



CHASING THE TB VACCINE

Prof. Helen McShane's Quest to End a Global Killer

December
2025

**“IMMUNIZATION IS A GLOBAL HEALTH AND DEVELOPMENT
SUCCESS STORY SAVING MILLIONS OF LIVES EVERY YEAR”**

WORLD HEALTH ORGANIZATION

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Chasing the TB Vaccine

**Prof. Helen McShane's Quest
to End a Global Killer**



Professor Helen McShane FRCP FMedSci is a leading British infectious disease physician and one of the world's most influential figures in tuberculosis (TB) vaccine development. A Professor of Vaccinology at the University of Oxford and Director of the Oxford NIHR Biomedical Research Centre, she has dedicated more than two decades to advancing vaccines for some of the world's most challenging infectious diseases.

Prof. McShane studied psychology (BSc, 1988) and medicine (MB BS, 1991) at the University of London. Early clinical work in Brighton during the height of the HIV epidemic proved formative: caring for severely ill patients shaped her conviction to combine clinical medicine with infectious disease research. Drawn to understudied pathogens, she chose *Mycobacterium tuberculosis* as her focus, a decision that would define her career.

After moving to Oxford as a specialist registrar, she won an MRC Clinical Training Fellowship and completed a PhD (2001/2002) on novel T-cell-targeted TB immunization strategies. Supported by successive Wellcome Trust fellowships, she rapidly established her own research programme and, in 2001, founded and began leading Oxford's TB vaccine group

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LETTER FROM EDITOR

Welcome to Vaccines Beat 18th issue!

In our *Coffee with an Expert* section, we had the privilege of speaking with **Professor Helen McShane**, one of the world's leading figures in **tuberculosis (TB) vaccine development**. Trained in psychology and medicine at the University of London, her early clinical work during the height of the HIV epidemic inspired her lifelong commitment to infectious disease research. Drawn to neglected pathogens, she chose *Mycobacterium tuberculosis* as her focus—a decision that shaped her groundbreaking career. Prof. McShane led the development of **MVA85A**, the first new TB vaccine candidate in more than 40 years to enter human efficacy trials and has been instrumental in advancing global clinical and scientific capacity for TB vaccine evaluation. She also chairs the **TBVI Advisory Committee** and has pioneered innovations such as controlled human mycobacterial challenge models, aerosol vaccine delivery, and advanced immunomonitoring. With over 100 peer-reviewed publications, she has mentored many of today's TB research leaders. Her conversation with us offered a candid and insightful view of the **current and future TB vaccine pipeline**—highlighting immunologic advances, the substantial challenges in clinical development, and the strategies needed to overcome them.

In this edition's *Editor's Corner*, we explore a critical public-health topic: **why every newborn should receive the Hepatitis B vaccine at birth—and the serious risks of foregoing this life-saving intervention**. We break down the science, the global epidemiology, and the long-term consequences of missed early protection.

Our *Best Practice* section highlights **updated vaccination guidelines and key clinical considerations for adults living with HIV**, offering practical, evidence-based insights to support clinicians in optimizing immunization strategies for this vulnerable population.

Finally, in our **Guest Contributor** section, **Dr. Mónica Reyes-Berlango**—a renowned pediatric infectious diseases specialist, professor, and current President of the Mexican Association of Pediatric Infectious Diseases—offers an exceptional commentary titled **“Why Immunization Committees Are Essential for Medical Societies.”** She clearly articulates the indispensable role these committees play, particularly within infectious disease disciplines, and highlights their core functions in shaping evidence-based policy, guiding educational initiatives, and strengthening clinical practice.

As always, this issue features carefully curated and up-to-date information on the ‘*Latest Scientific Publications*’ along with the most recent and important ‘*News and Alerts*’.

We hope you find this December issue both informative and engaging, and we look forward to continuing this shared commitment to advancing global health and building a healthier planet.



Enrique Chacon-Cruz, M.D., MSc
Chief Editor



Dr. Enrique Chacon-Cruz

Enrique Chacon-Cruz, M.D., MSc, Mexican-born medical doctor with a degree from Guadalajara, Mexico, and further specializations in Pediatrics and Infectious Diseases from institutions in Mexico City and the USA (Eastern Virginia Medical School). He also holds a Master's degree in Vaccinology and Drug Development from the University of Siena, Italy.

Currently, he is the CEO and Founder of "Think Vaccines" (Research, Education, and Consultancy for Vaccines and Vaccinology) based in Houston, Texas.

With over 140 research items published and/or presented at international meetings and more than 500 international lectures, all focused on vaccines, vaccination, clinical trials, and vaccine-preventable diseases. The latter conducted independently or in association with the Centers for Disease Control and Prevention (CDC), the University of California in San Diego, Eastern Virginia Medical School, and several other institutions.

Additionally, He is the President of the Immunization Committee of the Mexican Association of Pediatric Infectious Diseases, he is a member of the Mexican Committee for the Elimination of Measles, Rubella, and Congenital Rubella, member of the Immunization Committee of the European Society of Medicine and Overseas Fellow, Royal Society of Medicine, United Kingdom. He is also the former Director of the Mexican Active Surveillance Network for Bacterial Meningitis and the former Head of the Pediatric Infectious Diseases Department and the Research Department at the General Hospital of Tijuana, Baja-California, Mexico.

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Coffee with the Expert

CHASING THE TB VACCINE

Prof. Helen McShane's Quest to End a Global Killer

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Professor Helen McShane FRCP PhD FMedSci is a leading British infectious disease physician and one of the world's most influential figures in tuberculosis (TB) vaccine development. A Professor of Vaccinology at the University of Oxford and Director of the NIHR Oxford Biomedical Research Centre, she has dedicated more than two decades to advancing vaccines for some of the world's most challenging infectious diseases.

Prof. McShane studied psychology (BSc, 1988) and medicine (MB BS, 1991) at the University of London. Early clinical work in Brighton during the height of the HIV epidemic proved formative: caring for severely ill patients shaped her conviction to combine clinical medicine with infectious disease research. Drawn to understudied pathogens, she chose *Mycobacterium tuberculosis* as her focus, a decision that would define her career.

