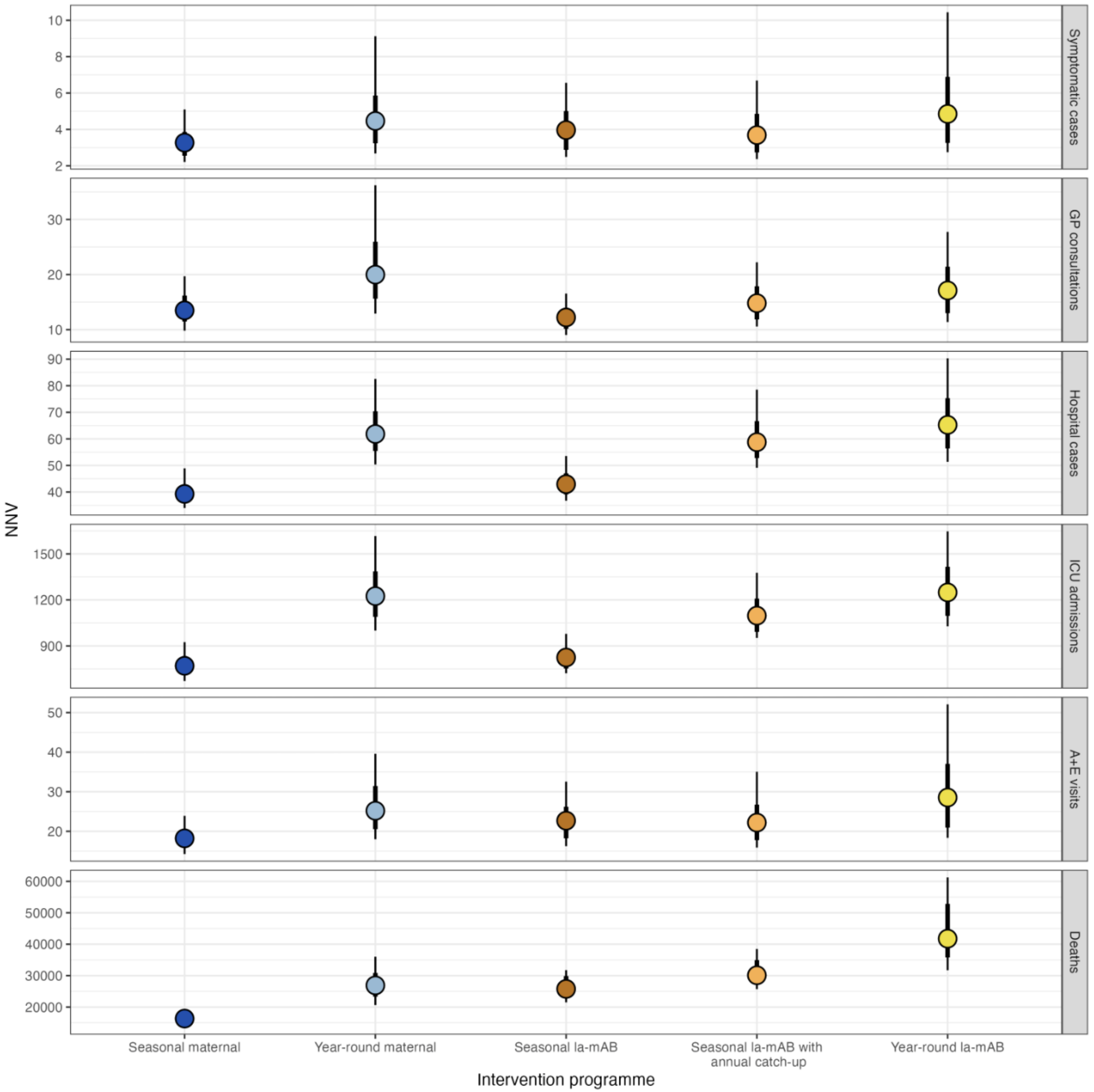
Modelling la-mAB (implementation)



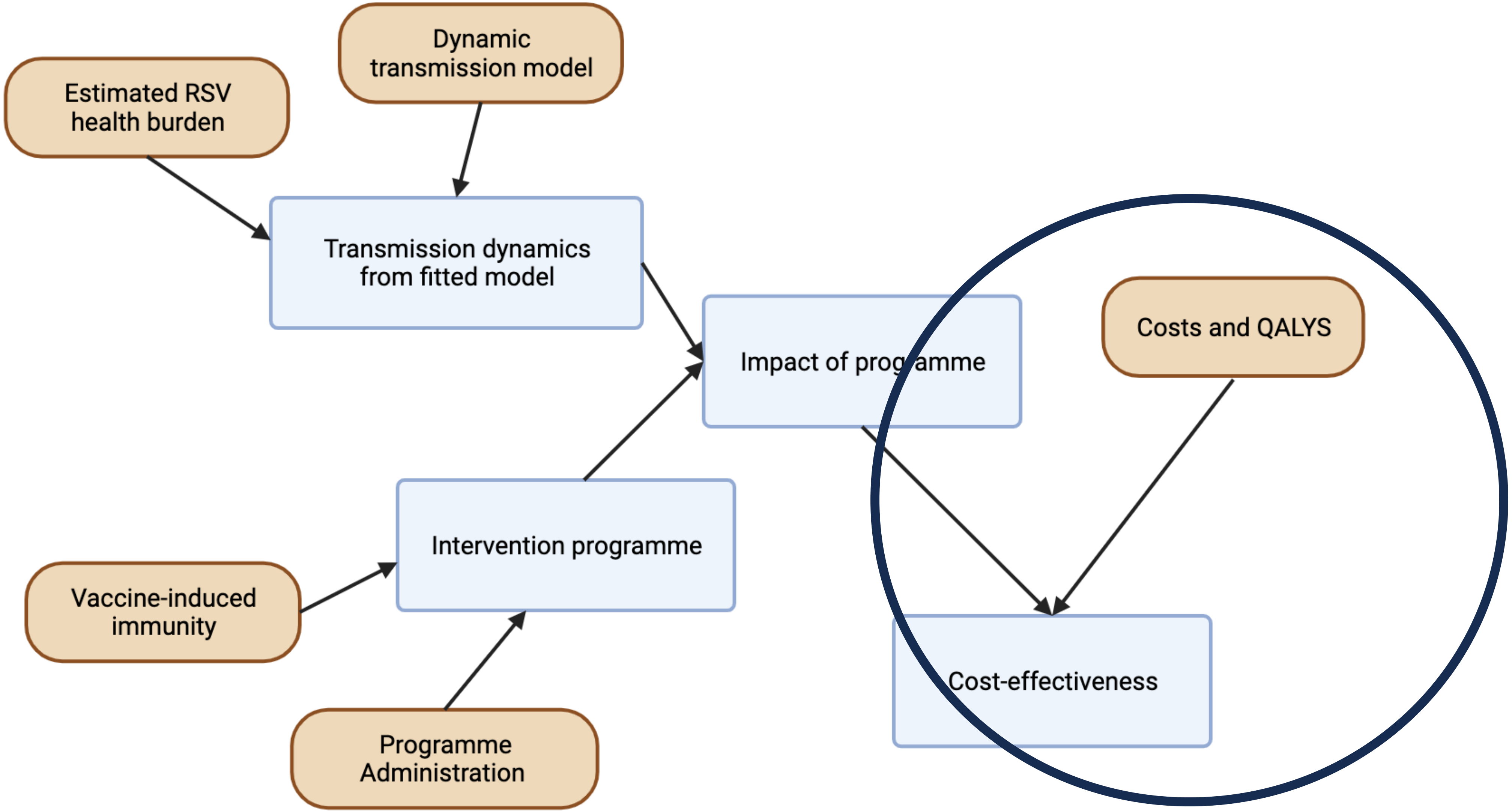
Metric	Annual number of cases averted seasonal (la-mAB) (mean, 95% CrI)	Annual number of cases averted seasonal (la-mAB) + annual catch-up (mean, 95% CrI)	Annual number of cases averted year-round (la-mAB) (mean, 95% CrI)
Symp.	82660 (47095-124161)	176110 (93511-263758)	136835 (59448-225610)
GP cons.	26102 (18677-34211)	43283 (28118-59113)	37606 (22342-54421)
A + E visit	14137 (9494-19032)	28881 (17837-39319)	22631 (11904-33786)
Hospital cases	7171 (5771-8414)	10549 (7958-12720)	9562 (6864-12066)
ICU admissions	377 (316-428)	570 (454-656)	499 (376-603)
Deaths	12 (10-14)	20 (16-24)	15 (10-20)

Comparison of impact





Overview of project



Economic parameters

QALY LOSS

SUBGROUP	QALY LOSS	REFERENCE
< 5 years Symptomatic	2.336×10^{-3} (0.269×10^{-3}–9.255×10^{-3})	Hodgson et al. 2020
≥5 years symptomatic	1.448×10^{-3} (0.135×10^{-3}–5.928×10^{-3})	
< 5 years hospitalisations	4.098×10^{-3} (0.624×010^{-3}–13.141×10^{-3})	
≥5 years hospitalisations	2.990×10^{-3} (0.346×10^{-3}–11.387×10^{-3})	

COSTS

GP consultations:

- £36. *Unit costs manual*

A + E Visits:

- **£182.28**. *National schedule of NHS costs (T0_)*

Hospital cases

	MEDIAN RSV-RELATED HOSPITAL ADMISSION COST (£, 95% CrI)	
AGE GROUP	SHORT-STAY ONLY	SHORT- AND LONG-STAY
<15 years of age	1100.23 (1029.66–1253.16)	1909.86 (1599.19– 3711.22)
>= 15 years of age	652.29 (585.37–740.31)	1753.21 (1233.30– 2739.47)

*Paediatric Acute Bronchiolitis with CC Score 0–5+ (PD15A–PD15D). *National schedule of NHS costs*

*Unspecified Acute Lower Respiratory Infection with/without Interventions 0–13+ (DZ22K–DZ22Q). *National schedule of NHS costs*

ICU admissions

AGE GROUP	MEDIAN RSV-RELATED ICU ADMISSION COST (£, 95% CrI)
<15 years of age	2905.20 (2282.80–3862.67)
>= 15 years of age	2324.80 (1948.25–2653.25)

* Paediatric Critical Care, Advanced Critical Care 1–5 (XB01Z–XB07Z). *National schedule of NHS costs*

*Adult Critical Care, 0–6+ Organs Supported (XC01Z–XC07Z).

Cost-effectiveness analysis

Cost-effectiveness analysis conducted according to NICE guidelines:

- Cost from perspective of NHS only (GBP)
- Health burden in QALYs
- 3.5% annual discount rate, 10-year time horizon
- ICER threshold at £20,000/QALY

Algorithm to determine most cost-effective programme (for a MC sample)

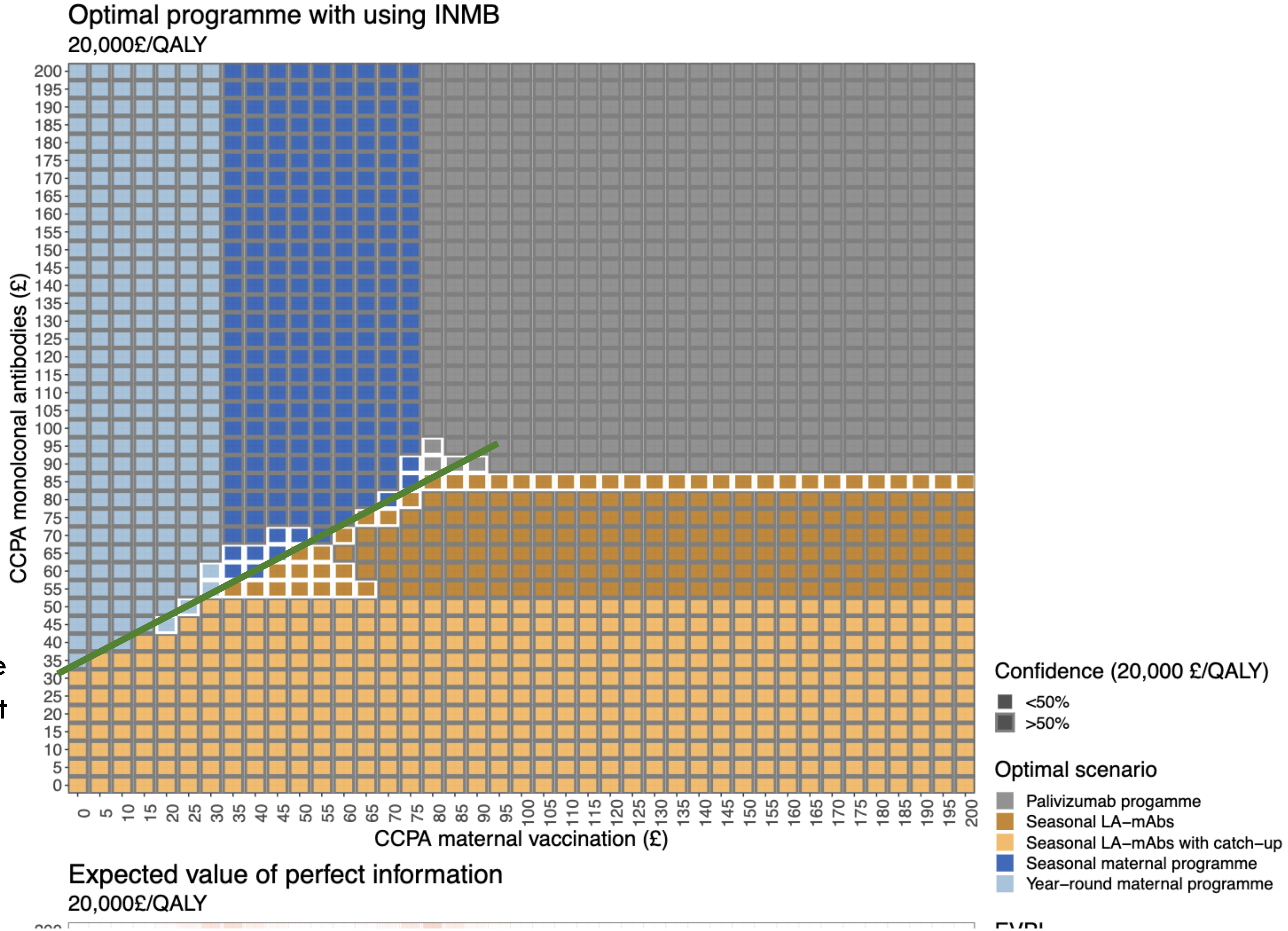
- A CCPA is picked for maternal vaccination (£0–200) + monoclonal antibodies (£0–200)
- Calculate costs (implementation + healthcare costs) for all five intervention programmes
- Calculate the INMB of each programme compared to Palivizumab only
- The programme with the greatest INMB is the most cost-effective programme

