Introducing new vaccines: Vaccination in Pregnancy

Australian Vaccinology Course
October 19-21, 2026

Professor Michelle Giles OAM

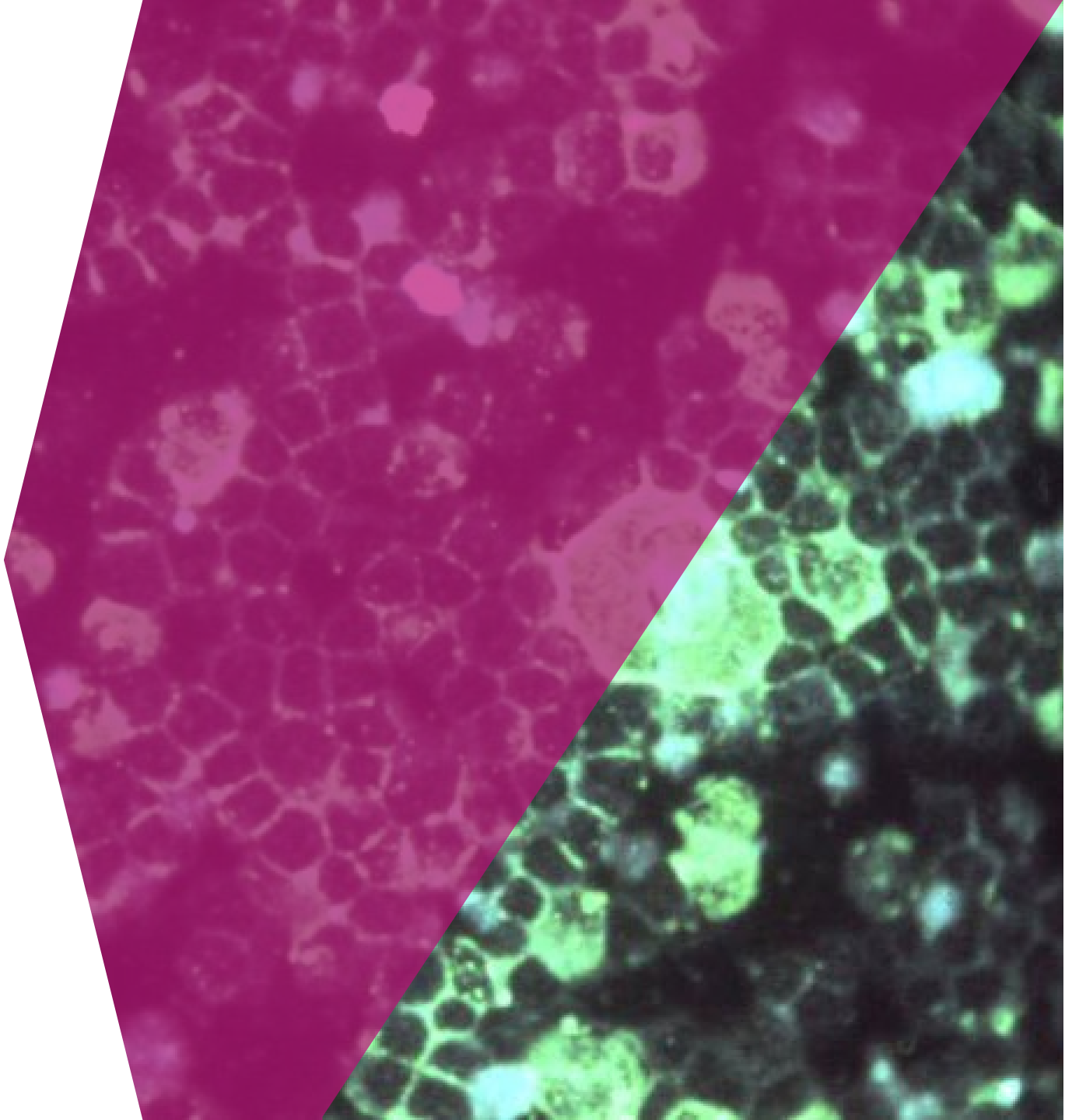
Department of Obstetrics and Gynaecology, Monash University

Department of Infectious Diseases, University of Melbourne



Declarations of Interest

- Head, Vaccine Research Group Doherty Institute
- Principal investigator on vaccine trials sponsored by Sanofi, Novavax, Moderna, GSK, CSL, Arcturus, MSD
- Past member of ATAGI (2016-2025)
- Research funding received from Pfizer
- Advisory Board CSL



First principles

Pregnant women are more susceptible to severe disease

Maternal vaccination reduces the vulnerable period in the infant leveraging unique immunological setting

‘Two for One’ deal

Pregnant women are more susceptible to vaccine preventable diseases



Smallpox (higher case fatality rate in 19th century)[1]



Influenza (Pandemics 1918, 1957, 2009)[3–5]



Measles (Greenland 1951)[2]

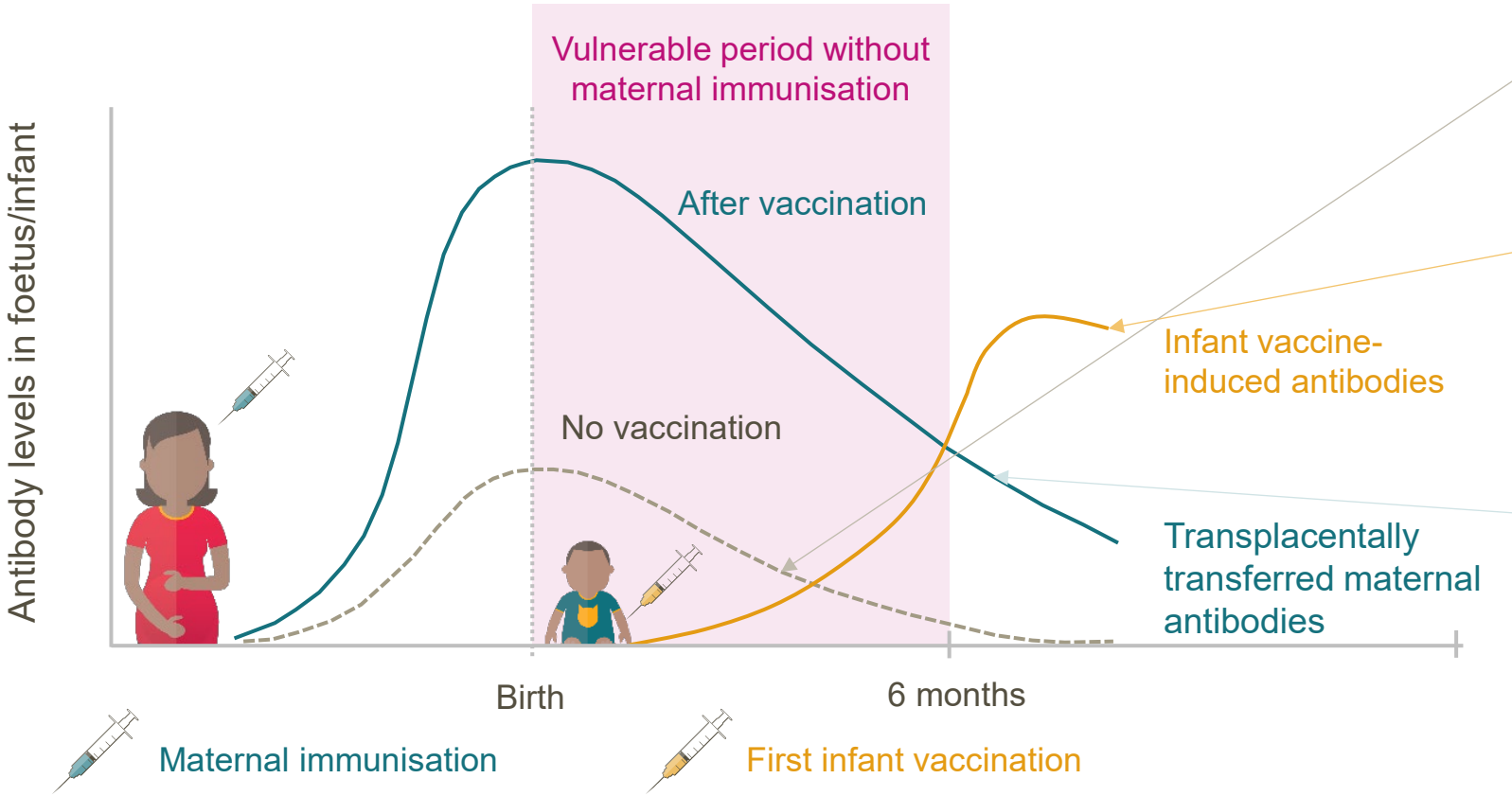


SARS-CoV-2[6]

1. Nishiura H. *Emerg Infect Dis* 2006;12:1119–1121.; 2. Christensen PE *et al. Acta Med Scand* 1953;144:430–49.; 3. Harris J. *JAMA* 1919;72:978–980; 4. Freeman DW, Barno A. *Am J Obstet Gynecol* 1959;78:1172–1175; 5. Siston AM *et al. JAMA* 2010;303:1517–1525; 6. Allotey J *et al. BMJ* 2020;370:m3320

Infants are particularly vulnerable to infectious diseases in the first 6 months of life

Maternal immunisation helps protect pregnant women and addresses this vulnerability in young infants



Passive immunity from maternal antibodies, **without maternal immunisation**, is frequently suboptimal

Infants are **not adequately protected** from infectious diseases until they have completed the primary vaccination series

This leaves a **period of vulnerability** without maternal immunisation

Maternal immunisation increases the level of transplacentally transferred antibodies and **extends the duration** of passive immunity

Figure adapted from Mukherjee P *et al. Eur Gynecol Obstet* 2021;3:2–12 with permission from the editors of European Gynecology & Obstetrics

Neonatal Fc Receptors Actively Transfer Maternal Antibody to the Fetus[1,2]

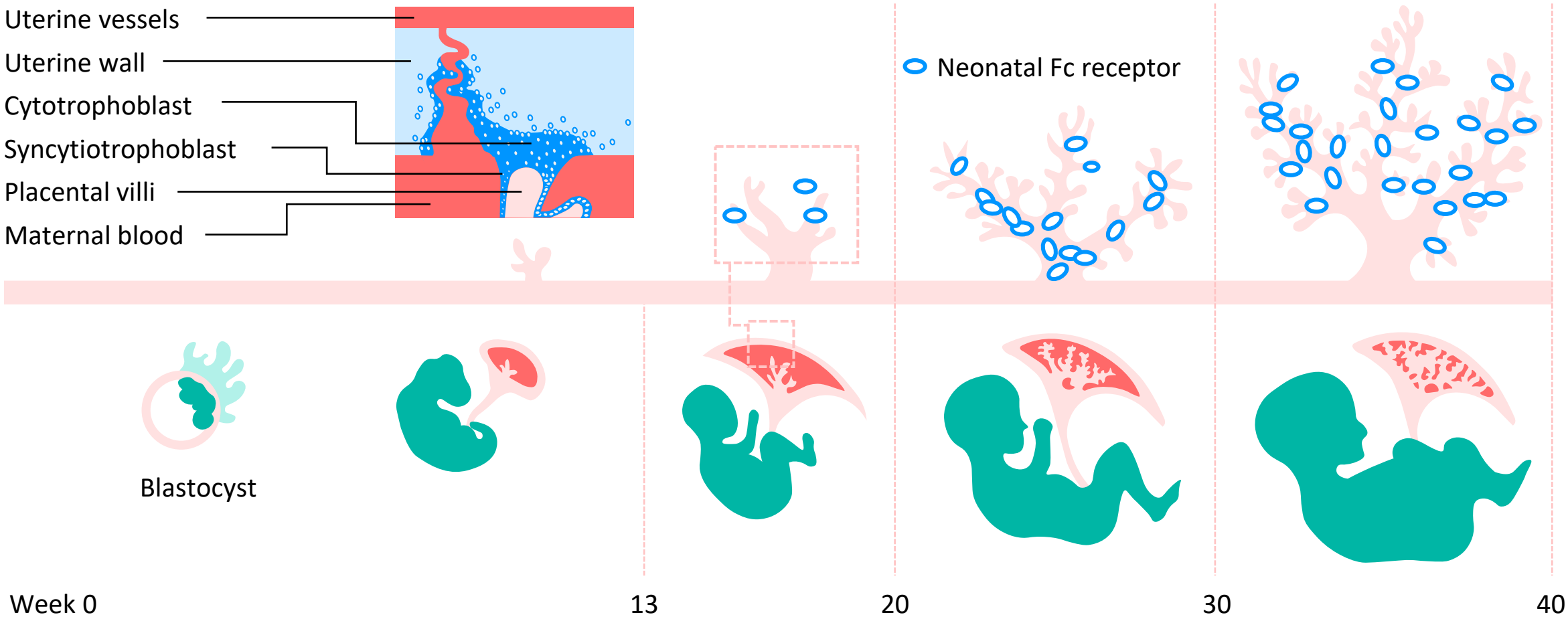


Figure adapted from the National Institutes of Health.[3]

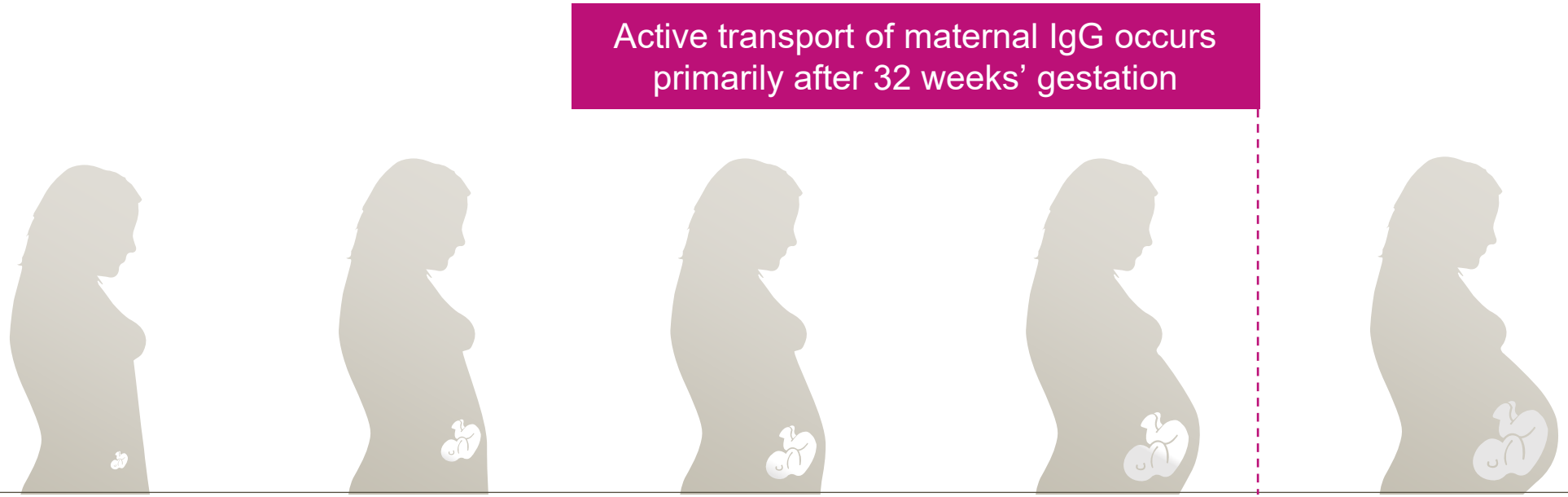
Fc, fragment crystallizable.

1. Palmeira P, et al. *Clin Dev Immunol.* 2012;2012:985646. 2. Albrecht M, Arck PC. *Front Immunol.* 2020;11:555. 3. National Institutes of Health. Human Placenta Project: How does the placenta form? Updated May 30, 2023. Accessed September 11, 2026. https://www.nichd.nih.gov/research/supported/human-placenta-project/how-does-placenta-form

Courtesy of Yasmeen Agosti

Maternal immunisation can optimise the amount of pathogen-specific IgG at birth

Placental transfer of IgG is generally linear, with the largest amount transferred in the third trimester



	1	2		3	
Trimester					
Fetal IgG	None when first pregnant	Starts to increase at Week 13[3]	5–10% of maternal levels at Weeks 17–22[1-3]	50% of maternal levels at Weeks 28–32[3]	Exceeds maternal levels by 20–30% at full-term[3]

IgG, immunoglobulin G

1. Abu Raya B *et al. Vaccine* 2014;32:5787–5793; 2. Naidu MA *et al. Am J Obstet Gynecol* 2016;215:237.e1–6; 3. Palmeira P *et al. Clin Dev Immunol* 2012;2012:985646;
4. Chu HY, Englund JA. *Clin Infect Dis* 2014;59:560–568

The “Two for One” Deal

- **To protect the pregnant woman** from infections that are potentially severe for herself (influenza)

- **To protect the infant in the first 6 months of life**:
  Passive immunity via transfer of vaccine-specific antibodies via the placenta to protect the baby in first months of life (influenza, pertussis, tetanus)

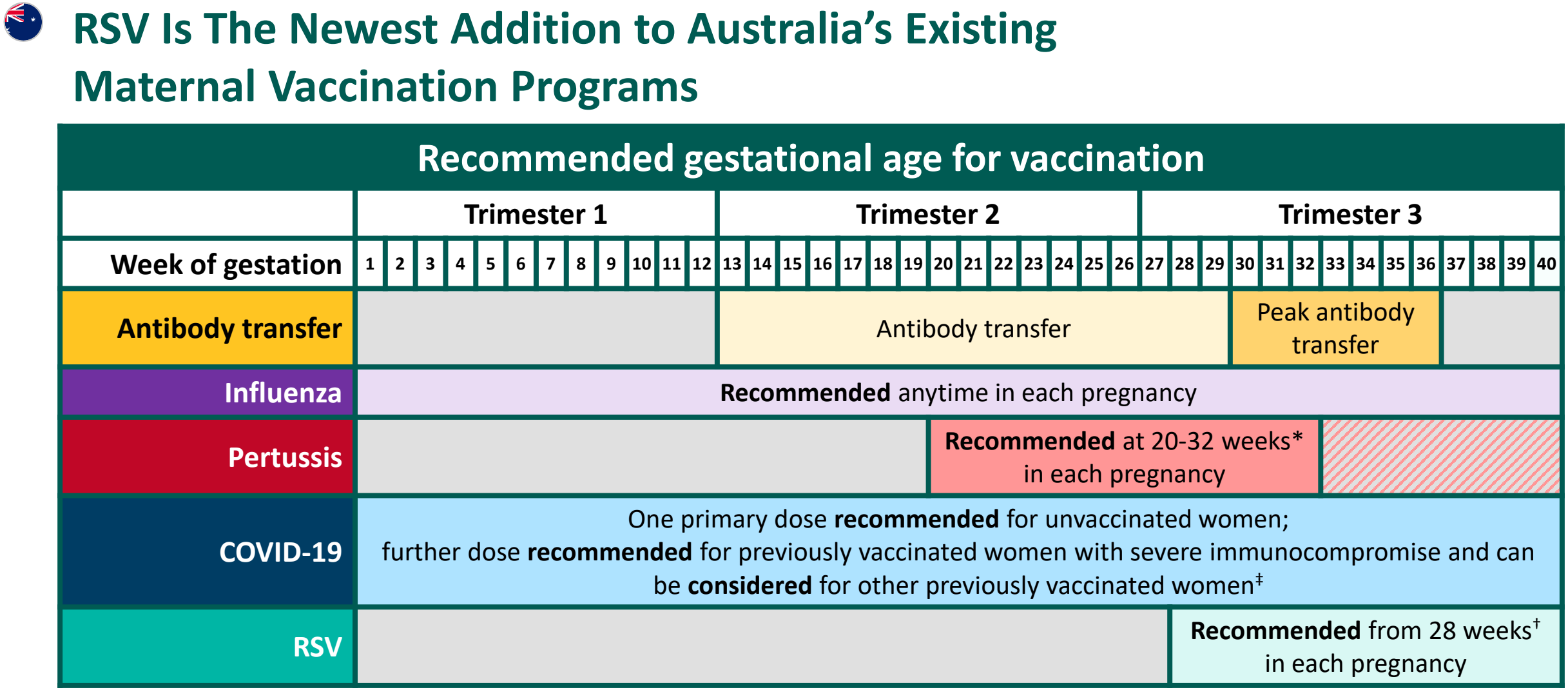


Maternal Vaccination Is an Established Strategy for Protecting Infants During Their Period of Highest Vulnerability

Tetanus toxoid[1]	Influenza, inactivated[1]	Acellular pertussis[1]	COVID-19[2,3]	Respiratory syncytial virus[4-6]
Year developed 1926	**Year developed** 1936	**Year developed** 1996	**Year developed** 2020	**Year developed** 2023
WHO recommends for pregnancy 1999; 2006*	**WHO recommends for pregnancy** 2012	**WHO recommends for pregnancy** 2014	**WHO recommends for pregnancy** 2021	**WHO recommends for pregnancy** 2025
Type of vaccine Protein or polysaccharide	**Type of vaccine** Inactivated or recombinant	**Type of vaccine** Protein	**Type of vaccine** mRNA; Non-replication vector	**Type of vaccine** Protein
Benefit Maternal ✓ | Infant ✓	**Benefit** Maternal ✓ | Infant ✓	**Benefit** Maternal ✓ | Infant ✓	**Benefit** Maternal ✓ | Infant ✓	**Benefit** Maternal TBC | Infant ✓

- *The WHO recommendation for elimination of both maternal and neonatal tetanus occurred in 1999. The first WHO position paper on tetanus vaccine in pregnancy was published in 2006.
- COVID-19, coronavirus disease 2019; mRNA, messenger ribonucleic acid; WHO, World Health Organization.
- 1. Kachikis A, et al. The history of maternal immunization. In: Leuridan et al, eds. *Maternal immunization*. 1st ed. Elsevier; 2019:3-24. 2. Etti M, et al. *Am J Obstet Gynecol.* 2022;226(4):459-474 3. World Health Organization. (2021). Interim recommendations for use of the Pfizer–BioNTech COVID-19 vaccine, BNT162b2, under emergency use listing: interim guidance, first issued 8 January 2021, updated 15 June 2021, updated 19 November 2021. World Health Organization. https://iris.who.int/handle/10665/349303 4. ABRYSVO® (Respiratory Syncytial Virus Vaccine) Summary of Product Characteristics. Pfizer Inc; June 1, 2026. https://www.ema.europa.eu/en/documents/product-information/abrysvo-epar-product-information_en.pdf 5. WHO. WHO position paper on immunization to protect infants against respiratory syncytial virus disease, May 2025. https://www.who.int/publications/i/item/WER10022 6. Simões EAF, et al. *Obstet Gynecol.* 2025;145(2):157-167. All URLs accessed June 9, 2026.

