Immunisation in a changing world – future opportunities

Professor Kristine Macartney
29 August 2025

Local and global initiatives to increase vaccination coverage

Global Summit: Health & Prosperity through Immunisation

Globally, many countries are embarking upon new (updated) National Immunisation Strategy development

Table 1. The 7 steps of NIS development

1. Preparation
Development of a **workplan** for developing (or updating) the NIS, including a **stakeh** and ToRs for Steering Committee and key teams/ working groups. Collection of documents for situation analysis.
Output: NIS planning complete and documentation available.

2. Situation Analysis
Review of existing documents related to immunization and the health system (plans, reports, reviews, assessments, surveys) to understand the underlying factors and root-causes of the successes and failures of the immunization programme, a draft situation analysis is prepared, discussed and agreed with stakeholders.
Output: Consolidated situation analysis report.

3. Strategy Development
Using the consolidated situation analysis, the development of the strategy can begin by asking "where do we want to go and why, and how do we get there?". The answers to these questions will support the setting of the **NIS vision and objectives**, taking care to align with the national health sector strategic priorities. Part of the strategy development stage is identifying the **key opportunities and obstacles for achieving the objectives**, for example, political, social or economic factors, based on which, interventions will be identified to either capitalize on these opportunities or mitigate against factors that could threaten the achievement of the objectives.
Output: NIS vision and consolidated 5 years objectives with interventions to achieve them.

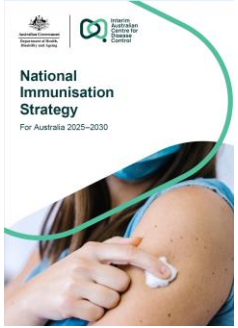
4. M&E Framework
The monitoring and evaluation (M&E) framework will be used to **measure progress on NIS implementation** and to take corrective action when needed. Assigning specific and measurable indicators is of critical importance, as is assigning accountability for achieving the indicators.
Output: Monitoring and Evaluation Framework.

5. Resource estimates
Once the interventions to achieve objectives have been identified, the NIS development team will **estimate the resource requirements** for implementing them using **NIS.COST**
Output: Resource requirements for the NIS.

6. Budget dialogue
Dialogue around NIS budget requirements will need to happen both with the government and external health partners, and, if sufficient resources are available, may involve scaling back the roadmap to align with a realistic expectation of committed resources.
Output: Consolidated budget for the NIS.

7. Approval and endorsement
With steps 1-6 completed the final NIS document is **endorsed** by the relevant in country stakeholders and any legal act or regulations needed to approve the NIS document and transform it into a governance tool are considered.
Output: Final version of NIS document with budget estimates.

Australia's National Immunisation Strategy 2025-2030



Vision	**A healthier Australia through immunisation**					
Mission	**To reduce the impact of vaccine-preventable diseases through high uptake of safe, effective and equitable immunisation across the lifespan**					
Priority Areas	**1. Improve access to immunisation, with a focus on equity for Aboriginal and Torres Strait Islander people and other priority populations**	**2. Build trust, understanding and acceptance of immunisation in communities**	**3. Use data more effectively to target immunisation strategies and monitor performance**	**4. Strengthen the immunisation workforce**	**5. Harness new technologies to respond to the evolving communicable disease and vaccine landscape**	**6. Implement sustainable reform in vaccine program governance, program delivery and accountability**
Strategic Goals	Partner with communities to understand barriers to access and co-design strategies to improve vaccine access.	Engage with communities to build trust and understanding in the value of immunisation, and to combat misinformation.	Improve the completeness, timeliness and transparency of Australian Immunisation Register (AIR) data, ensuring optimal quality and utility for all stakeholders.	Embed immunisation in preventive healthcare across the lifespan.	Strengthen government immunisation program preparedness for new vaccine rollouts, including by leveraging new technologies.	Strengthen collaborative ways of working between the Australian Government and state and territory governments to deliver vaccines under the NIP and emergency programs.
	Use innovative service delivery models to increase equitable access to immunisation across the lifespan.	Strengthen community partnerships for design, delivery and evaluation of tailored immunisation strategies.	Work towards creation of a whole of life, interactive, real-time dashboard of coverage data for all Australian Government-funded vaccines.	Enable immunisation providers to safely work to their full scope of practice and harmonise relevant workforce policies, training, and accreditation across all states and territories.	Systematise horizon scanning for emerging and newly vaccine-preventable diseases and the vaccine pipeline.	Support policies that improve confidence in vaccine safety and accountability, such as exploring the feasibility of a no-fault vaccine compensation scheme.
	Ensure vaccine access and uptake to reach agreed national targets and maintain elimination status of measles, rubella and polio.	Track community sentiment, including for priority groups.	Expand data linkage capacity, analysis and reporting for better monitoring of vaccine program coverage, effectiveness, safety and impact.	Support Aboriginal and Torres Strait Islander health workforce development to contribute to immunisation.	Champion vaccine research and development, and support pathways to commercialisation for Australian researchers and biotechnology industries.	Standardise monitoring and evaluation of national, and state and territory vaccine programs to improve outcomes.
	Consider additional evidence-informed targets.	Strengthen knowledge, confidence, and skills of immunisation providers to support informed vaccination choices.	Integrate and report timely surveillance data on diseases, vaccine coverage, safety, and social and behavioural insights.	Strengthen preparedness for immunisation workforce surge capacity in future health emergencies.	Maintain onshore vaccine manufacturing capacity for increased resilience against pandemics and supply chain threats.	Strengthen Australia's contribution to supporting regional and global immunisation efforts.
			Strengthen vaccine safety surveillance, including for new vaccines, to improve detection of rare or delayed onset adverse events.	Build expertise across the immunisation and vaccine-preventable disease workforce in all areas, including data analytics, disease surveillance and communications.		

Themes

Greater equity and access

Trust and understanding

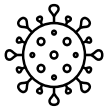
Data for decision making

Strengthening partnerships

Workforce

Innovation

Valuing vaccines



Preventing new pathogens

Equity

Global vaccine coverage

Key facts 2024

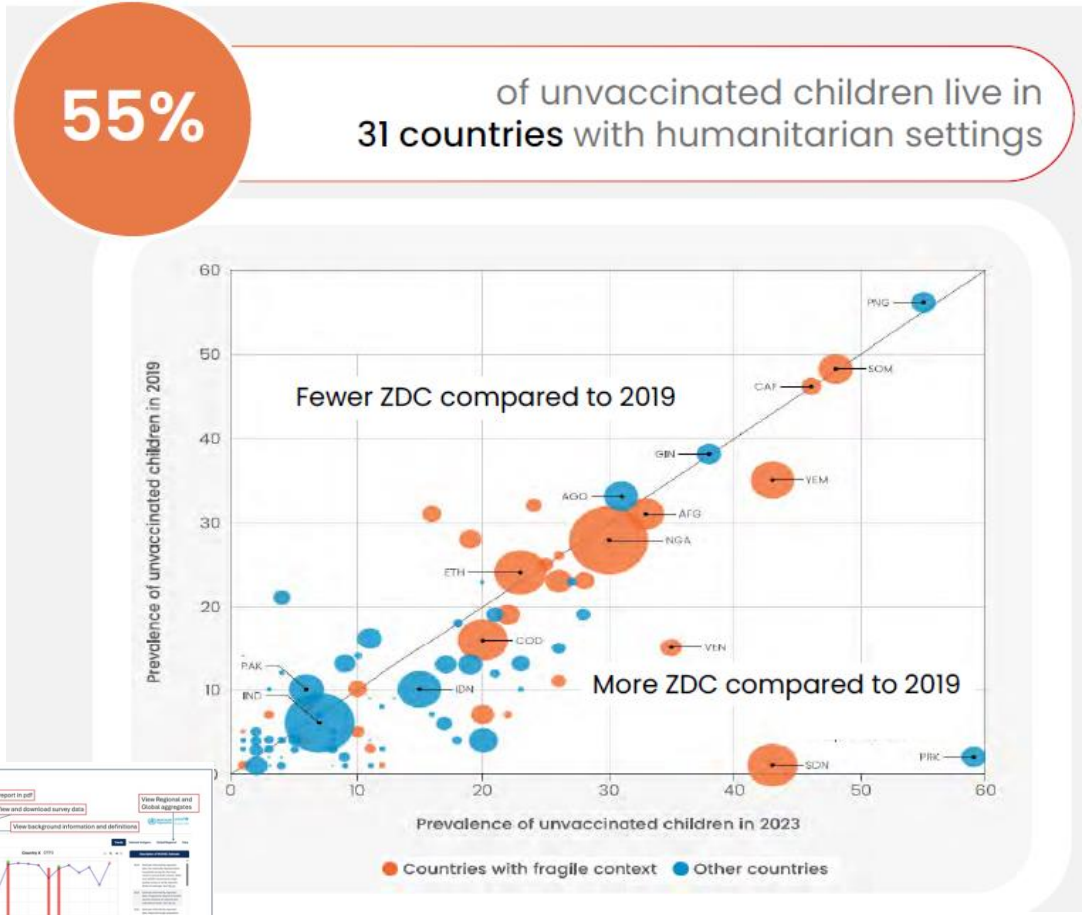
Globally 14.3 million children missed out on any vaccination – so-called zero-dose children.

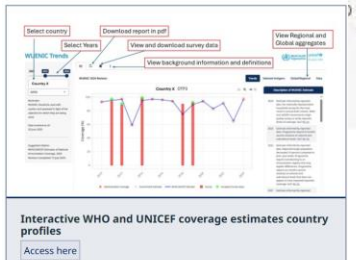
Coverage of 3rd dose of diphtheria, tetanus, and pertussis (DTP3) was 85%

84% of children had first dose of measles vaccine (still not at 2019 level of 86%).

First dose HPV vaccine in girls up from 27% in 2023 to 31%

Yellow fever vaccine in the countries at risk was 52%, well below the recommended 80%.





Greater equity

As news spread about the measles outbreak, President Joko Widodo ordered military and medical teams to bring supplies to remote villages.