After moving to Oxford as a specialist registrar, she won an MRC Clinical Training Fellowship and completed a PhD (2001) on novel T-cell-targeted TB immunization strategies. Supported by successive Wellcome Trust fellowships, she rapidly established her own research programme and, in 2001, founded and began leading Oxford's TB vaccine group.

Prof. McShane's team went on to develop MVA85A, the first new TB vaccine candidate in over 40 years to reach human efficacy testing, marking a milestone for global TB research. Her work has expanded the scientific and clinical infrastructure for TB vaccine evaluation globally, and helped build long-standing collaborative networks throughout Africa. She has also chaired the



TBVI Advisory Committee, guiding international efforts to advance promising vaccine candidates.

Her research portfolio is broad and pioneering: controlled human mycobacterial challenge models, aerosol vaccine delivery directly to the lungs, and advanced immunomonitoring techniques that push the field toward more precise, rapid evaluation of vaccine efficacy. She has authored over 180 peer-reviewed publications and served as a mentor to many scientists who now lead TB research worldwide.

Beyond TB, Prof. McShane has played major national roles in pandemic response. During COVID-19, she coordinated Oxford's and the UK's drug-trial programmes and now leads efforts to develop a SARS-CoV-2 controlled human infection model, which will improve understanding of protective immunity and accelerate next-generation vaccine testing.

Prof. McShane's contributions have been recognized through election as a Fellow of the Royal College of Physicians, an NIHR Senior

Investigator, and a Fellow of the Academy of Medical Sciences. She continues to serve as Deputy Head of Oxford's Medical Sciences Division and as an Honorary Consultant in infectious diseases.

Helen McShane's legacy lies not only in the vaccine candidates she has helped deliver, but in the transformation she has brought to the global TB research landscape. She has built international clinical trial capacity, trained generations of infectious disease researchers, and advanced scientific understanding of how the human immune system responds to TB. Her leadership has reshaped the pathway from laboratory discovery to human trials, bringing the world closer to the long-sought goal of an effective TB vaccine. Her work has also strengthened the UK's pandemic research readiness and continues to influence vaccine science far beyond TB

Inspired path

A medical doctor by training, Prof. McShane first became interested in infectious diseases while working as a resident in Brighton in the early 1990s, a city on the south coast of the UK with a large gay community at the onset of the HIV/AIDS epidemic. At that time, she cared for a ward full of young patients: men her own age, all dying from *Pneumocystis carinii*-*jirovecii* pneumonia (PCP) and disseminated mycobacterial infections.

"As a junior doctor, it was an incredibly formative time because it was a fascinating mix of palliative care and really interesting infectious diseases. So, that's what got me hooked on infectious diseases," Prof. McShane recalls.

She later encountered a growing number of tuberculosis (TB) cases in London, where the disease was undergoing a dramatic resurgence in the early days of the HIV/AIDS epidemic, before antiretroviral therapy became available.

"I just was completely fascinated by tuberculosis. This old disease that predates the pharaohs," she notes. "I realized that there were a lot of people working on HIV, a lot of research going on in HIV, but really no one seemed to be working on TB."

Prof. McShane remembers how difficult it was to pursue TB research at the time. Funding was scarce, and the field was small. Nonetheless, she accepted the challenge and moved to Oxford, committing her PhD entirely to TB research. She eventually secured funding that allowed her not

only to continue but to lead the TB program.

"And that's what I've done ever since," she reflects.

Advantages and limitations of BCG

Developed more than 100 years ago, Bacille Calmette-Guérin (BCG) remains the only licensed vaccine against TB. It is a live attenuated strain of *Mycobacterium bovis*, the bovine form of TB and the reason milk pasteurization became standard practice. WHO guidelines recommend administering BCG as close to birth as possible, as strong evidence shows it provides consistent and reliable protection against severe, disseminated TB in early childhood.

This includes TB that spreads beyond the lungs, particularly TB meningitis in infants. Its effectiveness in preventing these life-threatening forms of the disease is the primary reason BCG remains a cornerstone of childhood immunization programs worldwide.

"However, the problem is that BCG doesn't consistently protect against lung disease, particularly in adolescents and young adults, which is where the burden of the disease is. And, of course, is where the economic burden of TB is," she notes.

Still, the story is not as straightforward as saying BCG "doesn't work" against pulmonary TB. Two landmark studies, the British MRC trial in the UK and a study in North Alaskan Indigenous communities, showed that BCG can be highly effective against pulmonary disease in adolescents. But efficacy varies dramatically. In lower- and middle-income countries, where the burden of TB is highest, large trials such as the Chingleput study in India found little to no protection against lung disease.

"So, it's not true to say BCG doesn't work," she explains. "What's more correct is to say, it's highly variable in how well it works against lung disease. And that efficacy is lowest in high burden countries. It's also lowest close to the equator."

Despite its limitations, Prof. McShane emphasizes that the complexity of BCG's performance should not overshadow its well-documented ability to prevent severe, disseminated TB. For this reason, the WHO continues to recommend universal neonatal BCG vaccination worldwide.

BCG as an immune modulator

The so-called “non-specific” effects of BCG have long been controversial, largely because study results vary widely across regions. This inconsistency raises questions about whether these effects are genuine or influenced by confounding factors. Challenges include the absence of a fully established biological mechanism, variability among BCG strains and vaccination practices, and concerns about publication bias—issues heightened by the political and policy implications of such findings. These factors can affect mortality or infection risk independently of BCG, making it difficult to determine whether the vaccine itself is responsible.

“I think it is increasingly felt that there is something real here and that there really is a so-called non-specific effect of BCG,” Prof. McShane affirms.

One of the clearest examples of BCG’s non-specific immune activity is its long-standing global use in the treatment of non-muscle invasive bladder cancer. When administered intravesically, BCG provides robust protection against disease recurrence if cancer is detected early, demonstrating its capacity to modulate immune responses beyond TB.

This issue has become particularly important because two leading candidates in the new generation of BCG-replacement vaccines are being evaluated solely for their efficacy against TB. Investigating their potential non-specific effects is far more challenging, making it difficult to determine whether they match or exceed BCG’s broader immunological benefits.