Blicke, Beutels 2022, *Med Decis Making*

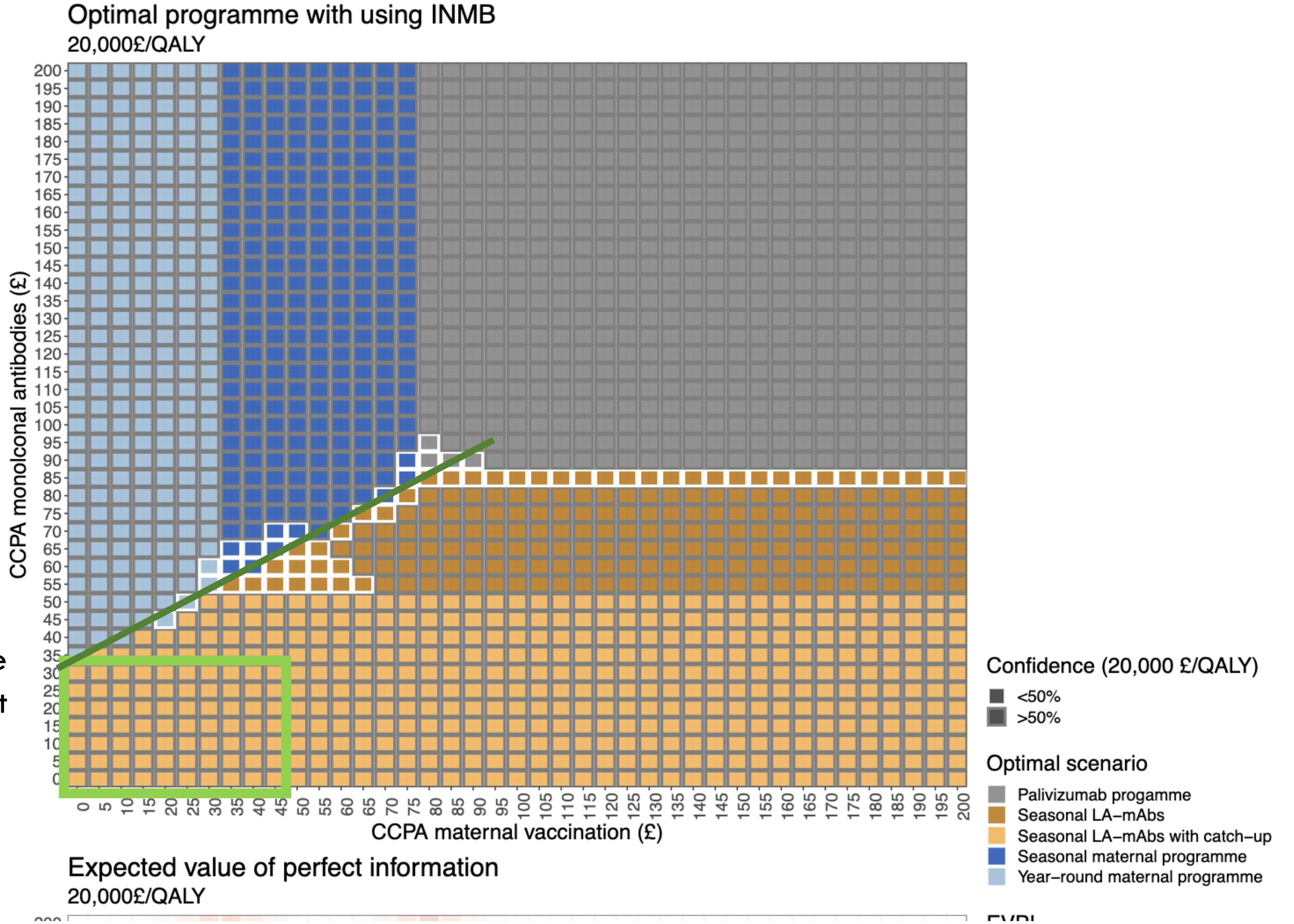
CCPA = cost of buying and administration of product per dose
NMB = (Incremental health gain) * 20000 – (Incremental cost gain)

Cost-effectiveness analysis

Product equivalence gradient



Cost-effectiveness analysis



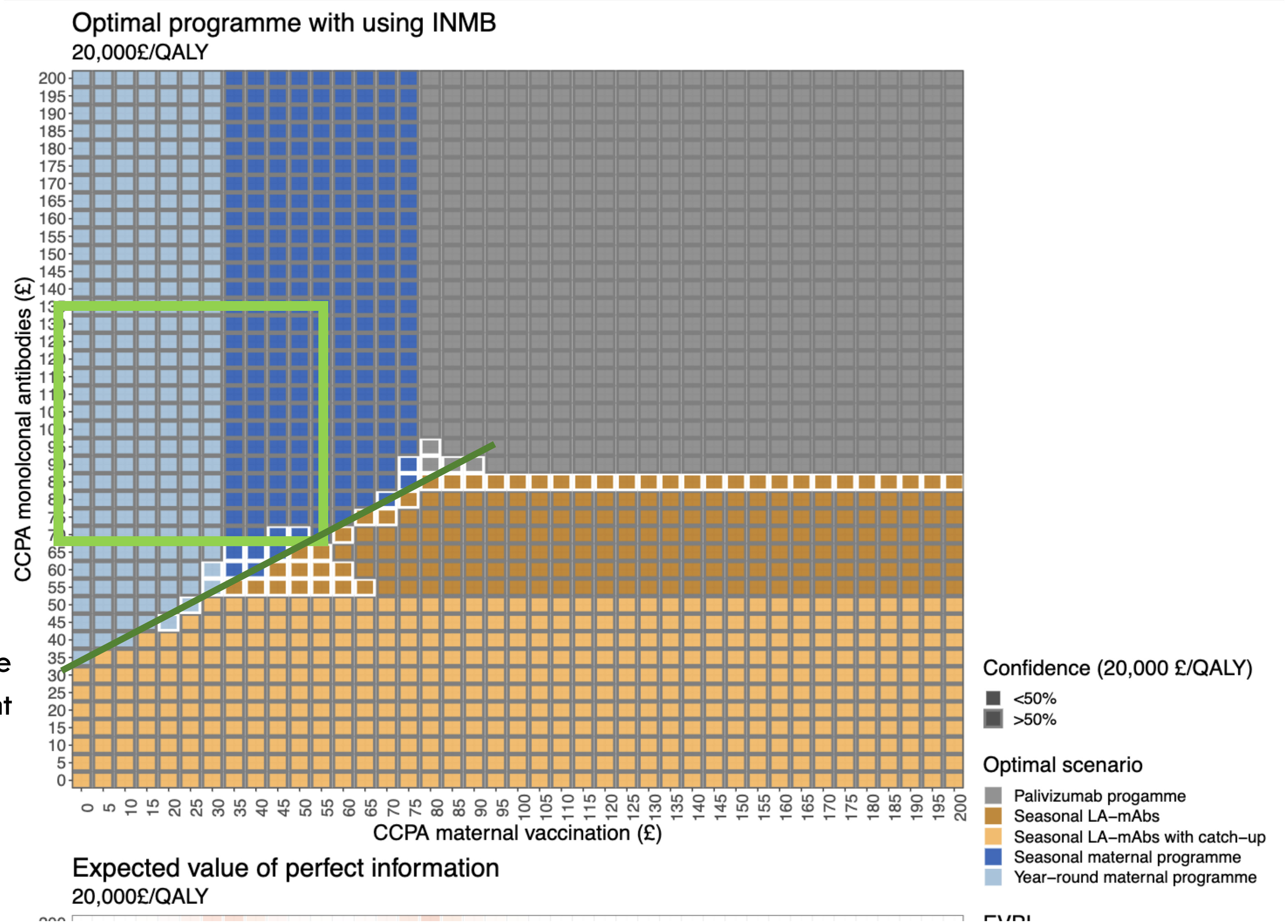
Product equivalence gradient

If both are priced low then monoclonal better

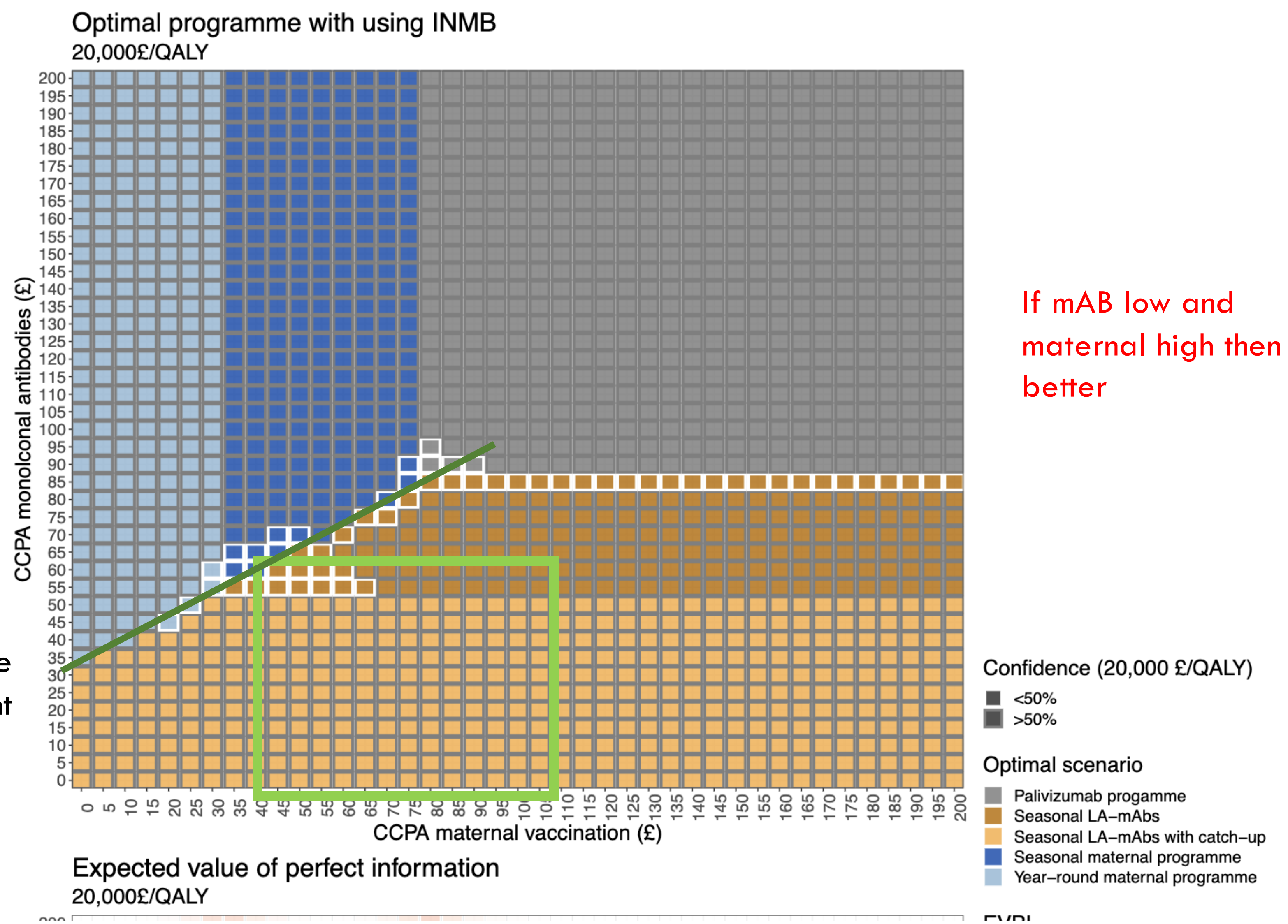
Cost-effectiveness analysis

If mAB high and maternal low then maternal better

Product equivalence gradient



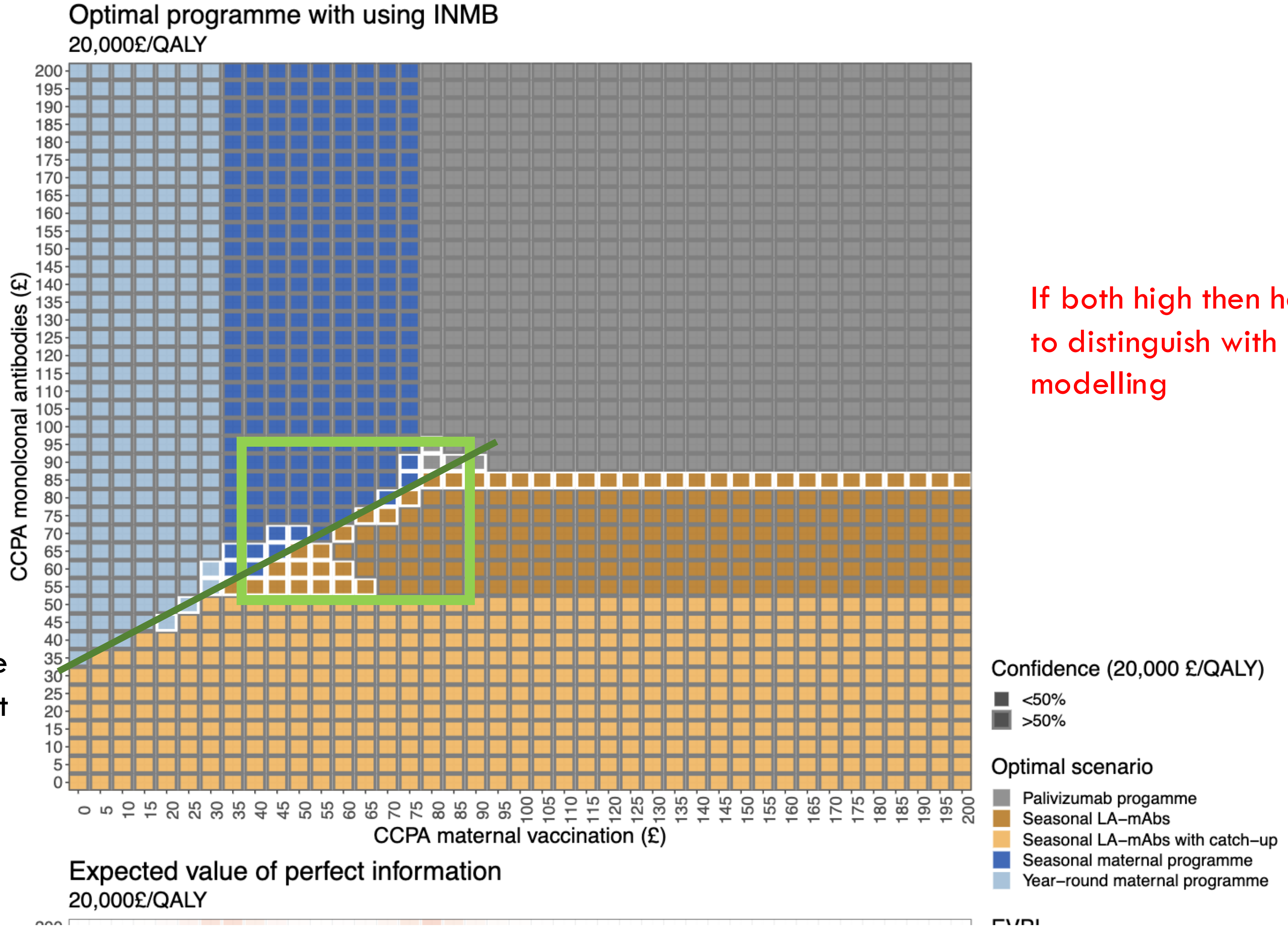
Cost-effectiveness analysis



Product equivalence gradient

If mAB low and maternal high then mAB better

Cost-effectiveness analysis



If both high then hard to distinguish with modelling

Product equivalence gradient

Take homes from modelling + cost-effectiveness

Maternal vaccine programme

- Year-round cost-effective up until £30–35 (to pregnant women, 60% cov)
- Seasonal cost-effective up until £75–80 (July until December pregnant women, 60% cov)

Nirsevimab

- Seasonal + catch-up cost-effective up until £50–55 (to birth, 90% cov)
- Seasonal cost-effective up until £85–90 (September until February to birth, 90% cov)

If priced similarly then difficult to differentiate between the two using CEA

Take homes from modelling + cost-effectiveness

Used to help inform JCVI decision make in June 2023:

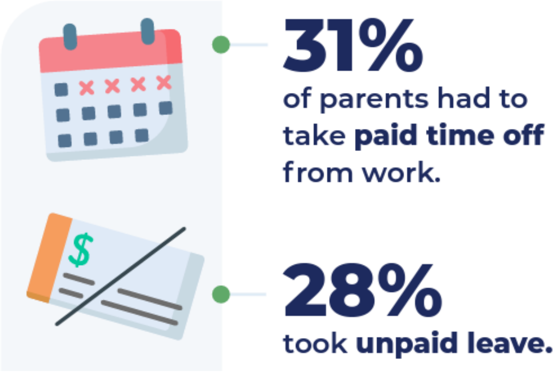
"JCVI advises that both products are suitable for a universal programme to protect neonates and infants from RSV. JCVI does not have a preference for either product and whether a maternal vaccination or a passive immunisation programme should be the programme chosen to protect neonates and infants. Therefore, subject to licensure of the maternal vaccine, both options should be considered for a universal programme."

https://www.gov.uk/government/publications/rsv-immunisation-programme-jcvi-advice-7-june-2023/respiratory-syncytial-virus-rsv-immunisation-programme-jcvi-advice-7-june-2023

Limitations

Priced according to NICE's guidelines

- Healthcare-payers perspective only
    - no societal costs



https://admin.allianceforpatientaccess.org/wp-content/uploads/2023/01/AfPA-and-NCfIH_The-Indirect-Impact-of-RSV_Survey-Report_Jan-2023.pdf

Potential impacts on other respiratory diseases, particularly IPD

- HARMONIE IIIB study shows 54% reductions in ALL LRTD-respiratory disease

https://www.globenewswire.com/news-release/2023/05/12/2667568/0/en/Press-Release-Nirsevimab-delivers-83-reduction-in-RSV-infant-hospitalizations-in-a-real-world-clinical-trial-setting.html

Acceptability between products

Monoclonal never given at birth before, is 90% too high?