A member of the Indonesian military attends to a child at the local hospital in Agats

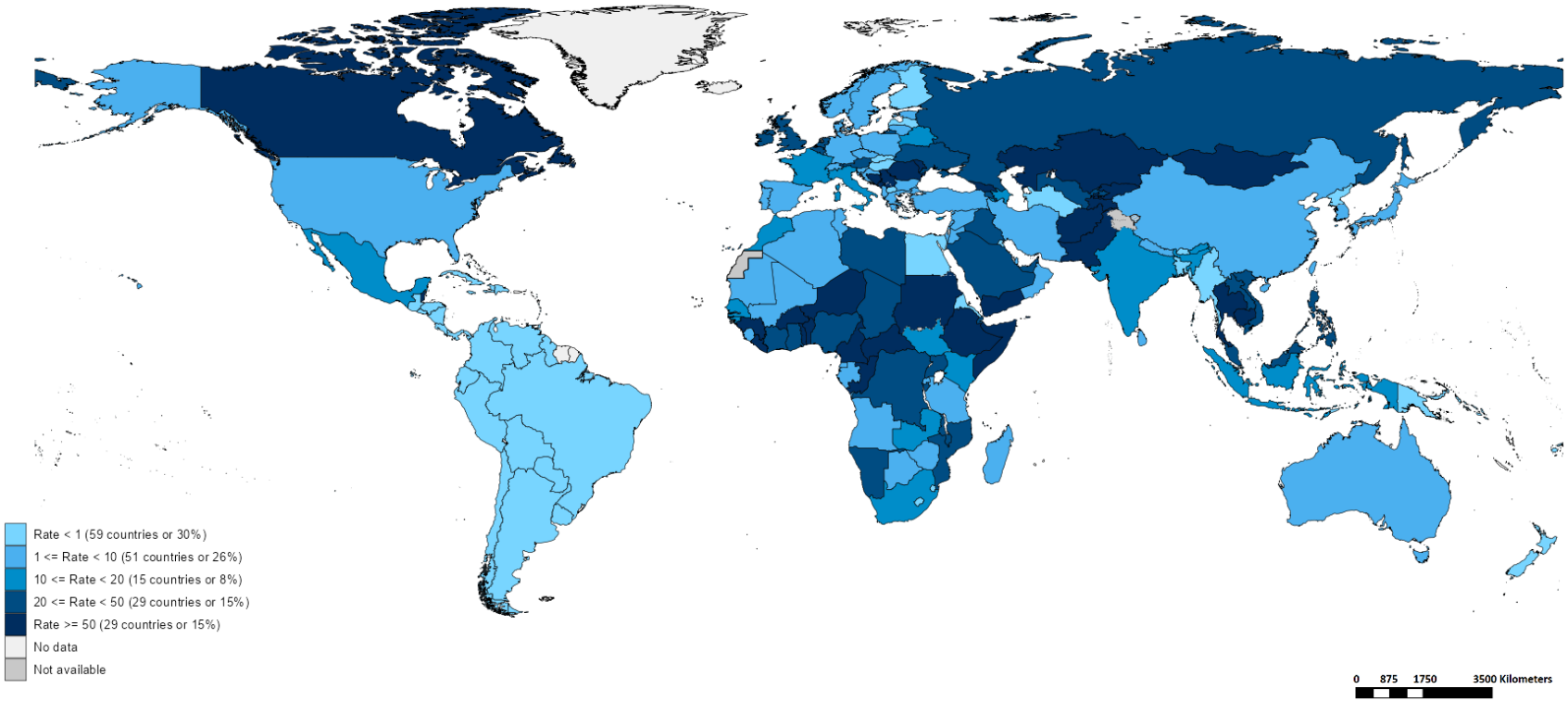
BBC

Indonesia's Papua province children starving in a land of gold

13 February 2018

Share

Global measles incidence rates per million (12 month period)



World Health Organization

Data source: IVB Database

Disclaimer: The boundaries and names shown and the designations used on this map do notimply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines

WPR Regional Verification Commission verifies measles elimination status in the Region

World Health Organization
Western Pacific Region

Country/Area	Population (in million)	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024
China	1425.8														
Japan	123.6														
Philippines	116.5														
Viet Nam	98.5														
Republic of Korea	51.8														
Malaysia	34.1														
Australia	26.3														
Cambodia	16.9														
Papua New Guinea	10.2														
China, Hong Kong SAR	7.5														
Lao People's Democratic Republic	7.6														
Singapore	6.0														
New Zealand	5.2														
Mongolia	3.4														
China, Macao SAR	0.7														
Brunei Darussalam	0.5														
Pacific Island Countries and areas	3.6														

Verified as having sustained measles elimination

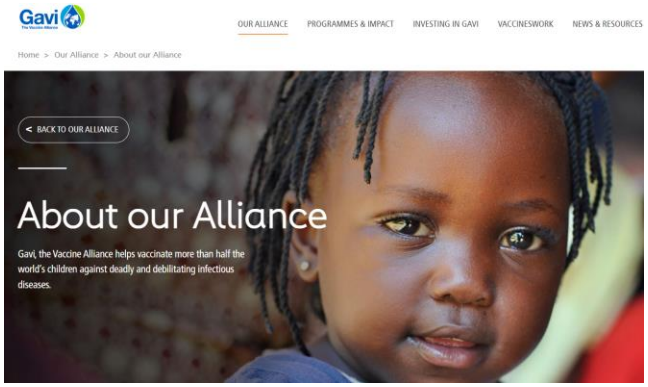
No endemic measles virus transmission

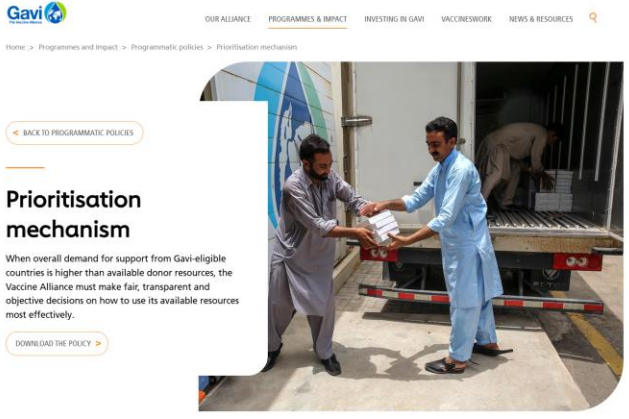
As of September 2024,

- **8 countries and areas** verified as having sustained measles elimination
- 2 countries achieved verification but lost

Verification of measles elimination typically involves the presentation of evidence across several key areas:

1. Measles epidemiology
2. Population immunity
3. Quality of epi and lab surveillance systems
4. Sustainability of the national immunization programme
5. Genotyping evidence





US$ 54 for US$ 1 spent

A study covering 73 Gavi-supported countries shows th for every US$ 1 spent on immunisation in the 2021–20 period, US$ 21 are saved in health care costs, lost wage and lost productivity due to illness and death. When considering the value people place on lives saved by vaccines – which is likely to include the value of costs averted plus the broader societal value of lives saved a people living longer and healthier lives – the return on investment is estimated to be US$ 54 per US$ 1 spent.

Sim S.Y., Watts E., Constenla D., Brenzel L., Patenaude B.N. Return On Investm From Immunization Against 10 Pathogens In 94 Low- And Middle-Income Cou 2001–20. Health Affairs. 2020.

The healthy markets goal

19 Through Gavi's market shaping efforts, the number of manufacturers supplying prequalified Gavi-supported vaccines remained at 19 in 2023 (with more than half based in low- and middle-income countries) – compared with 5 in 2001.

10 10 markets for vaccines and immunisation products exhibited acceptable levels of healthy market dynamics in 2023, meeting the target for the year.

10 10 innovative products were within the pipeline of commercial-scale manufacturers in 2023, continuing to exceed the Alliance target of 8 by 2025 well ahead of schedule.

1 1 new product with improved characteristics was newly offered to Gavi-supported countries in 2023, keeping the Alliance on track for its 2025 target: multivalent meningococcal conjugate vaccine (MMCV), the first conjugate vaccine to protect against the five predominant serogroups of meningococcal meningitis in Africa.

637[1]

vaccine introductions and preventive vaccination campaigns, 2000–2023

1 Excluding COVID-19 vaccination. Routine introductions and preventive vaccination campaigns relate to Gavi-supported vaccines against 16 infectious diseases, as of 2023. In the Gavi 1.0 and 2.0 strategic periods, introductions were completed for hepB mono and Tetra-DTP-hepB that are not counted here.

Gavi, the Vaccine Alliance is a public-private partnership that helps vaccinate more than half the world's children against some of the world's deadliest diseases.

>1.1bn

children vaccinated through routine programmes, 2000–2023 – more than 69 million in 2023 alone

The vaccine goal

56% The 57 Gavi-supported countries increased breadth of protection with vaccines in the Gavi portfolio to 56%, up 3 percentage points from 2022.

74 34 Gavi-supported vaccine introductions and preventive campaigns took place in 2023 – in addition to 40 outbreak response vaccination campaigns supported by Gavi.

14m >14 million girls fully immunised against HPV with Gavi support in 2023 – more than the previous ten years combined.

15 15 countries accessed cholera, meningococcal and yellow fever vaccines through Gavi-supported emergency stockpiles a total of 29 times in 2023.

>1.9bn

vaccinations through preventive vaccination campaigns, 2000–2023

>18.8m

future deaths averted, 2000–2023. In addition, >2.7m deaths were averted by COVAX across participating AMC low- and middle-income countries.

The equity goal

80% In 2023, Gavi-supported countries maintained DTP3 coverage at 80% (compared to the 84% global average).

69m >69 million children were reached with Gavi-supported routine vaccines in 2023 – more than in any year apart from 2019.

47 47 countries have installed more than 67,000 CCE units procured by UNICEF Supply Division through Gavi's CCEOP – nearly 5,200 in 2023 alone.

26 After several years of decline since 2019, average coverage of DTP3 in 26 low-income countries supported by Gavi held steady in 2023 – the only income group to avoid decline.

The sustainability goal

US$ 1.7bn by end 2023

In the face of fiscal challenges, climate change, conflict and instability, most Gavi-supported countries maintained or increased domestic resources for co-financing of Gavi-supported vaccines in 2023, bringing to US$ 1.7 billion their total contribution since the introduction of the co-financing policy in 2008.

215m US$ 215 million was contributed by countries towards the co-financing of Gavi-supported vaccines in 2023 – the highest amount yet and a testament to country ownership and the long-term financial sustainability of Gavi-supported vaccines.

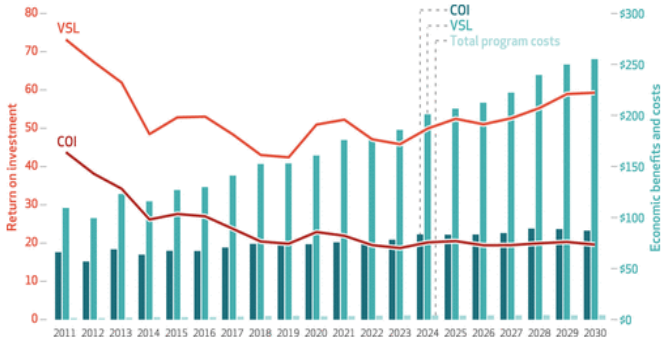
55 55 vaccine programmes originally introduced with Gavi funding are now self-financed by countries as of 2023, up from 40 in 2018.