“We need to look at the data from these new vaccines very closely to make sure that those vaccines are not non-inferior to BCG in terms of these non-specific effects—as well, of course, as looking at the efficacy of these new vaccines against their specific effects to protect against TB,” she emphasizes. “That’s very difficult,” she adds, noting that such data will likely need to be gathered through phase IV post-licensing surveillance.

Obstacles to a successful TB vaccine

Tuberculosis remains one of the most challenging pathogens to target with a vaccine. It is a remarkably sophisticated organism, capable of

evading and subverting the human immune system to avoid detection. An estimated quarter of the world’s population is latently infected with TB. In these individuals, the bacterium lies dormant and reactivates primarily when immune function becomes compromised.

Two major obstacles impede vaccine development: the absence of reliable immune correlates of protection and the limitations of animal models. Immune correlates of protection are the markers researchers use to determine whether a vaccine is likely to be effective. For TB, such correlates simply do not exist. While scientists understand certain immune responses that contribute to protection, they do not know which specific components correlate with actual immunity.

“For a pathogen as complex as TB, it’s very unlikely that there will be a simple, single immune correlate, like for Streptococcus pneumonia or Neisseria meningitidis, where we know you just need a certain level of a certain kind of antibodies and then your vaccine will protect,” Prof. McShane explains. “We don’t even know which aspect of immunity correlates with protection, let alone the level.”

In addition, it is unclear which, if any, animal model reliably predicts vaccine efficacy in humans. Researchers evaluate immune responses and animal data but, ultimately, must make informed judgments about which candidates appear most promising before advancing them into human trials.

“So, to a certain extent, TB vaccinology is empirical,” she acknowledges.

A third major challenge is the complexity and scale of efficacy trials. To date, M72/AS01e is the only new TB vaccine candidate that has demonstrated efficacy in humans, achieving 49.7% protection in a phase 2b trial. A phase 3 study is currently underway, but because TB incidence is relatively low even in high-burden settings—and because the disease is so complex—the trial requires 20,000 participants, will take five or more years to complete, and is projected to cost around half a billion USD.

“So that’s our problem. We can’t put lots of vaccines through that kind of efficacy trial,” Prof. McShane notes. “One of the things we need to do is work out how we can better test

whether vaccines will work before we get to that very difficult and very expensive stage.”

Most promising TB candidates

According to Prof. McShane, the field of TB vaccines can broadly be divided into two categories. The first includes whole-organism vaccines, designed to replace BCG. The second comprises subunit vaccines, which deliver one or two specific TB proteins along with a delivery system or adjuvant, are designed to boost a neonatal BCG vaccination.

The most advanced subunit vaccine is M72/AS01e. It is a protein-adjuvant vaccine that combines two TB proteins, the 32- and 39-kilodalton antigens, delivered with an adjuvant called AS01. To date, M72 is the only TB vaccine to demonstrate efficacy in a phase 2b trial, and a phase 3 trial is currently underway.

“And the field, I think it’s fair to say, awaits that phase 3 result with anticipation and a little nervousness. This is, at the moment, the most promising vaccine,” Prof. McShane confirms.

Other candidates, including the protein-adjuvant vaccine H107 and TB vaccines using mRNA technology, are still in early-phase studies.

Among BCG replacement vaccines, two leading candidates are in phase 3 trials. The first, MTBVAC, is a first-in-class vaccine: a rationally attenuated strain of *Mycobacterium tuberculosis* developed specifically for human use. With promising preclinical animal data, it is currently being tested in infants.

The second, VPM1002, is a genetically modified strain of BCG that expresses listeriolysin, aiming to engage a different immune processing pathway and enhance the vaccine’s immunogenicity.

“So, I think that those three candidates are the [ones] being tested in phase 3 trials, and the world awaits that data with interest,” Prof. McShane shares enthusiastically.

Prof. McShane’s current work

Historically, the first vaccine developed by Prof. McShane and her team was MVA85A, which uses a modified Vaccinia virus (MVA) that is harmless to humans. This virus carries a gene from the TB bacterium, stimulating an immune response.

“This was the first new TB vaccine to go into clinical trials anywhere in the world,” she recalls. “Phase 2B testing in infants in South Africa showed that the vaccine was safe but, unfortunately, MVA85A did not improve efficacy compared with BCG alone. Obviously, that was an enormously disappointing result.”

Despite this setback, the team was committed to extracting as much insight as possible from the trial. They analyzed immune correlate samples to gain unique insights into protective immunity, which are now guiding the development of next-generation TB vaccines.

“We’ve been identifying new protective antigens in a number of different ways, using reverse vaccinology and immunopeptidomic approaches, to start from scratch,” Prof. McShane explains.

TB has roughly 4,000 antigens, so selecting the most promising ones presents a significant challenge.

“We’ve identified a number of antigens that are protective when given alone to mice. We are now combining them with an optimal delivery system,” she continues. “So, in a subunit vaccine, you take the antigens and then you take the delivery system. We’ve looked at a number of delivery systems: mRNA, protein/adjuvant combinations and recombinant viral vectors.”

One other avenue they are exploring is delivering vaccines directly into the lungs

“There’s increasing data from animal models that delivering a new TB vaccine into the lungs may be the most protective way to develop a new TB vaccine. Because, of course, that mimics the natural route of infection,” she explains.

The team is currently seeking funding to advance the most promising candidates into Good Manufacturing Practice (GMP) production and clinical trials.

Inhaled TB vaccine candidates

Because TB immunity is strongly T-cell-mediated, delivering TB antigens directly into the lungs could, in theory, provoke granulomatous or type IV hypersensitivity reactions similar to those seen in natural TB infection. For this reason, inhaled TB vaccines undergo rigorous preclinical evaluation to assess potential lung immunopathology.

Prof. McShane and her team have closely monitored the safety of these vaccines in early studies. To date, inhaled vaccines appear to be very safe for a range of respiratory pathogens, including TB. The next step is to conduct trials in high-burden TB countries to confirm safety in these populations and to evaluate the immune responses they induce.

“If a vaccine isn’t safe, it’s not going to go anywhere,” she asserts.