Maternal vaccination coverage varies (40–80%)

Looked at many different coverage assumptions when informing policy

Acknowledgements

Model development

Dr. Katie Atkins
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Dr. Jasmina Panovska-Griffiths

Prof Mark Jit
Prof Stefan Flasche

Further guidance on policy

Dr. Conall Watson
Dr. Edwin van Leeuwen
Dr. Neil Wilkins
Dr. Jonathon Crofts

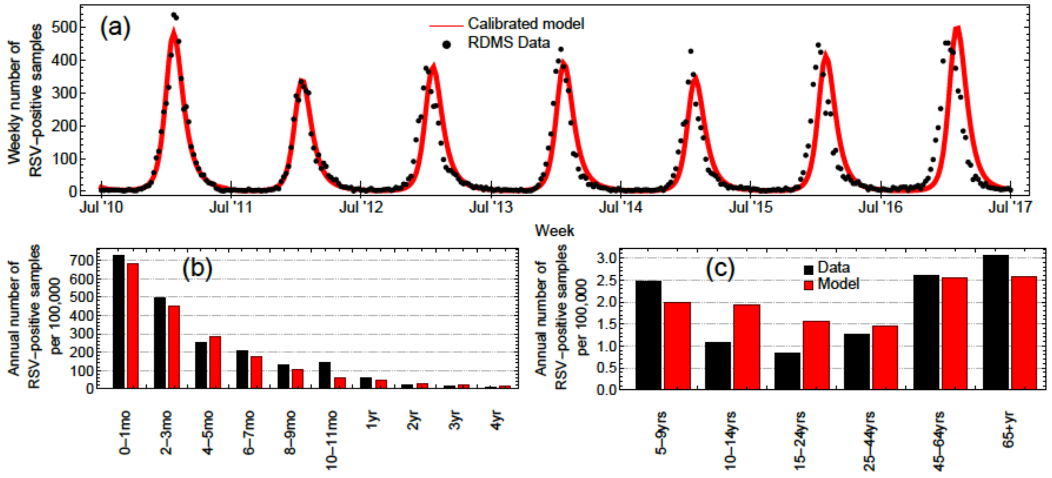
+ Members of the JCVI

Questions?

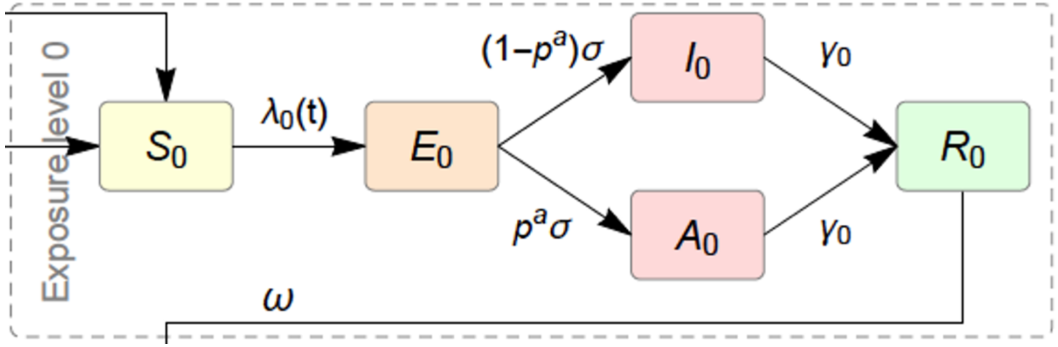
Extra slides

Modelling RSV transmission

SEIRS model fitted to RDMS (RSV positive samples)



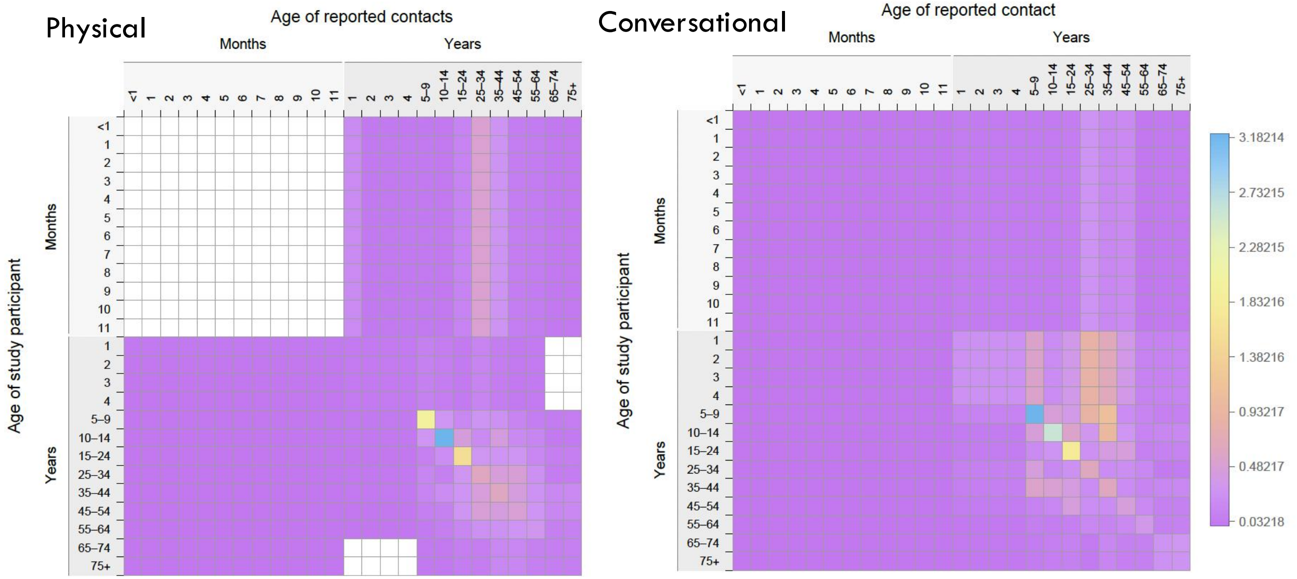
SEIRS model per age group



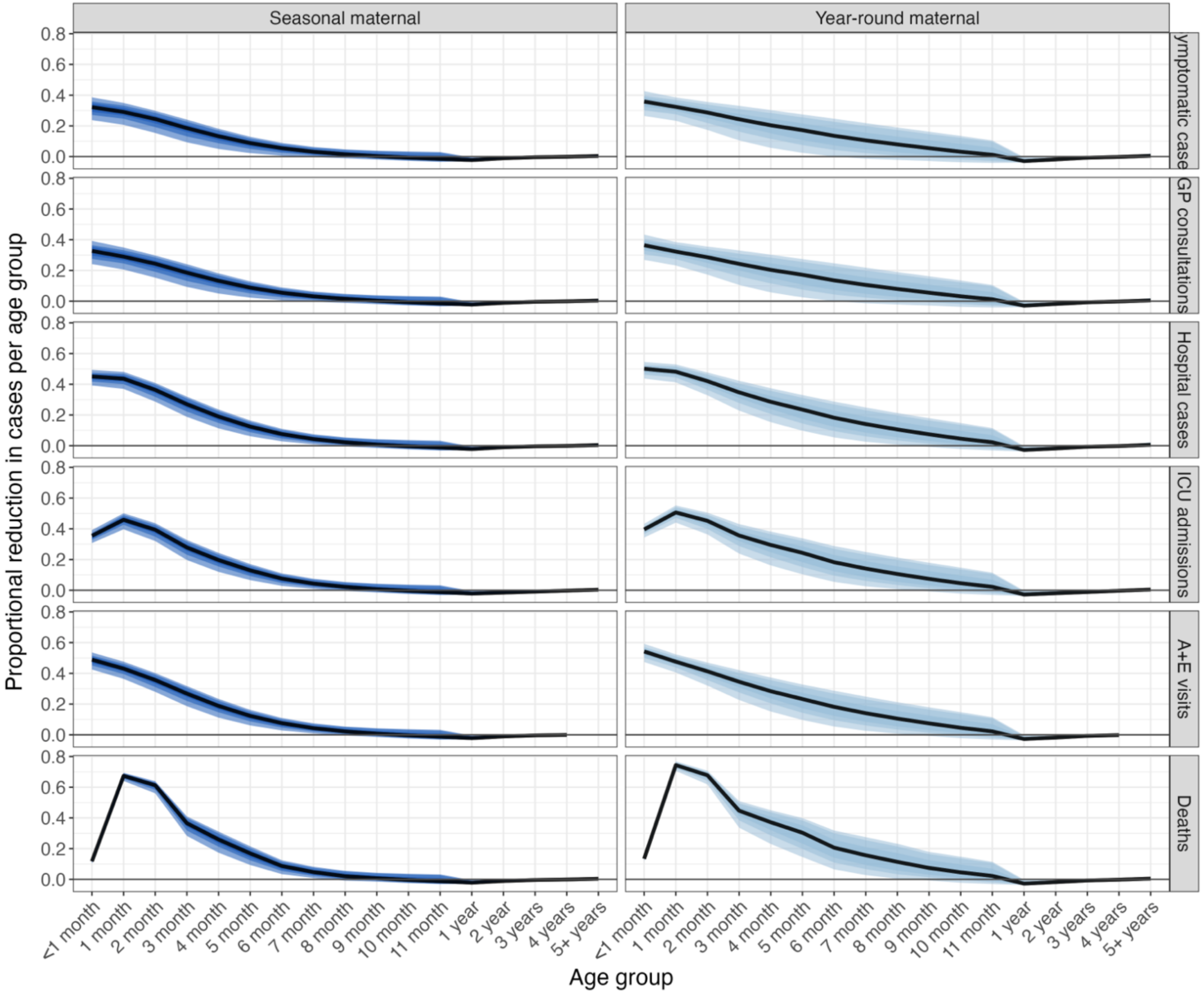
25 age groups:

Monthly up to 11 months, 1, 2, 3, 4, 5-9, 10-14, 15-24, 25-34, 35-44, 45-54, 55-64, 65-74, 75+ years

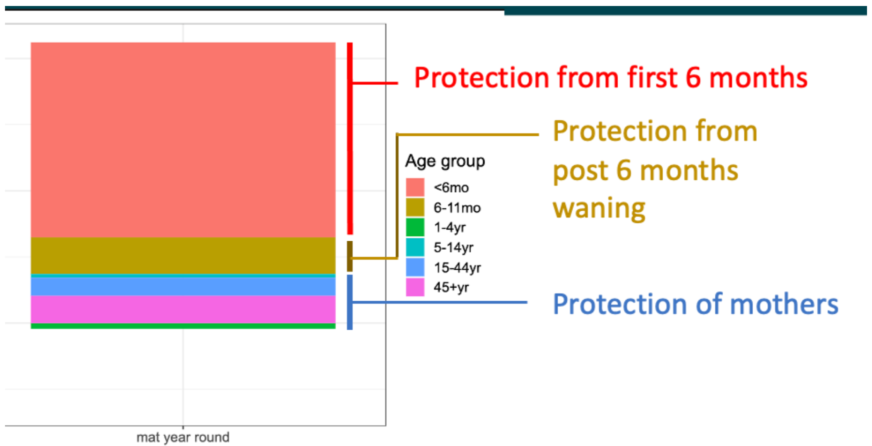
Contact matrix from POLYMOD



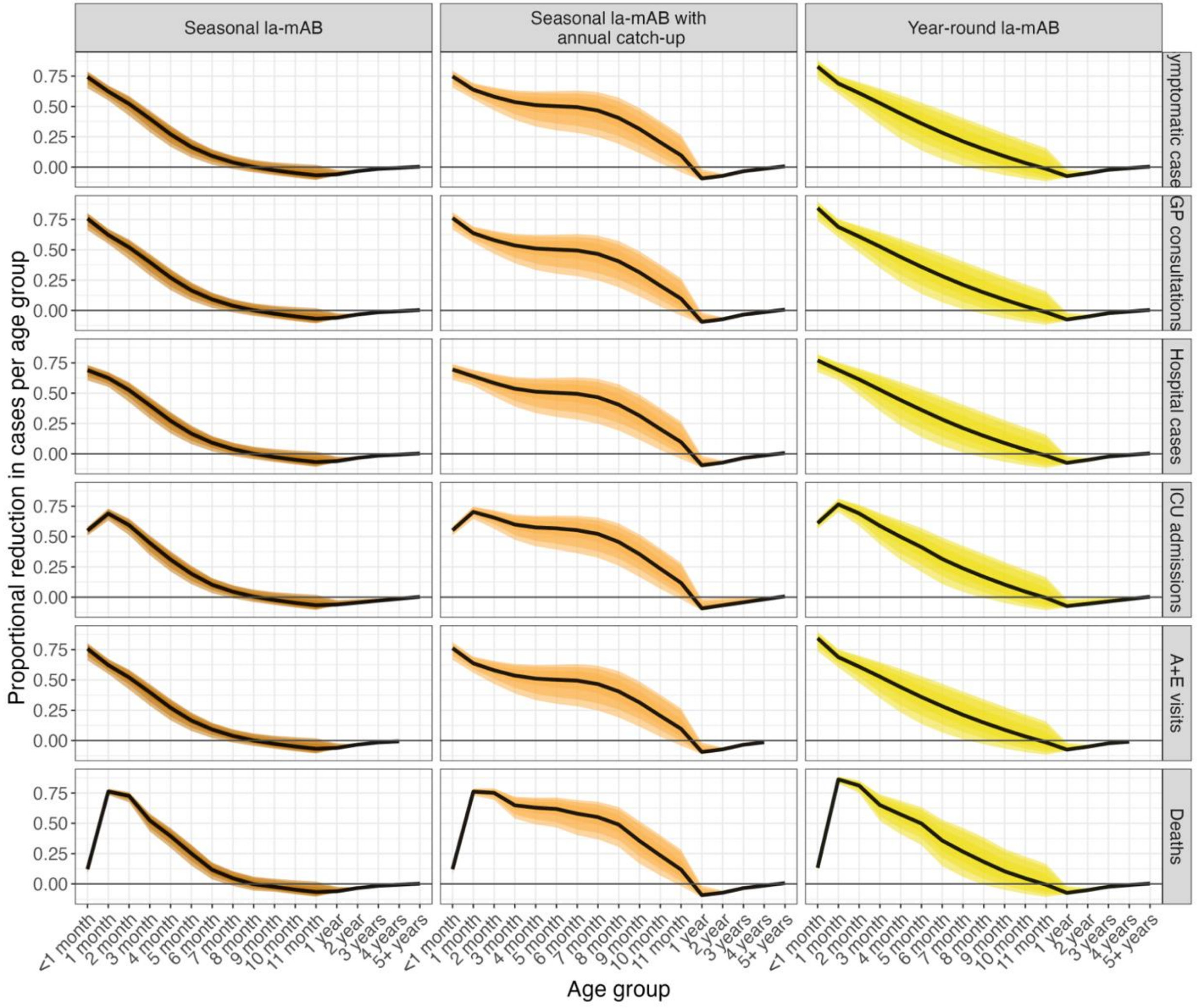
Impact of MV programmes



Metric	Annual number of cases averted seasonal (mean, 95% CrI)	Annual number of cases averted year-round (mean, 95% CrI)
Symptomatic	64,079 (39,999-91,887)	94,754 (44,705-152,103)
GP cons.	15,225 (10,324-20,700)	20,705 (11,261-31,570)
A + E visit	11,307 (8,508-14,257)	16,284 (10,300-22,663)
Hospital cases	5,162 (4,154-5,979)	6,587 (4,939-8,092)
ICU admissions	264 (220-303)	333 (252-408)
Deaths	13 (11-15)	15 (11-20)



Modelling la-mAB (implementation)