100% 100% of countries fully met their 2023 co-financing obligation – except four waivers for humanitarian crises.

Valuing vaccines

And prioritisation and optimization of programs…..

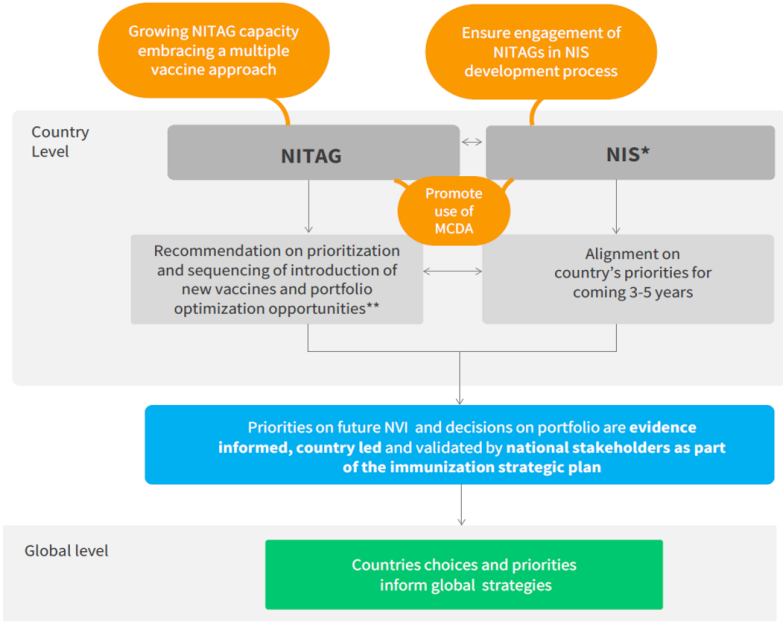
Exhibit 5 Return on investment (ratio of net benefits to costs) and economic benefits and immunization program costs (in billions) for ninety-four low- and middle-income countries, 2011–30



COI: Cost of illness approach
VSL: Value of a statistical life approach

Vaccine Prioritization: Deciding which new vaccines to introduce in next 3-5 years and in what sequence according to the needs and context of a given country.

Vaccine Optimization: Consider opportunities to improve current vaccine portfolios, such as switching products, changing vaccine presentations, or modifying schedules.

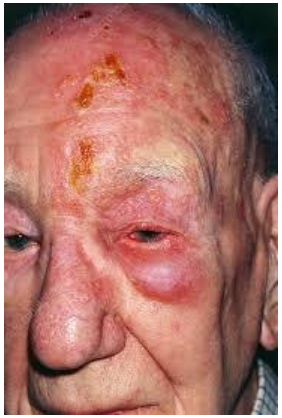


A number of multi-criteria decision-making support tools exist (4+) to assist.

Return On Investment From Immunization Against 10 Pathogens In 94 Low- And Middle-Income Countries, 2011–30 | Health

Full value of vaccines: “Indirect” or “off target” effects

Case study: rHZ vaccine and dementia



Article

A natural experiment on the effect of herpes zoster vaccination on dementia

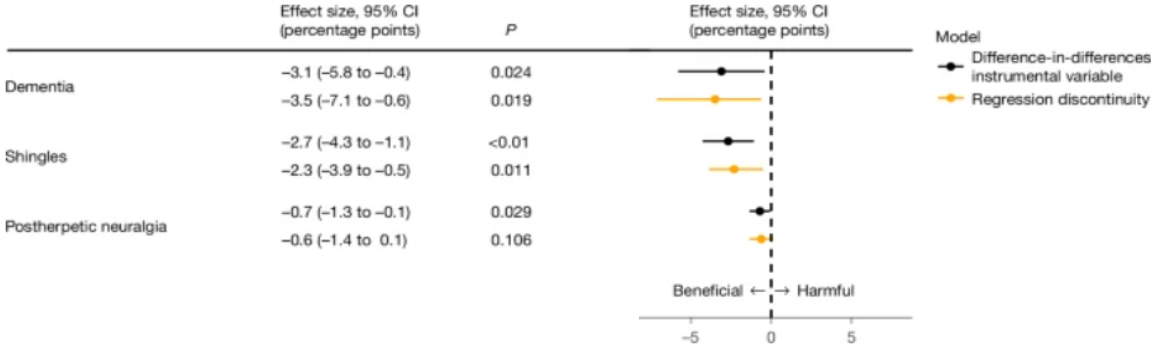
https://doi.org/10.1038/s41586-025-08800-x
Received: 4 November 2023
Accepted: 18 February 2025
Published online: 2 April 2025

Markus Eyting[1,2,3,9], Min Xie[1,4,9], Felix Michalik[1,4], Simon Heß[5], Seunghun Chung[1] & Pascal Geldsetzer[1,6,7,8]✉

Neurotropic herpesviruses may be implicated in the development of dementia[1–5]. Moreover, vaccines may have important off-target immunological effects[6–9]. Here

Evidence from observational "natural experiment" studies, such as those in Wales and Australia, suggests a causal link between herpes zoster (shingles) vaccination and a reduced risk of dementia. The studies found that vaccinated individuals experienced a decrease in new dementia diagnoses over several years, with one study showing a ~20% relative reduction in risk and an additional 3.5 percentage point absolute reduction. While the Shingrix vaccine is a newer, more effective version of the shingles vaccine used in these studies, it also demonstrated a similar dementia-reducing effect compared to an older vaccine and is linked to the same virus implicated in dementia. The protective effect of the vaccine for dementia was stronger in women, and the underlying mechanism is likely that the varicella zoster virus plays a role in the development of dementia, which vaccination inhibits.

Fig. 4: Comparison of effect estimates between the DID-IV and regression discontinuity approach.



Further Research Needed:

While encouraging, randomized controlled trials are needed to confirm these findings, determine the optimal population groups and timing for vaccine administration, and better quantify the causal effect.

Workforce

WHO projects a global health workforce shortage of 11 million workers by 2030

Nursing workforce grows, but inequities threaten global health goals

العربية | 中文 | Français | Русский | Español

12 May 2025 | News release | Reading time: 4 min (1013 words)

The global nursing workforce has grown from 27.9 million in 2018 to 29.8 million in 2023, but wide disparities in the availability of nurses remain across regions and countries, according to the State of the World's Nursing 2025 report, published by the World Health Organization (WHO), International Council of Nurses (ICN) and partners. Inequities in the global nursing workforce leave many of the world's population without access to essential health services, which could threaten progress towards universal health coverage (UHC), global health security and the health-related development goals.

Media Contacts

WHO Media Team

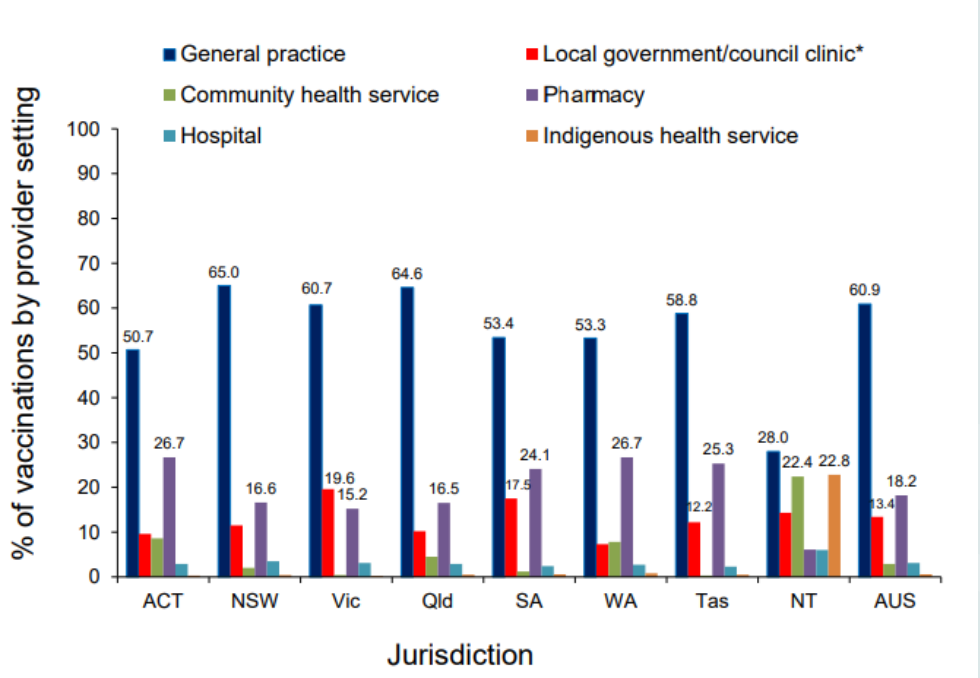
World Health Organization
Email: mediainquiries@who.int

- majority of shortages in low- and lower-middle-income countries

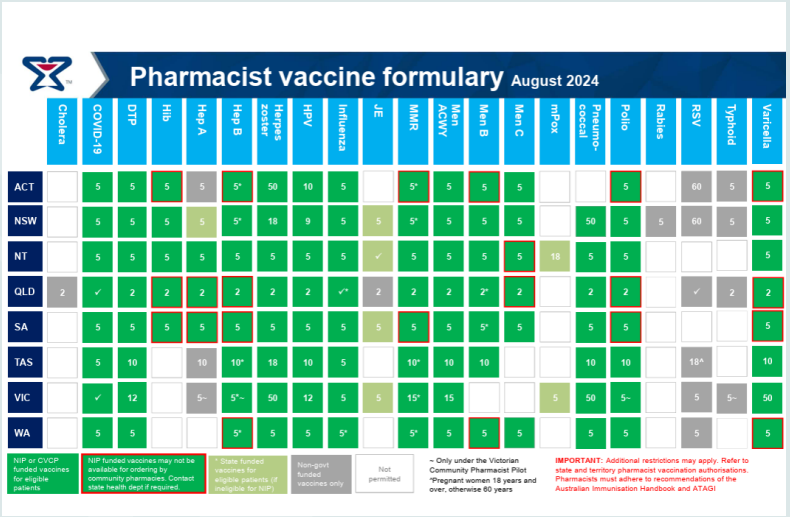
- persistent global crisis driven by
  - chronic under-investment in health education and training
  - weak health information systems
  - difficulties deploying workers to rural areas
  - challenging international migration of health workers