Human challenge studies

Human challenge models involve deliberately exposing volunteers to a pathogen under highly controlled clinical conditions. These models have been used for decades to accelerate vaccine development, most notably for malaria, where they contributed to the development of both RTS,S and R21 vaccines.

“They are particularly useful when vaccine development is difficult or complex, and there’s no better example of that than TB,” Prof. McShane remarks.

Unlike malaria and other pathogens for which challenge models exist—such as dengue, typhoid, and gonorrhea—she does not consider it ethical to expose volunteers to virulent *Mycobacterium tuberculosis*.

“So we have to find a workaround, and there are groups developing attenuated strains of TB that we could use in challenge models,” she shares.

To initiate work in this area, her team used BCG, a live attenuated strain of *Mycobacterium bovis* already licensed for human use. They administered BCG intradermally and collected punch biopsies from the injection site to quantify bacterial load. Their findings showed that prior BCG vaccination reduces BCG recovery from skin biopsies, providing evidence that the model measures a biologically meaningful effect.

“The limitation, of course, is that this model doesn’t mimic the natural route of TB infection,” she notes.

To address this, they developed an aerosol BCG challenge model, in which

BCG is nebulized into the lungs. Using bronchoscopy, they collect lung wash samples and quantify bacterial load to assess the protective effect of prior BCG vaccination.

“In our preliminary data to date, we see that in people who have not had a previous BCG vaccination, we can recover BCG from that bronchoalveolar lavage fluid taken two weeks after an aerosol BCG challenge, whereas we cannot recover BCG from people who have previously been vaccinated with BCG – again suggesting the model is measuring a biologically meaningful effect” she says.

The team is expanding this model to other settings. In an NIH-funded study, they are testing the aerosol BCG challenge to evaluate the preliminary efficacy of a candidate vaccine, IDRI-93-GLSE.

“We [know] a challenge model won’t replace animal models, and it won’t replace human immunogenicity. But we think it will be a tool that will complement those two tools and help us select which vaccine should go forward to efficacy testing,” Prof. McShane hopes.

Regarding regulatory barriers for new TB vaccines, she identifies the size, scale, complexity, and cost of efficacy trials as the main challenges.

“Working with regulators to understand how we can together better design efficacy trials that regulators would accept and are feasible and affordable, I think is the most pressing issue,” she says.

Prof. McShane believes access to a TB vaccine is less about policies and more about money. She says that there’s very little commercial market for new TB drugs and TB vaccines. She thinks the world must support R&D for TB vaccines and drugs because the world in the 21st century is small, and TB anywhere is a problem everywhere.

“TB predates the pharaohs and yet in the 21st century still kills more people than any other infectious disease,” she concludes. “The world ignores TB at its peril.”

News & Alerts

MOST RELEVANT MONTHLY NEWS ON VACCINATION AND EMERGING DISEASES WITH BIBLIOGRAPHIC ALERTS

A summary of the latest News & Alerts in the fields of vaccinology, vaccines, vaccination, and vaccine-preventable diseases. We curate the latest information on regulatory updates, emerging trends, breakthroughs in vaccine technology, vaccine safety and efficacy, global immunization developments and outbreak alerts, as a resource to keep our community informed.

Gavi and UNICEF announce equitable pricing deal for malaria vaccine to protect 7 million more children by end of decade.

Gavi, the Vaccine Alliance and UNICEF today announced a new agreement that will make the R21/Matrix-M™ malaria vaccines significantly more accessible and affordable, paving the way to protect more children from one of the world's deadliest diseases. The deal, backed by Gavi and executed by UNICEF, is expected to generate up to US\$ 90 million in savings for Gavi and countries, equivalent to more than 30 million additional doses – enabling the full vaccination of nearly 7 million more children against malaria over the next five years. The deal is financed by Gavi through an advance payment enabled by the innovative International Finance Facility for Immunisation (IFFIm) mechanism.

Published: November 23, 2025.

<https://www.unicef.org/press-releases/gavi-and-unicef-announce-equitable-pricing-deal-malaria-vaccine-protect-7-million>.

Bangladesh Dengue Crisis: 5 New Deaths Push 2025 Toll Past 380.

The dengue outbreak in Bangladesh continues to claim lives with five new fatalities reported. Total deaths for 2025 have now reached 382, surpassing last year's toll of 575. Health authorities are urging immediate medical attention at the first sign of fever to prevent complications. The government has issued comprehensive guidelines including eliminating standing water and using

mosquito nets for protection (but no vaccination).

Published: November 30, 2025.

<https://www.newkerala.com/news/o/dengue-claims-five-lives-bangladesh-2025-death-toll-crosses-979>.

Brazil approves world's first single-dose dengue vaccine.

Brazil's health regulatory agency authorises the use of Butantan-DV for people aged 12 to 59.

Published: November 27, 2025.

<https://www.thedailystar.net/health/news/brazil-approves-worlds-first-single-dose-dengue-vaccine-4045236>.

World AIDS Day 2025. Overcoming disruption, transforming the AIDS response – World AIDS Day 2025.

The theme of this year's World AIDS Day is "Overcoming disruption, transforming the AIDS response." The commemoration of World AIDS Day, which will take place on 1 December 2025, is an important opportunity to highlight the impact that the funding cuts from international donors have had on the response to AIDS as well as to showcase the resilience of countries and communities stepping up to protect the gains made and drive the HIV response forward. In 2025, a historic funding crisis is threatening to unravel decades of progress. HIV prevention services are severely disrupted. Community-led services, vital to reaching marginalized populations, are

being deprioritized while the rise in punitive laws criminalizing same-sex relationships, gender identity, and drug use is amplifying the crisis, making HIV services inaccessible. <https://www.unaids.org/en/2025-world-aids-day>.

Mauritania now offers the six-in-one childhood vaccine. Here's why that matters.

Mauritania has added the hexavalent vaccine to its national immunisation programme: a major advance that brings protection against six serious diseases – diphtheria, tetanus, whooping cough, hepatitis B, *Haemophilus influenzae* type b (Hib) and polio – into a single injection.

Published: November 28, 2025.

<https://www.gavi.org/vaccineswork/mauritania-now-offers-six-in-one-childhood-vaccine-why-that-matters>.

European CDC: Scenarios for pre-pandemic zoonotic influenza preparedness and response.