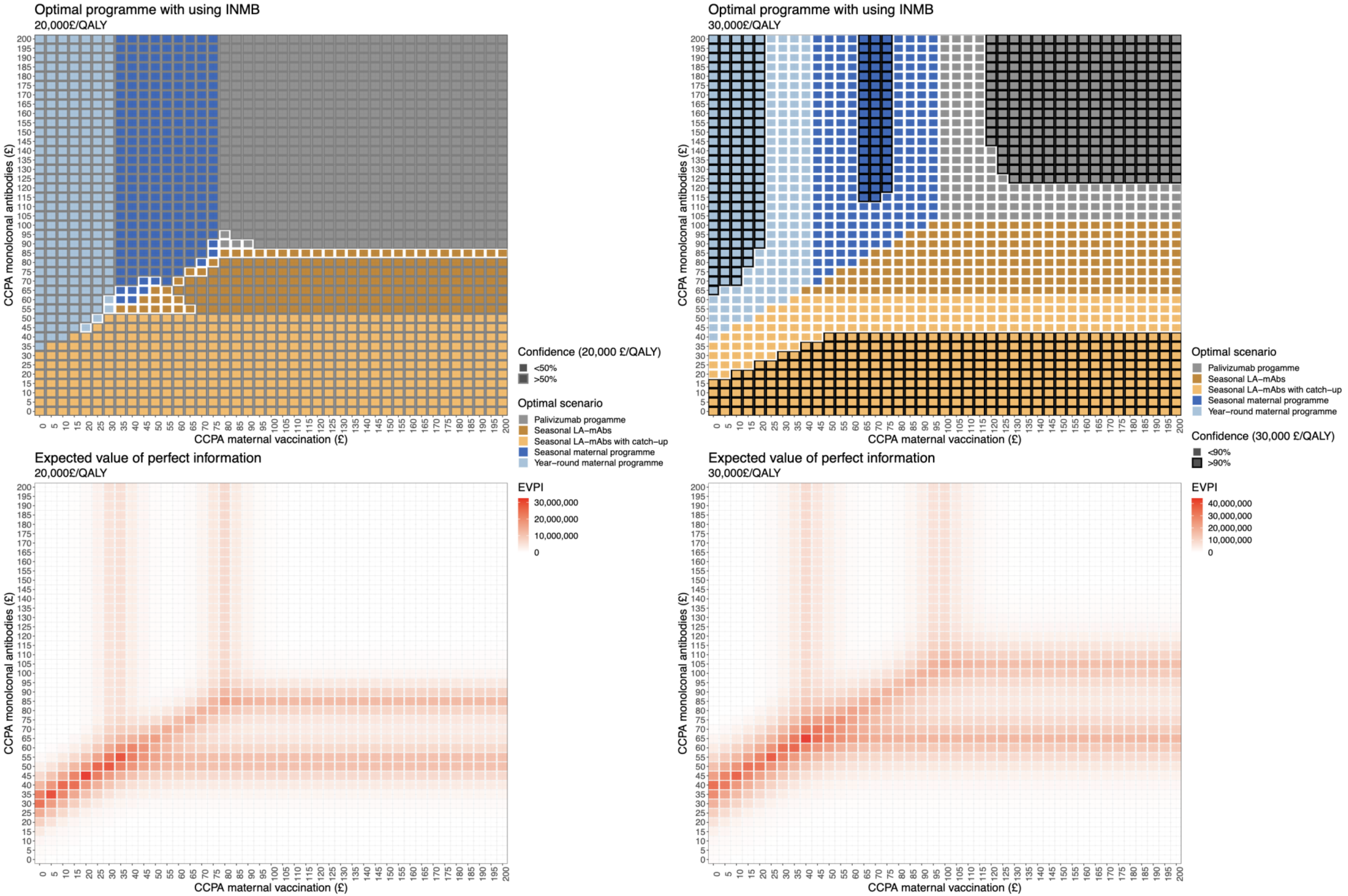


Metric	Annual number of cases averted seasonal (la-mAB) (mean, 95% CrI)	Annual number of cases averted seasonal (la-mAB) + annual catch-up (mean, 95% CrI)	Annual number of cases averted year-round (la-mAB) (mean, 95% CrI)
Symp.	82660 (47095-124161)	176110 (93511-263758)	136835 (59448-225610)
GP cons.	26102 (18677-34211)	43283 (28118-59113)	37606 (22342-54421)
A + E visit	14137 (9494-19032)	28881 (17837-39319)	22631 (11904-33786)
Hospital cases	7171 (5771-8414)	10549 (7958-12720)	9562 (6864-12066)
ICU admissions	377 (316-428)	570 (454-656)	499 (376-603)
Deaths	12 (10-14)	20 (16-24)	15 (10-20)

Short-stay costs

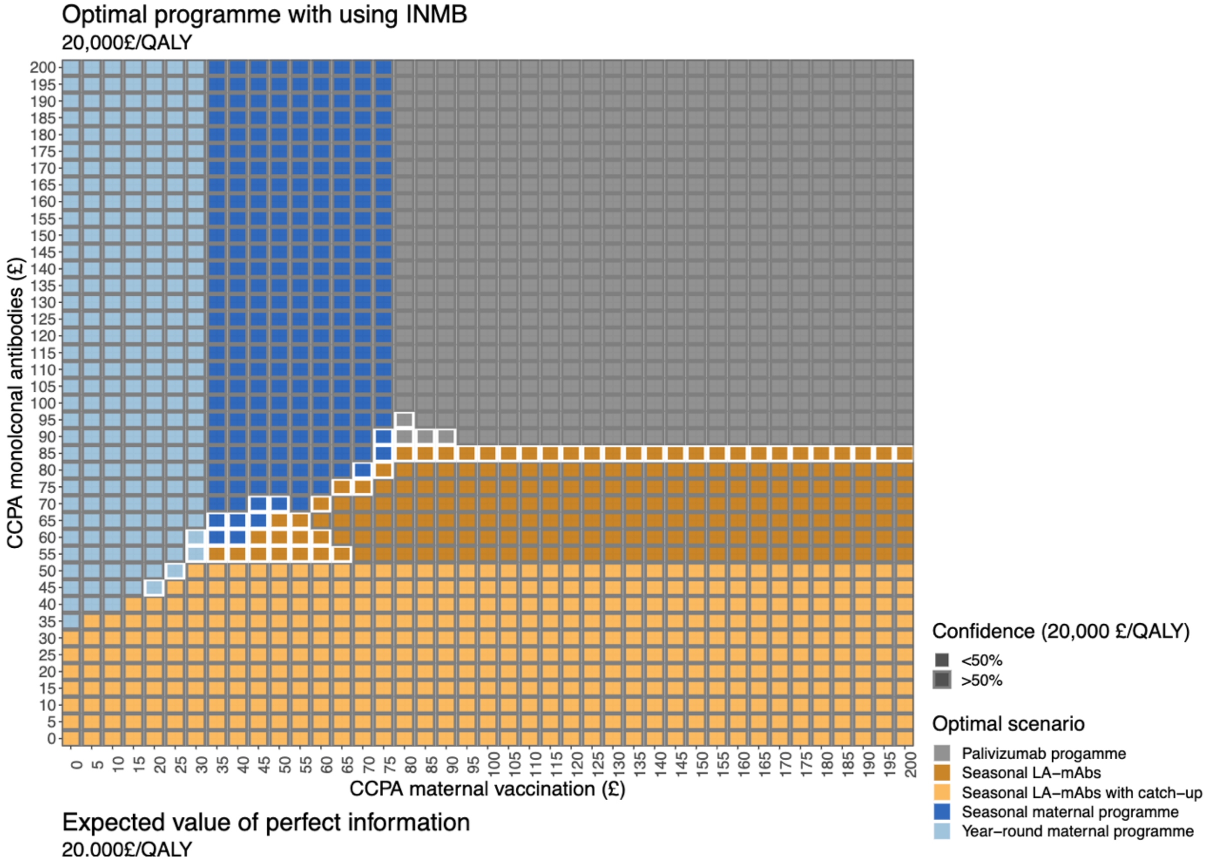
Max £75–80 a dose of maternal vaccine (20k ICER)

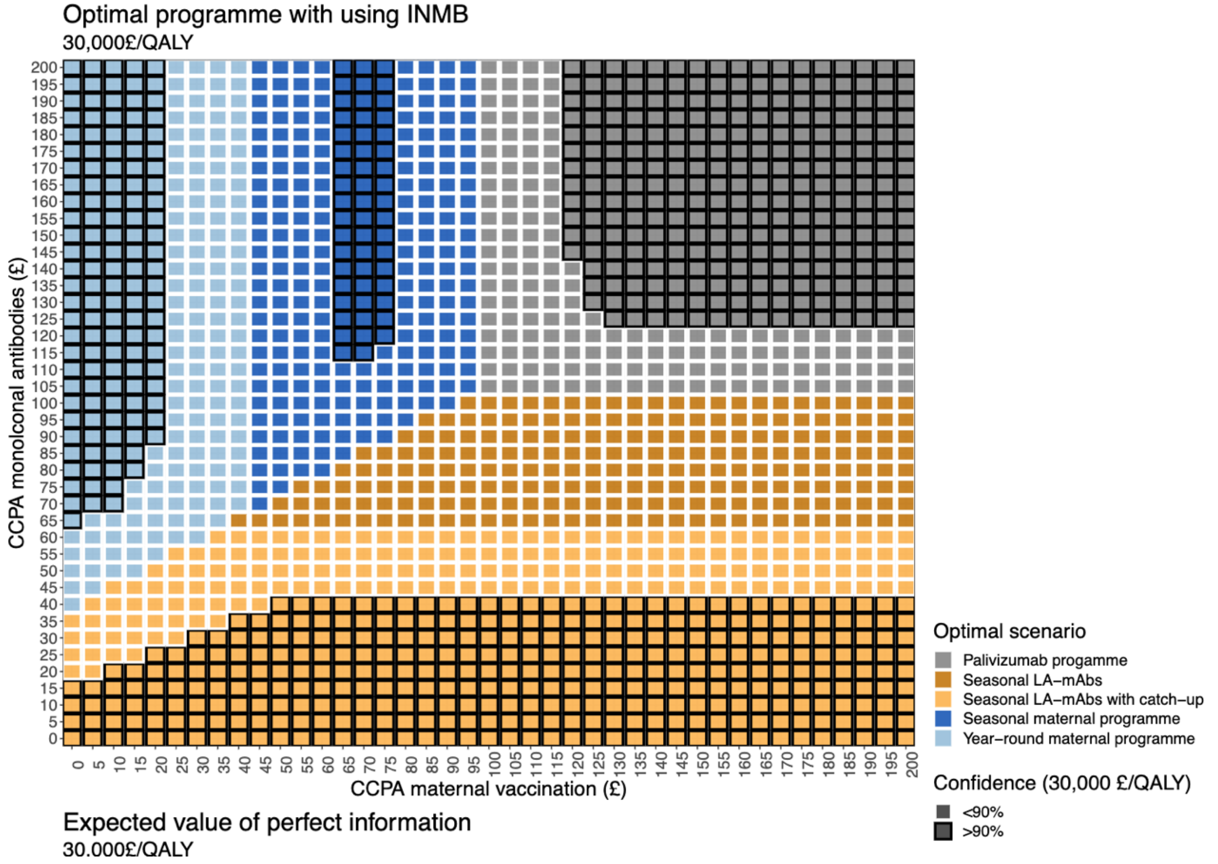
Max £85-90 a dose for LA-mABs (20k ICER)