RSV Is The Newest Addition to Australia's Existing Maternal Vaccination Programs



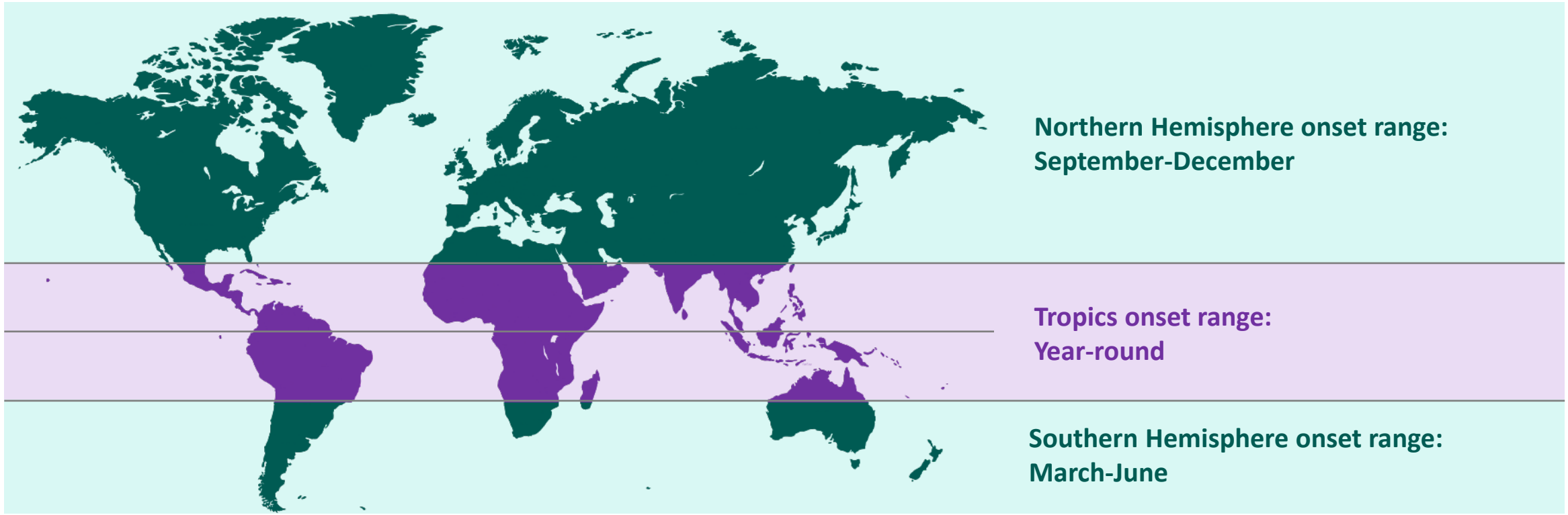
Reproduced from NCIRS.

*If the pertussis vaccine is not administered between the recommended interval of 20-32 weeks, it can be given after 32 weeks. If it is administered between 13 and 20 weeks, it does not need to be readministered. Pertussis vaccine comes as combination diphtheria-tetanus-pertussis formulation. †If the RSV vaccine is administered before 28 weeks, it does not need to be readministered. Nirsevimab (monoclonal antibody) is recommended at birth only for infants with high-risk medical conditions or who were not protected by RSV vaccine administered during pregnancy (ie, vaccine not given; delivery occurred within 2 weeks of vaccination; mother with severe immunocompromise; infant received exchange transfusion; etc). ‡Further doses are not routinely recommended for healthy, previously vaccinated pregnant women but can be considered based on risk factors and personal preference.

COVID-19, coronavirus disease 2019; NCIRS, National Centre for Immunisation Research and Surveillance; RSV, respiratory syncytial virus.

National Centre for Immunisation Research and Surveillance Australia. Vaccine recommendations for pregnant women – a guide for health professionals. Updated February 27, 2026. Accessed April 6, 2026. https://ncirs.org.au/vaccine-recommendations-pregnant-women-guide-health-professionals

Globally, RSV Epidemics Are Typically Seasonal and Last an Average of 5-6 Months[1]



Temperate climates:
Annual winter epidemics[2,3]

Tropical climates:
Year-round spread possible[4]

RSV, respiratory syncytial virus.

1. Obando-Pacheco P et al. *J Infect Dis.* 2018;217:1356-1364. 2. Li Y et al. *Lancet Glob Health.* 2019;7:e1031-e1045. 3. Hall CB et al. *Curr Top Microbiol Immunol.* 2013;372:39-57.
4. Munoz FM et al. Respiratory syncytial virus. In: *Maternal Immunization*. Elsevier; 2020;213-234.



Influenza

Cobram flu victim and and first-time mum Sarah Hawthorn discharged from Melbourne hospital

A Cobram flu victim who woke from a three-month coma unaware she'd given birth has been discharged from hospital in Melbourne.

The Border Mail understands the bubbly first-time mum, who contracted Influenza A in the later stages of pregnancy, is recovering at home and undergoing rehabilitation after spending months in intensive care.



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Top doctor warns pregnant women over deadly flu



"At some point the U
of gun control. More ›

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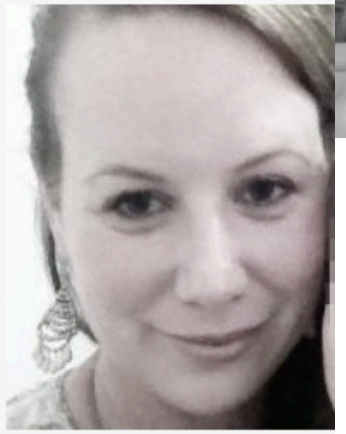
Canberra mother dies from influenza complications amid 'one of worst flu se record'

Updated 26 Sep 2017, 1:44pm

A Canberra mother of two has died of complications from influenza in what health authorities say is "one of the worst flu seasons on record" in Australia.

Jennifer Thew, from Gungahlin in Canberra's north, died over the weekend after contracting influenza.

Acting chief health officer Dr Andrew Pengilley said to his knowledge the "fit, young" woman was the only young adult in the country who had died from influenza this year.



MONASH University

Influenza infection causes harm to the pregnant woman, the fetus and the newborn infant



For the pregnant woman
- Increased morbidity
- Hospitalisation
- Increased risk of death

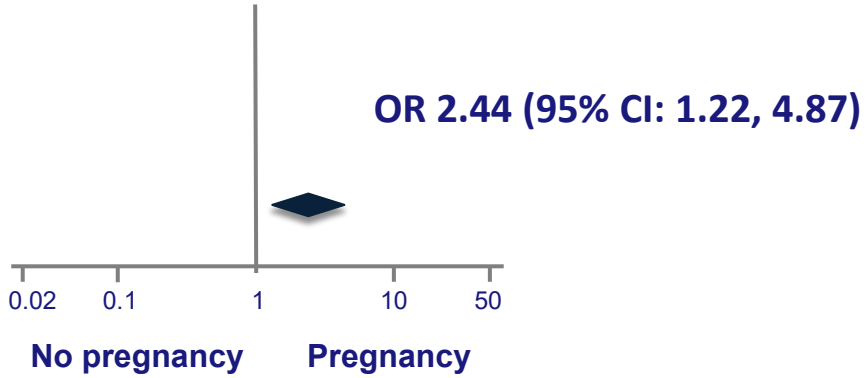
For the fetus
- Fetal growth restriction
- Fetal distress
- Fetal mortality
- Preterm delivery
- Caesarean delivery



For the newborn
- Low birth weight
- Paediatric intensive care
- Neonatal death
- Hospital admission for the infant

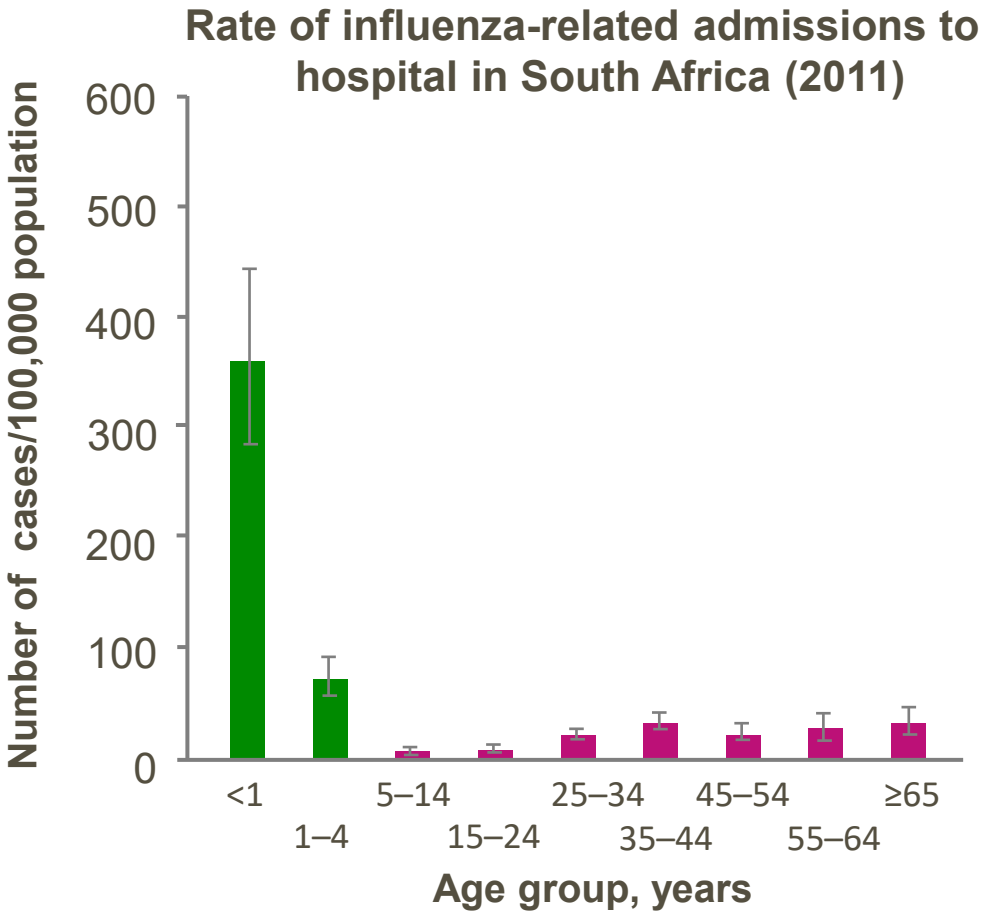
Pregnant women were more than twice as likely to be admitted to hospital with influenza than non-pregnant women

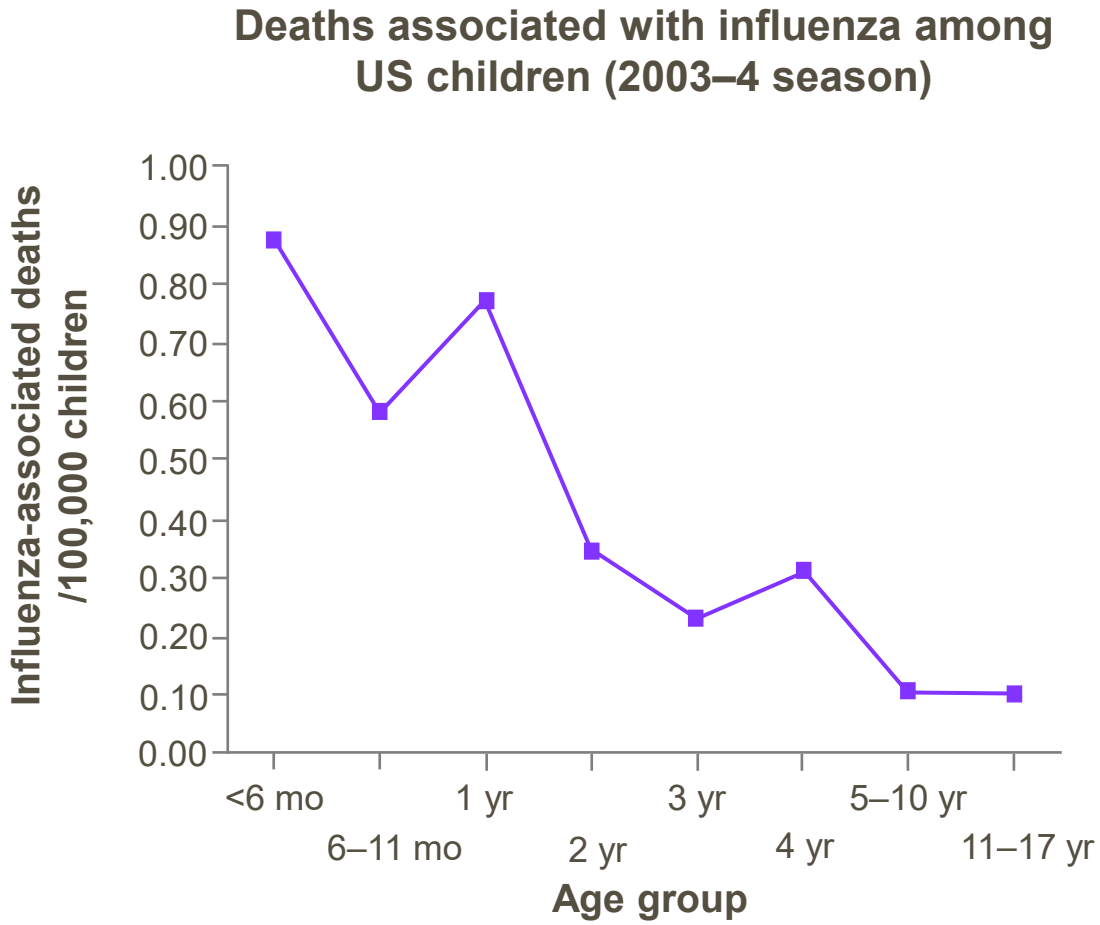
Odds of being admitted to hospital with influenza



Review of 152 observational studies (most conducted during the 2009 flu pandemic)

Infants aged <1 year are more likely to need hospitalisation or to die from complications of influenza