The aim of this framework is to guide a scalable public health response to influenza of zoonotic origin in EU/EEA countries and provide options for preparing and responding to different possible pre-pandemic scenarios. They have defined 14 scenarios based on specific epidemiological and virological factors, including animal origin, characteristics of human cases (number and exposure context), severity signals, that are then further defined based on the presence of virus mammalian adaptation, antiviral resistance and mismatch with available pre-pandemic vaccines and/or candidate vaccine viruses.

The document provides a detailed guide and a simple downloadable Excel tool for defining and scoring the different scenarios based on early triggers, promoting transparency and coherence across countries, integrating a One Health perspective, through focusing on the public health side of the response measures; it describes the baseline/escalating public health actions that should be in place/implemented to ensure a timely and effective response.

Published: December 4, 2025.

<https://www.ecdc.europa.eu/en/publications-data/scenarios-pre-pandemic-zoonotic-influenza-preparedness-and-response>.

France confirms 2 MERS coronavirus cases in returning travelers.

Two cases of Middle East Respiratory

Syndrome coronavirus (MERS-CoV) have been confirmed in France in individuals who recently returned from travel abroad, according to the French Ministry of Health.

Published: December 4, 2025.

https://bnonews.com/index.php/2025/12/france-confirms-2-mers-coronavirus-cases-in-returning-travelers/#google_vignette.

World Bank Group: Low-Income Countries Spend Just \$17 Per Capita Annually on Health.

Despite efforts by many developing countries to sustain health spending under fiscal pressure, investments remain insufficient to fund essential health services—critical for saving lives, creating jobs, and driving growth—according to a new World Bank Group report released today.

Published: November 19, 2025.

<https://www.worldbank.org/en/news/press-release/2025/11/19/health-financing-challenges-opportunities-changing-aid-landscape-grph#:~:text=At%20a%20Crossroads%3A%20Prospects%20for,basic%20package%20of%20essential%20services>.

Sabin Vaccine Institute's Investigational Marburg Vaccine Delivered to Ethiopia for Outbreak Response.

The Sabin Vaccine Institute (Sabin) has sent more than 640 doses of its investigational cAd3-Marburg Vaccine to Ethiopia to support the country's response to its first-ever outbreak of Marburg virus disease. Marburg is a highly contagious hemorrhagic fever disease and can have a high case fatality rate of up to 88%. There are currently no licensed vaccines or treatments for Marburg.

Published: December 4, 2025.

<https://www.globenewswire.com/news-release/2025/12/04/3200238/0/en/Sabin-Vaccine-Institute-s-Investigational-Marburg-Vaccine-Delivered-to-Ethiopia-for-Outbreak-Response.html>.

New strain of flu hitting US: What are the symptoms?

The new strain, called subclade K, has made its way to the U.S. after spreading quickly through countries such as the UK, Canada and Japan. H3N2 symptoms include fever, chills, body aches, headache, extreme fatigue, congestion or runny nose, and coughing. It is increasing among children and young adults.

Published: December 5, 2025.

<https://www.al.com/news/2025/12/new-strain-of-flu-hitting-us-what-are-the-symptoms.html>.

Aluminium is crucial to vaccines — and safe.

Why are US advisers debating it? Adjuvants are compounds that boost immune responses, improving the ability of vaccines to elicit long-lasting immunity against infectious diseases. Adjuvants can work in different ways. Some adjuvants trigger low levels of inflammation at the injection site, thereby boosting recruitment of immune cells to where they are needed and encouraging the cells to linger there. Others are more specific, activating molecular signalling pathways in certain classes of immune cells. Decades of use and scrutiny by regulators have clearly established that the benefits of using aluminium adjuvants outweigh any potential risks.

Published: December 4, 2025.

<https://www.nature.com/articles/d41586-025-03955-z>.

How a 'nightmare' cholera outbreak brought Nepali hospitals to the brink.

Beginning in August, cholera hospitalised thousands in the southern city of Birgunj. In mid-October, a million doses of vaccine brought relief.

Published: December 3, 2025.

<https://www.gavi.org/vaccineswork/how-nightmare-cholera-outbreak-brought-nepali-hospitals-brink-overwhelm#:~:text=At%20a%20glance-,More%20than%201%2C500%20people%20were%20hospitalised%20with%20cholera%20in%20southern,on%20floors%20and%20in%20corridors>.

Highly contagious virus detected in New York wastewater.

A highly contagious virus that spread rapidly across New York City last winter may make a resurgence. Sometimes referred to as the stomach flu or stomach bug, the norovirus illness causes vomiting and diarrhea. Recent wastewater testing has detected the virus around New York.

Published: December 5, 2025.

<https://pix11.com/news/local-news/highly-contagious-virus-detected-in-new-york-wastewater/>.

WHO: Avian Influenza A(H5N5) - United States of America.

On 15 November 2025, WHO was notified of the 71st confirmed human case with influenza A(H5) since early 2024 in the United States of America— the first human case reported in the United States of America since February 2025. On 20 November, U.S. Centers for Disease Control and Prevention (CDC) laboratory sequencing verified the virus as influenza A(H5N5), representing the first globally reported human case caused by an influenza A(H5N5) virus.

Published: December 5, 2025.

<https://www.who.int/emergencies/disease-outbreak-news/item/2025-DON590>.

CDC: ACIP Recommends Individual-Based Decision-Making for Hepatitis B Vaccine for Infants Born to Women Who Test Negative for the Virus.

The Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) today voted 8 to 3 to recommend individual-based decision-making for parents deciding whether to give the hepatitis B vaccine, including the birth dose, to infants born to women who test negative for the virus. For those infants not receiving the birth dose, ACIP suggested in its recommendation that the initial dose be administered no earlier than two months of age.

Published: December 5, 2025.

<https://www.cdc.gov/media/releases/2025/2025-acip-recommends-individual-based-decision-making-for-hepatitis-b-vaccine-for-infants-born-to-women.html>.

New mpox strain identified in England.