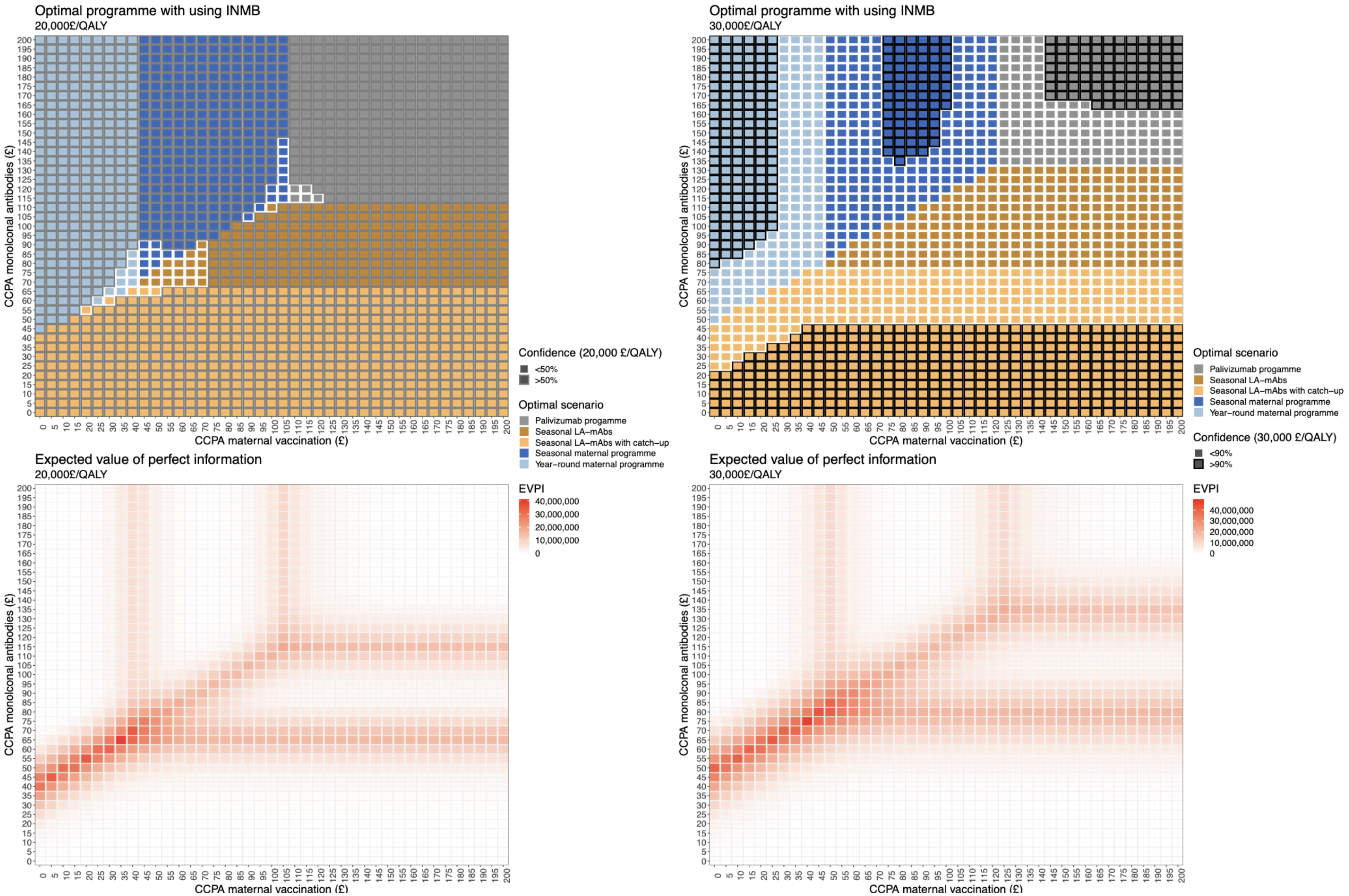
Short-stay costs

More uncertainty

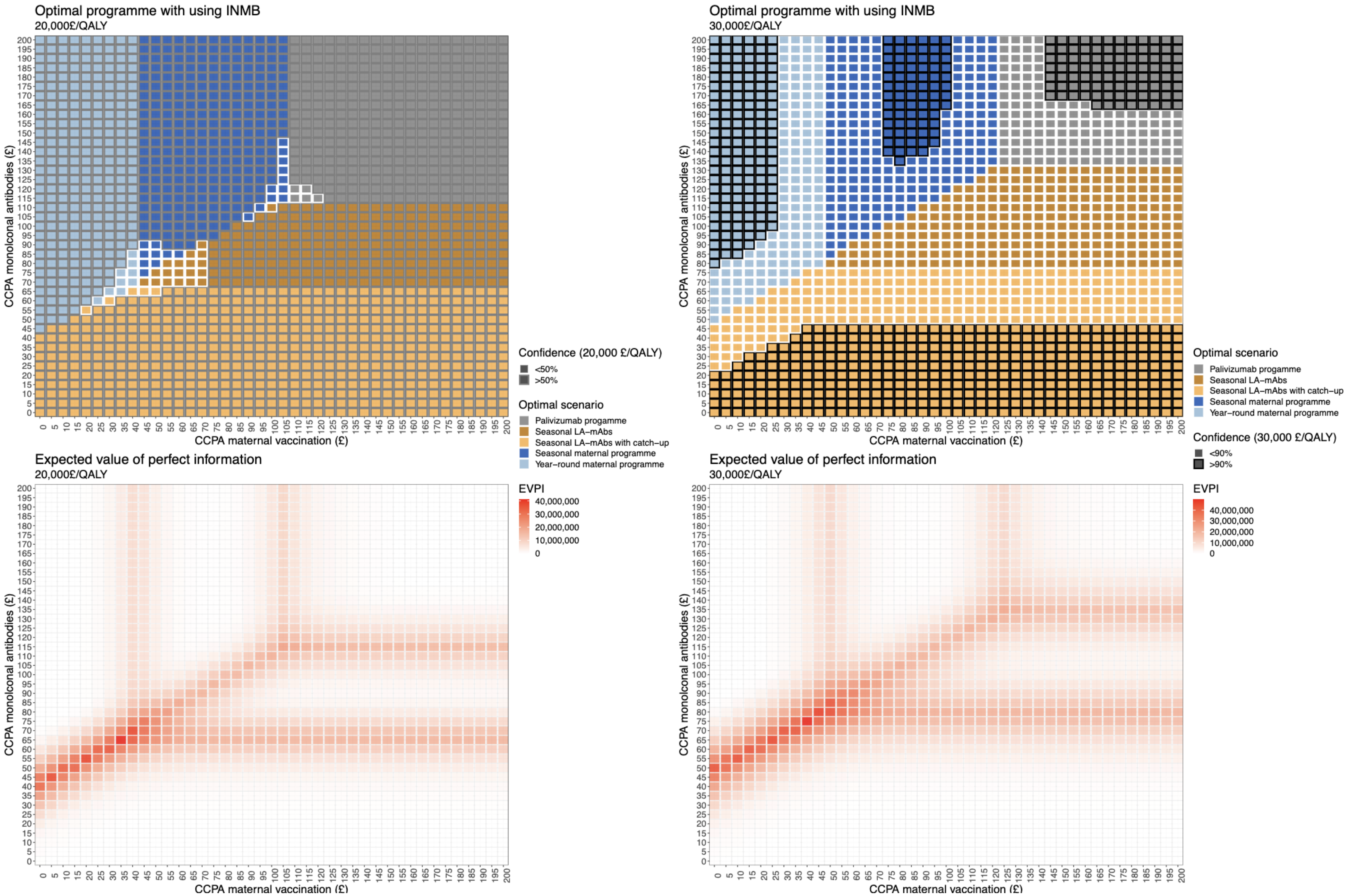




No catch-up for LA-mABs

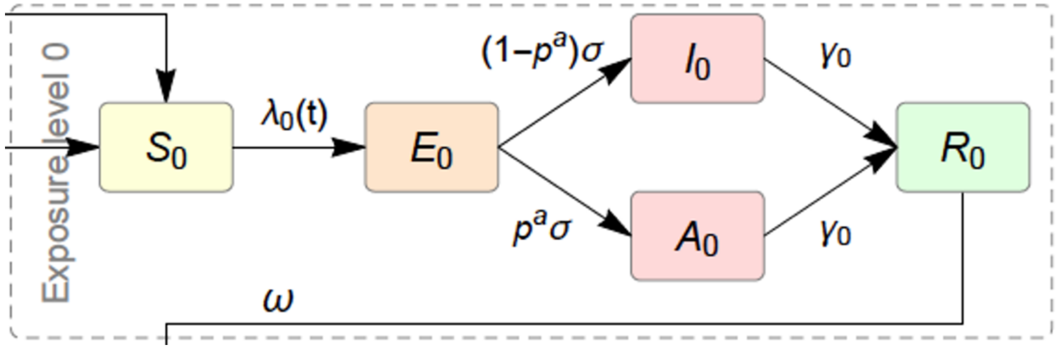


Long + short-stay costs



Modelling RSV transmission

SEIRS model fitted to RDMS (RSV positive samples)



S: susceptible

E: exposure but not yet infectious

A: Infected but asymptomatic

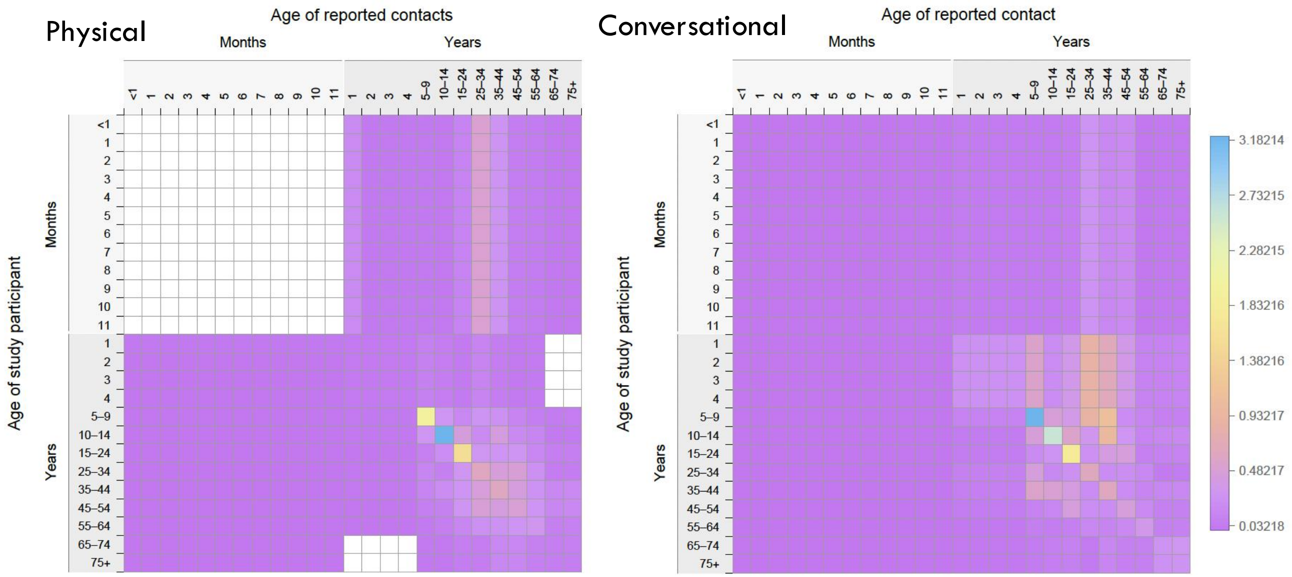
I: Infected but symptomatic

R: Post-infection immunity (temp)

25 age groups:

Monthly up to 11 months, 1, 2, 3, 4, 5-9, 10-14, 15-24, 25-34, 35-44, 45-54, 55-64, 65-74, 75+ years

Contact matrix from POLYMOD



Update risks

Symptomatic cases
- Taken from model

Hospital cases
- Reeves et al. 2017 *Influenza Other Respir Viruses*
- Reeves et al. 2019 *J Infect*
- **Taylor et al. 2016 *BMJ***
- Sharp et al. 2022 *Influenza Other Respir Viruses*

GP consultations
- Cromer et al. 2017 *Lancet Public Health*
- **Taylor et al. 2016 *BMJ***
- **Fleming et al. 2015 *BMC Inf Dis***

Annual burden health outcomes of RSV in England and Wales

↓

Estimated risk of health outcome per infection

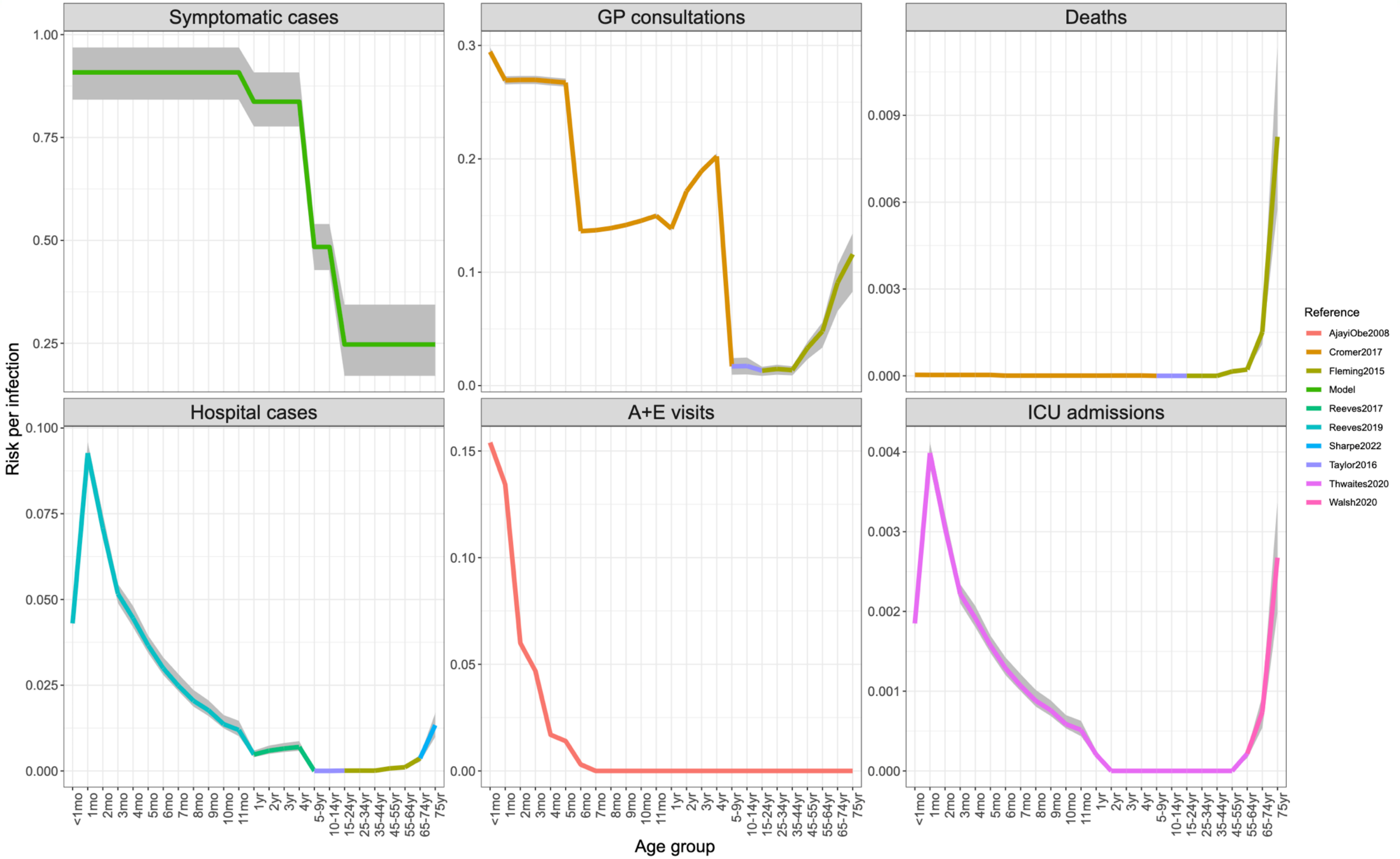
ICU
- Thwaites et al. 2020 *Eur J Pediatr*
- **Walsh et al. 2022 *Health Sci Rep***

A+E
- Ajayi-Obe et al. 2008 *Epidemiol Infect*

Deaths
- Cromer et al. 2017 *Lancet Public Health*
- **Li et al. 2023 *Infect Dis Ther***

Update risks

Risk per infection:
outcome incidence/
model predicted
incidence



Updated Economic parameters

QALY LOSS

SUBGROUP	QALY LOSS	REFERENCE
< 5 years Symptomatic	2.336×10^{-3} (0.269×10^{-3}–9.255×10^{-3})	Hodgson et al. 2020
≥5 years symptomatic	1.448×10^{-3} (0.135×10^{-3}–5.928×10^{-3})	
< 5 years hospitalisations	4.098×10^{-3} (0.624×010^{-3}–13.141×10^{-3})	
≥5 years hospitalisations	2.990×10^{-3} (0.346×10^{-3}–11.387×10^{-3})	

COSTS

GP consultations:

- £36. *Unit costs manual*

A + E Visits:

- **£182.28**. *National schedule of NHS costs (T0_)*

Hospital cases

	MEDIAN RSV-RELATED HOSPITAL ADMISSION COST (£, 95% CrI)	
AGE GROUP	SHORT-STAY ONLY	SHORT- AND LONG-STAY
<15 years of age	1100.23 (1029.66–1253.16)	1909.86 (1599.19– 3711.22)
>= 15 years of age	652.29 (585.37–740.31)	1753.21 (1233.30– 2739.47)

*Paediatric Acute Bronchiolitis with CC Score 0–5+ (PD15A–PD15D). *National schedule of NHS costs*

*Unspecified Acute Lower Respiratory Infection with/without Interventions 0–13+ (DZ22K–DZ22Q). *National schedule of NHS costs*

ICU admissions

AGE GROUP	MEDIAN RSV-RELATED ICU ADMISSION COST (£, 95% CrI)
<15 years of age	2905.20 (2282.80–3862.67)
>= 15 years of age	2324.80 (1948.25–2653.25)

* Paediatric Critical Care, Advanced Critical Care 1–5 (XB01Z–XB07Z). *National schedule of NHS costs*

*Adult Critical Care, 0–6+ Organs Supported (XC01Z–XC07Z).

Modelling maternal vaccination (implementation)

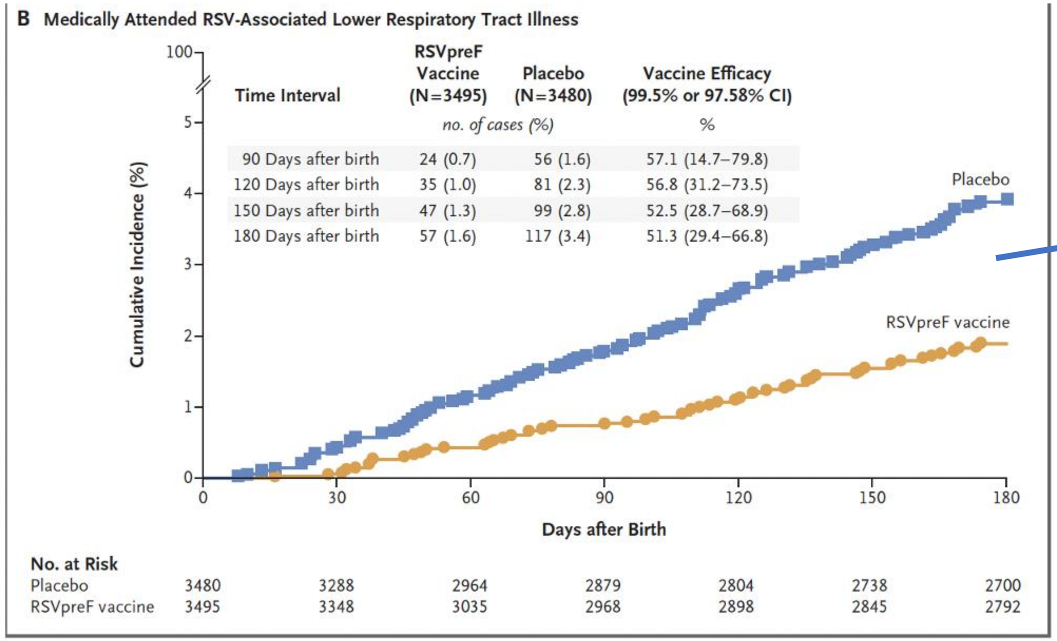
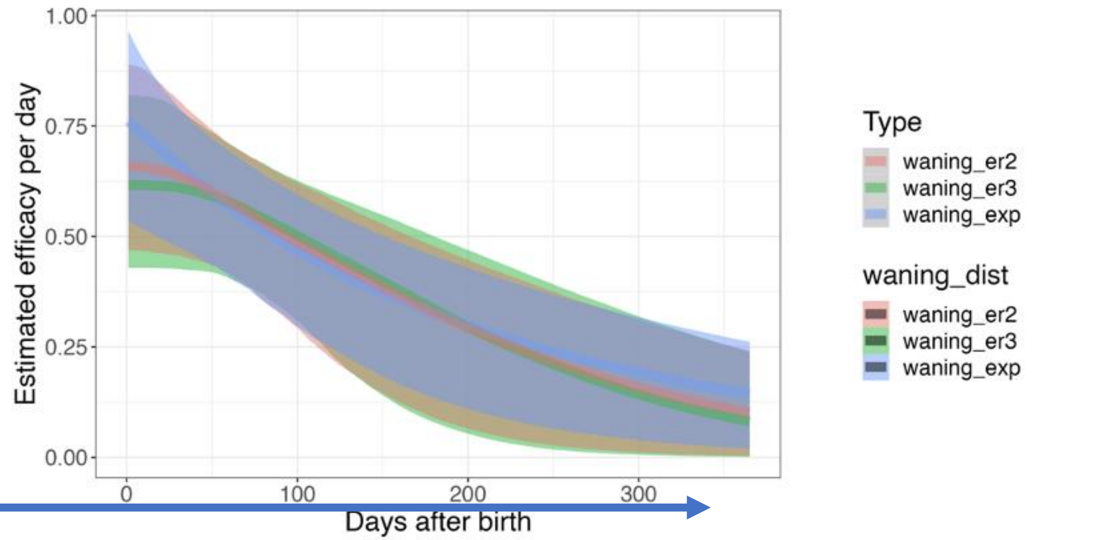
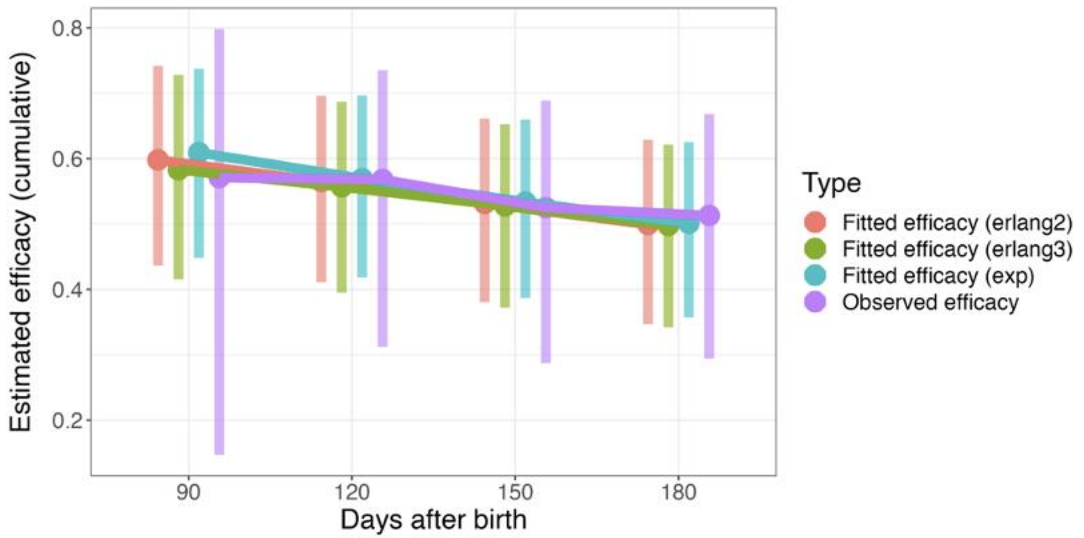


Figure 4. Figure 1b, taken from [Kampmann2023]. The Kaplan-Meier plots show the efficacy of RSVPreF3 vaccine in preventing Medically Attended RSV-Associated Lower Respiratory Tract Illness in infants.