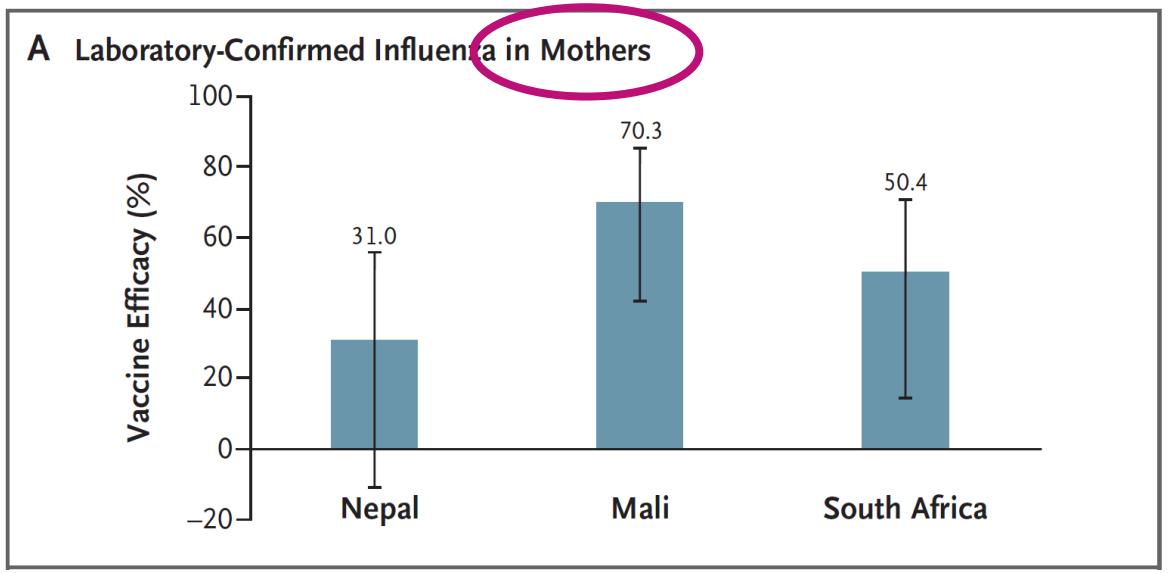


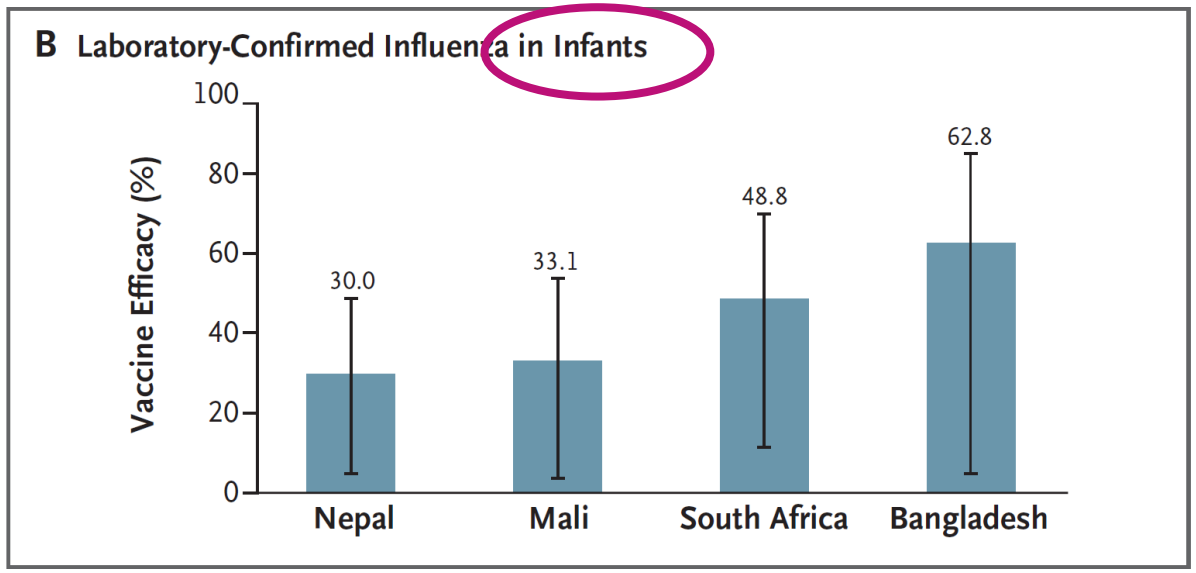


Efficacy of influenza vaccination during pregnancy

Results from four RCTs show that maternal immunisation is efficacious

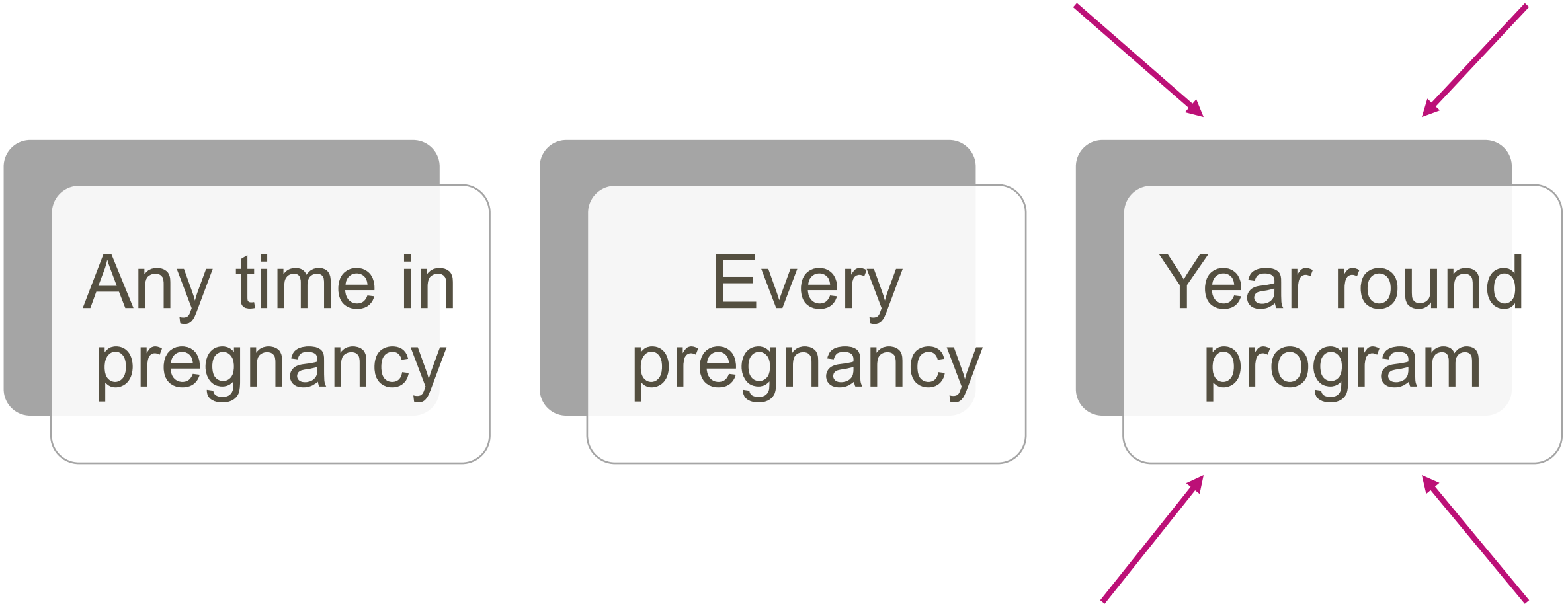
Estimated efficacy of influenza vaccination during pregnancy for preventing laboratory-confirmed influenza in infants and mothers





1. Omer SB. *N Engl J Med* 2017;376:1256–1267; 2. Zaman K *et al., NEJM* 2008;359:1555–1564; 3. Madhi SA *et al. N Engl J Med* 2014;371:918–931; 4. Tapia MD *et al. Lancet Infect Dis* 2016;16:1026–1035

Influenza Recommendations



Why a year-round influenza program?



Main benefit: Maternal Protection



0 weeks gestation

Vaccination window

40 weeks gestation

LNMP January

Influenza season

EDD October

Why a year-round influenza program?



Main benefit: Maternal protection in pregnancy depends on timing received (eg April vs severe disease 28+ weeks in November)
Reduced infant protection over influenza season



0 weeks gestation

Vaccination window

40 weeks gestation

LNMP May

Influenza season

EDD February
6 months old in August

Why a year-round influenza program?



Main benefit: Maternal protection vs infant vs neither



0 weeks gestation

Vaccination window

Wait for new vaccine?
March/April – risk of PTB

40 weeks gestation

LNMP August

Influenza season

Vaccinate January?





EDD May
6 months across influenza season



Pertussis

The burden of pertussis impacts infants

In children aged <1 year with pertussis disease in the USA:

~50%
require hospital treatment



Hospitalisation rates are highest in those aged **<3 months**, followed by those aged **3–6 months**

Complications include:



Apnoea
61%



Pneumonia
23%



Convulsions
~1%



Encephalopathy
0.3%

1 in 100
might die



Three infant deaths from pertussis reported in 2023 in New Zealand

Pertussis deaths in New Zealand without community transmission—an infant immunity gap?

Peter B. McIntyre,[a,] Emma Best,[b] Catherine A. Byrnes,[b] Owen Sinclair,[c] Adrian Trenholme,[b] and Cameron C. Grant[b]*

[a]Dunedin School of Medicine, University of Otago, New Zealand
[b]Faculty of Medical and Health Sciences, The University of Auckland, New Zealand
[c]Te Whatu Ora Health New Zealand Waitemata, New Zealand

Attention was first drawn to development of a post-COVID "immunity debt" in children in late 2021, attributed to reduced community exposure to pathogens transmitted by the respiratory route.[1] Subsequent evidence from multiple European countries has supported this concept for both viruses (especially respiratory syncytial virus (RSV)) and bacteria (especially invasive disease due to Group A Streptococcus), supported by no increase in invasive bacterial diseases not transmitted by

Organization in 2014—the historical New Zealand rate of 10.1 was higher than Australia, Canada, Denmark, and Sweden (3.7–4.2) but comparable to Israel, Portugal and England and Wales (7.4–8.8).[6] A cluster of 14 deaths in 2012 in England and Wales (19.1 per million live births),[6] prompted a precedent-setting emergency maternal pertussis vaccination programme but occurred in the context of large increases in notified pertussis, especially among adolescents.[7]

The Lancet Regional Health - Western Pacific 2023;37: 100850

Published Online 20 July 2023
https://doi.org/10.1016/j.lanwpc.2023.100850

Effectiveness of pertussis vaccination during pregnancy

Results from two studies in England show maternal vaccination is effective

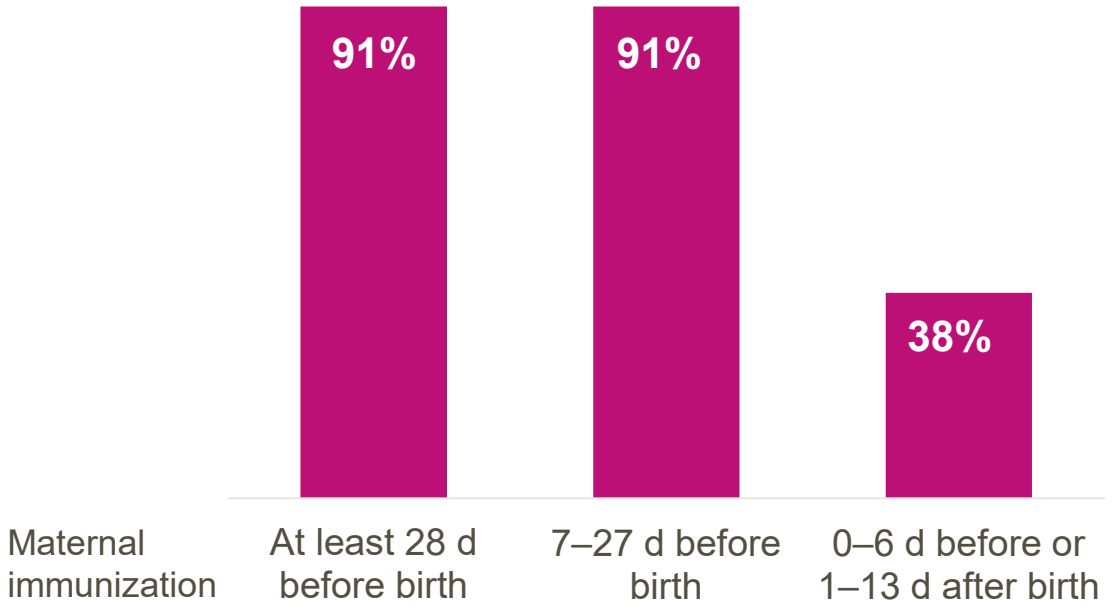
Effectiveness of maternal pertussis vaccination in England: an observational study

Gayatri Amirthalingam, Nick Andrews, Helen Campbell, Sonia Ribeiro, Edna Kara, Katherine Donegan, Norman K Fry, Elizabeth Miller, Mary Ramsay

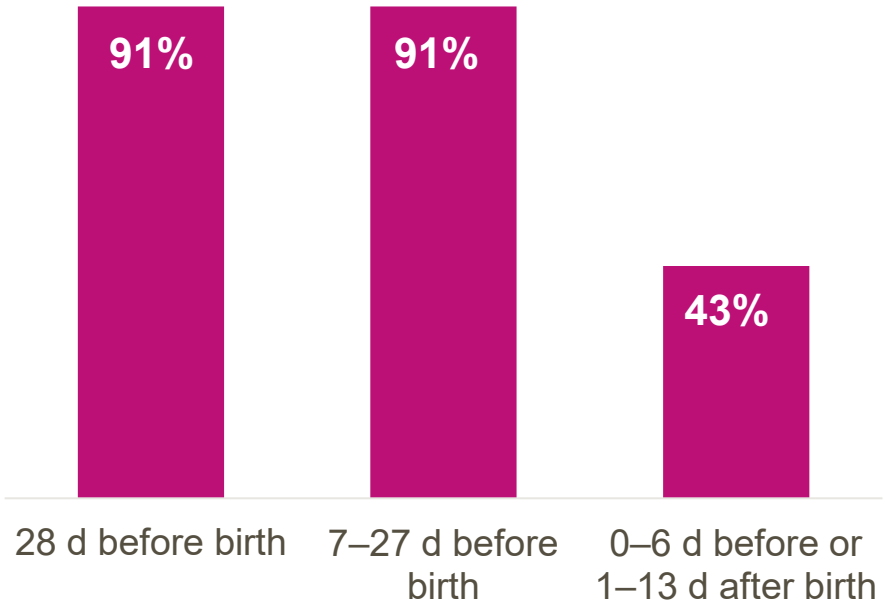
Sustained effectiveness of the maternal pertussis immunization program in England 3 years following introduction

Gayatri Amirthalingam, Helen Campbell, Sonia Ribeiro, Norman K Fry, Mary Ramsay, Elizabeth Miller, Nick Andrews

Vaccine effectiveness in infants <3 months of age



Vaccine effectiveness



1. Amirthalingam G *et al. Lancet* 2014;384:1521–1528; 2. Amirthalingam G *et al. Clin Infect Dis* 2016;63(suppl 4):S236–S243

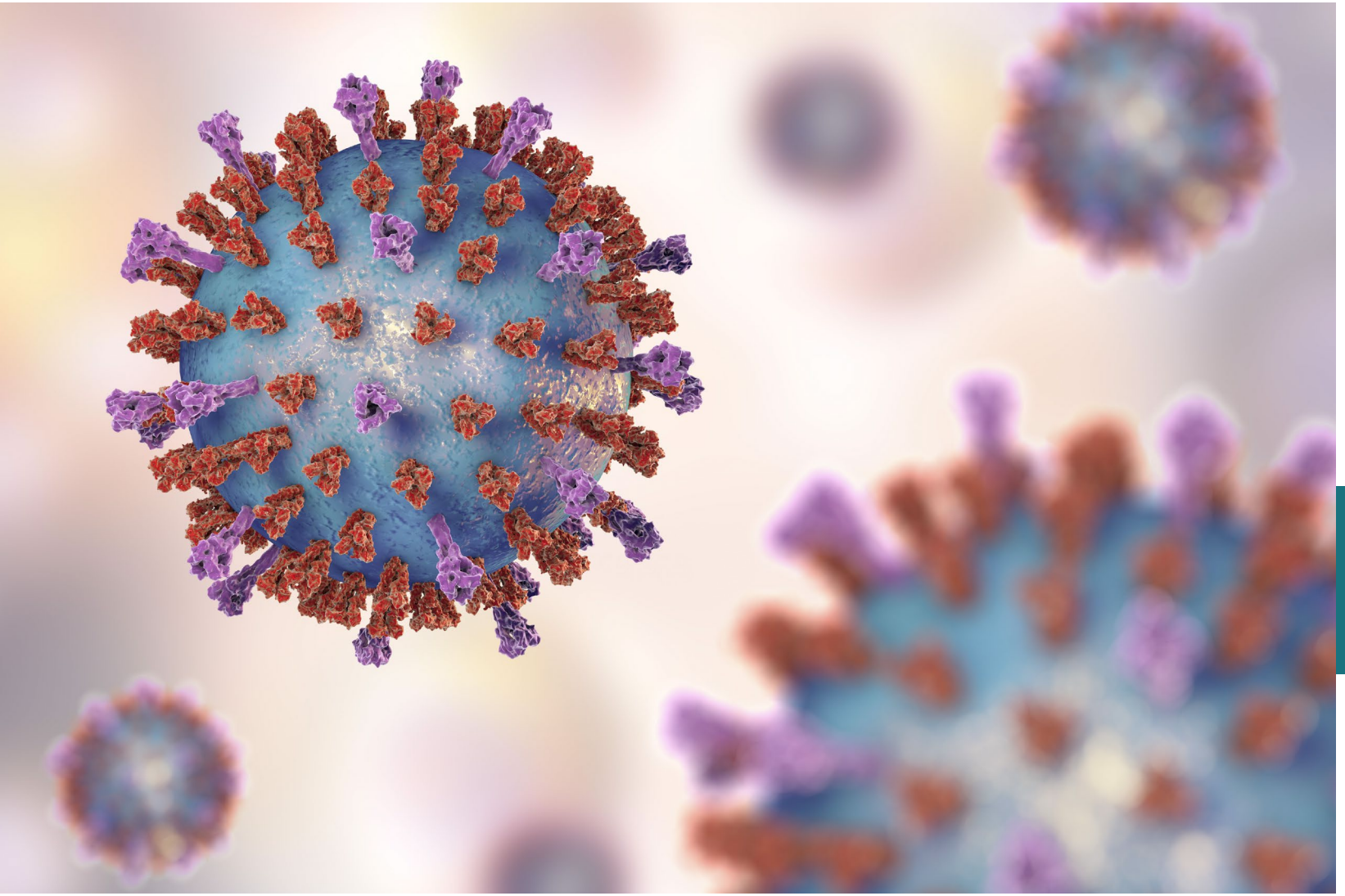
Should you vaccinate partners or other care givers?

Pertussis Recommendations

From 20 weeks

Every pregnancy

Year round program

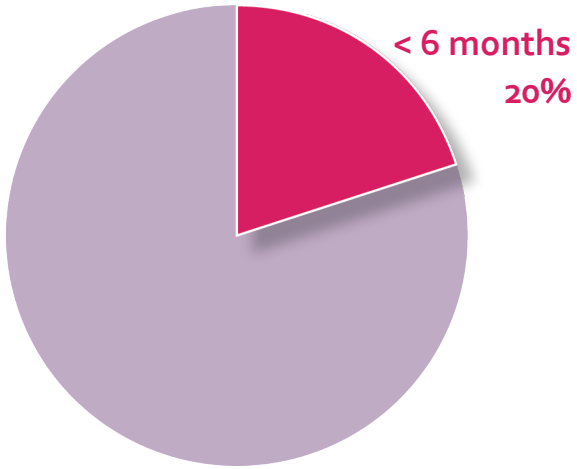


RSV

Annual global pediatric RSV disease burden (< 5 years of age)

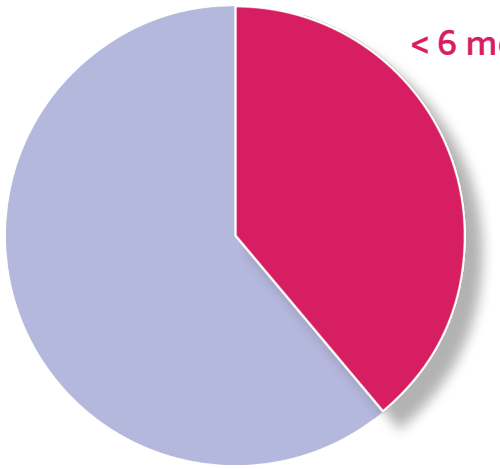
LEADING CAUSE OF SEVERE RESPIRATORY INFECTION

33,000,000
episodes



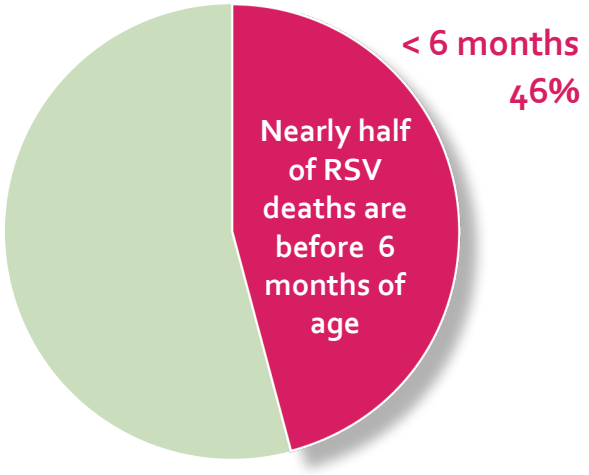
LEADING CAUSE OF PEDIATRIC HOSPITALIZATION

3.6 million
hospitalizations



IMPORTANT CAUSE OF PEDIATRIC MORTALITY

101,000
deaths



TOTAL GLOBAL CHILD MORTALITY DUE TO RSV

3.6% < 6 MONTHS

2.3% < 5 YEARS

Reference: Li Y, et al. *Lancet* 2022.