A new strain of mpox, previously called monkeypox, has been detected in a person in England, say UK health officials. The virus is a mix of two major types of the mpox virus, and was found in someone who recently returned from travelling in Asia. Officials say they are still assessing the significance of the new strain. The UK Health Security Agency (UKHSA) says it is normal for viruses to evolve. Getting vaccinated remains the best way to protect against severe disease – although an mpox infection is mild for many.

Published: December 8, 2025.

<https://www.bbc.com/news/articles/>

[cm2087goz9po?at_link_id=1ACAF060-D43F-11F0-B2C8-9467B4C6735D&at_ptr_name=twitter&at_campaign_type=owned&at_link_origin=BBCNews&xtor=AL-71-%5Bpartner%5D-%5Bbbc.news.twitter%5D-%5Bheadline%5D-%5Bnews%5D-%5Bbizdev%5D-%5Bisapi%5D&utm_medium=social&utm_social_handle_id=612473&utm_social_post_id=618114020&at_link_type=web_link&at_format=link&at_campaign=Social_Flow&at_bbc_team=editorial](https://www.bbc.com/news/health-612473?at_medium=social&at_campaign=Social_Flow&at_bbc_team=editorial&at_link_id=1ACAF060-D43F-11F0-B2C8-9467B4C6735D&at_ptr_name=twitter&at_campaign_type=owned&at_link_origin=BBCNews&xtor=AL-71-%5Bpartner%5D-%5Bbbc.news.twitter%5D-%5Bheadline%5D-%5Bnews%5D-%5Bbizdev%5D-%5Bisapi%5D&utm_medium=social&utm_social_handle_id=612473&utm_social_post_id=618114020&at_link_type=web_link&at_format=link&at_campaign=Social_Flow&at_bbc_team=editorial).

WHO: Malaria. Key facts

Globally in 2024, there were an estimated 282 million malaria cases and 610 000 malaria deaths in 80 countries. The WHO African Region carries a disproportionately high share of the global malaria burden. In 2024, the WHO African Region was home to 95% of malaria cases (265 million) and 95% (579 000) of malaria deaths. Children under 5 accounted for about 75% of all malaria deaths in the Region.

Published: December 4, 2025.

<https://www.who.int/news-room/fact-sheets/detail/malaria>.

In Kenya, smaller vaccine vials may mean more children protected.

235 health facilities in Kenya are trialling a switch from ten-dose to five-dose measles-rubella (MR) vaccine vials. It promises to be an impactful change. In one sub-district hospital, lower-dose measles-rubella vaccine vials are spurring hopes of fewer frustrations and improved coverage.

Published: December 5, 2025.

<https://www.gavi.org/vaccineswork/kenya-smaller-vaccine-vials-may-mean-more-children-protected-against-measles-and#:~:text=At%20a%20glance-,235%20health%20facilities%20in%20Kenya%20are%20trialling%20a%20switch%20from,session%2C%20vaccine%20must%20be%20discarded>.

Oxford Vaccine Group: World's first phase II Nipah Virus trial launch.

The University of Oxford has launched the world's first phase II clinical trial of a Nipah Virus vaccine candidate.

Published: December 9, 2025.

<https://www.ovg.ox.ac.uk/news/worlds-first-phase-ii-nipah-virus-vaccine-trial-launch>.



Latest Relevant Publications

LATEST PUBLISHED PAPERS AND COMMENTARIES FROM THE CHIEF EDITOR

Latest impactful scientific publications that stand out for their potential bearing on healthcare. We introduce groundbreaking research findings, innovative treatment modalities, results from phase 1 to 3 vaccine clinical trials, or paradigm-shifting discoveries that redefine our understanding of infectious diseases and therapeutic approaches for all vaccine-preventable diseases.

01

Razzini JL, Palau J, Solovey G, Guinazu G, Sosa EM, Orta SR. **Impact and effectiveness of RSV maternal immunization on infant hospitalizations in Buenos Aires: a hospital-based, multicentre, retrospective surveillance cohort study.** *The Lancet Regional Health – Americas* 2025; 52: 101296.

doi: <https://doi.org/10.1016/j.lana.2025.101296>

Editorial comment: This excellent Argentinian study evaluated the impact of RSVpreF maternal immunization (MI) on RSV-related acute lower respiratory tract infection (ALRTI) hospitalizations using a hospital-based, multicenter retrospective cohort, with vaccine effectiveness (VE) estimated through a nested test-negative case-control analysis. A total of 3373 infants were included, 323 of whom were born during the vaccination period and eligible for VE assessment. The adjusted VE of RSVpreF MI against RSV-ALRTI hospitalization was 80.8% (95% CI: 62.8–90.5%) in infants <3 months and 66.1% (95% CI: 30.1–83.8) in infants <6 months. VE for PICU admission reached 87.2% (95% CI: 52.6–97.0), and 88.6% (95% CI: 62.3–97.1) for prolonged hospital stays among infants <6 months. Overall, RSV-ALRTI hospitalizations in infants <6 months decreased by 33.6% (95% CI: 29.5–37.2) in 2024 compared with expected levels from previous years. The number needed to immunize to prevent one RSV-related hospitalization was 83.9 (95% CI: 65.9–185.4).

02

Wang C, Lai X, Abbas K, Pouwels KB, Zhang H, Jit M, Fang H. **Health impact and economic evaluation of the Expanded Program on Immunization in China from 1974 to 2024: a modelling study.** *Lancet Public Health*. 2025 Dec;10(12):e1045–e1054.

doi: [https://doi.org/10.1016/S2468-2667\(25\)00039-8](https://doi.org/10.1016/S2468-2667(25)00039-8)

Editorial comment: This study used mathematical modelling to evaluate the impact of China's EPI on eight high-burden vaccine-preventable diseases (measles, pertussis, hepatitis B, tuberculosis, hepatitis A, Japanese encephalitis, meningitis A, and poliomyelitis), accounting for non-linear vaccine effects. Based on the calendar year approach (1974–2024), the EPI was estimated to avert 703 million cases (95% CrI: 699.5–722.8), 2.48 million deaths (2.14–2.97), and 160 million DALYs (145–197). Using the birth cohort approach, the program was predicted to avert 707 million cases (703.9–727.0), 7.01 million deaths (6.95–7.87), and 279 million DALYs (266–316) over the lifetime of vaccinated cohorts.