Health outcome	Efficacy e_d (point-estimate, 180 days)	Disease protection proportion (f_d)
Infection	51.3%	0
Symptomatic	51.3%	0
GP consultations	51.3%	0
A + E attendances	69.4%	0.35
Hospital admission	69.4%	0.35
ICU admissions	69.4%	0.35
Death	69.4%	0.35

0.093 (95% 0.001–0.237) of infants still have protection 365 days after vaccination.



Modelling la-mAB (implementation)

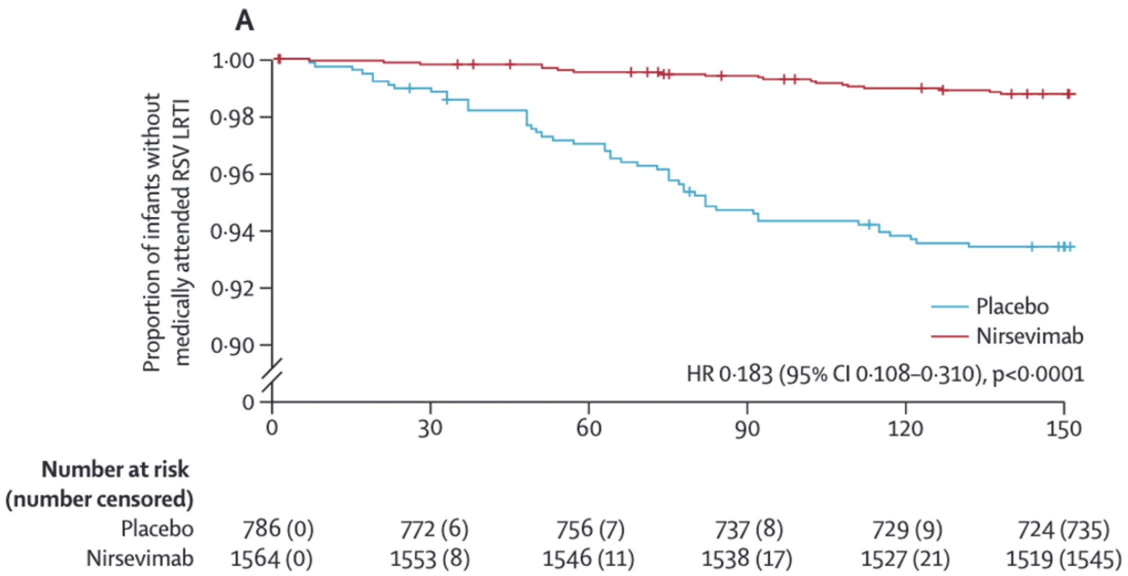


Figure 7. Figure 1A, taken from [Simoes2023]. The Kaplan-Meier plots show the efficacy of Nirsevimab in preventing Medically Attended RSV-Associated Lower Respiratory Tract Illness in infants.

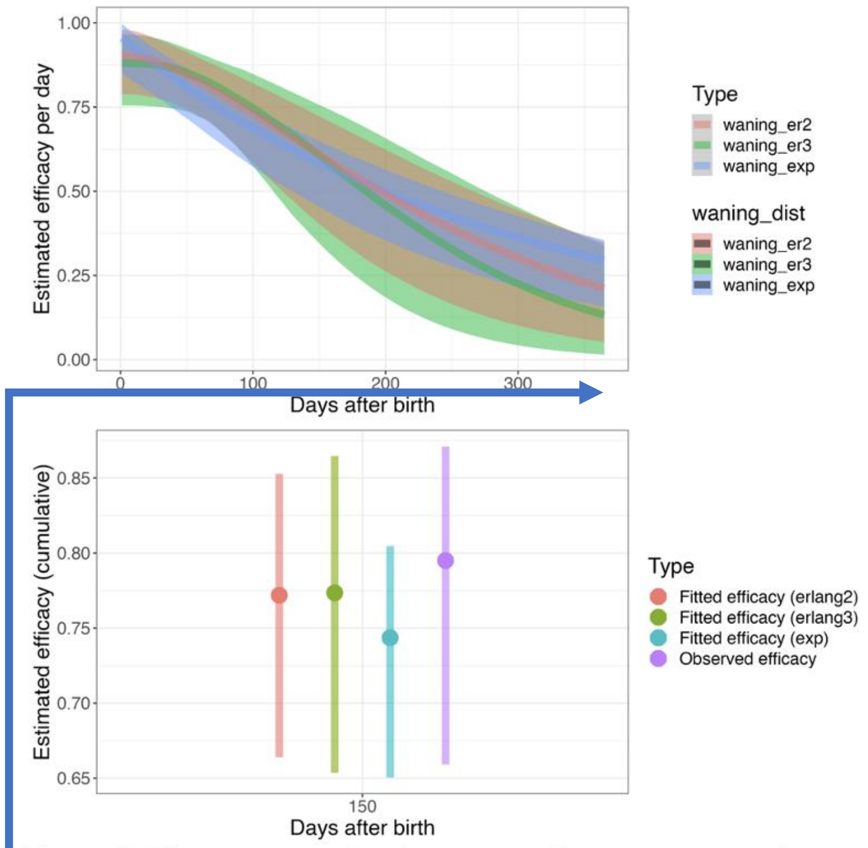


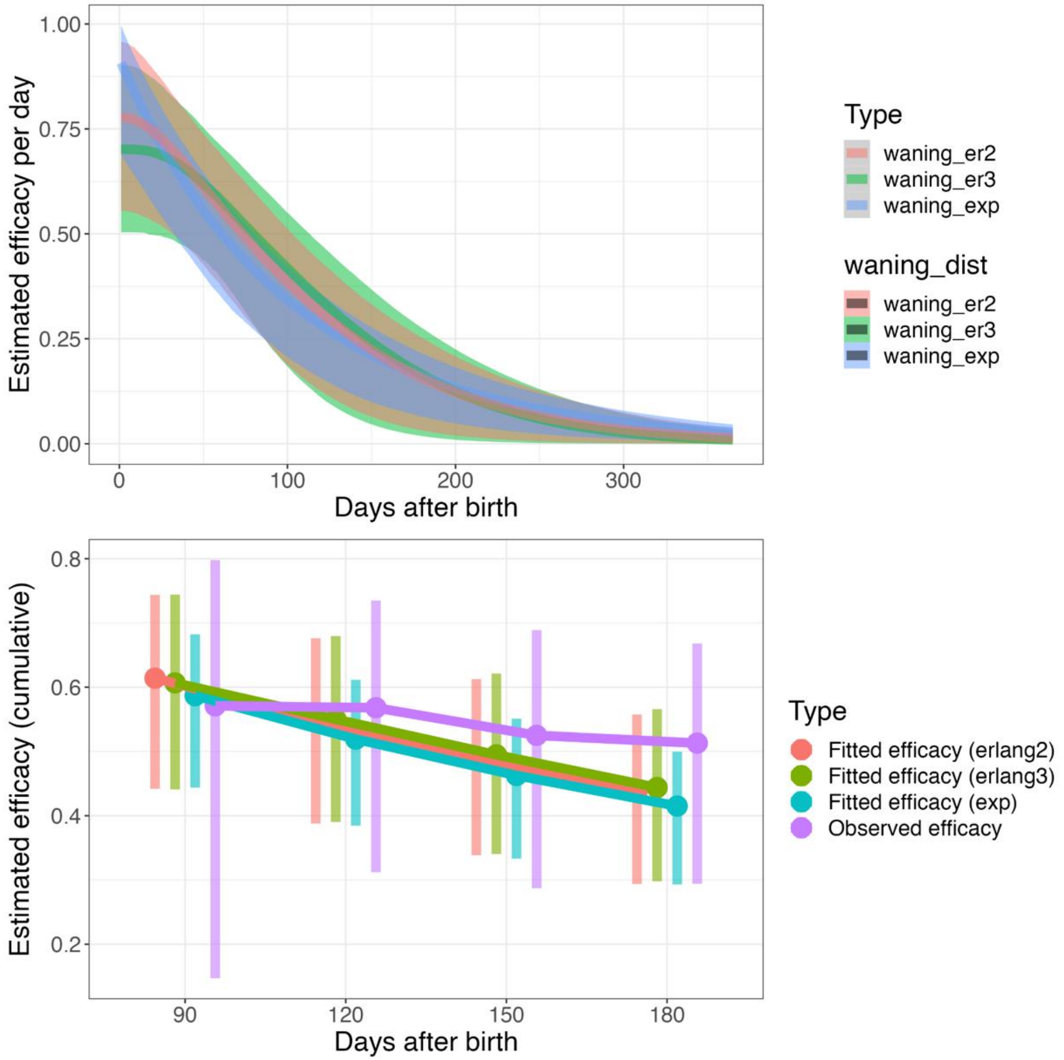
Figure 9. The posterior distributions and comparison to the quoted e

Health outcome	Efficacy e_d (point-estimate, 180 days)	Disease protection proportion (f_d)
Infection	79.5%	0
Symptomatic	79.5%	0
GP consultations	79.5%	0
A + E attendances	79.5%	0
Hospital admission	79.5%	0
ICU admissions	86.0%	0.08
Death	86.0%	0.08

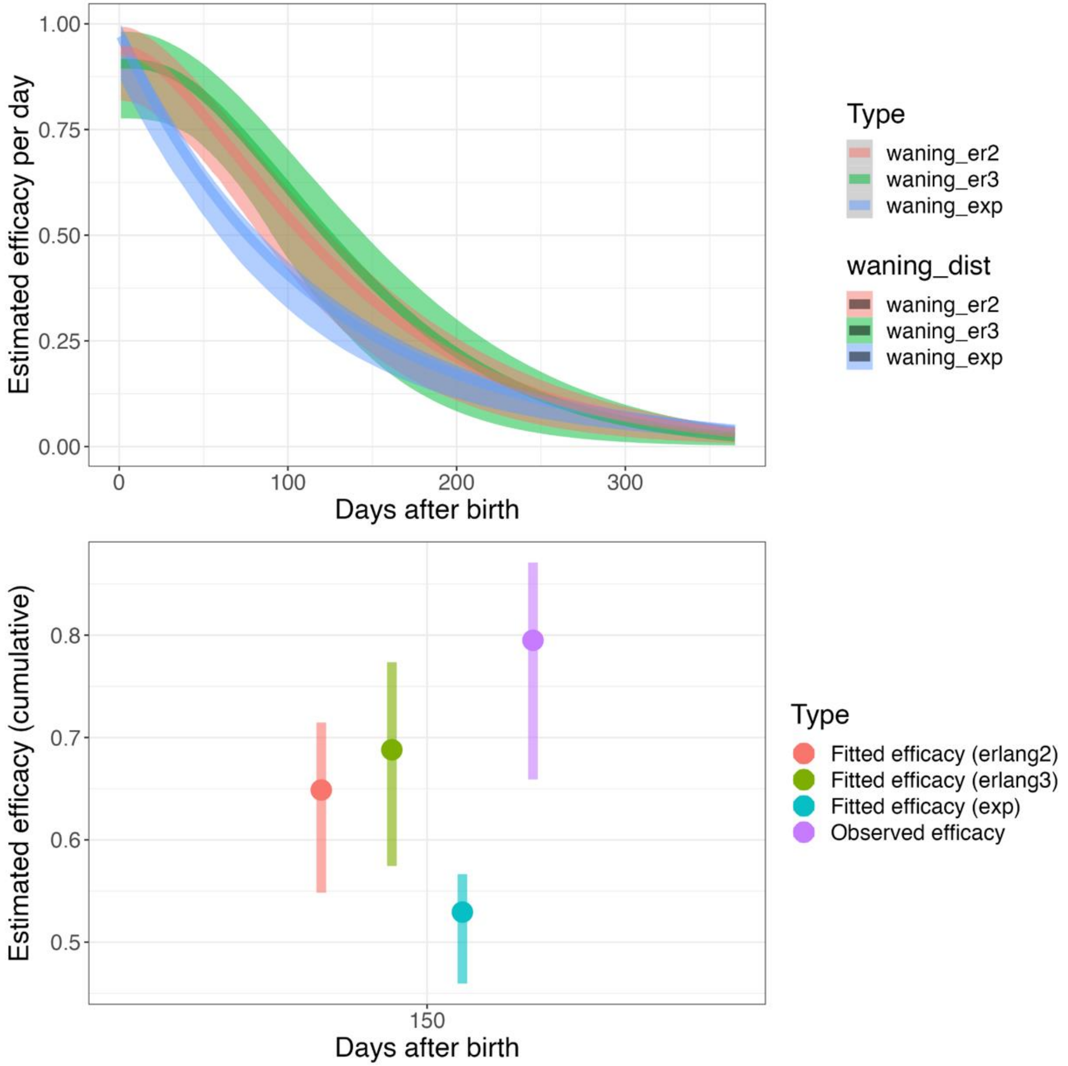
0.148 (95% 0.015–0.338) of infants still have protection 365 days after vaccination.