- shortfall requires increased investment in
  - health workforce
  - focusing on training
  - fair compensation, protection, and retention
  - build resilient health systems

Immunisation providers in Australia



NCIRS 2023 coverage report – more detail data available



NCIRS National Centre for Immunisation Research and Surveillance Australia

Trust and understanding

LISTEN to the Immunisation Workforce: Factors impacting improving coverage rates in Australia*

- Resource intensive to follow-up overdue children
- Lack of and costs to pre-call
- Workforce issues
- Access to appointments
- Family knowledge about schedule (no Save the Date app)
- Vaccine fatigue
- Practices accessing QI funding to undertake projects that are less resource intensive
- ANI's ability to vaccinate independently while practice maintains financial viability
- Difficulty utilising AIR reports
- Time practices already spend supporting catch-ups with little financial incentive
- Lack of knowledge regarding coverage trends
- School attendance rates and opportunities for catch-up

*Courtesy NCIRS PHN ISP Program and Social Science team NCIRS: Childhood vaccination barriers in Australia – key findings summary | NCIRS

National Vaccination Insights project: under 5 yrs

Aim

Collect data on the barriers to vaccination

Purpose

Inform the selection of strategies to improve vaccination uptake

Strategy recommendations

Informed by data on barriers, workshops with stakeholders, literature, and consultations with experts

Next steps

Repeat survey in September 2025 (parents of children <5 years, adult influenza)

possible of expansion to other groups

Four priorities for improving immunisation coverage

Make vaccination services more affordable, easy to access and use

Examples

Increase bulk billing of vaccination appointments

Deliver vaccines after work hours and in different settings (e.g., general practice, community clinics, pharmacies)

Support conversations with parents about vaccination

Examples

Fund healthcare providers for dedicated, paid time for vaccination conversations

Embed communication training in healthcare providers' professional development

Increase community understanding and confidence in, vaccination

Examples

Engage communities in designing and sharing of vaccination messages using trusted community advocates

Automate vaccination reminder system to alert patients of upcoming vaccinations

Improve immunisation stakeholders' access to quality, real-time data

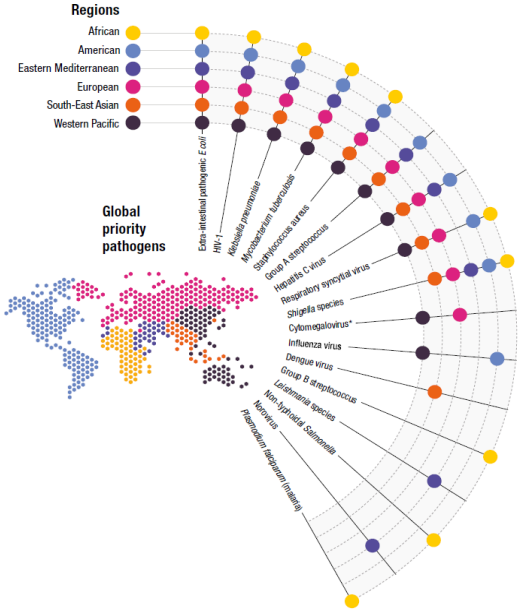
Examples

Change the Australian Immunisation Act 2015 to enable better sharing of vaccination uptake data at the practice level

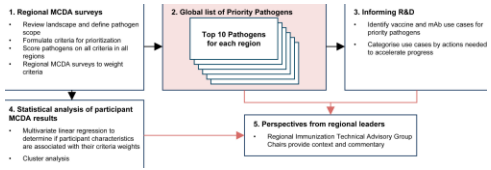
Give stakeholders access to up-to-date vaccination information through an online dashboard

Preventing new pathogens

And pandemic response



*Provisional result due to lack of systematic burden data



Identifying WHO global priority endemic pathogens for vaccine research and development (R&D) using multi-criteria decision analysis (MCDA): an objective of the Immunization Agenda 2030

Mateusz Hasso-Agopsowicz,[a,*] Angela Hwang,[b,c] Maria-Graciela Hollm-Delgado,[a] Isis Umbelino-Walker,[b] Ruth A. Karron,[d] Raman Rao,[e] Kwaku Poku Asante,[f] Meru Sheel,[g] Erin Sparrow,[a] and Birgitte Giersing[a]

Action categories:	Research	Advance Product Development	Prepare to Implement
Pathogens:	• Group A streptococcus • Hepatitis C virus • HIV-1 • *Klebsiella pneumoniae*	• Cytomegalovirus • Influenza virus (broadly protective vaccine) • *Leishmania* species • Non-typhoidal *Salmonella* • Norovirus • *Plasmodium falciparum* (malaria) • *Shigella* species • *Staphylococcus aureus*	• Dengue virus • Group B streptococcus • Extra-intestinal pathogenic *E coli* • *Mycobacterium tuberculosis* • Respiratory syncytial virus
Characteristics:	Few candidates in early clinical development or substantial technical challenges	Diverse candidates in development, including those in phase 2 studies	Candidates with high potential for approval by a WHO-listed authority before 2030
Recommended actions:	• Identify research gaps • Improve surveillance and burden estimates • Develop target product profiles • Assess potential vaccine value • Develop tools to improve technical feasibility	• Stimulate investment by raising awareness of opportunities for impact • Develop tools to inform decision-making (such as correlates of protection and economic models) • Create consensus on regulatory and policy pathways	• Build awareness of emerging products • Assemble evidence needed for policy decisions • Establish mechanisms for long-term, equitable access to approved products

Actions continue to introduce new vaccines and improve existing ones

Categories are a continuum and vaccine use cases often span categories. Research and product development continue throughout the product lifecycle. Category definitions and recommended actions were developed by the research team. Category assignments were reviewed and endorsed by PDVAC in December 2023.

Table 2: Action categories for global priority pathogens for vaccine R&D, based on the most advanced unmet use case for each pathogen as of December 2023.

Worlds first two malaria vaccines

13 MAY 2024

Malaria vaccine: WHO position paper – May 2024

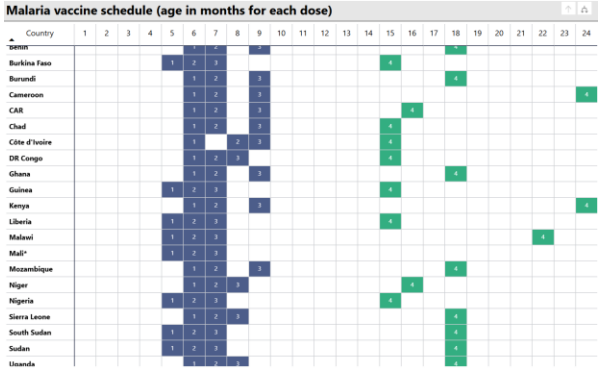
Weekly Epidemiological Record

Download | Read More

- Two malaria vaccines, RTS,S/AS01 and R21/Matrix-M
- Target *P. falciparum* infection in children
- they are not designed to interrupt malaria transmission
- no known cross-protection with other *Plasmodium* species
- 3+1 schedule
- MVIP country-level pilot (in Ghana, Kenya and Malawi)

"WHO recommends the use of malaria vaccines for the prevention of *P. falciparum* malaria in children living in malaria endemic areas, prioritizing areas of moderate and high transmission"

Malaria vaccine use on track to protect 14 million children in 2025 & 50 million children by 2030



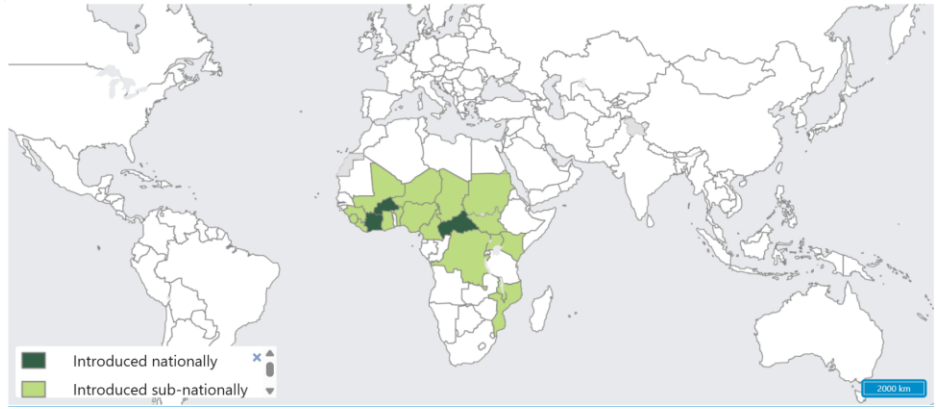
21

Total countries introduced

Country	Launch date
Malawi	Apr 2019
Ghana	May 2019
Kenya	Sep 2019
Cameroon	Jan 2024
Burkina Faso	Feb 2024
Sierra Leone	Apr 2024
Benin	Apr 2024
Liberia	Apr 2024
Côte d'Ivoire	Jul 2024
South Sudan	Jul 2024
Mozambique	Aug 2024
CAR	Aug 2024
Niger	Sep 2024
Chad	Oct 2024

Malaria Vaccine Introduction Status

WHO recommends the use of malaria vaccines for the prevention of P. falciparum malaria in children living in malaria endemic areas, prioritizing areas of moderate and high transmission. Some countries are introducing malaria vaccines in parts of the country. Reasons may include the local malaria burden, funding availability, and/or past constraints in vaccine supply, which have now been resolved.



Mentimeter

Malaria vaccine efficacy

What is the reported ‘ballpark’ efficacy of the RTS,S and the R21 malaria vaccines, respectively, against malaria in young children?

A. 30% and 75% (in presence of bed nets)

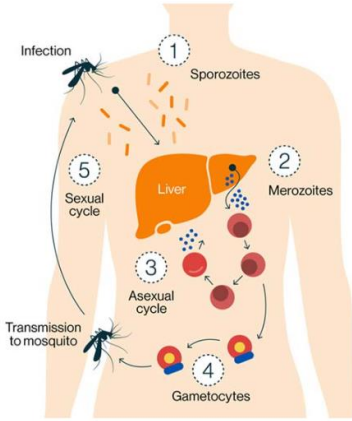
B. 70% and 90% (in absence of bed nets)

C. 60% for both (in presence of bed nets)

D. 50% irrespective of other prevention measures

Life-cycle of the malaria parasite

1. The cycle begins when highly mobile ‘sporozoites’ are transferred from mosquito to human, when the mosquito bites.
2. The sporozoites travel to the liver, where they infect liver cells, multiply and mature into ‘merozoites’. The current malaria vaccines are designed to block infection at this stage – before the parasites grow out of control.
3. The merozoites leave the liver and infect red blood cells, where they continue to grow and multiply, destroying the red blood cells and infecting others.
4. Some merozoites eventually develop into sexual forms of the parasite called ‘gametocytes’. When another mosquito bites, they enter its gut and reproduce, producing new sporozoites.
5. These migrate to the mosquito’s salivary glands, and the cycle begins again.