03

Johansen ND, Modin D, Pardo-Seco J, Rodriguez-Tenreiro-Sánchez C, Loiacono MM, Harris RC, Dufournet M, van Aalst R, Chit A, Larsen CS, Larsen L, Wiese L, Dalager-Pedersen M, Claggett BL, Janstrup KH, Duran-Parrondo C, Piñeiro-Sotelo M, Cribreiro-González M, Conde-Pájaro M, Mirás-Carballal S, González-Pérez JM, Solomon SD, Sivapalan P, Martel CJ, Jensen JUS, Martínón-Torres F, Biering-Sørensen T; DANFLU-2 Study Group; GALFLU Trial Team. **Effectiveness of high-dose influenza vaccine against hospitalisations in older adults (FLUNITY-HD): an individual-level pooled analysis.** *Lancet*. 2025 Nov 22;406(10518):2425–2434.

doi: [https://doi.org/10.1016/S0140-6736\(25\)01742-8](https://doi.org/10.1016/S0140-6736(25)01742-8)

Editorial comment: FLUNITY-HD was a prespecified, individual-level pooled analysis of two harmonized pragmatic randomized trials comparing high-dose influenza vaccine (HD-IIV) with standard-dose influenza vaccine (SD-IIV) in older adults.

The primary outcome—hospitalization for influenza or pneumonia—occurred in 0.56% of HD-IIV recipients (1312/233,311) versus 0.62% of SD-IIV recipients (1437/233,009), yielding a relative vaccine effectiveness (rVE) of 8.8% (95% CI: 1.7–15.5; $p=0.0082$).

HD-IIV also significantly reduced: Cardiorespiratory hospitalizations: 2.02% vs 2.16% (rVE 6.3%; 95% CI: 2.5–10.0; $p=0.0006$); laboratory-confirmed influenza hospitalizations: 0.11% vs 0.16% (rVE 31.9%; 95% CI: 19.7–42.2; $p<0.0001$); all-cause hospitalizations: 8.54% vs 8.73% (rVE 2.2%; 95% CI: 0.3–4.1; $p=0.012$).

04

Cortes-Azuero O, O'Driscoll M, Ribeiro Dos Santos G, de Jesus R, de Lima STS, Scarponi D, Mukandavire C, Deol A, Kraemer MUG, de Souza WM, Salje H. **The epidemiology of chikungunya virus in Brazil and the potential impact of vaccines: a mathematical modelling study.** *Lancet Infect Dis*. 2025 Nov 27:S1473-3099(25)00605-X.

doi: [https://doi.org/10.1016/S1473-3099\(25\)00605-X](https://doi.org/10.1016/S1473-3099(25)00605-X)

Editorial comment: This study quantified annual CHIKV infection and disease burden across Brazil's 27 federative units from 2014–2024 using a Bayesian mathematical model integrating 12 serosurveys, 488,234 confirmed cases, and 1,719 deaths. The authors then projected the impact of vaccination for 2025–2029 under several rollout strategies. They estimated that 18.3% (95% CrI: 16.5–20.3) of Brazil's population has been infected since 2014, with highest risk in the northeast and southeast. Only 1.13% (1.07–1.19) of infections were detected by surveillance, with symptomatic illness more common with older age and in females. Vaccinating 40% of individuals ≥ 12 years (≈ 73 million doses) with a vaccine 70% effective against infection and 95% against disease could avert up to 1.6 million cases (0.5–3.0) and 198 deaths (61–359) over five years.

05

Jiao B, Sato R, Mak J, Patenaude B, de Villiers M, Deshpande A, Gamkrelidze I, Gaythorpe KAM, Hallett TB, Jit M, Li X, Lopman B, Nayagam S, Razavi-Shearer D, Tam Y, Woodruff KH, Hogan D, Mengistu T, Verguet S. **Financial risk protection from vaccines in 52 Gavi-eligible low- and middle-income countries: A modeling study.** *PLoS Med*. 2025 Nov 4;22(11):e1004764.

doi: <https://doi.org/10.1371/journal.pmed.1004764>

Editorial comment: In this study, the authors used a microsimulation model to estimate the number of catastrophic health expenditure (CHE) cases averted by a range of vaccines across 52 Gavi-eligible countries, stratified by wealth quintile. They evaluated vaccines against five pathogens—hepatitis B (routine and birth dose), *H. influenzae* type b, rotavirus, measles (routine and campaign doses), and *S. pneumoniae*. All vaccines, individually and combined, generated substantial financial risk protection (FRP), preventing an estimated ~ 200 million CHE cases from 2000 to 2030. Notably, about half of all averted CHE cases occurred among the poorest quintiles. The first dose of measles vaccine had the greatest impact, averting approximately 1,400 CHE cases per 10,000 vaccinated. Overall, the findings highlight the powerful FRP benefits of vaccines, particularly for the most disadvantaged populations.

06

Sampri A, Shi W, Bolton T, Ip S, Knight R, Walker V, Denholm R, Raffetti E, Keene S, Allara E, Jiang X, Kontopantelis E, Denaxas S, Khunti K, Conrad N, Pagel C, Hardelid P, Sterne JAC, Brown KL, Whiteley WN, Cezard G, Wood AM; CVD-COVID-UK/COVID-IMPACT Consortium and the Longitudinal Health Wellbeing COVID-19 National Core Study. **Vascular and inflammatory diseases after COVID-19 infection and vaccination in children and young people in England: a retrospective, population-based cohort study using linked electronic health records.** *Lancet Child Adolesc Health.* 2025 Dec;9(12):837–847.

doi: [https://doi.org/10.1016/S2352-4642\(25\)00247-0](https://doi.org/10.1016/S2352-4642(25)00247-0)

Editorial comment: In this population-based retrospective study of nearly 14 million individuals under 18 years in England (2020–2022), 28% had a COVID-19 diagnosis. Infection was linked to markedly increased risks during the first week for arterial and venous thromboembolism, thrombocytopenia, myocarditis/pericarditis, and inflammatory conditions. Although risks declined after the first month, elevated rates of venous thromboembolism, thrombocytopenia, and myocarditis/pericarditis persisted for over 12 months. Among more than 9 million vaccine-eligible children (5–17 years), 37% received at least one BNT162b2 dose. Vaccination was associated with a small, short-term increase in myocarditis/pericarditis within four weeks, but the risk remained far lower than that observed after COVID-19 infection.