Original slide developed by PATH, UMC Utrecht, and the World Health Organization. Last updated: December 2023

RSV Kills More Children Aged <1 Year Than Any Other Single Pathogen Except Malaria

Global disease burden:
2,031,474 deaths during days 28-364
of life in 2010

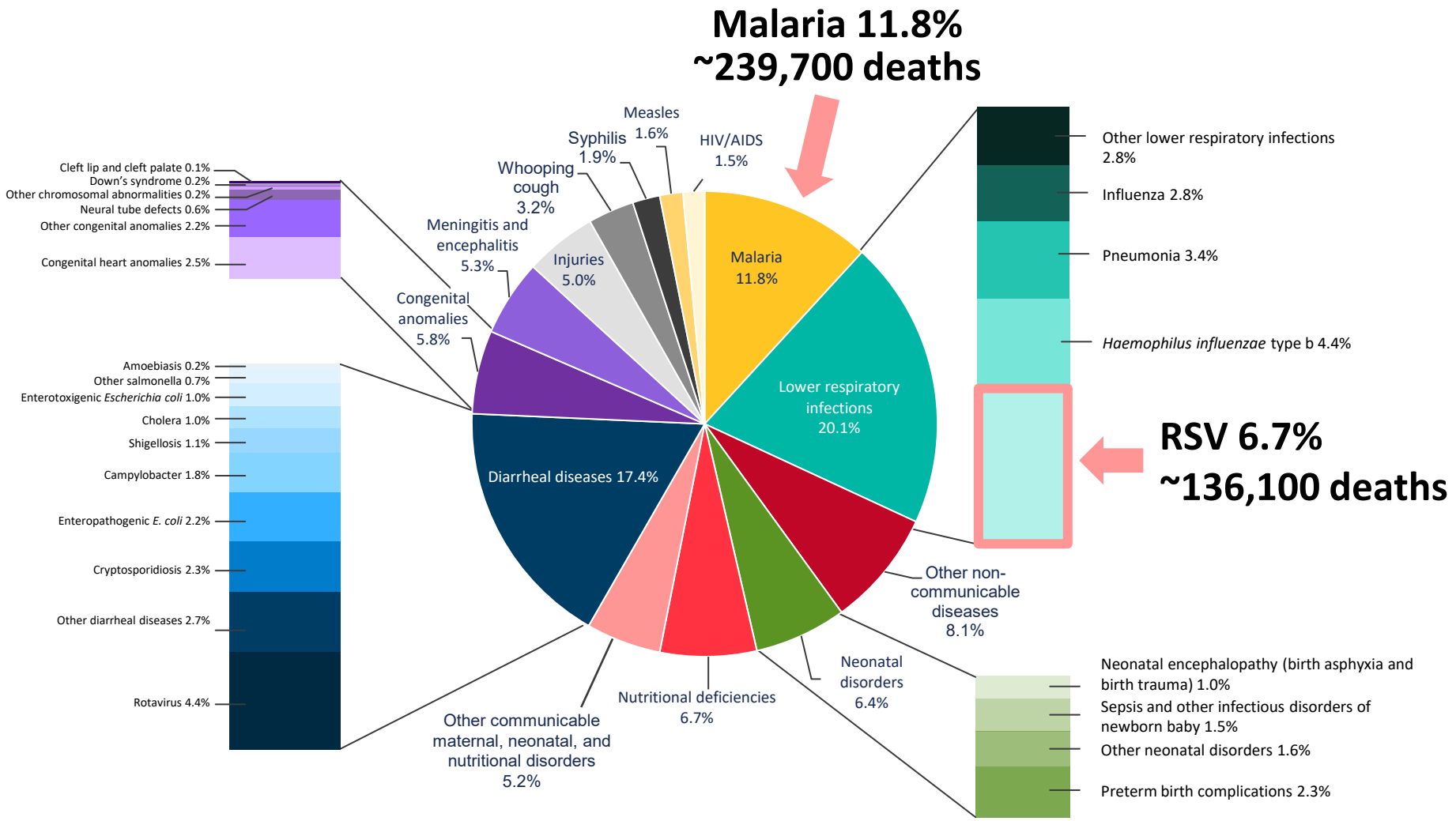


Figure adapted from Lozano R et al.
RSV, respiratory syncytial virus.
Lozano R, et al. *Lancet*. 2012;380(9859):2095-2128.

Two Strategies Have Been Developed to Help Prevent RSV Lower Respiratory Tract Disease (LRTD) in Infants*

RSV maternal vaccine[1]



RSVpreF maternal vaccine

Neonates are born with maternal antibodies against RSV, which **help protect against LRTD caused by RSV from birth up to 6 months of age**

RSV monoclonal antibodies[2-4]



Nirsevimab, clesrovimab, and palivizumab

Neonates and infants receive RSV-specific monoclonal antibodies, which **help protect against LRTD caused by RSV during their first RSV season†**

***Licensure and availability in local markets may vary. †Children who remain vulnerable to severe RSV disease are eligible to receive nirsevimab or palivizumab during their second RSV season.[2,3]**

LRTD, lower respiratory tract disease; RSV, respiratory syncytial virus; RSVpreF, RSV prefusion F vaccine.

1. ABRYSVO® (Respiratory Syncytial Virus Vaccine) Summary of Product Characteristics. Pfizer Inc; September 14, 2026. https://www.ema.europa.eu/en/documents/product-information/abrysvo-epar-product-information_en.pdf.
2. Beyfortus® (nirsevimab) Summary of Product Characteristics. Sanofi S.A.; February 23, 2026. https://www.ema.europa.eu/en/documents/product-information/beyfortus-epar-product-information_en.pdf. 3. Synagis® (palivizumab) Summary of Product Characteristics. AstraZeneca AB; October 11, 2023. https://www.ema.europa.eu/en/documents/product-information/synagis-epar-product-information_en.pdf. 4. Enflonsia® (clesrovimab) Summary of Product Characteristics. Merck Sharp & Dohme B.V.; April 22, 2026. https://www.ema.europa.eu/en/documents/product-information/enflonsia-epar-product-information_en.pdf All accessed September 15, 2026.

Phase 3 clinical study evidence

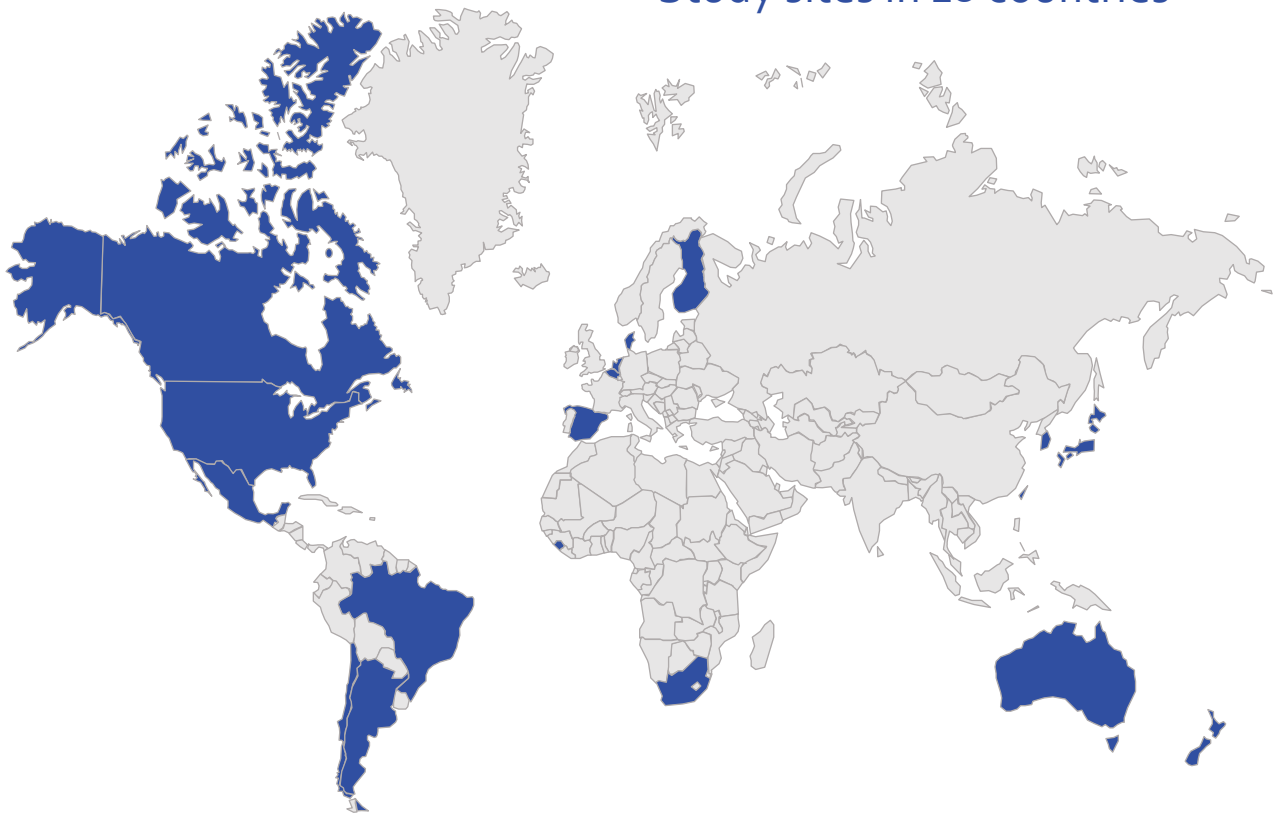
pre-F RSV maternal vaccine efficacy and safety in infants born to women vaccinated during pregnancy

Study product: Abrysvo™

7,392 pregnant participants ≤49 years between ≥ 24 and ≤ 36 weeks gestation

7,128 infants enrolled

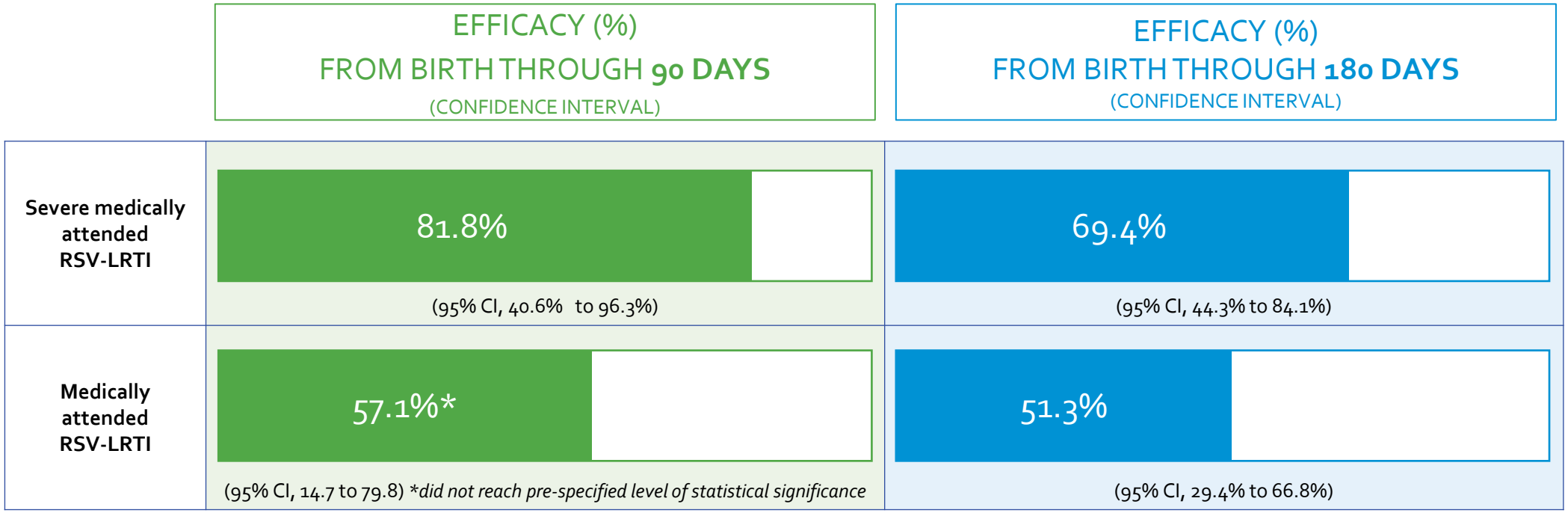
Study sites in 18 countries



Reference: Kampmann B, et al. *New England Journal of Medicine.* 288(16):2023.

Original slide developed by the World Health Organization and PATH. Last updated: January 2024.

Pre-F RSV maternal vaccine efficacious against severe medically attended RSV in infants

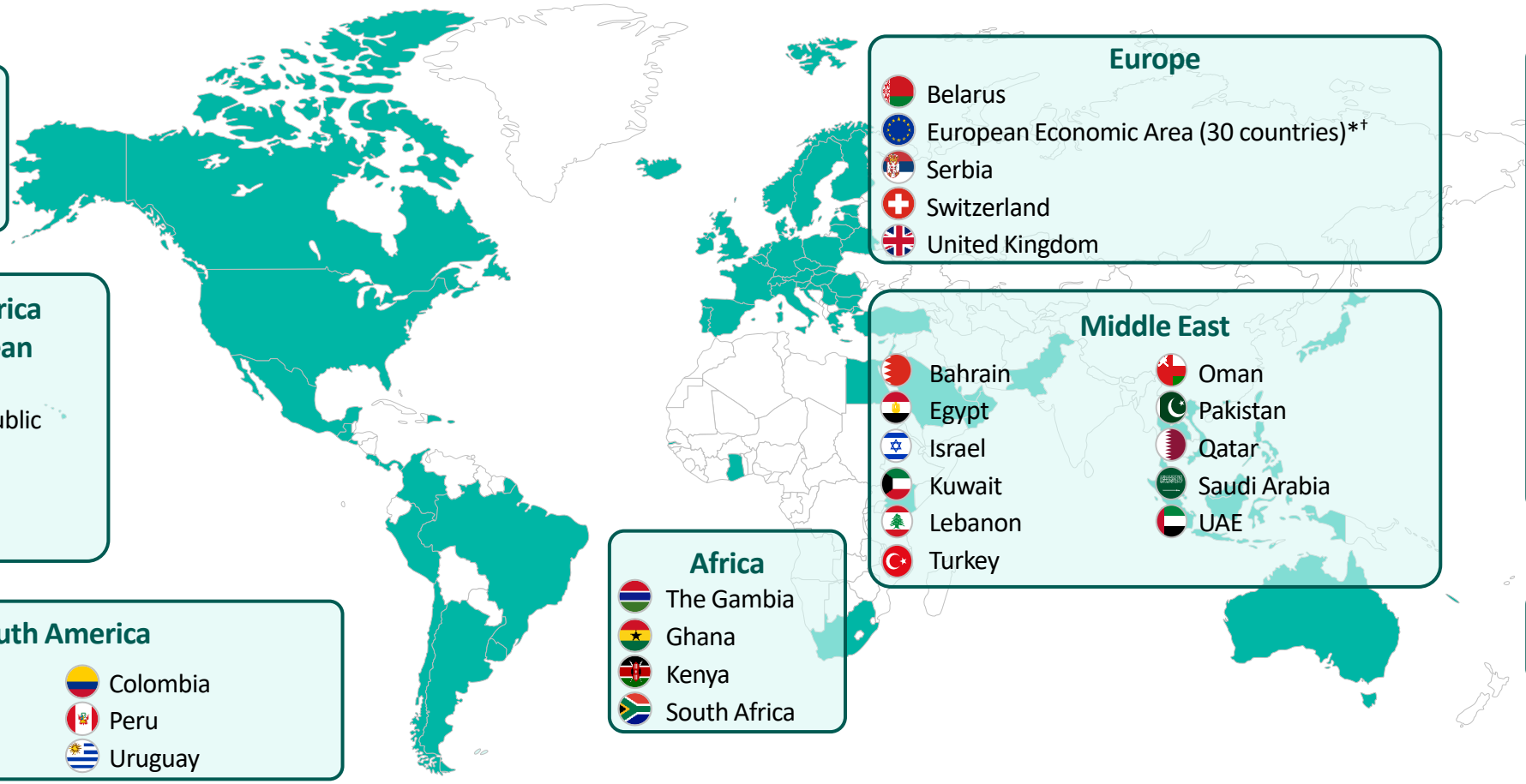


Efficacy remains high through first, most critical 6 months after birth—when infants are at greatest risk.

Reference: Kampmann B, et al. *New England Journal of Medicine.* 288(16):2023.

Original slide developed by the World Health Organization and PATH. Last updated: January 2024.

Over 70 Countries Have Approvals for Use of RSVpreF in Pregnant Individuals to Help Protect Infants Against RSV Disease



North America
- Canada
- United States†
- Mexico

Central America and Caribbean
- Costa Rica
- Dominican Republic
- El Salvador
- Guatemala
- Panama

South America
- Argentina
- Brazil
- Chile
- Colombia
- Peru
- Uruguay

Europe
- Belarus
- European Economic Area (30 countries)*†
- Serbia
- Switzerland
- United Kingdom

Middle East
- Bahrain
- Egypt
- Israel
- Kuwait
- Lebanon
- Turkey
- Oman
- Pakistan
- Qatar
- Saudi Arabia
- UAE

Africa
- The Gambia
- Ghana
- Kenya
- South Africa

Asia
- Hong Kong SAR
- Indonesia
- Japan
- Macau SAR
- Malaysia
- Philippines
- Singapore
- South Korea
- Taiwan
- Thailand
- Vietnam

Oceania
- Australia

*According to Eurostat, EEA includes Austria, Belgium, Bulgaria, Croatia, Czechia, Denmark, Cyprus, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Spain, Slovakia, Slovenia, and Sweden.
†Including autonomous, unincorporated, and/or overseas territories of the US and France.
RSV, respiratory syncytial virus; RSVpreF, RSV prefusion F vaccine; SAR, Special Administrative Region; UAE, United Arab Emirates.

USA: Abrysvo (respiratory syncytial virus vaccine) prescribing information. EEA: Abrysvo summary of product characteristics. Canada: Abrysvo product monograph. UK: Abrysvo powder and solvent for solution for injection. Summary of product characteristics. Argentina: Vademécum Nacional de Medicamentos. Bahrain: https://nhra.bh/Departments/PPR/MediaHandler/GenericHandler/documents/departments/PPR/ Medicines/List/PPR_LISTS_Registered Medicine Price List_20240722.xlsx. Japan: Recombinant RS virus vaccine (pmda.go.jp). Macau: 澳門特區藥品資料查詢 (ssm.gov.mo). Australia: Australian Product Information - ABRYSVO® (Recombinant Respiratory Syncytial Virus (Prefusion F Protein) Vaccine. Brazil: Anvisa Parecer Público de Avaliação de Medicamento. Saudi Arabia: Drugs List | Saudi Food and Drug Authority (sfda.gov.sa). United Arab Emirates: Registered Medical Product Directory | More | Ministry of... (mohap.gov.ae). Hong Kong: Search Drug (drugoffice.gov.hk). Uruguay: Comisión Nacional Asesora de Vacunaciones. Thailand: Details of Medicinal Product. Qatar: List of registered pharmaceutical products with prices. Singapore: Product Details - Therapeutic Products (hsa.gov.sg). Dominican Republic: Certificado de Registro Sanitario (msp.gob.do). Switzerland: Swissmedic Journal 08/2024. Chile: Ficha Productos Registrados (ispch.gob.cl). Israel: מאגר התרופות (health.gov.il). Philippines: FDA Verification Portal. Taiwan: Taiwan Food and Drug Administration. Egypt: Egyptian Drug Authority Assessment Report for Biological Medicinal Product. Peru: Registro Sanitario Productos Farmacéuticos. Mexico: Consulta de Registros Sanitarios. Oman: List of registered and priced pharmaceutical medicine. Indonesia: Abrysvo Local Product Document. South Africa: Abrysvo-PI-approved-10-Dec-2024. El Salvador: Superintendencia de Regulacion Sanitaria Expediente Electronico Unidad de Registro y Visado. Panama: MINSA – DNDF. Belarus: Данные о регистрационном удостоверении на лекарственное средство. Türkiye: ABRYSVO 0.5 mL IM KUB. Malaysia: QUEST 3+ Product Search. Costa Rica: Regístrelo. Pakistan: Minutes of the 344th Meeting of the Registration Board Held on 31st December, 2024 to 02nd January, 2025 – Drug Regulatory Authority of Pakistan. Ghana: FDA Products Registry. Guatemala: Registros Sanitarios Vigentes de Productos Farmacéuticos. Lebanon: Lebanon National Drugs Database. Vietnam: Cục Quản lý Dược - Bộ Y tế. Gambia: Medicines Control Agency Registered Products. Kenya: PPB - eCTD. Serbia: DOPUNU SPISKA. Korea: 의약품안전나라 > 통합검색 > 의약품등 정보검색. Colombia: consulta registros sanitarios | Invima.
Eurostat: European Economic Area (EEA) - Statistics Explained. All URLs accessed September 2026.