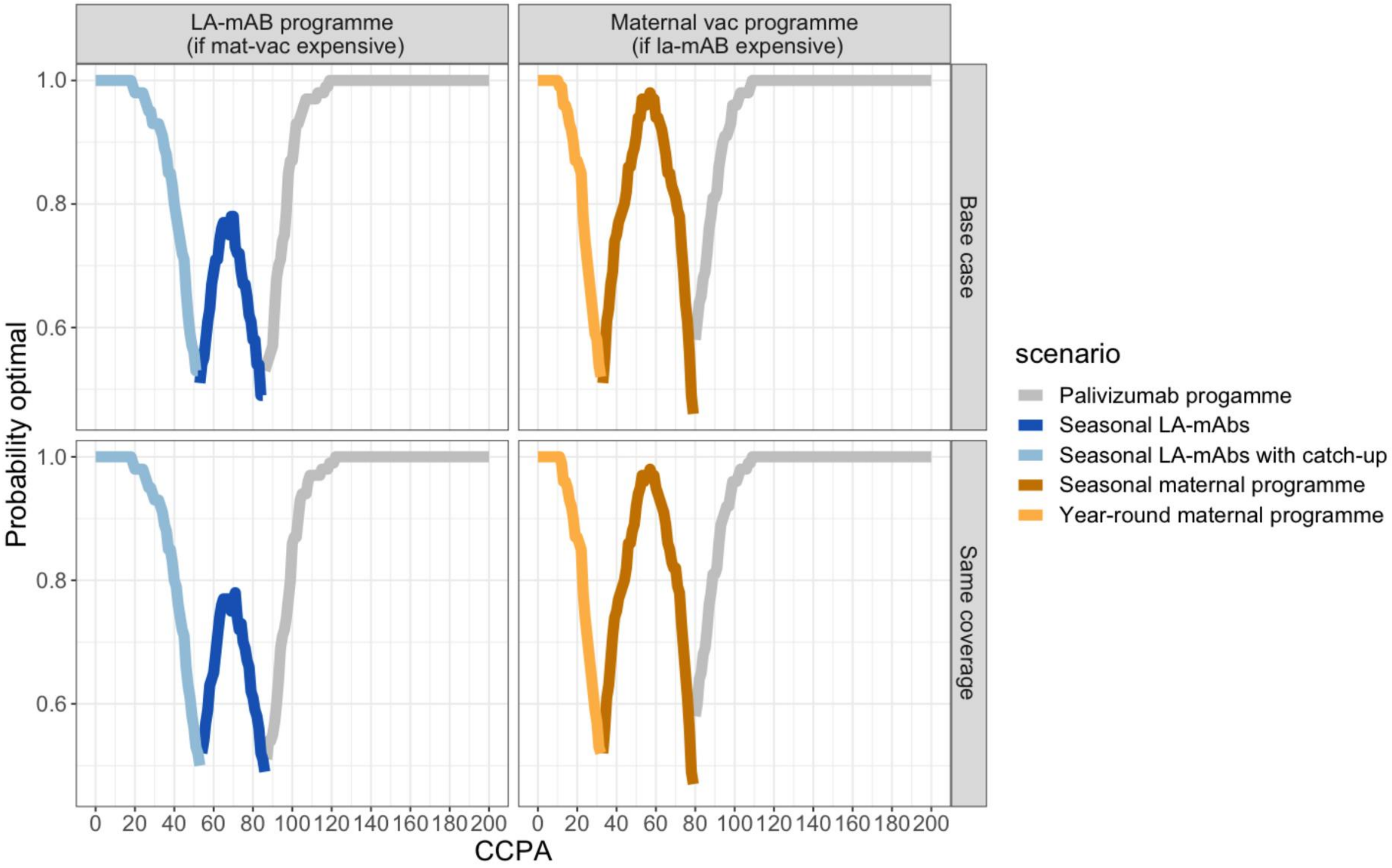
Bounded efficacy (single year)

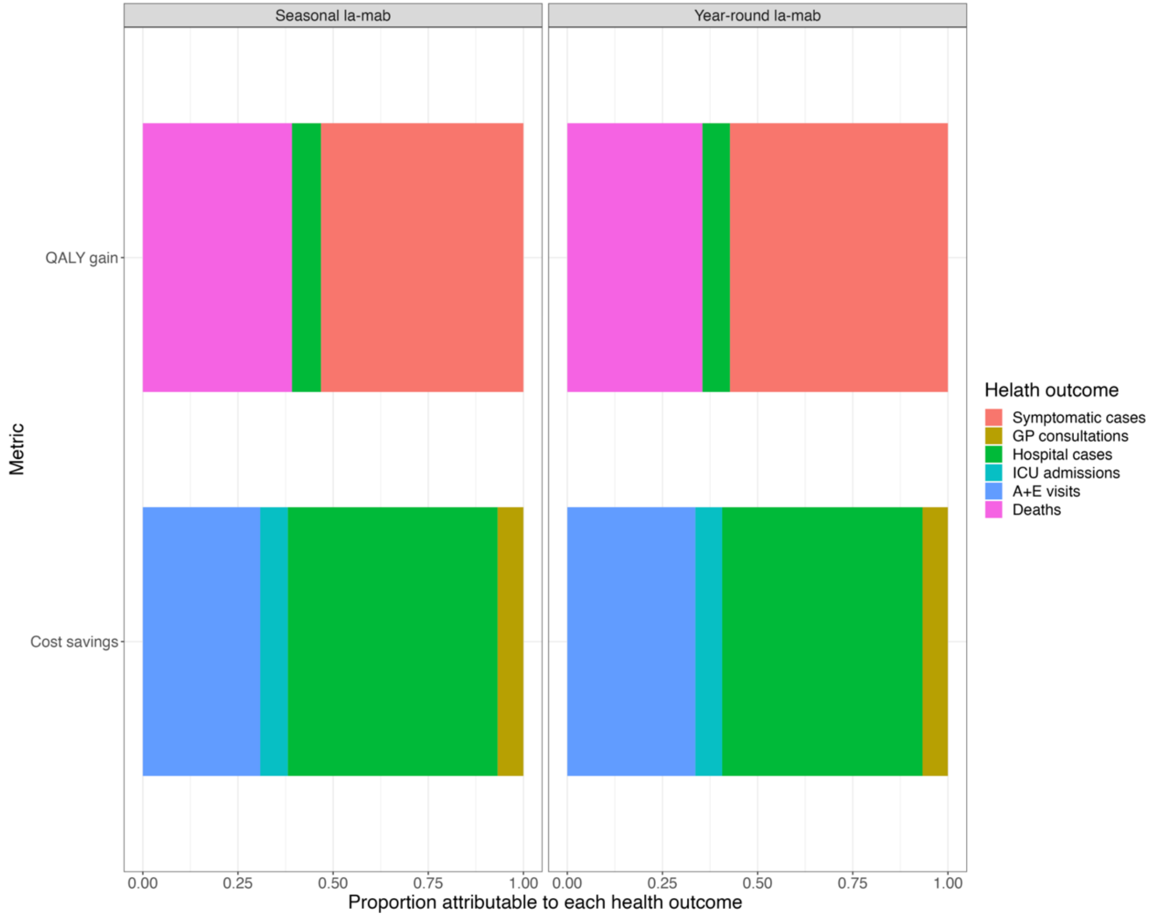
Maternal vaccination



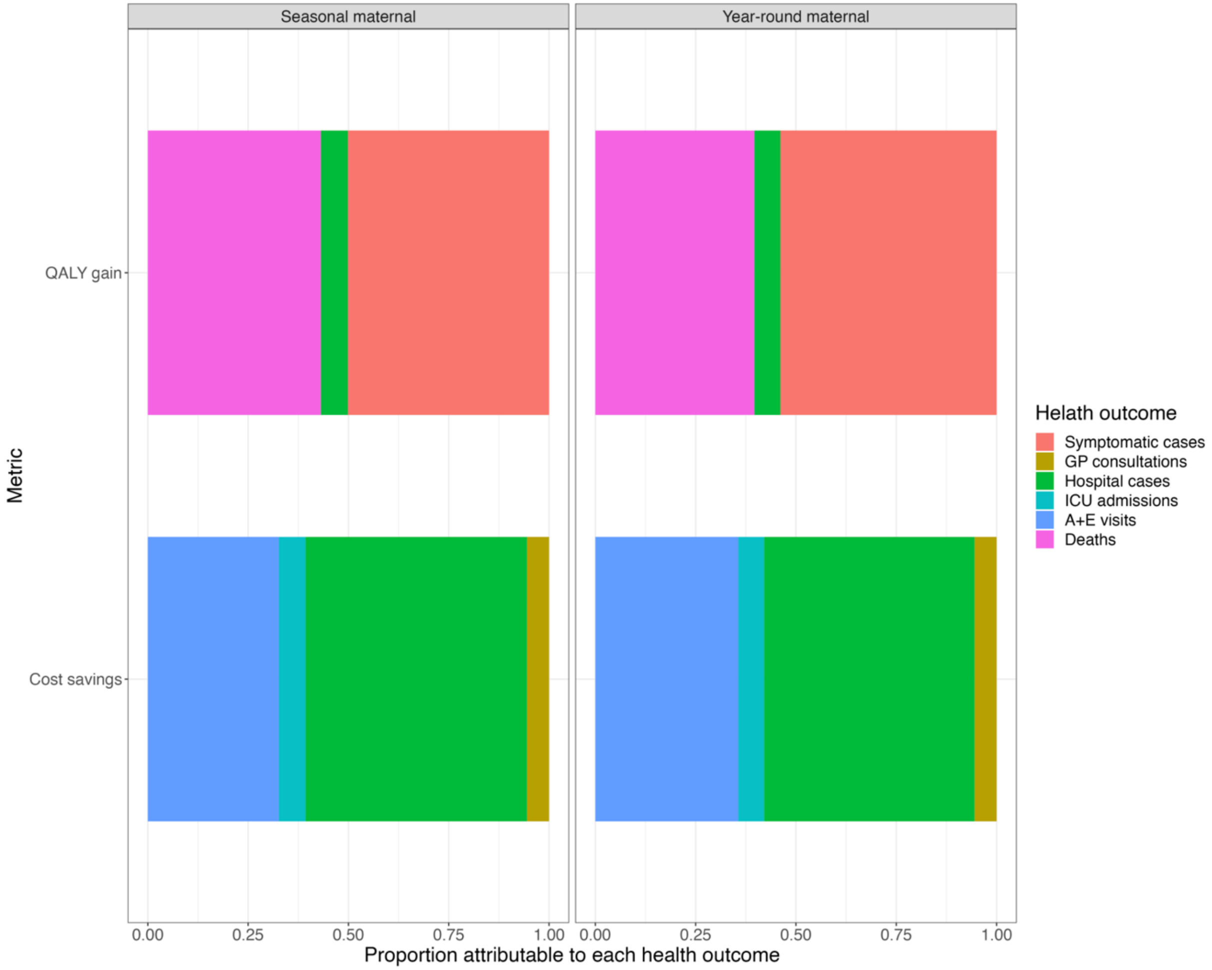
Monoclonal antibodies




LA-mAB programme
(if mat-vac expensive)
Maternal vac programme
(if la-mAB expensive)
Base case
Same coverage
Probability optimal
1.0
0.8
0.6
CCPA
0 20 40 60 80 100 120 140 160 180 200
scenario
Palivizumab progamme
Seasonal LA-mAbs
Seasonal LA-mAbs with catch-up
Seasonal maternal programme
Year-round maternal programme



Seasonal la-mab
Year-round la-mab
QALY gain
Cost savings
Metric
0.00
0.25
0.50
0.75
1.00
Proportion attributable to each health outcome
Helath outcome
Symptomatic cases
GP consultations
Hospital cases
ICU admissions
A+E visits
Deaths



Seasonal maternal
Year-round maternal
QALY gain
Cost savings
Metric
0.00
0.25
0.50
0.75
1.00
Proportion attributable to each health outcome
Helath outcome
Symptomatic cases
GP consultations
Hospital cases
ICU admissions
A+E visits
Deaths

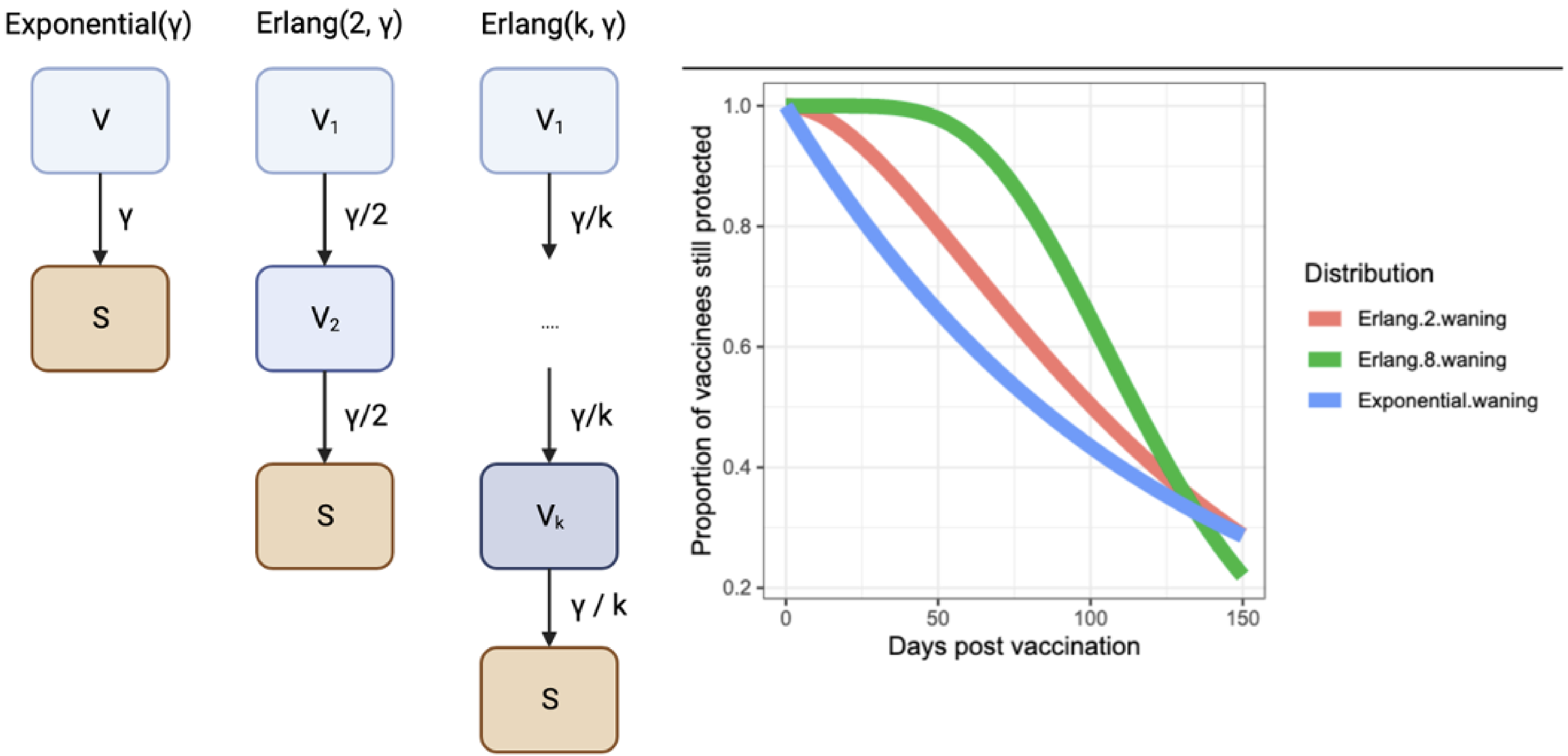
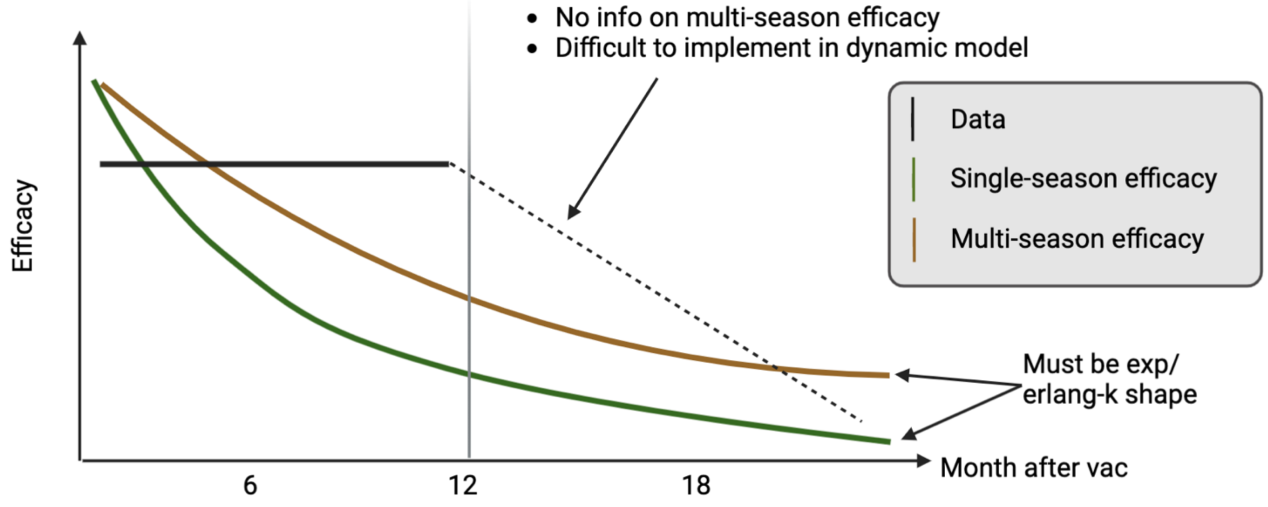
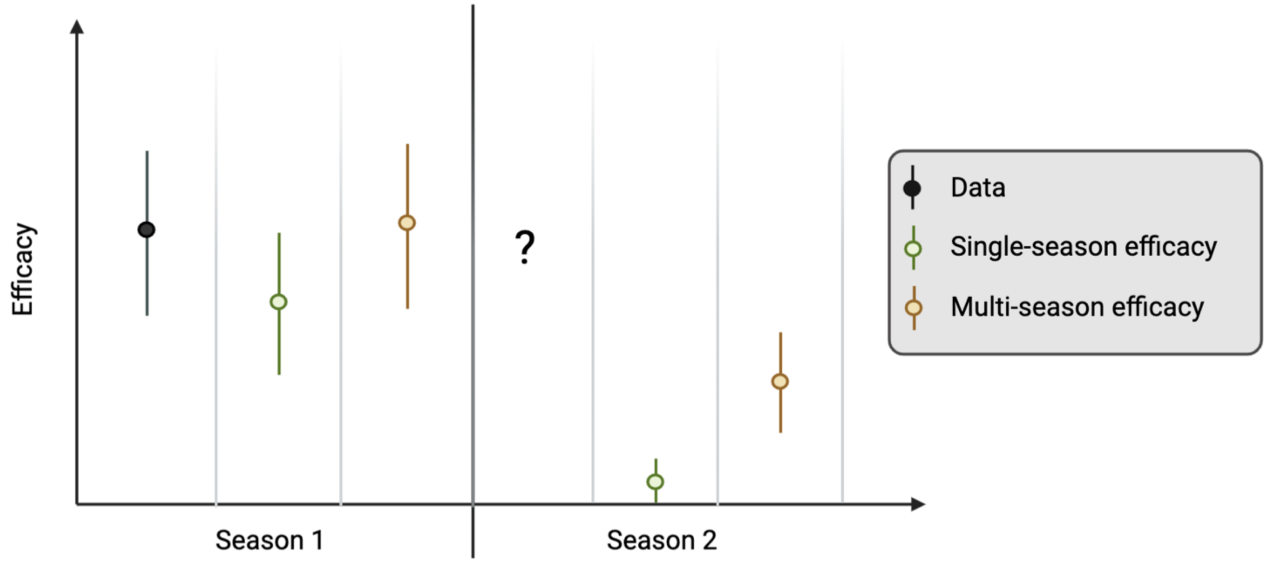