Two vaccines, one target: How the RTS,S and R21 malaria vaccines work

After decades of development and testing, the malaria vaccines now being rolled out across Africa are the first to ever successfully target a parasite, rather than a virus or bacterium. But how do these revolutionary vaccines work?

Both vaccines trigger the production of antibodies that block sporozoites from infecting liver cells. Those that do manage to break through are targeted by T cells, which are also activated by the vaccines.

*Access to an insecticide-treated bednet was optimised for all screened children.

Efficacy and safety of RTS,S/AS01 malaria vaccine with or without a booster dose in infants and children in Africa: final results of a phase 3, individually randomised, controlled trial

RTS,S Clinical Trials Partnership*

Summary

Background The efficacy and safety of the RTS,S/AS01 candidate malaria vaccine during 18 months of follow-up have been published previously. Herein, we report the final results from the same trial, including the efficacy of a booster dose.

Lancet 2015; 386: 31–45
Published Online

Safety and efficacy of malaria vaccine candidate R21/Matrix-M in African children: a multicentre, double-blind, randomised, phase 3 trial

Mehreen S Datoo, Alassane Dicko*, Halidou Tinto*, Jean-Bosco Ouédraogo, Mainga Hamaluba†, Ally Olotu†, Emma Beaumont, Fernando Ramos Lopez, Hamtandi Magloire Natama, Sophie Weston, Mwajuma Chemba, Yves Daniel Compaore, Djibrilla Issiaka, Diallo Salou, Athanase M Some, Sharon Omenda, Alison Lawrie, Philip Bejon, Harish Rao, Daniel Chandramohan, Rachel Roberts, Sandesh Bharati, Lisa Stockdale, Sunil Gairola, Brian M Greenwood, Katie J Ewer‡, John Bradley, Prasad S Kulkarni, Umesh Shaligram, Adrian V S Hill, the R21/Matrix-M Phase 3 Trial Group§

Summary

Background Recently, we found that a new malaria vaccine, R21/Matrix-M, had over 75% efficacy against clinical malaria with seasonal administration in a phase 2b trial in Burkina Faso. Here, we report on safety and efficacy of the vaccine in a phase 3 trial enrolling over 4800 children across four countries followed for up to 18 months at seasonal sites and 12 months at standard sites.

Lancet 2024; 403: 533–44
Published Online
February 1, 2024
https://doi.org/10.1016/S0140-6736(23)02511-4

TB Vaccine Pipeline

Vaccine candidates under clinical development

There are 16 vaccine candidates in the pipeline as of May 2025, of which 8 are in active trials. The candidates are placed under the phase which corresponds to the most advanced ongoing or completed trial.

Platform

- Mycobacterial - Live attenuated
- Mycobacterial - Inactivated
- Viral vector
- Protein/Adjuvant
- RNA

Trial staus

- Active trials
- No active trials

Candidate target population

- Elderly
- Adults
- Adolescents
- Children
- Infants
- People living with HIV
- -Mtb — People without Mtb infection
- +Mtb — People with Mtb infection
- aTBd — People with active TB disease
- MDR — People with MDR-TB
- cTB — People cured of active TB

Primary candidate indication

- *POI* — Prevention of Infection
- *POD* — Prevention of Disease
- *POR* — Prevention of Recurrence
- *Thp* — Therapeutic

Stop TB Partnership
WORKING GROUP ON NEW TB VACCINES

Information reported by vaccine sponsors or found in clinical trial registries or other public sources

Institutions listed are vaccine sponsors and development partners

TB Vaccine Pipeline

TB vaccine candidates in active clinical trials

There are 8 candidates in active clinical trials as of May 2025.

Platform

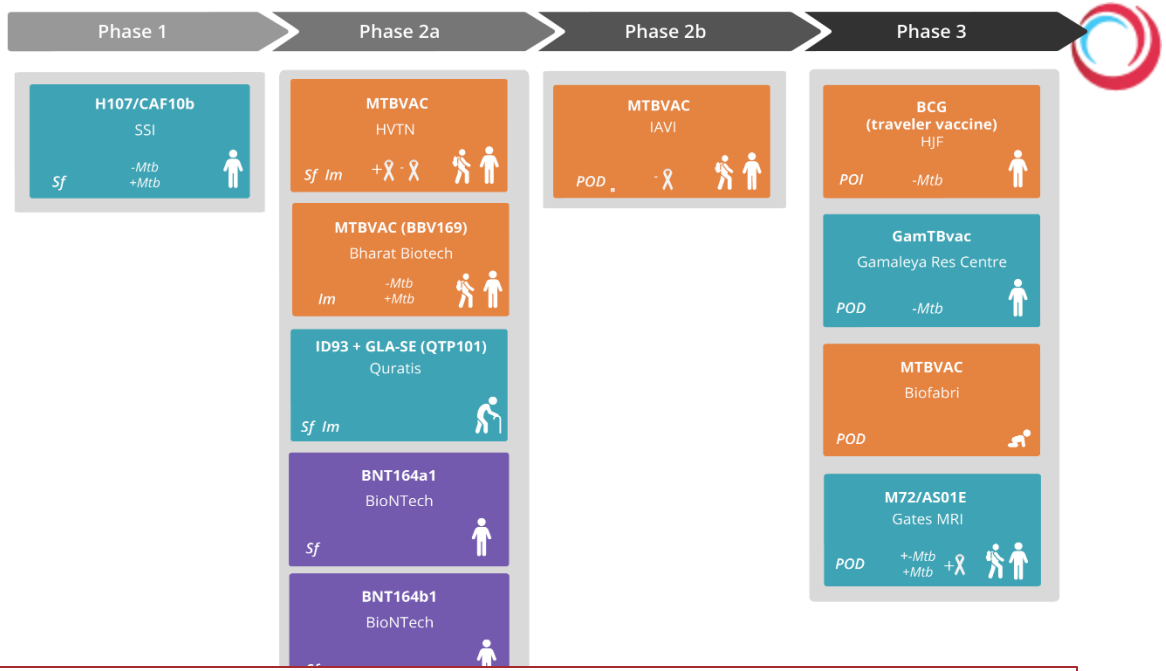
- Mycobacterial - Live attenuated
- Mycobacterial - Inactivated
- Viral vector
- Protein/Adjuvant
- RNA

Trial target population

- Elderly
- Adults
- Adolescents
- Children
- Infants
- People living with HIV

Primary endpoint

Sf	Safety
Im	Immunogenicity
POI	Prevention of Infection
POD	Prevention of Disease
POR	Prevention of Recurrence
Thp	Therapeutic



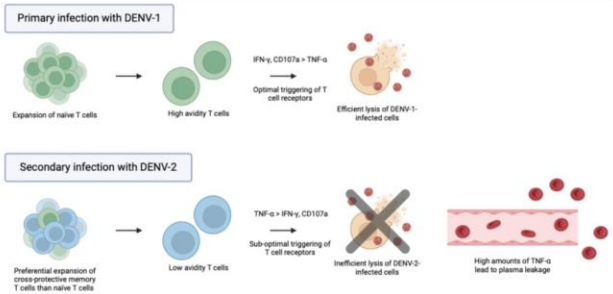
THE WORLD URGENTLY NEEDS NEW TB VACCINES

TB remains a major global health threat. In 2022, an estimated 10.6 million people became sick with TB and 1.3 million people died from TB.

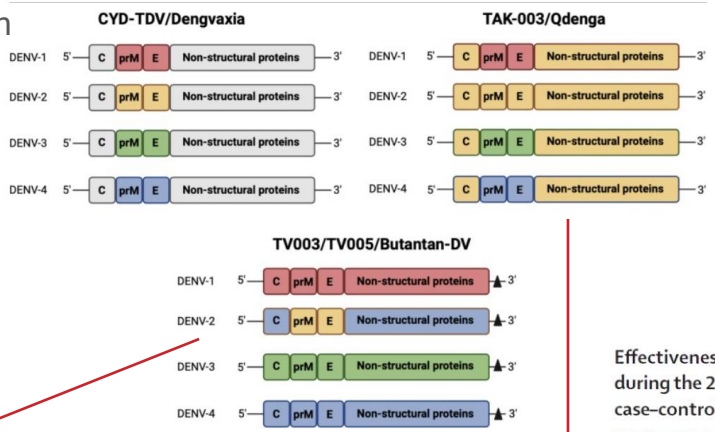
The only licensed vaccine to prevent TB – **the 100-year old BCG vaccine** – provides moderate, although important, protection against severe TB in infants and young children, but it does not adequately protect adolescents and adults, who are most at risk for developing and spreading TB.