Over 30 Countries Have Recommended RSV Maternal Vaccination to Help Protect Infants From RSV Disease

National and regional recommendations by gestational age

24-36 weeks

- Slovenia (year round)
- Poland (year round)
- Norway
- Bulgaria (year round)
- Slovakia (year round)

28-36 weeks

- Belgium
- Estonia
- Czech Republic
- Canada*†
- Taiwan
- Colombia (year round)
- Japan (year round)
- Qatar (year round)
- El Salvador (year round)
- Vietnam (year round)
- S. Arabia (year round)‡
- South Africa (year round)

≥28 weeks until delivery

- WHO (third trimester); prequalified in March 2025
- UK (year round)
- Australia (year round)
- Brazil (year round)
- Ecuador (year round)

32-36 weeks

- US
- Argentina
- PAHO
- Luxembourg
- France
- UAE (year round)
- Austria
- Sicily, Italy
- Switzerland§
- Uruguay‖
- Costa Rica
- Cyprus (year round)
- Greece
- Denmark
- Panama (year round)
- Kuwait
- Mexico
- Peru (year round)
- Bahrain (year round)¶

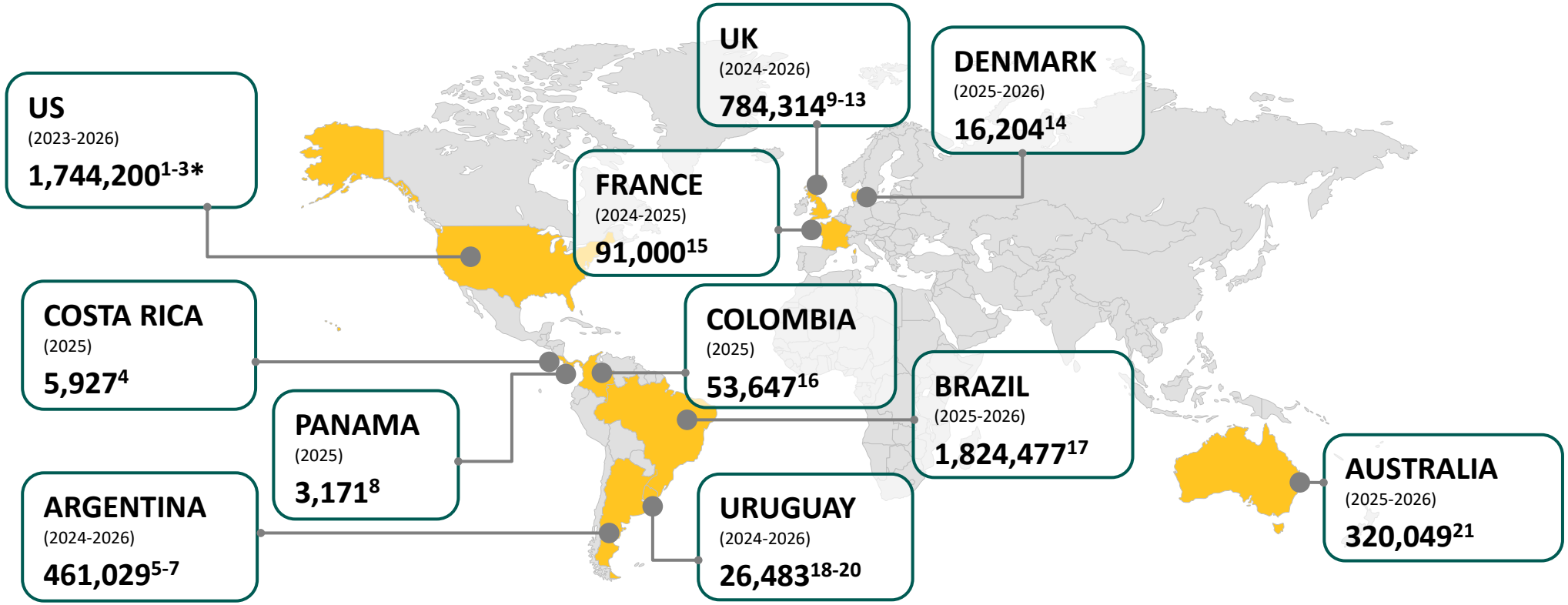
Legend

- Not reimbursed
- Reimbursed

*Off label; indicated at 32-36 weeks of gestation. †Currently reimbursed only in Ontario. ‡Ideally administered seasonally between September and January. §Administration recommended from October to February if the due date is before the end of March. ‖From 32 to 38$^{6/7}$ weeks of gestation. ¶From 32 weeks of gestation onwards and at least 2 weeks prior to delivery.
PAHO, Pan American Health Organization; RSV, respiratory syncytial virus; S, Saudi; WHO, World Health Organization.

Slovenia: PREDLOG PROGRAMA (nijz.si). Poland: RSV (Respiratory Syncytial Virus) - District Sanitary and Epidemiological Station in Warsaw - Portal Gov.pl. Norway: RSV-vaksine – håndbok for helsepersonell. Bulgaria: Lex.bg - Закони, правилници, конституция, кодекси, държавен вестник, правилници по прилагане. Slovakia: Rozhodnutie číslo S22833-2026-SFLP-34553; Abrysvo, INN-respiratory syncytial virus vaccine (bivalent, recombinant). Belgium: Report 9760 - Preventive strategies against RSV disease in children. Estonia: Immunoprofülaktika ekspertkomisjoni 03.09.2025 koosoleku päevakord ja soovitused. Czech Rep: Vakcinace.eu - Doporučení České vakcinologické společnosti ČLS JEP k imunizaci proti respiračnímu syncyciálnímu viru pro děti a těhotné ženy. Canada: An Advisory Committee Statement (ACS) National Advisory Committee on Immunization (NACI) syncytial virus (RSV): Canadian Immunization Guide; Respiratory Syncytial Virus (RSV) prevention programs | ontario.ca. Taiwan: 呼吸道融合病毒疫苗 (RSV Vaccine). Colombia: Colombia da paso histórico en prevención de la mortalidad infantil: Minsalud incorpora la vacuna materna contra el Virus Sincitial Respiratorio al PAI. Japan: The 64th Meeting of the Vaccination and Vaccine Subcommittee of the Health and Science Council. Qatar: Ministry of Public Health - News Details. El Salvador: Esquema de Vacunación 2026. Vietnam: QUYẾT ĐỊNH Ban hành tài liệu chuyên môn "Hướng dẫn Quốc gia các dịch vụ chăm sóc sức khỏe sinh sản về nội dung Chăm sóc trước khi có thai và trước khi sinh" Saudi Arabia: مرجعيات عامة لإدراج -لقاح الفيروس المخلوي التنفسي في الخدمة الصحية- النسخة الثالثة 003.pdf WHO: WHO position paper on immunization to protect infants against respiratory syncytial virus disease, May 2025; WHO prequalifies first maternal respiratory syncytial virus vaccine. UK: Respiratory syncytial virus: the https://assets.publishing.service.gov.uk/media/6a2015a4730aece621f09866/Green_Book_RSV_20260603.pdf book, chapter 27a. South Africa: Use of the Bivalent Respiratory Syncytial Virus (RSV) Vaccine (Abrysvo™, Pfizer) During Pregnancy for the Prevention of RSV–Associated Lower Respiratory Tract Disease in Infants; Abrysvo-PI-approved-10-Dec-2024.pdf. Uruguay: Vacunación contra el Virus Respiratorio Sincitial (VRS) - Documento Técnico 2026. Ecuador: Daniel Noboa impulsa un hito en salud prenatal con la incorporación, por primera vez, de la vacuna contra el virus causante de la bronquiolitis y neumonía en Ecuador – Ministerio de Salud Pública. Brazil: Ministério da Saúde fecha parceria para produção nacional da vacina contra o vírus sincicial respiratório e sua oferta no SUS em novembro deste ano. Australian Immunisation Handbook. Respiratory syncytial virus (RSV). US: Fleming-Dutra KE, et al. *MMWR Morb Mortal Wkly Rep*. 2023;72(41):1115-1122. Argentina: Boletín Oficial de la República Argentina – Ministerio de Salud – Resolución 4218/2023. PAHO: PAHO Technical Advisory Group (TAG) on Immunization provides regional recommendations on vaccines against dengue, respiratory syncytial virus, and issues statement on ongoing use of COVID-19 vaccines. Luxembourg: Recommandations du Conseil supérieur des maladies infectieuses. France: Haute Autorité de Santé. Vaccination maternelle contre le VRS: une nouvelle possibilité pour protéger le nouveau-né. UAE: Ministerial decree no. 189 of the year 2025 regarding the amendment of the national preference for immunization. Austria: Impfplan Österreich. Sicily: KM_C284e-20240920123458. Switzerland: BAG-Bulletin. Costa Rica: Costa Rica inicia vacunación contra el virus respiratorio sincitial en mujeres embarazadas. Cyprus: Εθνικό Πρόγραμμα Εμβολιασμών Ενηλίκων και Ειδικών Ομάδων - Υπουργείο Υγείας - Gov.cy. Greece: Εθνικό Πρόγραμμα Εμβολιασμών Ενηλίκων 2025. Denmark: Indstilling til indførelse af tilbud om RSV-vaccination til gravide | Sundhedsstyrelsen. Panama: Esquema Nacional de Vacunación. Kuwait: Respiratory syncytial virus vaccination and antibody immunization are optional vaccinations. Mexico: Lineamientos Generales PVU 2026. Peru: Esquema Nacional de Inmunizaciones. Bahrain: Immunizations - Ministry of Health. Bahrain: MoH Initiatives related to 2030 vision - Ministry of Health. All URLs accessed September 18, 2026.

Over 5.3 Million Doses Have Been Administered to Pregnant Individuals in Select Countries With Publicly Available Information

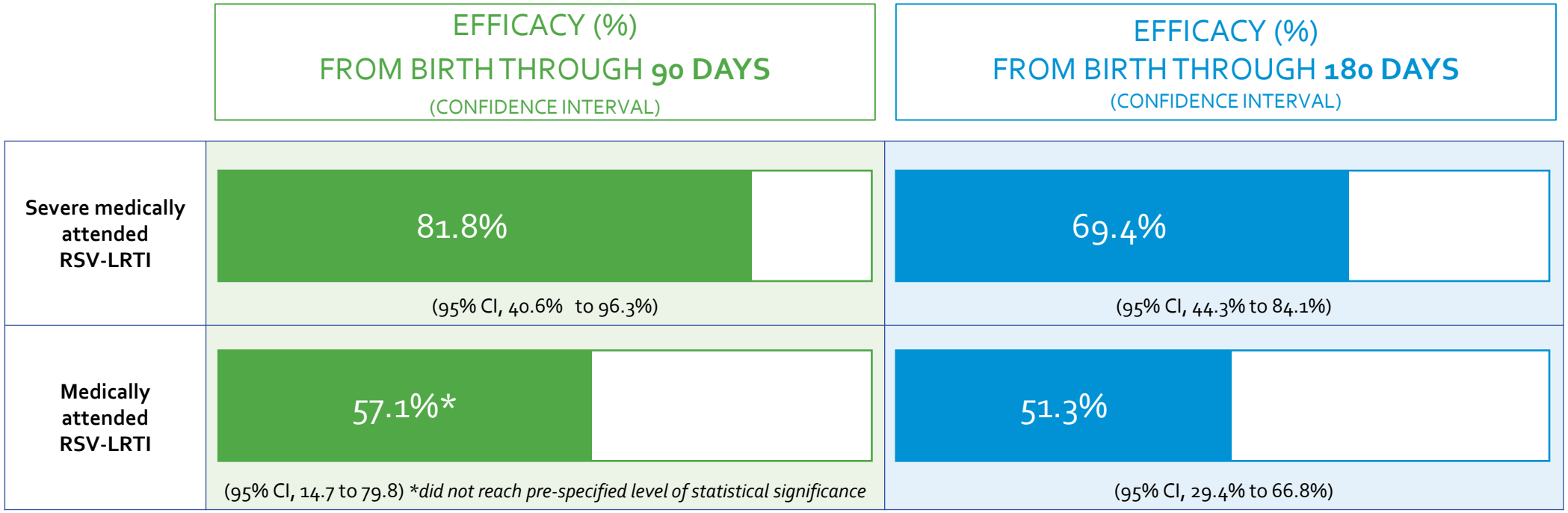


RSVpreF maternal vaccination is approved in over 70 countries†; only countries with publicly available uptake data are shown here

*2024-2025 and 2025-2026 uptake calculated based on the eligible pregnant population in US during these seasons, assumed to be 1.8 million, similar to the 2023-2024 season.[1] †Please refer to slide 10 for an overview of countries that have approved RSVpreF and associated reference citations.
RSV, respiratory syncytial virus; RSVpreF, RSV prefusion F vaccine; UK, United Kingdom; US, United States.

1. Stokley S; CDC. Implementation and Uptake of Nirsevimab and Maternal Vaccine. Advisory Committee on Immunization Practices (ACIP); June 2024. https://www.cdc.gov/acip/downloads/slides-2024-06-26-28/02-RSV-Mat-Peds-Stokley-508.pdf 2. Centers for Disease Control and Prevention. 2024-25 respiratory syncytial virus (RSV) vaccination coverage, pregnant women, United States. Published April 9, 2025. https://www.cdc.gov/rsvvaxview/dashboard/2024-25-pregnant-women-coverage.html 3. Centers for Disease Control and Prevention. Respiratory syncytial virus (RSV) vaccination coverage, pregnant women, United States. Published March 11, 2026. https://www.cdc.gov/rsvvaxview/dashboard/pregnant-women-coverage.html 4. Caja Costarricense De Seguro Social Costa Rica. 5 927 embarazadas y sus bebés protegidos contra el virus respiratorio sincitial. August 14, 2025. https://aissfa.ccss.sa.cr/noticias/noticia?v=204405459082 5. Minesterio de Salud (Argentina). Coberturas de vacunación: Calendario Nacional 2024. September 10, 2025. https://www.argentina.gob.ar/sites/default/files/10-30-nacion-cnv_2024-10_09_2025_v2.pdf 6. Minesterio de Salud (Argentina). Coberturas de vacunación: Calendario Nacional 2025. June 3, 2026. https://www.argentina.gob.ar/sites/default/files/2019/05/nacion_-_cnv_2025.pdf 7. Minesterio de Salud (Argentina). Salud presentó la evaluación preliminar de la vacuna contra el virus sincicial respiratorio. June 1, 2026. https://www.argentina.gob.ar/noticias/salud-presento-la-evaluacion-preliminar-de-la-vacuna-contra-el-virus-sincicial-respiratorio 8. Ministerio de Salud de la República de Panamá. Minsa ha aplicado más de 6 mil vacunas contra el Virus Sincitial Respiratorio. August 27, 2025. https://www.minsa.gob.pa/noticia/minsa-ha-aplicado-mas-de-6-mil-vacunas-contra-el-virus-sincitial-respiratorio 9. National Health Service England. Vaccinations: RSV. 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Updated April 20, 2026. https://www.ssi.dk/vaccinationer/tilslutning-til-bornevaccinationsprogrammet 15. Ministère de la Santé, des Familles, de l'Autonomie et des Personnes handicapées. Bronchiolite du nourrisson : le ministère de la Santé et de l'Accès aux Soins lance la campagne de prévention 2025-2026 le 1er septembre. Published August 28, 2025. https://sante.gouv.fr/actualites-presse/presse/communiques-de-presse/article/bronchiolite-du-nourrisson-le-ministere-de-la-sante-et-de-l-acces-aux-soins 16. Ministerio de Salud y Protección Social (Colombia). Colombia supera la meta de vacunación materna contra el Virus Sincitial Respiratorio y protege a más de 53 mil recién nacidos. Published February 10, 2026. https://www.minsalud.gov.co/Comunicaciones/noticias/2026/Paginas/colombia-supera-meta-de-vacunacion-materna-contra-virus-sincitial-respiratorio.aspx 17. Brasil Ministério da Saúde - Vacinação do Calendário Nacional. 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Australian respiratory surveillance report – 24 August to 6 September 2026. Published September 11, 2026. https://www.cdc.gov.au/sites/default/files/2026-09/australian-respiratory-surveillance-report-24-august-to-6-september-2026.pdf All URLs accessed September 2026.

Pre-F RSV maternal vaccine efficacious against severe medically attended RSV in infants

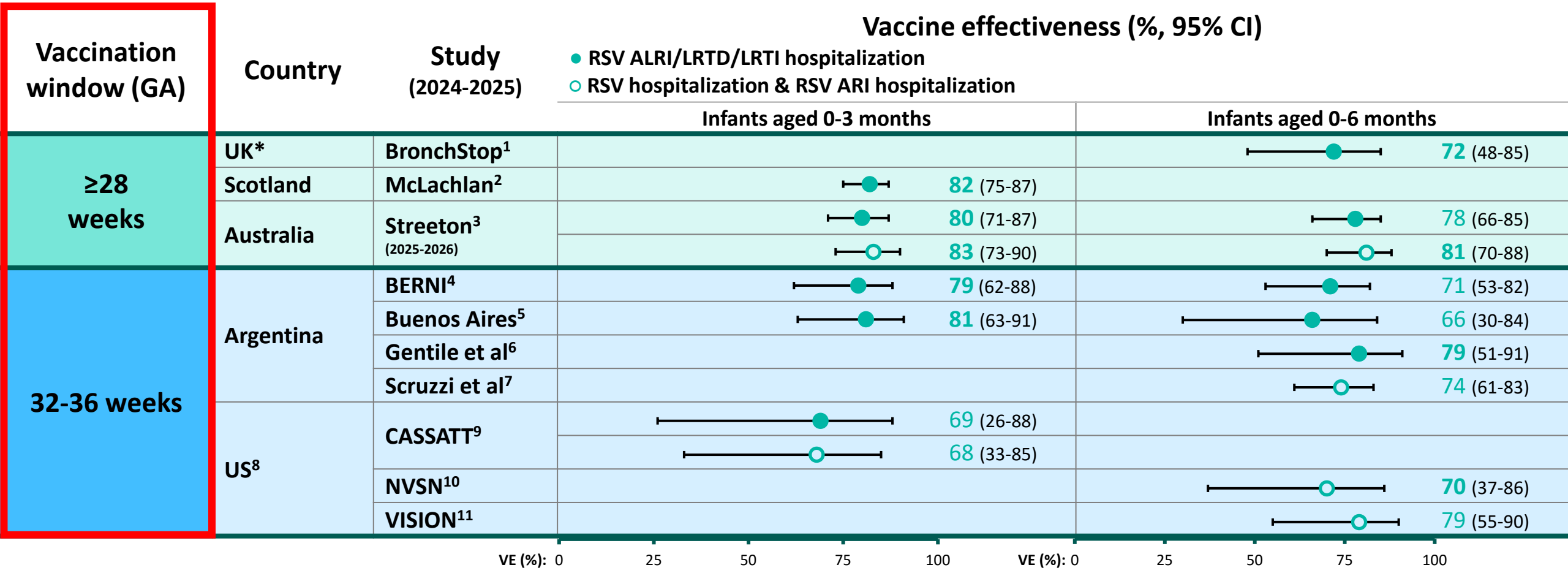


Efficacy remains high through first, most critical 6 months after birth—when infants are at greatest risk.

Reference: Kampmann B, et al. *New England Journal of Medicine.* 288(16):2023.

Original slide developed by the World Health Organization and PATH. Last updated: January 2024.