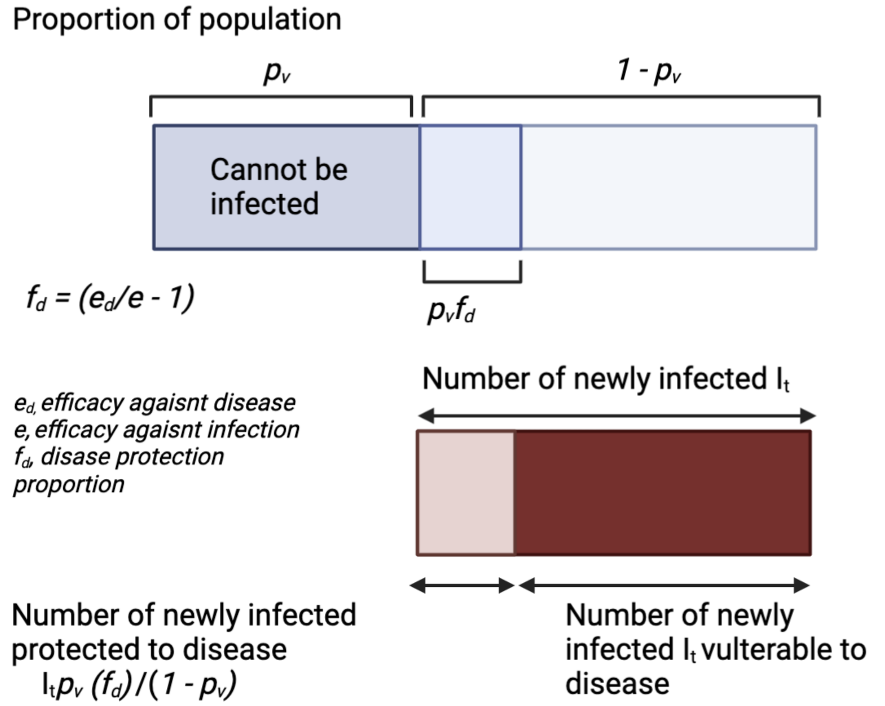
Figure 2. Schematic showing the relationship between exponential and erlang-k distributions in the context of dynamic transmission modelling. By chaining k compartments, the waning following an Erlang-k distribution which has more flexibility in waning structure in comparison to an Exponential distribution.





Disease-specific efficacy

At time t, for age group a and risk group v:



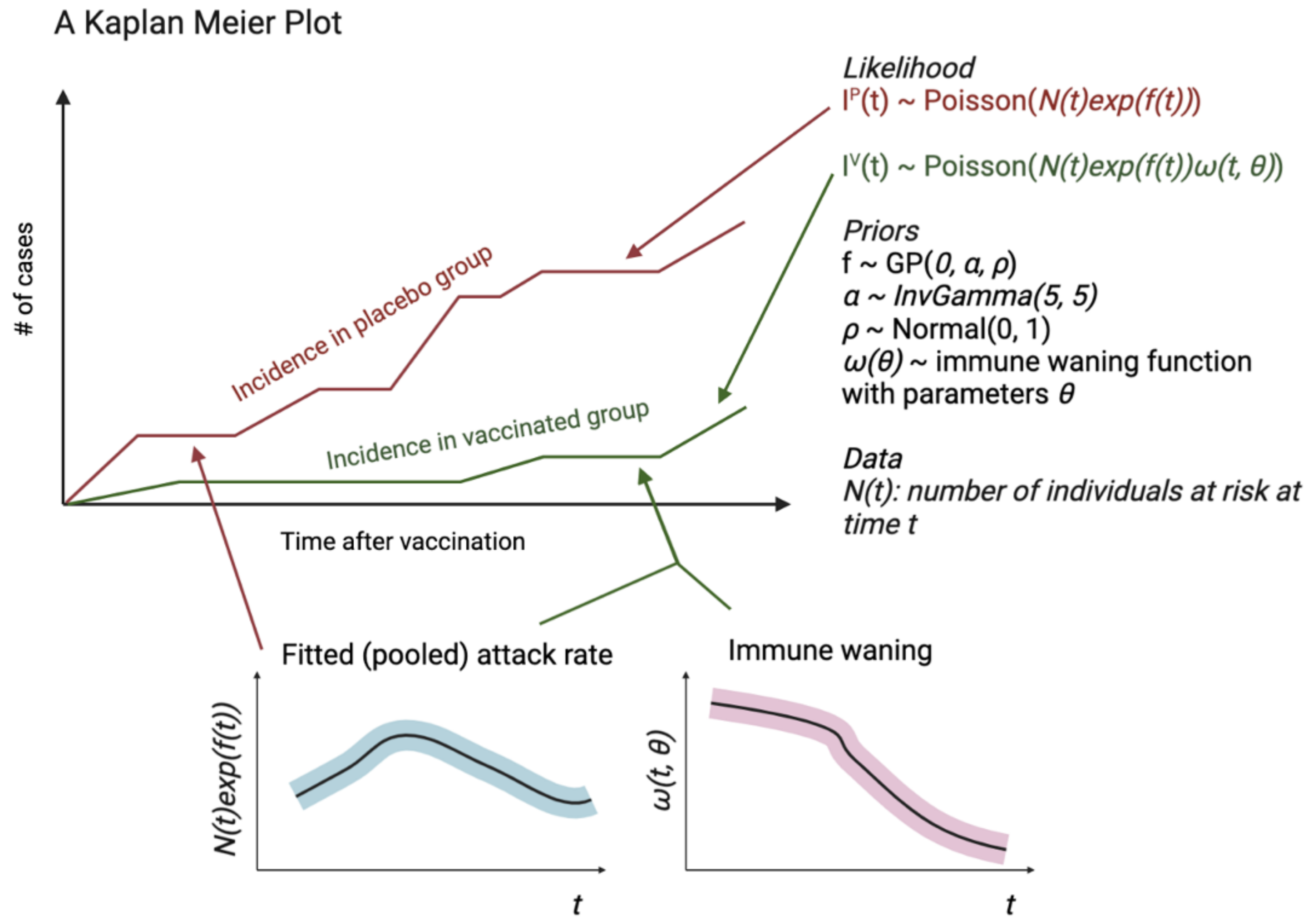
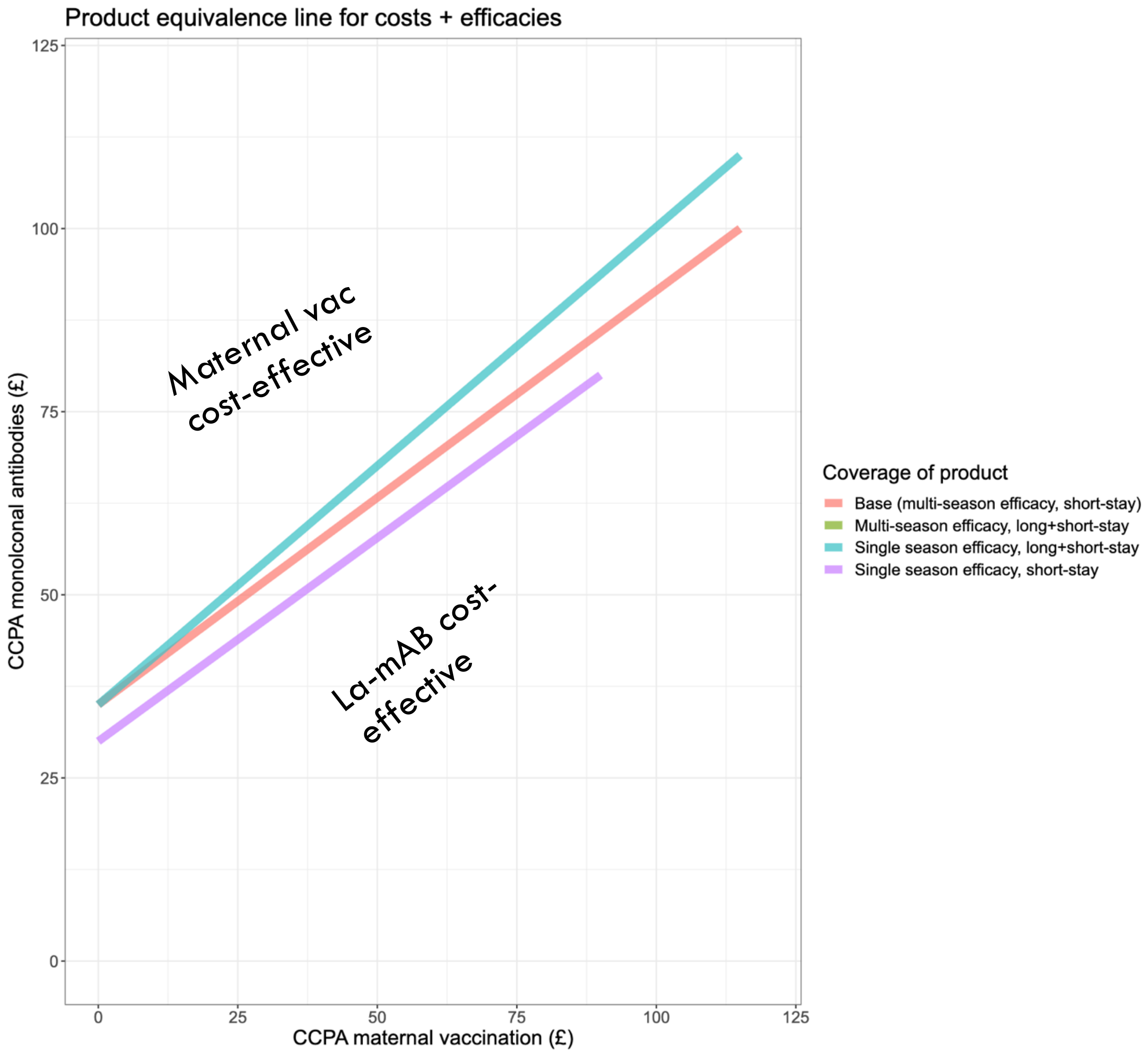
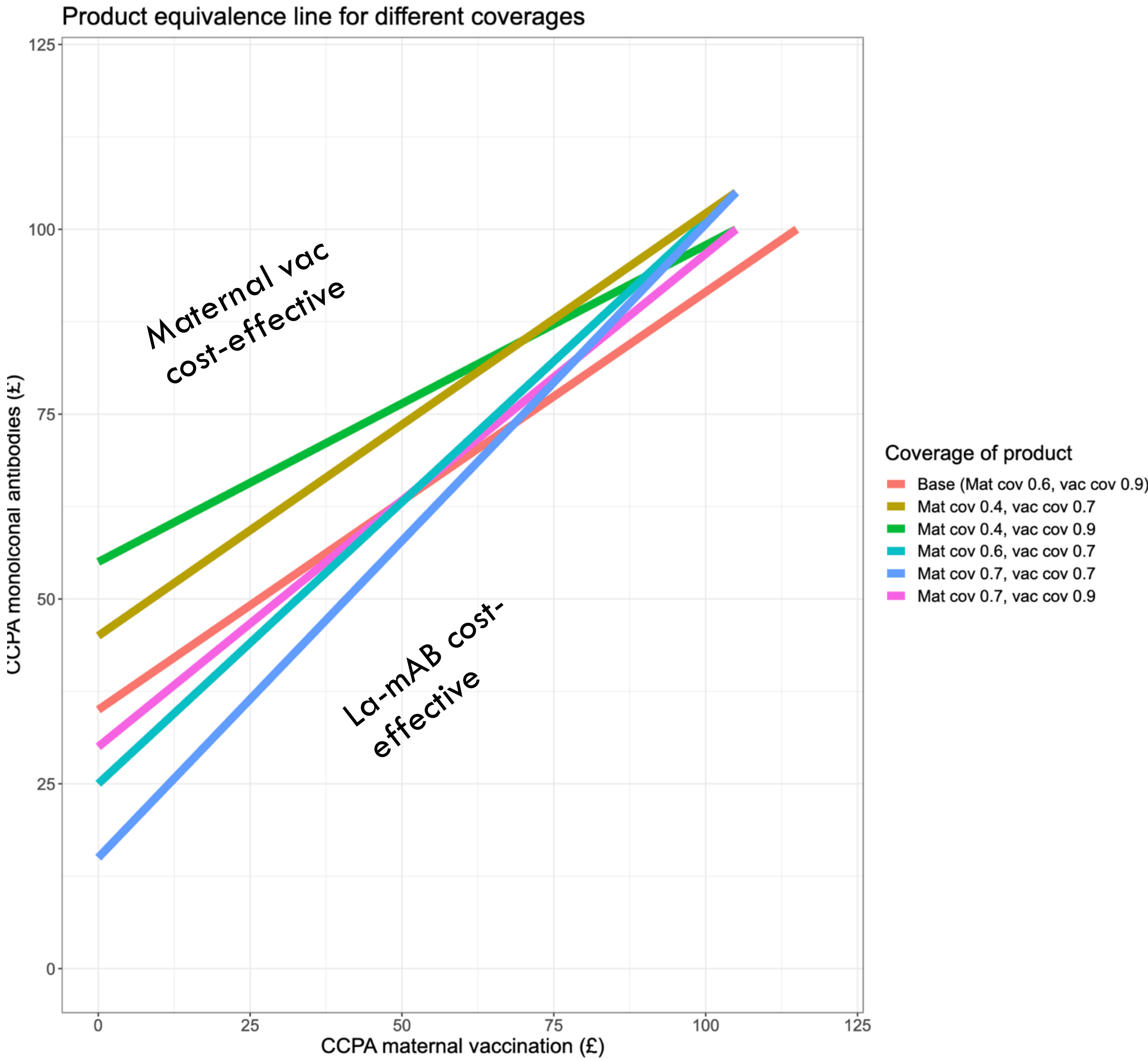


Figure 1. Schematic showing the hierarchical Bayesian model to estimate the time-varying efficacy given a Kaplan Meier plot.


Product equivalence line for costs + efficacies
CCPA monoclonal antibodies (£)
CCPA maternal vaccination (£)
0
25
50
75
100
125
Maternal vac
cost-effective
La-mAB cost-
effective
Coverage of product
Base (multi-season efficacy, short-stay)
Multi-season efficacy, long+short-stay
Single season efficacy, long+short-stay
Single season efficacy, short-stay


Product equivalence line for different coverages
CCPA monoclonal antibodies (£)
CCPA maternal vaccination (£)
0
25
50
75
100
125
Maternal vac
cost-effective
La-mAB cost-
effective
Coverage of product
Base (Mat cov 0.6, vac cov 0.9)
Mat cov 0.4, vac cov 0.7
Mat cov 0.4, vac cov 0.9
Mat cov 0.6, vac cov 0.7
Mat cov 0.7, vac cov 0.7
Mat cov 0.7, vac cov 0.9