Almost 90% of people with TB disease are adolescents and adults

Dengue vaccines



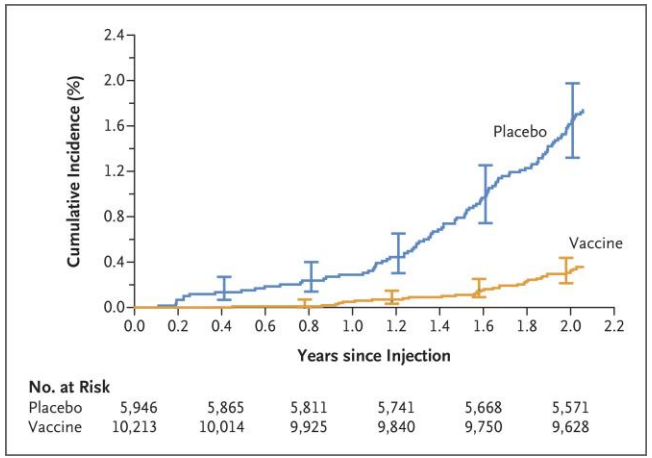
Not in use



Effectiveness of the TAK-003 dengue vaccine in adolescents during the 2024 outbreak in São Paulo, Brazil: a test-negative case–control study

Otavio T Ranzani, Felippe Lazar Neto, Lisany Krug Mareta, Thiago Sanches Brumatti, Roberto Dias de Oliveira, Patricia Vieira da Silva, Edinéia Ribeiro dos Santos, Tatiana Lang D' Agostini, Regiane A Cardoso De Paula, Natalie E Dean, Albert I Ko, Derek A T Cummings, Jason R Andrews, Matt D T Hitchings, Julio Croda

Cumulative Incidence of Virologically Confirmed Dengue through 2-Year Follow-Up – TV003/TV005Butantan-DV Phase 3 study



Kallás EG et al. N Engl J Med2024;390:397-408

Not yet registered

62% - 67% vaccine effectiveness

	Number of cases, controls	Vaccine effectiveness*	
		Unadjusted (95% CI)	Adjusted (95% CI)†
Symptomatic dengue (N=92 621)			
Unvaccinated	43 282, 46 725	Reference	Reference
First dose	570, 1784	62·5% (58·7–65·9)	50·2% (45·0–54·9)
Second dose	21, 239	89·9% (85·5–93·0)	61·7% (39·9–75·6)
Symptomatic dengue by time after first dose (N=92 361)			
Unvaccinated	43 282, 46 725	Reference	Reference
≤13 days	318, 461	19·1% (6·8–29·7)	27·8% (16·4–37·7)
14–27 days	68, 269	70·0% (61·8–76·4)	67·4% (57·2–75·1)
28–59 days	103, 469	74·0% (67·9–78·9)	63·9% (55·1–71)
60–89 days	38, 241	81·6% (75·2–86·3)	64·4% (49·6–74·8)
≥90 days	43, 344	85·7% (80·4–89·6)	49·7% (30·4–63·6)
Hospitalisation with dengue (N=49 871)			
Unvaccinated	1349, 46 725	Reference	Reference
First dose	13, 1784	74·8% (56·6–85·4)	67·5% (43·4–81·3)

*Vaccine effectiveness estimates were obtained from mixed logistic regression models with random intercepts for each surveillance area. †In the adjusted estimates, we included as covariates age, sex, self-reported race or skin colour, presence of absence of chronic comorbidities, and calendar time.

Table 2: Vaccine effectiveness against symptomatic, virologically confirmed dengue and hospitalisation with dengue

Innovation

CEPI

Preparing for future pandemics

CEPI, the Coalition for Epidemic Preparedness Innovations, is a global partnership working to accelerate the development of vaccines and other biologic countermeasures against epidemic and pandemic threats.

Strengthening disease surveillance and global early-warning systems

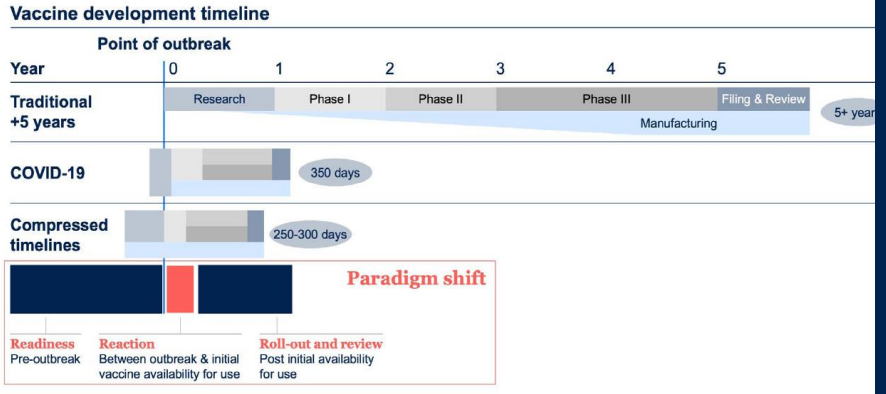
Establishing global manufacturing capacity to make top-quality, safe, and effective new vaccines quickly

Speeding up identification of immune response markers

Getting clinical trial and laboratory networks at the ready

Creating vaccine libraries against representative pathogens from virus families with greatest pandemic potential

Supported by enabling regulatory, policy and financing architecture



5 areas of innovation needed to make delivery of pandemic vaccines within 100 days a reality

ACTIVE CEPI-FUNDED VACCINE CANDIDATE PORTFOLIO BY PHASE

CEPI

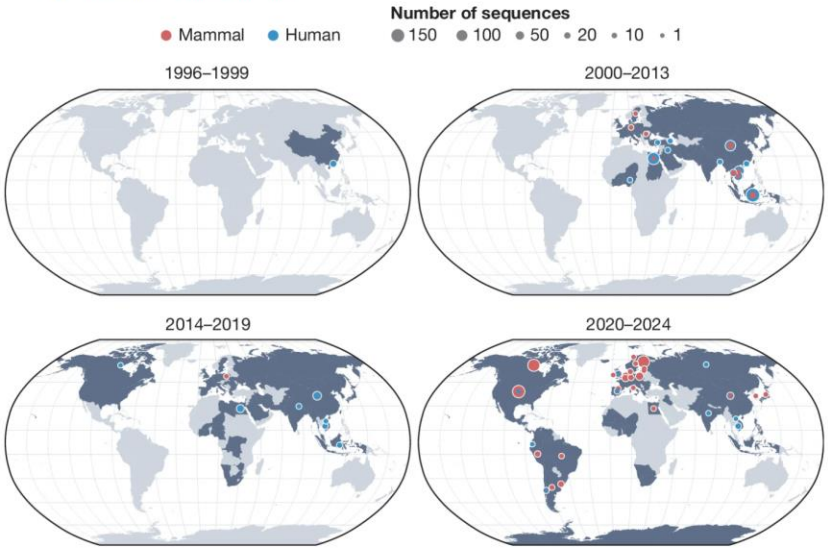
	Preclinical	Phase I	Phase II	Phase IIb/III & III	Registration
Lassa fever	University of Oxford		IAVI		
MERS	Uvax	IDT; Barinthus/ University of Oxford			
Nipah		PHV; University of Oxford			
Rift Valley fever	UC Davis; Afrigen	Wageningen U.	University of Oxford and KEMRI – Wellcome Trust		
Chikungunya				IVI/Bharat	Valneva
COVID-19*					SK Bioscience; Biological E; Moderna; Clover; Novavax; AZ/Oxford; University of Hong Kong
Broadly protective Betacoronavirus	VIDO; Panacea/ THSTI; IVI consortium; CPI/CalTech; Bharat/U Syd/ExcellGene; NEC; SK Bioscience; Intravacc				
Mpox			BioNTech		

(*) CEPI has also funded booster studies of SARS-CoV-2 vaccines developed by Medigen and Vaxxinity

Highly pathogenic H5 avian influenza

Fig. 1: Geographical distribution of HPAI H5 viruses sampled in birds and mammals between 1996 and 2024.

From: The global H5N1 influenza panzootic in mammals



Dark grey shading indicates countries with HPAI H5 virus sequences that are available on the GISAID database, specifically from the A/goose/Guangdong/1/1996(H5N1) (Gs/Gd) lineage that emerged in China in 1996. Blue (human) and red (non-human mammals) circles are sized in proportion to the number of H5 GISAID sequences from that country and time period. Map made with Natural Earth.

Prepare for a bird flu pandemic now, virologists urge

Leading virologists from 40 countries warn of critical gaps in pandemic preparedness and outline a plan for readying the world.

9 May 2025 • 3 min read • **by** Priya Joi **Republish this article**

Nobel geese walking with herd of goats in the background. Credit: Freepik

The global H5N1 influenza panzootic in mammals | Nature

Office of the Chief Science Advisor of Canada | Bureau du conseiller scientifique en chef du Canada

Canada

Managing Avian Flu:

A Science Roadmap and Action Plan

A Report from the Chief Science Advisor of Canada

February 2025

https://science.gc.ca/site/science/sites/default/files/documents/h5n1-report-

Food and Agriculture Organization of the United Nations

Post-2020 Avian Influenza Control Framework in ASEAN

Adopted at the 45th AMAF

https://asean.org/wp-content/uploads/2024/12/Post-2020-Avian-Influenza-Control-Framework-in-ASEAN-3.pdf

Australian Government Department of Health and Aged Care

Interim Australian Centre for Disease Control

Communicable Diseases network AUSTRALIA

Avian Influenza in Humans

CDNA National Guidelines for Public Health Units

Version 2.0

August 2024

https://www.health.gov.au/sites/default/files/2024-10/avian-influenza-in-humans-cdna-national-guidelines-for-public-health-units.pdf

Enhancing the response to avian influenza in the US and globally

Maggie L. Bartlett,[a,b,*] Peter Palese,[c,a] Meghan F. Davis,[b,a] Sten H. Vermund,[a,d] Christian Bréchot,[a,d] Jared D. Evans,[e,a] Lauren M. Sauer,[e,a] Albert Osterhaus,[f,a] Andrew Pekosz,[b,a] Martha Nelson,[g,a] Elyse Stachler,[h,a] Florian Krammer,[i,a] Gage Moreno,[h,a] Gene Olinger,[j,a] and Marion Koopmans[k,a]

Food and Agriculture Organization of the United Nations

World Organisation for Animal Health

Global Strategy for the Prevention and Control of High Pathogenicity Avian Influenza (2024–2033)

Achieving sustainable, resilient poultry production systems

https://www.woah.org/app/uploads/2025/02/web-gf-tads-hpai-strategy-woah.pdf

HIGHLY PATHOGENIC AVIAN INFLUENZA RESPONSE PLAN

THE RED BOOK

FAD PReP

Foreign Animal Disease Preparedness & Response Plan

USDA United States Department of Agriculture

United States Department of Agriculture • Animal and Plant Health Inspection Service • Veterinary Services

UPDATED MAY 2017

https://www.aphis.usda.gov/sites/default/files/hpai_response_plan.pdf

Australian Government Department of Health and Aged Care

Australian Centre for Disease Control

Communicable Diseases network AUSTRALIA

National guidelines for avian influenza: protecting people who work with birds

https://www.health.gov.au/sites/default/files/2024-12/cdna-national-guidelines-for-avian-influenza-protecting-people-who-work-with-birds-and-wildlife_0.pdf