RSVpreF Maternal Vaccination Demonstrated Effectiveness Across Different Gestational Age Windows



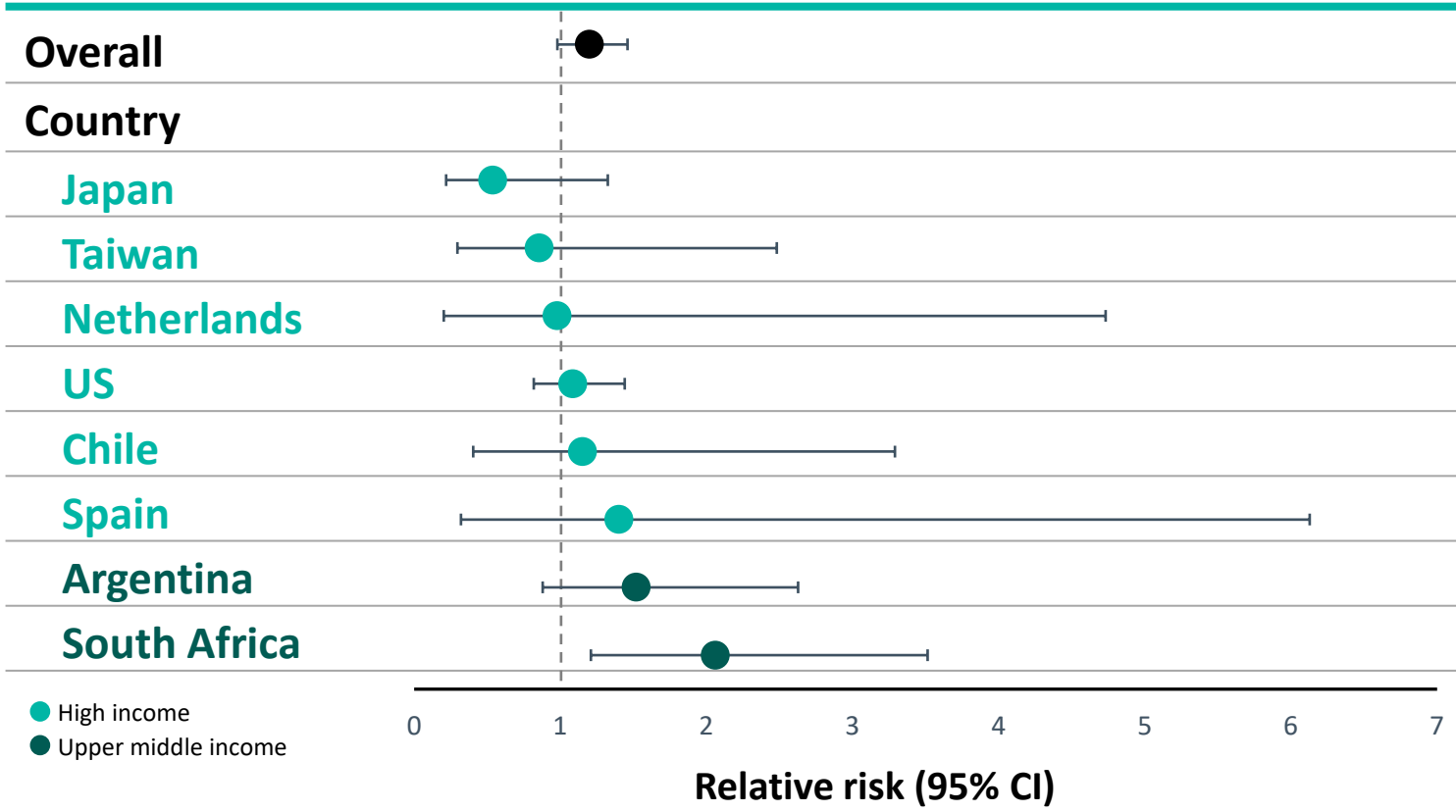
*England and Scotland

ALRI, acute lower respiratory infection; ALRI, acute lower respiratory tract infection; CI, confidence interval; LRTD, lower respiratory tract disease; LRTI, lower respiratory tract infection; NVSN, New Vaccine Surveillance Network; RSV, respiratory syncytial virus; RSVpreF, RSV prefusion F vaccine; RWE, real-world effectiveness; UKHSA, United Kingdom Health Security Agency; VE, vaccine effectiveness; VISION, Virtual SARS-CoV-2, Influenza, and Other respiratory viruses Network.

1. Williams TC, et al. *Lancet Child Adolesc Health.* 2025;9(9):655-662. 2. McLachlan I, et al. *Lancet Infect Dis*. 2026;26(4):362-373. 3. Wadia U, et al. *JAMA Pediatr.* 2026:e263391. doi:10.1001/jamapediatrics.2026.3391 4. Pérez Marc G, et al. *Lancet Infect Dis.* 2025;25(9):1044-1054. 5. Razzini JL, et al. *Lancet Reg Health Am.* 2025;52:101296. doi:10.1016/j.lana.2025.101296 6. Gentile A, et al. *Pediatr Infect Dis J.* 2025;44(10):988-994. 7. Scruzzi GF, et al. *Arch Argent Pediatr*. 2025;123(6):e202510741. 8. Fleming-Dutra KE, et al. *MMWR Morb Mortal Wkly Rep*. 2023;72(41):1115-1122. 9. Rick AM, et al. *JAMA Netw Open.* 2026;9(6):e2616773. doi:10.1001/jamanetworkopen.2026.16773 10. Moline HL, et al. *JAMA Pediatr.* 2026;180(3):314-324. 11. MacNeil A. Effectiveness and impact of RSV prevention products in infants during the 2024–2025 RSV season. Presented at ACIP, June 25, 2025. https://www.cdc.gov/acip/downloads/slides-2025-06-25-26/03-MacNeil-Mat-Peds-RSV-508.pdf All URLs accessed September 2026.

An Imbalance in Preterm Birth Rates Was Observed With 1 Non–High-Income Country Being Statistically Significant

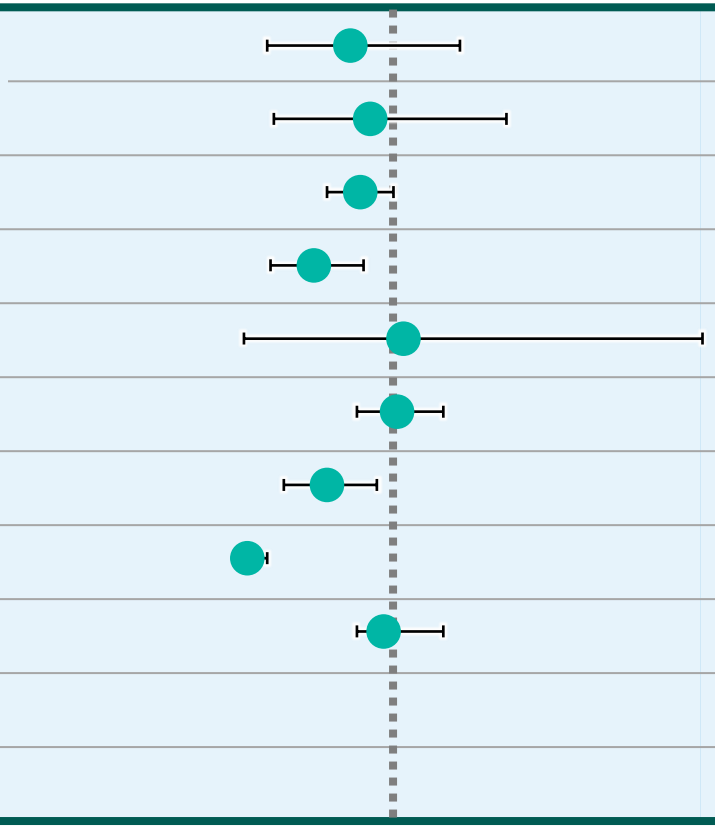
Preterm births by country (countries with >5 preterm births)[1]	RSVpreF 120 µg n (%)	Placebo n (%)	Relative risk
Overall	207 (5.7)	172 (4.7)	1.20 (0.98, 1.46)
Country			
Japan	7 (3.0)	13 (5.6)	0.54 (0.22, 1.33)
Taiwan	6 (4.6)	7 (5.4)	0.86 (0.30, 2.48)
Netherlands	3 (3.1)	3 (3.2)	0.98 (0.20, 4.73)
US	95 (5.7)	87 (5.3)	1.09 (0.82, 1.44)
Chile	7 (8.1)	6 (7.1)	1.15 (0.40, 3.29)
Spain	4 (3.4)	3 (2.4)	1.40 (0.32, 6.13)
Argentina	31 (6.6)	20 (4.4)	1.52 (0.88, 2.63)
South Africa	39 (8.3)	19 (4.0)	2.06 (1.21, 3.51)



CI, confidence interval; RSVpreF, respiratory syncytial virus prefusion F vaccine; wGA, weeks of gestation.
Madhi SA et al. *Obstet Gynecol*. 2025;145:147-156 (including supplementary appendix).

Real-World Data Suggest No Association Between RSV Maternal Vaccination and Preterm Birth

Vaccination	Country	Study	N	Risk (95% CI)
32-36 weeks[1]	US	Son et al[2]	2973	aOR: **0.87** (0.62-1.20)
				HR: **0.93** (0.64-1.34)
		CDC[3]	13,966	aRR: **0.90** (0.80-1.00)
		Michnick et al[4]	13,714	aHR: **0.76** (0.63-0.91)
		Blauvelt et al[5]	647	aOR: **1.03** (0.55-1.93)
		Hsieh et al[6]	6387	RR: **1.01** (0.89-1.15)
		Solsman et al[7]	24,213	aOR: **0.80** (0.67-0.95)
	Argentina	Scruzzi et al[8]	21,303	RR: **0.56** (0.51-0.62)
	France	Gabet et al[9]	49,782	wIRR: **0.97** (0.89-1.15)
≥28 weeks	UK	Razai et al[10]	911	*P*=0.980
		UKHSA[11]	NR	No association

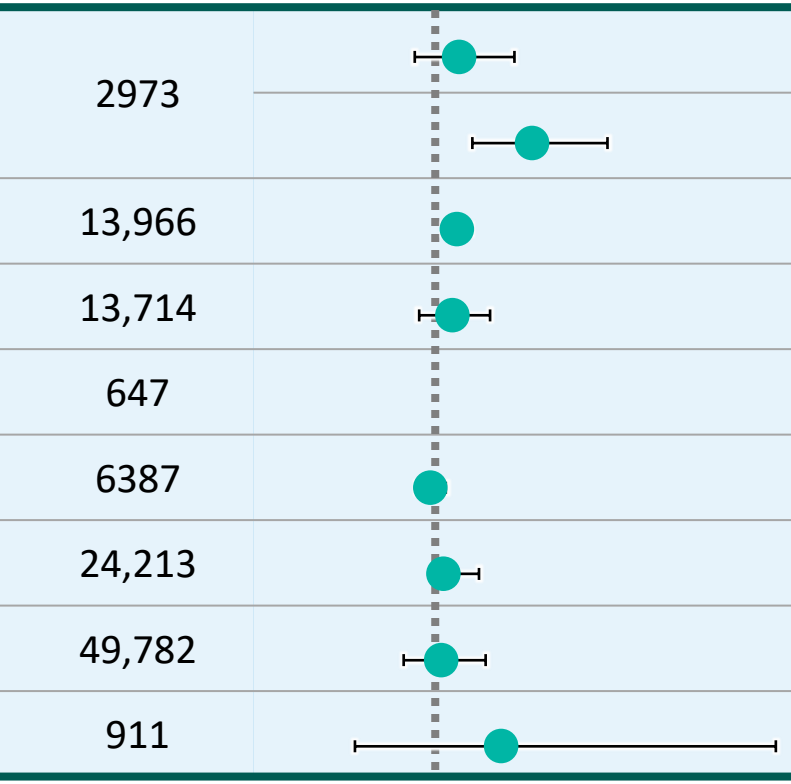


a, adjusted; CDC, Centers for Disease Control and Prevention; CI, confidence interval; HR, hazard ratio; NR, not reported; OR, odds ratio; RR, risk ratio; RSV, respiratory syncytial virus; RWE, real-world evidence; UK, United Kingdom; UKHSA, United Kingdom Health Security Agency; US, United States; wIRR, weighted incidence rate ratio by inverse probability of treatment weighting.

1. Fleming-Dutra KE, et al. *MMWR Morb Mortal Wkly Rep*. 2023;72(41):1115-1122. 2. Son M, et al. *JAMA Netw Open*. 2024;7(7):e2419268. doi:10.1001/jamanetworkopen.2024.19268 3. DeSilva M. Prenatal RSVpreF vaccine safety 2023–2024 respiratory season. The Vaccine Safety Datalink (VSD). Presented at: ACIP Meeting; June 25, 2025. Accessed March 26, 2026. https://www.cdc.gov/acip/downloads/slides-2025-06-25-26/04a-DeSilva-Mat-Peds-RSV-508.pdf 4. Michnick AI, et al. *JAMA*. 2026;335(5):456-459. 5. Blauvelt CA, et al. *JAMA Netw Open*. 2025;8(2):e2460735. doi:10.1001/jamanetworkopen.2024.60735 6. Hsieh TYJ, et al. *Am J Obstet Gynecol*. 2025;233(5):e181-e190. 7. Solsman AM, et al. *Obstet Gynecol*. 2026;147(1):127-130. 8. Scruzzi GF, et al. *Medicina (B Aires)*. 2025;85(5):999-1007. 9. Gabet A, et al. *Obstet Gynecol*. 2026;147(1):118-126. 10. Razai MS, et al. *BMJ Open*. 2025;15(9):e101592. doi:10.1136/bmjopen-2025-101592 11. United Kingdom Joint Committee on Vaccination and Immunisation. Minute of the meeting held on 01 October 2025. Accessed May 15, 2026. https://app.box.com/s/iddfb4ppwkmtjusir2tc/file/2044018962188

Real-World Data Show an Inconsistent Association Between RSV Maternal Vaccination and Hypertensive Disorders of Pregnancy

Vaccination	Country	Study	N	Risk (95% CI)
32-36 weeks[1]	US	Son et al[2]	2973	aOR: **1.10** (0.90-1.35)
				HR: **1.43** (1.16-1.77)
		CDC[3]	13,966	aRR: **1.09** (1.03-1.15)
		Michnick et al[4]	13,714	aHR: **1.07** (0.92-1.24)
		Blauvelt et al[5]	647	*P*=0.08
		Hsieh et al[6]	6387	RR: **0.97** (0.91-1.04)
		Solsman et al[7]	24,213	aOR: **1.03** (0.90-1.19)
	France	Gabet et al[8]	49,782	wIRR: **1.02*** (0.85-1.22)
≥28 weeks	UK	Razai et al[9]	911	aOR: 1.29 (0.63-2.53)



Lower risk 0 0.5 1 1.5 2 2.5 3 Higher risk

*Preeclampsia only.

a, adjusted; CDC, Centers for Disease Control and Prevention; CI, confidence interval; HR, hazard ratio; OR, odds ratio; RR, risk ratio; RSV, respiratory syncytial virus; RWE, real-world effectiveness; UK, United Kingdom; US, United States; wIRR, weighted incidence rate ratio by inverse probability of treatment weighting.

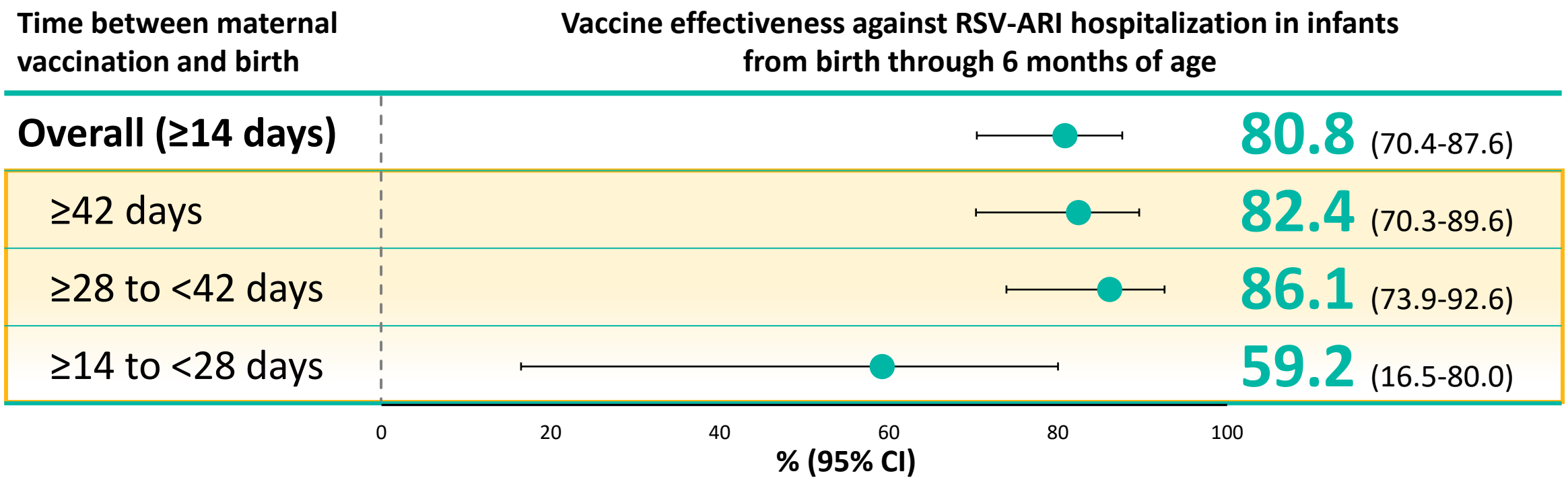
1. Fleming-Dutra KE et al. *MMWR Morb Mortal Wkly Rep*. 2023;72(41):1115-1122 2. Son M et al. *JAMA Netw Open*. 2024;7(7):e2419268. 3. DeSilva M. Prenatal RSVpreF vaccine safety 2023–2024 respiratory season. The Vaccine Safety Datalink (VSD). ACIP Meeting, June 25, 2025. Accessed June 2026. https://www.cdc.gov/acip/downloads/slides-2025-06-25-26/04a-DeSilva-Mat-Peds-RSV-508.pdf 4. Michnick AI, et al. *JAMA*. 2026;335(5):456-459. 5. Blauvelt CA et al. *JAMA Netw Open*. 2025;8(2):e2460735. 6. Hsieh TYJ et al. *Am J Obstet Gynecol*. 2025;233(5):e181-e190. 7. Solsman AM et al. *Obstet Gynecol*. 2026;147(1):127-130. 8. Gabet A et al. *Obstet Gynecol*. 2026;147(1):118-126. 9. Razai MS et al. *BMJ Open*. 2025;15(9):e101592.

Within Subtypes of Hypertensive Disorders of Pregnancy, Absolute Differences Between Vaccinated and Unvaccinated Groups Were Small

	Increasing severity							
	Gestational hypertension		Preeclampsia		HELLP syndrome		Eclampsia	
Study, % (n)	RSV vaccinated	Not RSV vaccinated	RSV vaccinated	Not RSV vaccinated	RSV vaccinated	Not RSV vaccinated	RSV vaccinated	Not RSV vaccinated
DeSilva et al[1]	**8.8%** (1064)*	**7.6%** (922)*	**8.8%** (1189)	**7.5%** (1010)	—	—	**0.3%** (38)†	**0.4%** (49)†
Kitano et al[2]	**20.6%** (2316)	**18.9%** (2126)	**12.2%** (1369)	**13.6%** (1536)	—‡	—‡	—‡	—‡
Michnick et al[3] [interim cohort analysis]	**9.7%** (635)	**9.7%** (635)	**5.9%** (389)§	**5.6%** (367)§	**0.2%** (13)	**0.2%** (13)	—	—
Son et al[4]	**15.1%** (153)	**13.9%** (273)	**6.6%** (67)	**6.6%** (130)	**0.2%** (2)	**0.1%** (2)	**0.1%** (1)	**0.1%** (1)

*Gestational hypertension excludes matched pairs with chronic hypertension.[1] †Reported as eclampsia or HELLP syndrome.[1] ‡Counts ≤10 suppressed due to TriNetX privacy rules.[2]
§Reported as preeclampsia or eclampsia.
CDC, Centers for Disease Control and Prevention; HELLP, Hemolysis, Elevated Liver enzymes, and Low Platelets; NR, not reported; RSV, respiratory syncytial virus; RWE, real-world evidence.
1. DeSilva M, et al. *Obstet Gynecol*. Published online June 18, 2026. doi:10.1097/AOG.0000000000006354 2. Kitano T, et al. *Vaccines*. 2026;11(1):53. 3. Michnick AI, et al. *JAMA*. 2026;335(5):456-459. 4. Son M, et al. *JAMA Netw Open*. 2024;7(7):e2419268.