UK Health Security Agency

Managing the human health risk of avian influenza in poultry and wild birds

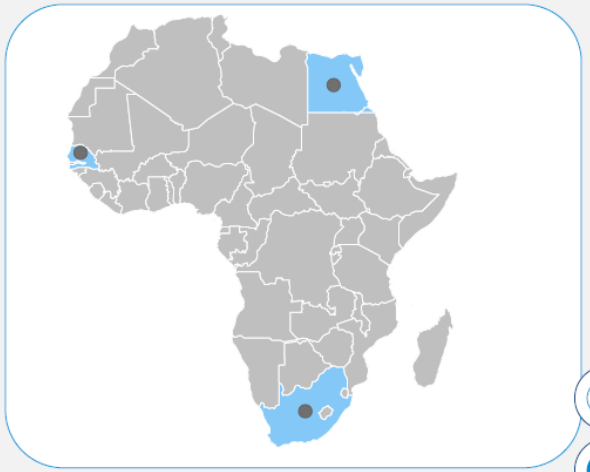
Guidance for health protection teams

Version 6.0: January 2023

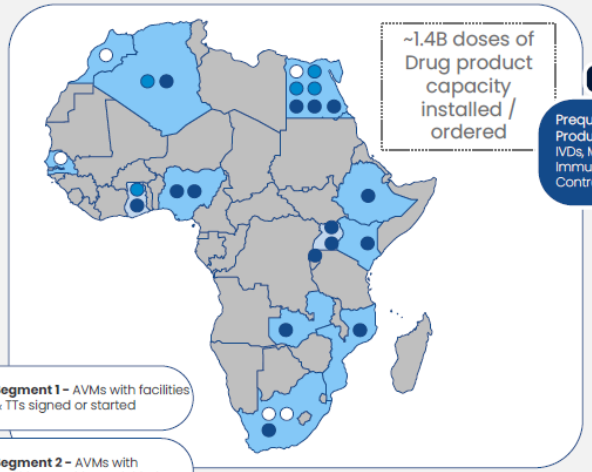
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1132418/avian-influenza-guidance-and-algorithms-for-managing-incidents-in-birds.pdf

Regionalization of vaccine manufacturing, including WHO mRNA Technology Transfer Programme

Prior to 2020, there were 3 mfcts. capable of commercial-scale* vaccine manufacturing, across all technologies



....While in 2024, there are 25 African vaccine manufacturing projects with commercial-scale* ambitions in the pipeline



Segment 1 – AVMs with facilities & TTs signed or started

Segment 2 – AVMs with facilities awaiting TT initiation

Segment 3 – AVMs with facilities in development

mRNA Technology Transfer Programme

Guidance for best practices for clinical trials

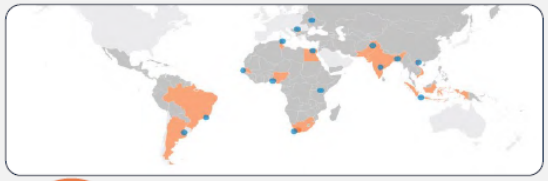
GTH-B Global Training Hub for Biomanufacturing

WHO Health Technology Access Program (HTAP)

WHOSAGE

Prequalification of Medical Products
IVDs, Medicines, Vaccines & Immunization Devices, Vector Control

WHO Global Benchmarking Tool (GBT) for evaluation of national regulatory system of medical products



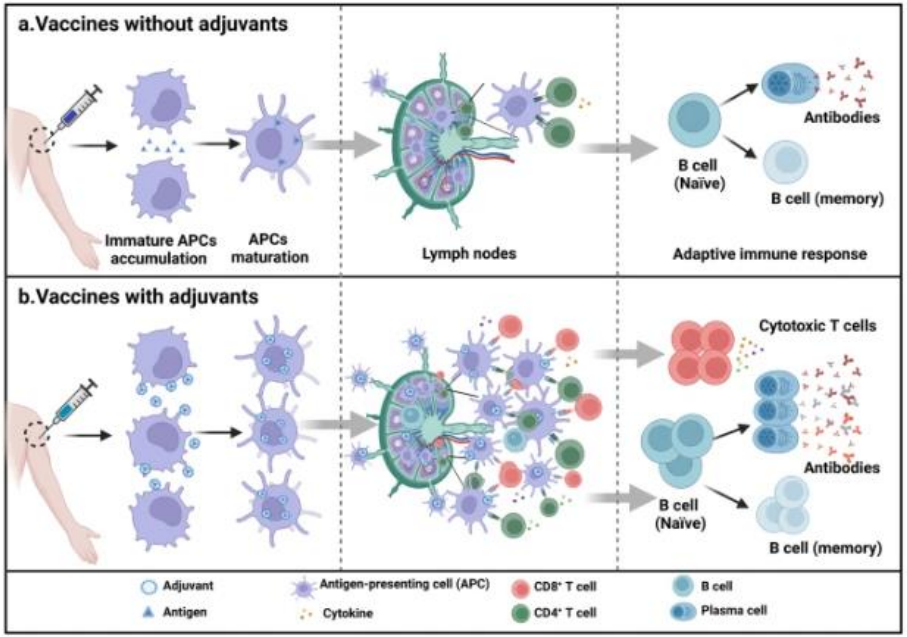
13 partner manufacturers trained

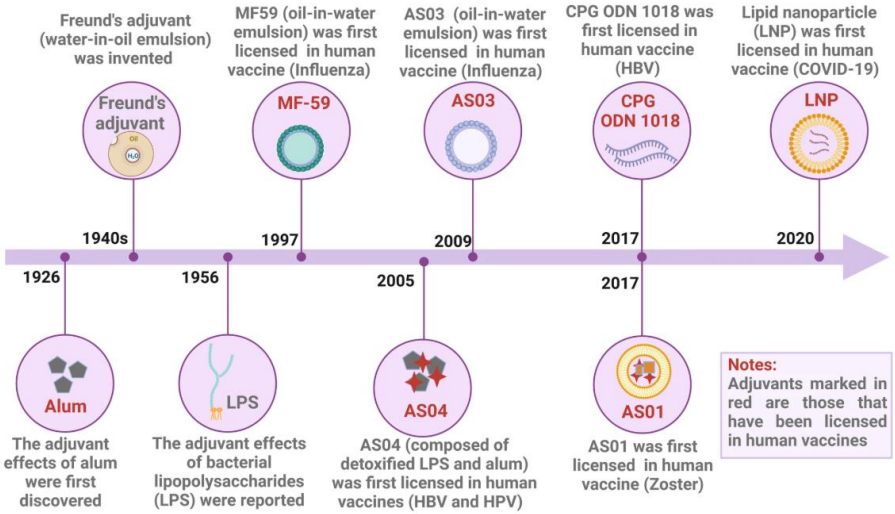
11 manufacturers could produce mRNA vax for human use by 2030

* Commercial-scale defined as production scale of 1Mn+ doses/year; mapping courtesy of CHAI, PATH & Africa CDC

Innovation

Vaccine design and delivery: Adjuvants





25 adjuvant library CEPI

Adjuvants can also help with dose sparing

The adjuvants joining the library are provided by:

- Allergy Therapeutics (UK)
- Access to Advanced Health institute, AAHI (US) – 6 adjuvants
- CHA Vaccine Institute (Korea)
- Chengdu MaxVax (China) – 3 adjuvants
- Clover Biopharmaceuticals (China)
- Croda (UK/Denmark) – 2 adjuvants
- The Global Health Drug Discovery Institute (China)
- National Research Council Canada/Glycovax (Canada)
- Jiangsu Recbio Technology (China) – 2 adjuvants
- Panacea (India)
- Parr Biotechnology (China) – 2 adjuvants
- Shionogi & Co. (Japan)
- Statens Serum Institute (Denmark) – 2 adjuvants
- Sumitomo Pharma (Japan)

World-first library of vaccine-enhancing adjuvants launches | CEPI

Vaccine adjuvants: mechanisms and platforms | Signal Transduction and Targeted Therapy

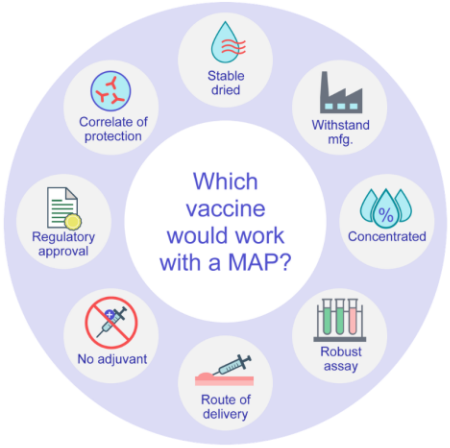
Will we ever just have vaccine patches?

VAXXAS IN THE NEWS

August 25, 2025

VAXXAS SECURES ~A$90M IN FUNDING TO COMMERCIALISE NEEDLE-FREE VACCINATION DELIVERY TECHNOLOGY

MORE NEWS



https://www.path.org/who-we-are/programs/mdht/mapresources/

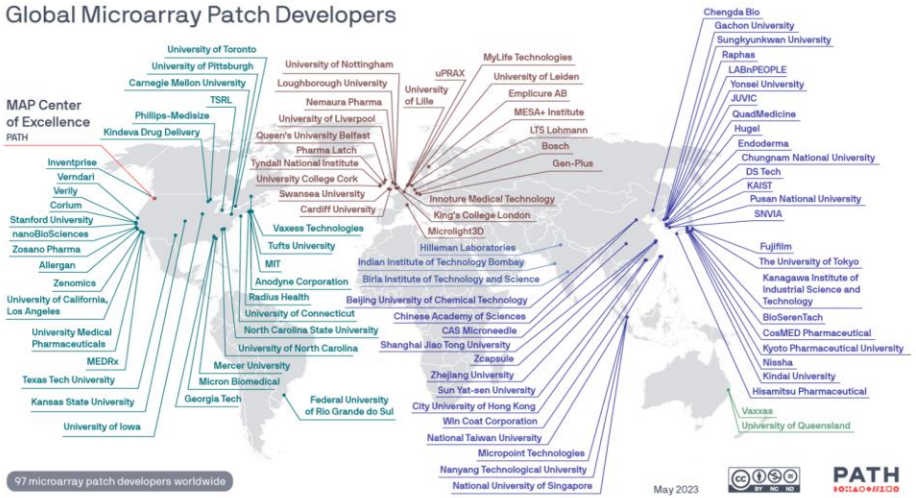
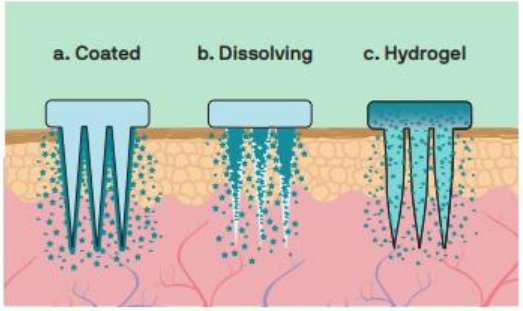
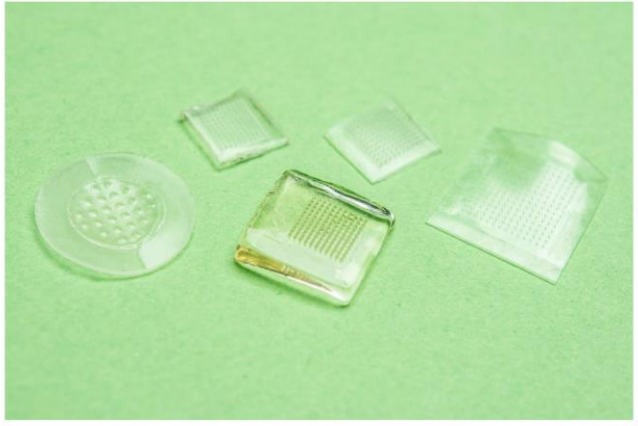


FIGURE 1. Types of microarray patches include (a) coated, (b) dissolving, and (c) hydrogel.