Australia (STREETON): Vaccine Effectiveness Observed By Time Between Maternal Vaccination and Birth



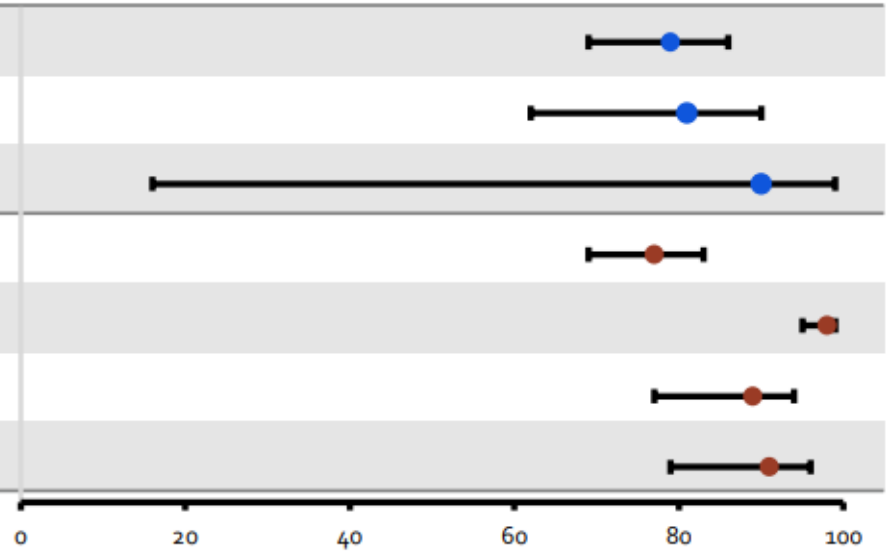
Emerging data may suggest that vaccine effectiveness is higher in settings where vaccination begins at 28 vs 32 weeks of gestation

Study limitations include but are not limited to: Potential residual confounding, particularly from unmeasured factors; temporal changes in RSV circulation could contribute to bias; possible exposure misclassification; heterogeneity in testing and admission practices may introduce selection bias.

From STREETON (Study of Real World Vaccine Effectiveness of Maternal RSVpreF Vaccination Against RSV in Hospitalized Infants in Australia) retrospective, case-control, test-negative study.
Figure adapted from Wadia U, et al. *JAMA Pediatr.* 2026:e263391. doi:10.1001/jamapediatrics.2026.3391
ARI, acute respiratory infection; CI, confidence interval; RSV, respiratory syncytial virus; RWE, real-world evidence; wGA, weeks of gestation.
Wadia U, et al. *JAMA Pediatr.* 2026:e263391. doi:10.1001/jamapediatrics.2026.3391

Observational data indicate nirsevimab is working as expected (vs. RCT results) during the first RSV season after approval among infants in their first RSV season

Outcome/Analysis	Vaccine efficacy/effectiveness (%)
Clinical trial, RSV-associated LRTI	79 (69-86)
Clinical trial, RSV-associated LTRI with hospitalization	81 (62-90)
Clinical trial, RSV-associated LRTI with ICU admission	90 (16-99)
VISION, RSV-associated emergency department visits	77 (69-83)
VISION, RSV-associated hospitalization	98 (95-99)
NVSN, medically attended RSV-associated ARI episode	89 (77-94)
NVSN, RSV-associated hospitalization	91 (79-96)



Results may not be comparable across studies due to differences in outcome definitions, timing, and other factors.

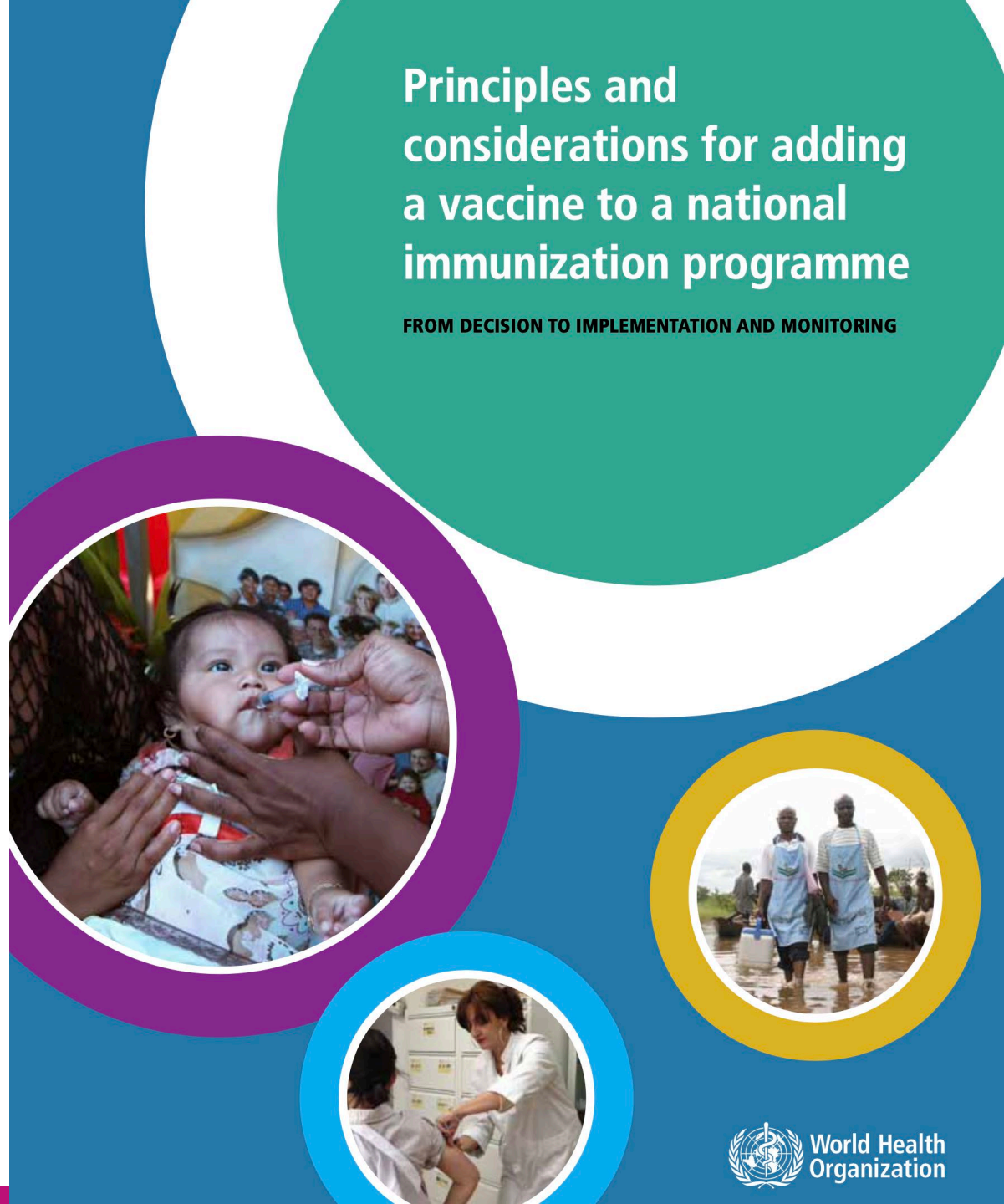
https://www.cdc.gov/mmwr/volumes/72/wr/mm7234a4.htm

RCT = randomized clinical trial | ARI = acute respiratory illness

Slide courtesy Nigel Crawford

Nirsevimab impact: ACIP meeting, June 2024

Implementation in the antenatal setting



Common barriers to vaccination in pregnancy

Pregnant women

- Concerns about **safety/side effects/harm**
- Perceiving themselves **not to be at risk** of the disease
- Belief that the **disease is not serious**
- **Misconceptions** that the vaccine causes disease, illness, death or other negative outcomes
- **Fear of needles**
- **No provider recommendation**
  - Receipt of a healthcare provider's recommendation was the factor most frequently reported as a reason for vaccination among pregnant women

Healthcare providers

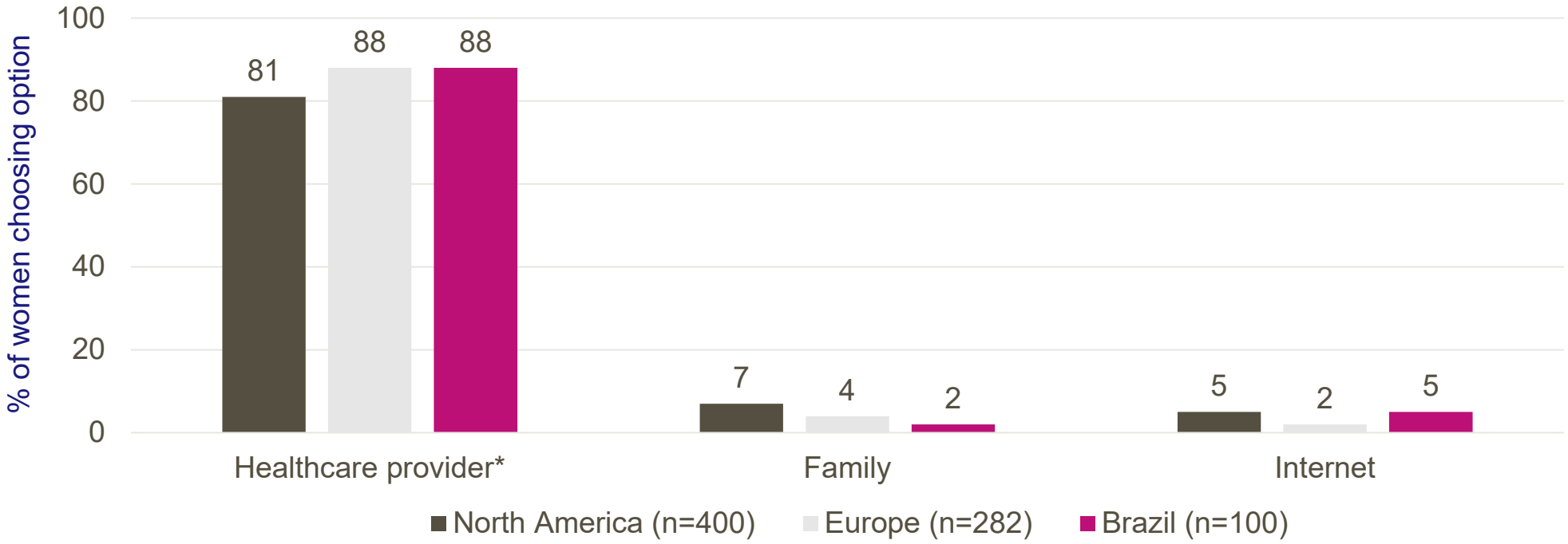
- **Lack of knowledge**/education
- Considered vaccination **outside their remit**
- Not enough **time**
- **Concerns** about vaccine **safety and efficacy**
- Perceived low risk of disease
- Perceived **lack of clinical trial data** with vaccines in pregnant women
- Administrative difficulties (e.g., logistical issues around staff, obtaining the vaccine, financial concerns)

1. Lutz CS, et al. Vaccine 2018;36:7445–55; 2. Hobeika E, et al. Hum Vaccin Immunother 2018;14:1501–8; 3. Bonville CA, et al. Hum Vaccin Immunother 2015;11:713–8;
4. Dubé E, et al. Hum Vaccin Immunother 2020;16:2789–99.

Healthcare providers are regarded by women as the most credible source of information on vaccination in pregnancy

Online survey of 782 pregnant women from North America, Europe and Brazil

Who is the most credible source of information on vaccination in pregnancy?



*Physician or midwife/nurse practitioner.

Patwardhan M, Gonik B. J Womens Health Safety Res 2019;3:90–8.

Giles *et al. BMC Pregnancy and Childbirth* (2021) 21:771
https://doi.org/10.1186/s12884-021-04248-9

BMC Pregnancy and Childbirth

‘Deeply appalled’: politicians condemn alleged attack after independent MP Helen Haines critically injured

Anthony Albanese says his thoughts are with Indi MP after arrest of driver in Wangaratta

- Who is Helen Haines, the MP allegedly attacked in Victoria?
- What we know so far
- Get our new political email, free app or daily news podcast



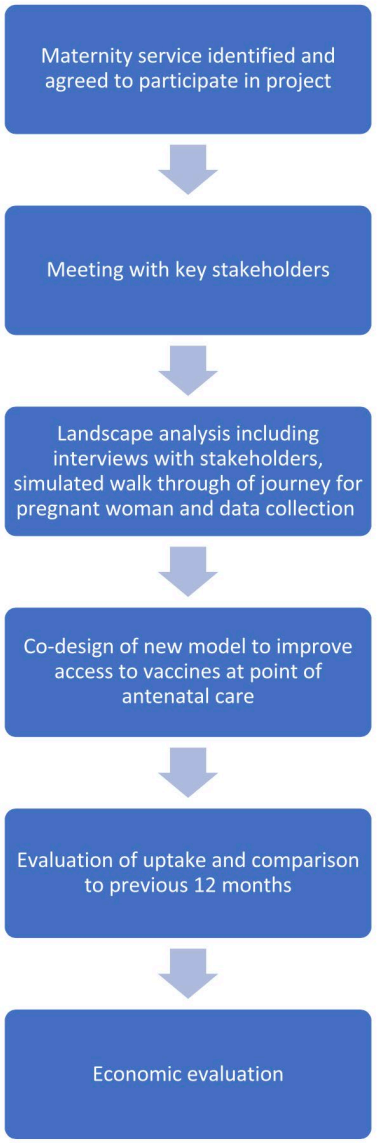
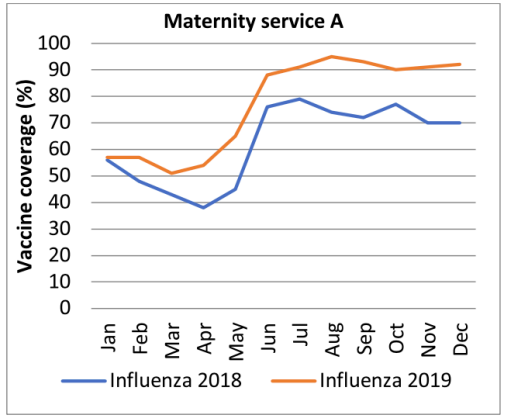
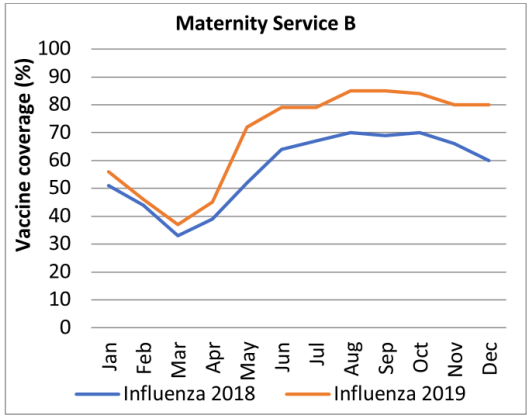
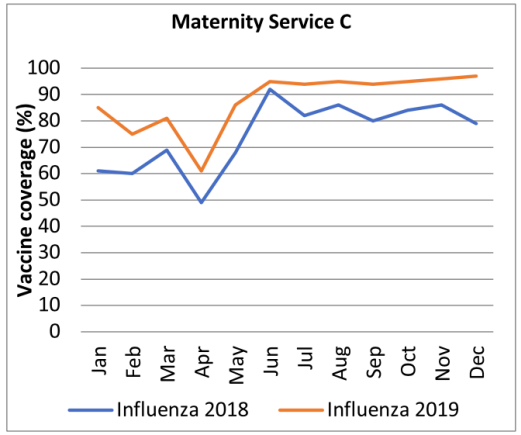
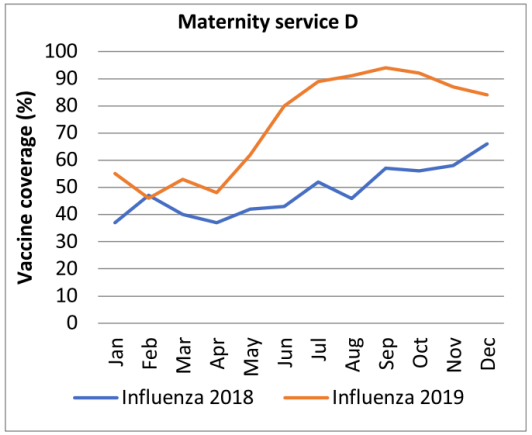


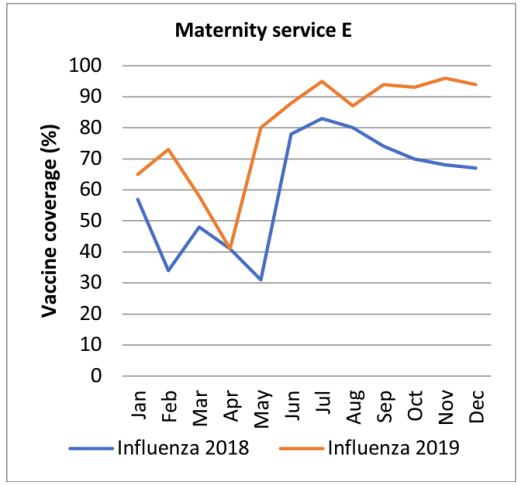
Fig. 1 An overview of the steps in the project











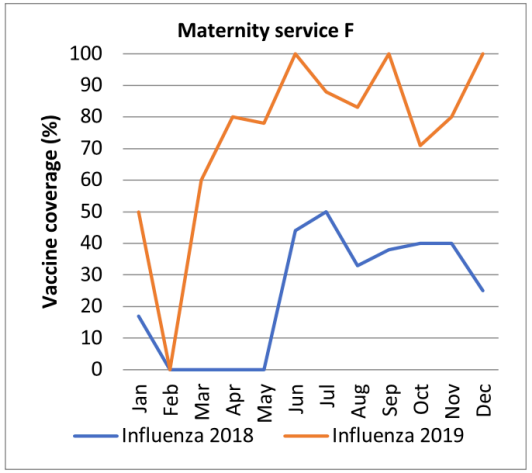


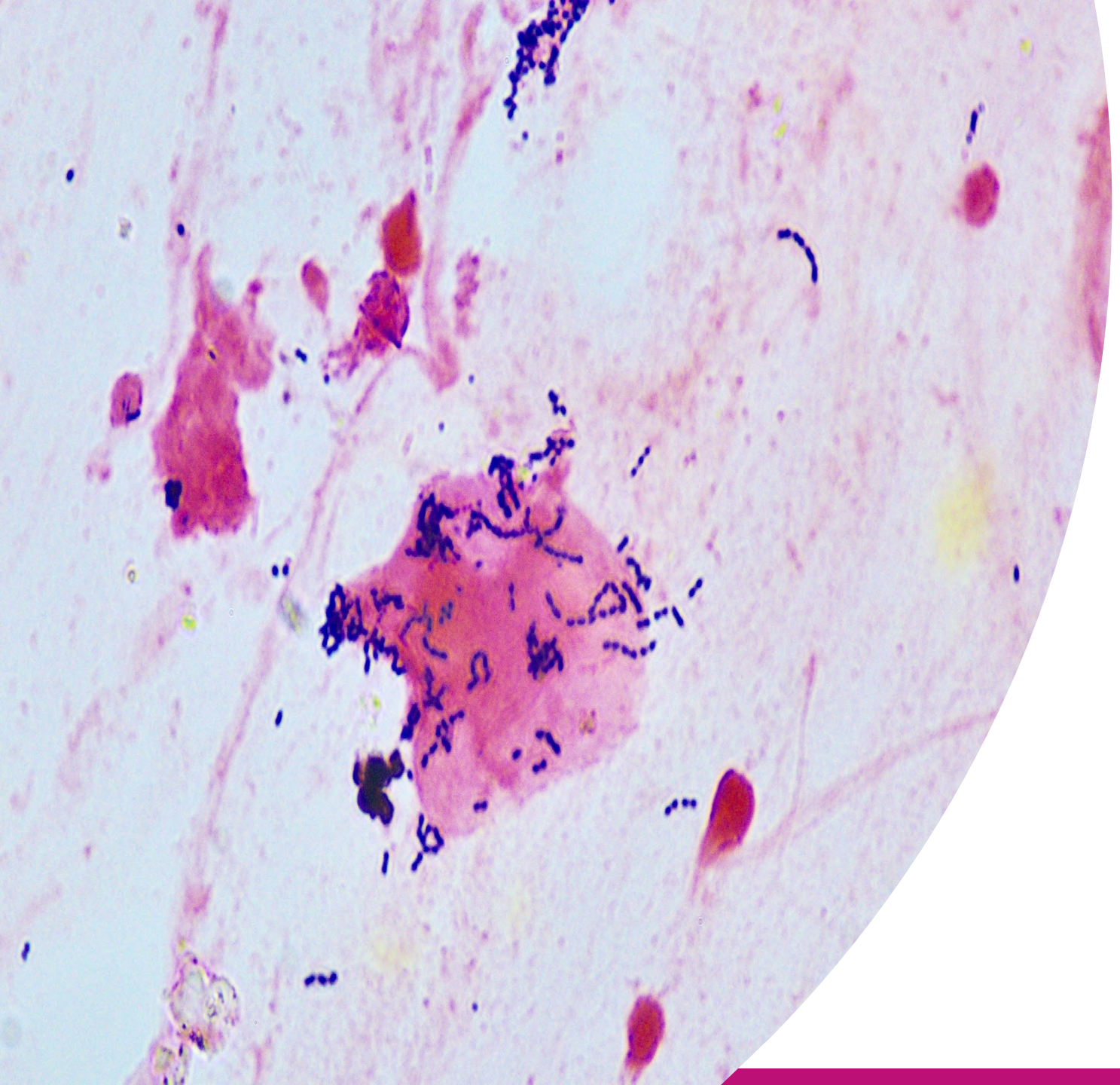
Fig. 2 Maternal influenza vaccine coverage per month (2018 compared to 2019) for each maternity service

Key messages

- There is no ‘one size fits all’ model to improve coverage
  - Midwife, pharmacist, primary care
- Project ownership and vaccine champions are powerful
  - Encouragement, expertise, support, role in monitoring implementation, identifying and finding solutions
- Interventions are only as good as the quality of data
  - Data essential to identify low coverage, monitor success of implementation, feedback to HCPs
- Understanding the local landscape is essential
  - Locally developed solutions to improve access need to be context specific

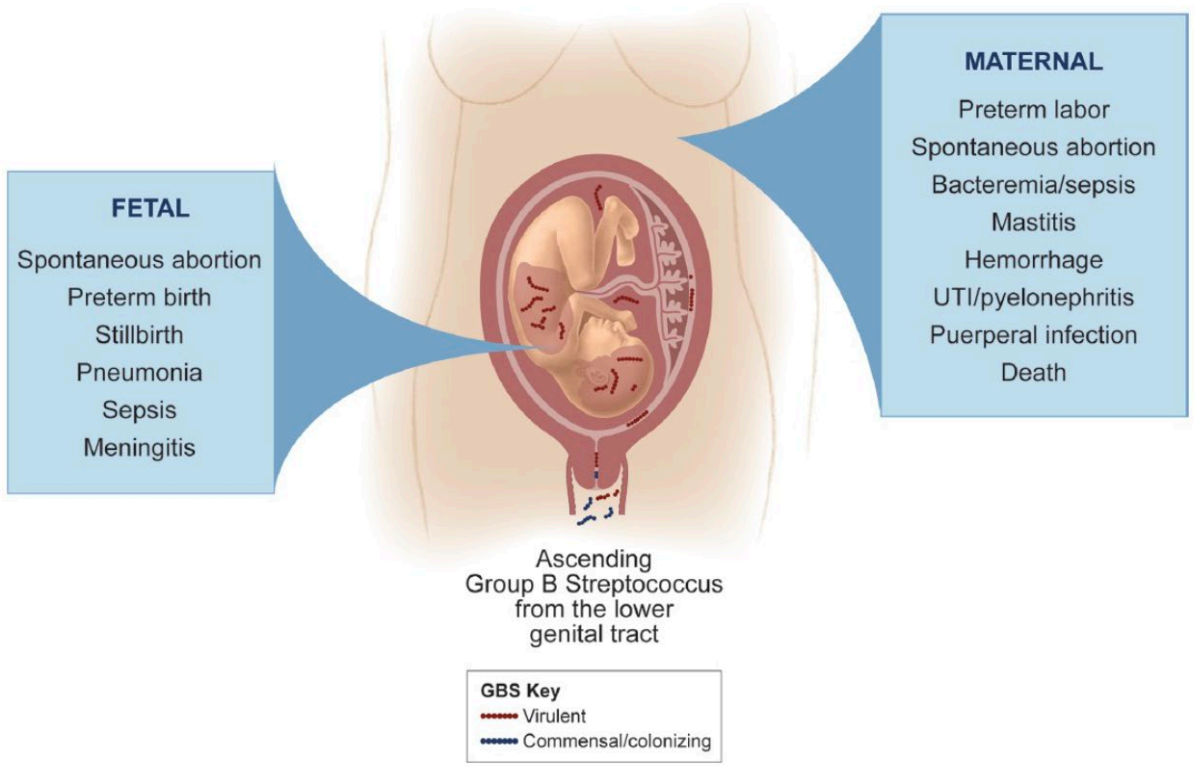
Key considerations when implementing a new vaccine in pregnancy

- Country level considerations
  - Public health priority of disease
  - Disease burden
  - Other disease and control measures
- Vaccine
  - Performance and characteristics
  - Supply
  - Economic and financial issues
- Planning and managing introduction
  - Plan, policy, integration
  - Optimal schedule
  - Training healthcare workers
- Monitoring and evaluation



Group B streptococcus

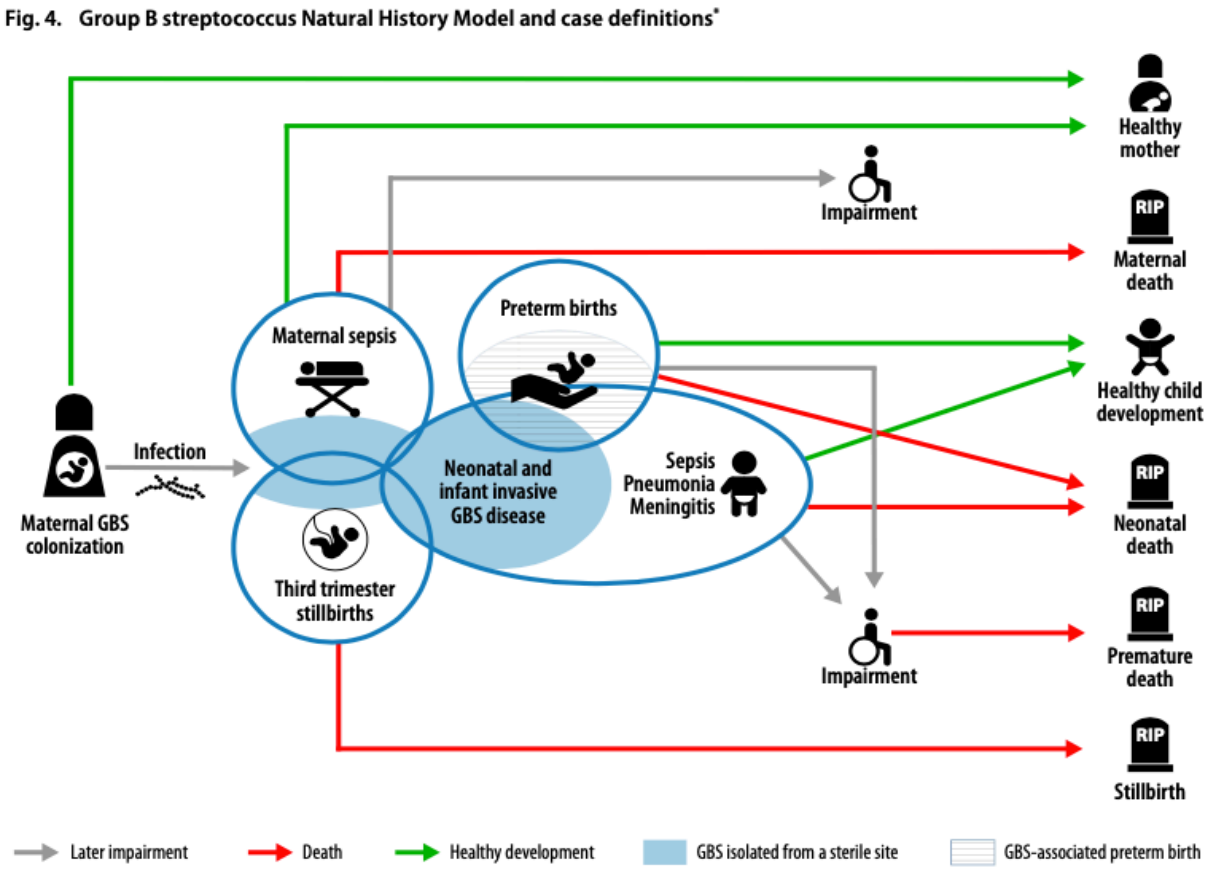
STREPTOCOCCUS AGALACTIAE





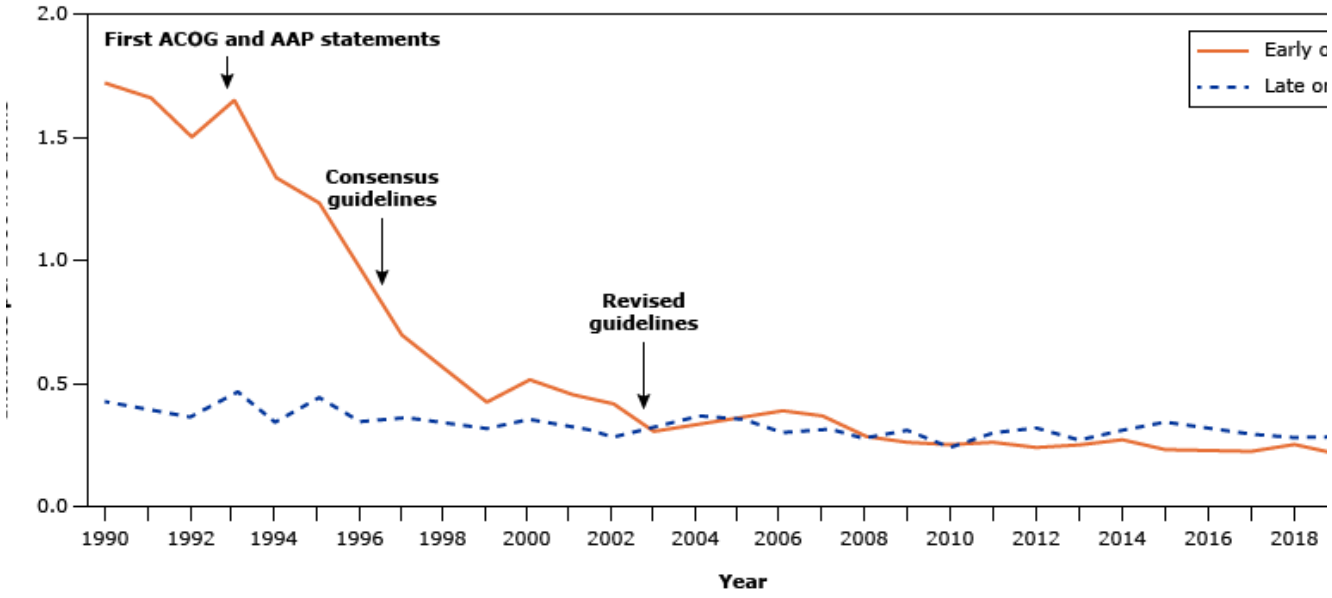
Brokaw A, et al. 2021. Front. Cell. Infect. Microbiol. 11:720789.

Disease burden



- 392,000 infants experience invasive GBS cases per year
  - 91,000 infant deaths
  - 40,000 neurodevelopmental impairment
  - 46,000 stillbirths
  - 518,000 preterm births
- Sub-Saharan Africa accounts for approximately 15% of the world's population but about half of the burden of GBS cases and deaths

Group B streptococcus vaccine: full value of vaccine assessment. Geneva: World Health Organization; 2021. Licence: CC BY-NC-SA 3.0 IGO.



Neonates

- EOGBS: usually within 24 hours to day 6 (sepsis, pneumonia, meningitis)
- LOGBS: day 7-89
- Late LOGBS: >3 months
- Estimated incidence 0.5/1000 live births
- Decline seen since introduction of IAP but not on extremely preterm infants and no impact on LOGBS



Group B Streptococcus (GBS) Vaccine Pipeline

Maternal immunization strategy protecting newborns from sepsis, meningitis, and pneumonia.

GBS6 (Pfizer)

Platform: Hexavalent conjugate (Ia, Ib, II, III, IV, V)

Status: Phase 3 Trial (BEATRIX)

Global recruitment started Aug 2025. Primary completion expected late 2028. Single maternal dose. Holds FDA Breakthrough & EMA PRIME status.

GBS-AlpN / GBS-NN2 (MinervaX)

Platform: Protein subunit (AlphaC, Rib, Alp1, Alp2/3)

Status: Phase 2 Completed / Phase 3 Planned

Positive Phase 2 data in pregnant women and infants. Induces cross-strain functional antibodies via a 2-dose maternal regimen. EMA PRIME status.

IVT GBS-06 (Inventprise)

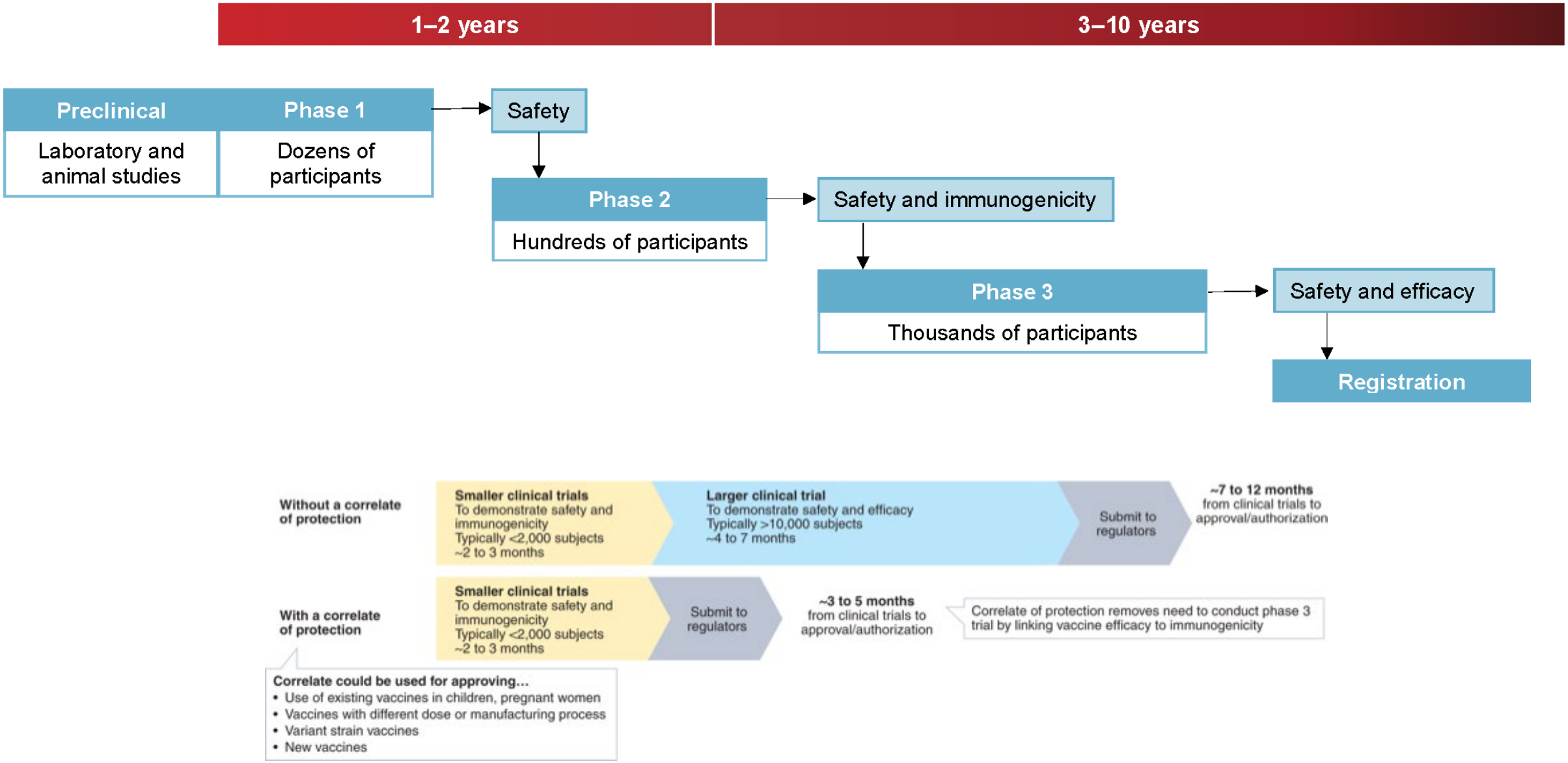
Platform: Hexavalent conjugate (Ia, Ib, II, III, V, VI)

Status: Phase 1/2 Clinical Development

Supported by the Gates Foundation. Announced positive interim Phase 1/2 results in Feb 2026. Evaluated in women of childbearing age.

Strategic Alignment: Prioritized under the WHO 'Defeating Meningitis by 2030' global roadmap to secure safe, affordable maternal immunizations globally.

Conventional pathway of vaccine development



Nature Medicine ISSN 1546-170X (online)

Key considerations when implementing a new vaccine in pregnancy: GBS in Australia

- Country level considerations
  - Public health priority of disease- **Yes?**
  - Disease burden- **not notifiable**
  - Other disease and control measures- **IAP**
- Vaccine
  - Performance and characteristics
  - Supply
  - Economic and financial issues- **Cost effectiveness; comparator**
- Planning and managing introduction
  - Plan, policy, integration- **addition to 3 (+4) existing vaccines**
  - Optimal schedule- **24-26 weeks trial, no coadministration in trial**
  - Training healthcare workers
- Monitoring and evaluation

Key messages

- Maternal immunisation leverages a unique immunological situation facilitating “two for one” deal
- An established strategy since 1999
- Three vaccines recommended in Australia, every pregnancy (funded, established effectiveness and safe)
- Coadministration optional
- Access, access, access
- 3 critical components of discussion: recommendation, safety and benefit to baby

7th INTERNATIONAL NEONATAL & MATERNAL IMMUNIZATION SYMPOSIUM

Advancing global equity and access through maternal and neonatal immunization

Adelaide, Australia. February 14-17, 2027



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Thank you