Assortment of microarray patches from different technology developers. Photo: PATH/Patrick McKern.

A measles and rubella vaccine microneedle patch in The Gambia: a phase 1/2, double-blind, double-dummy, randomised, active-controlled, age de-escalation trial

Ikechukwu Adigweme, Mohammed Yisa, Michael Ooko, Edem Akpalu, Andrew Bruce, Simon Donkor, Lamin B Jarju, Baba Danso, Anthony Mendy, David Jeffries, Anne Segonds-Pichon, Abdoulie Njie, Stephen Crooke, Elina El-Badry, Hilary Johnstone, Michael Royals, James L Goodson, Mark R Prausnitz, Devin V McAllister, Paul A Rota, Sebastien Henry, Ed Clarke

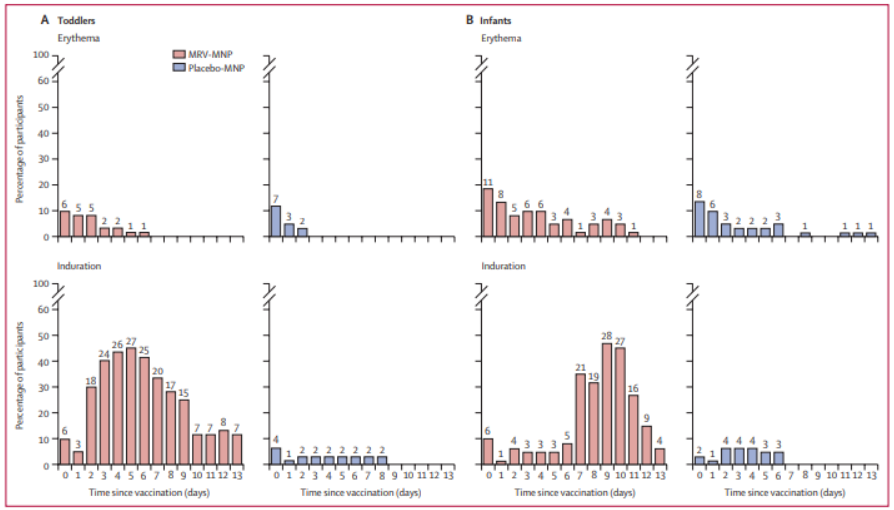


Figure 2: **Local solicited adverse events—toddler and infant cohorts**
(A) Toddler cohort (B) Infant cohort. Numbers represent the absolute number of participants, from among the 60 in each randomisation group and cohort, affected on each day. All local reactions were mild in severity. In addition, one toddler had mild tenderness on day 8 following MRV-MNP and one toddler had mild tenderness on day 1 following placebo-MNP (data not shown graphically). MNP=microneedle patch. MRV=measles and rubella vaccine. SC=subcutaneous.

› Vaccines (Basel). 2024 Nov 6;12(11):1258. doi: 10.3390/vaccines12111258.

Measles–Rubella Microarray Patches Phase III Clinical Trial Framework: Proposal and Considerations

https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(24)00532-4/fulltext

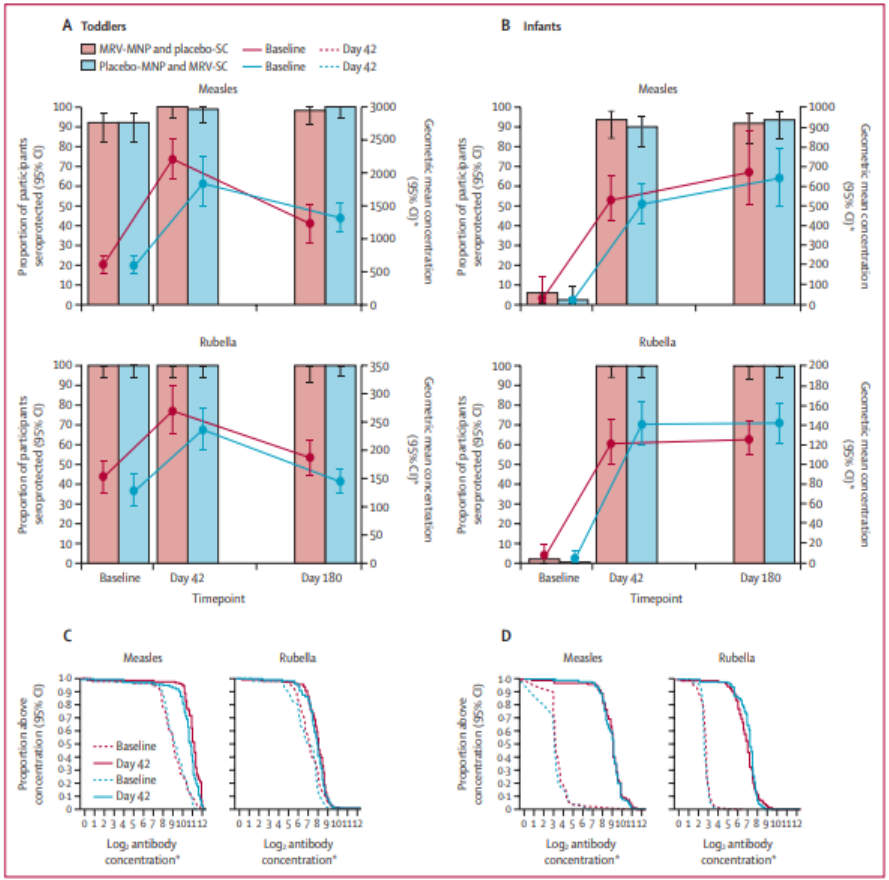


Figure 4: **Serum neutralising antibody seroprotection levels, geometric mean antibody concentrations, and reverse cumulative distribution curves—toddler and infant cohorts**
Toddler cohort (A) and infant cohort (B) measles and rubella serum neutralising antibody seroprotection rates (solid bars) and 95% CIs. Seroprotection rates are defined as the percentage of evaluable participants with an antibody concentration higher than 200 mIU/mL for measles and higher than 10 IU/mL for rubella. Toddler cohort (C) and infant cohort (D) measles and rubella serum neutralising antibody baseline and day 42 reverse cumulative distributions curves. MNP=microneedle patch. MRV=measles and rubella vaccine. SC=subcutaneous. IU=international unit. *Measles geometric mean concentrations are measured in mIU/mL. Rubella geometric mean concentrations are reported in IU/mL.

Intranasal vaccines

Influenza – live attenuated vaccine

UK Health Security Agency

Guidance

Flu vaccination programme 2025 to 2026: information for healthcare practitioners

Updated 7 August 2025

https://www.gov.uk/government/publications/flu-vaccination-programme-information-for-healthcare-practitioners/flu-vaccination-programme-2023-to-2024-information-for-healthcare-practitioners#live-attenuated-influenza-vaccine-laiv

Produced for Northern Hemisphere since 2003

- USA registration 2-49 years
- UK registration 2-18 years
  - School-based programs in UK for many years
  - Similar vaccine effectiveness to inactivated (parenteral) influenza vaccine
  - Australia….. Soon????

Recommendations for the use of LAIV

LAIV should be offered to eligible children aged 2 to less than 18 years unless contraindicated.

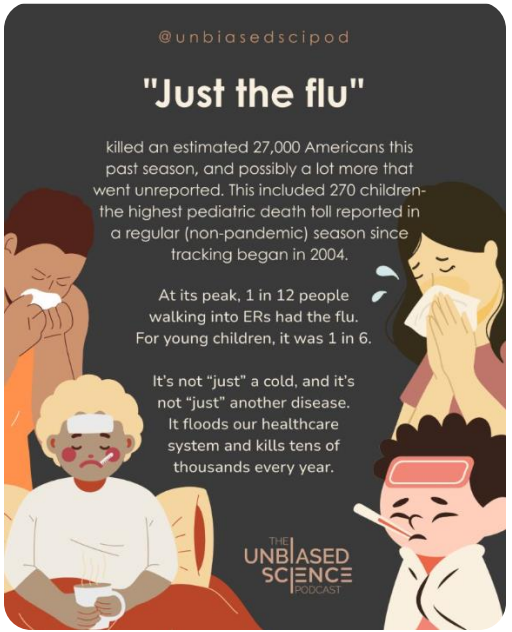
Influenza vaccines for children are centrally procured by UKHSA and should be ordered through ImmForm. As the vaccines are supplied free of charge via ImmForm they will not be reimbursed as part of the NHS annual influenza programme.

Table 2 shows the recommended vaccines for children.

Table 2. Recommended vaccines for children

Eligible group	Type of influenza vaccine
Children in a clinical risk group aged from 6 months to less than 2 years	Offer IIVc [footnote 1]
Children in a clinical risk group aged 2 to under 18 years	Offer LAIV If LAIV is contraindicated (or it is otherwise unsuitable) offer IIVc [footnote 1]
Aged 2 and 3 years on 31 August 2025 All eligible school aged children (reception year to year 11)	Offer LAIV If LAIV is contraindicated (or it is otherwise unsuitable) offer IIVc [footnote 1]

Only one LAIV vaccine is available. LAIV is manufactured by AstraZeneca, was first approved for use in the USA in 2003 (18) and has been sold in many countries since. It is marketed as Fluenz for the UK and EU market, and FluMist for the USA market. Fluenz and FluMist are the same product in different packaging.



Data for decision-making

3. Use data more effectively to target immunisation strategies and monitor performance

Improve the completeness, timeliness and transparency of Australian Immunisation Register (AIR) data, ensuring optimal quality and utility for all stakeholders.

Work towards creation of a whole of life, interactive, real-time dashboard of coverage data for all Australian Government-funded vaccines.

Expand data linkage capacity, analysis and reporting for better monitoring of vaccine program coverage, effectiveness, safety and impact.


MAKE
CHANGE
HAPPEN