07

Walker RJ, Kingpriest PT, Gong J, Naisanga M, Ashraf MN, Roberti J, Lang T. **Global perspectives on infectious diseases at risk of escalation and their drivers.** *Sci Rep.* 2025 Nov 4;15(1):38630.

doi: <https://doi.org/10.1038/s41598-025-22573-3>

Editorial comment: A total of 3,752 globally diverse participants contributed to this two-step, mixed methods adapted Delphi study. First, an online survey of health workers and researchers (n=3,700) identified infectious diseases perceived to pose the greatest escalation risk and the factors driving them. Second, thematic workshops held in Africa, Asia, and Latin America (n=169) explored these drivers in depth. While survey respondents highlighted growing concern about tuberculosis, workshop participants underscored the rising threat of vector-borne diseases. Across regions, climate change, socioeconomic pressures, and increasing antimicrobial resistance were viewed as key forces accelerating these infection risks. This study offers valuable insight into global infectious disease priorities, distinguished by its large scale, diverse stakeholder input, and broad geographic representation.

08

Hills SL, Shlim DR, Schofield S, Wilson ME, Barnett ED, Chen LH, Christensen KJ, Staples JE. **Chikungunya vaccination for travelers: Practical guidance for clinical decision-making.** *J Travel Med.* 2025 Nov 20:taaf118.

doi: <https://doi.org/10.1093/jtm/taaf118>

Editorial comment: Two vaccines are now licensed for the prevention of chikungunya: IXCHIQ, a live-attenuated vaccine manufactured by Valneva, and VIMKUNYA, a virus-like particle vaccine produced by Bavarian Nordic. One or both products are already available in several countries, including Brazil, Canada, the United Kingdom, the United States, and multiple European nations and territories.

Although the lack of head-to-head studies limits direct comparison, the vaccines differ in ways that are important when advising travelers. The study summarizes key considerations—including immunogenicity and safety data, travel-related recommendations, and guidance for use during pregnancy and breastfeeding—to support informed decision-making.

09

Nowzari F, Nowzari F, Kian M, Zahedi M, Samimi K, Karimzadeh A, Tanideh N, Mussin NM, Tamadon A. **Evolution and trends in non-viral mRNA Cancer vaccines: A scoping review from 2015 to 2025.** *Vaccine*. 2025 Dec 5;71:128059.

doi: <https://doi.org/10.1016/j.vaccine.2025.128059> Epub ahead of print. PMID: 41352221.

Editorial comment: This scoping review synthesizes clinical trials conducted between 2015 and 2025 evaluating non-viral mRNA-based cancer vaccines, with a focus on trends in delivery platforms—ex vivo dendritic-cell (DC) vaccines versus in vivo lipid-based systems—and their distribution across cancer types. Statistical analyses (linear regression and Fisher's exact test) reveal a significant association between ex vivo DC platforms and brain/CNS cancers ($p = 0.00042$), with no meaningful correlation between DC vaccine administration routes and cancer type ($p = 0.25$). This review provides a data-driven overview of the evolving landscape, identifying key gaps in delivery optimization, reporting consistency, and methodological standardization. Two companion articles examine ex vivo DC vaccine approaches and advances in in vivo mRNA vaccine technologies in greater detail.

10

Gatwood J, Gomez-Espinosa E, Fusco N, Stempniewicz N, Singer D. **Real-world utilization and potential clinical and economic value of recombinant zoster vaccine and select preventive services recommended for older adults in the United States.** *Vaccine*. 2025 Dec 6;71:128015.

doi: <https://doi.org/10.1016/j.vaccine.2025.128015>

Editorial comment: In this targeted literature review, EMBASE, Medline, and Emcare were searched for publications from 2012–2022 reporting utilization, clinical outcomes, and economic data for the recombinant zoster vaccine (RZV) and five key comparator preventive services. Economic modeling studies reported the following estimated incremental cost-effectiveness ratios (ICERs) per quality-adjusted life-year (QALY):

- RZV vs no herpes zoster vaccination (≥ 50 years): \$1,407–\$91,156
- Influenza vaccination vs no vaccination (≥ 65 years): \$8,833–\$15,001
- Tdap vs Td vaccination (reflecting added pertussis protection; ≥ 65 years): \$17,150–\$336,108
- Hepatitis B vaccination vs no vaccination (≥ 50 years): \$371,606–\$541,461
- Pneumococcal vaccination vs no vaccination (≥ 50 years): \$15,000–\$38,000

11

Chang CY, Nasreen S, Sadarangani M, Cragg JJ, Marra F. **Effect of pneumococcal conjugate vaccine booster dose on prevention of invasive pneumococcal disease in British Columbia, 2003–2018.** *Vaccine*. 2025 Dec 3;71:128066.

doi: <https://doi.org/10.1016/j.vaccine.2025.128066>

Editorial comment: In this Canadian study, annual invasive pneumococcal disease (IPD) incidence was estimated using Poisson regression, with population at risk adjusted for immunization coverage. Adjusted incidence rate ratios (aIRRs) were calculated by serotype group, age, and vaccine schedule period. Among 598 IPD cases, 53.2% were unvaccinated, 31.8% received a full primary + booster schedule (2–3 primary doses plus 1 booster), and 15.1% received primary doses only (1–3 doses). Compared with unvaccinated children, the aIRR was 0.13 (95% CI: 0.10–0.17) for the primary + booster group and 0.32 (95% CI: 0.22–0.48) for the primary-only group. The primary + booster schedule showed a 61% lower incidence than primary-only (aIRR 0.39; 95% CI: 0.26–0.60). A schedule including a booster dose was associated with a significantly reduced IPD incidence, supporting the continued promotion of the full 2 + 1 (primary + booster) pneumococcal vaccine schedule to reduce disease burden in children.

12

Lu L, Lu X, Luo W. **Personalized Cancer Vaccines: Current Advances and Emerging Horizons.** *Vaccines.* 2025; 13(12):1231.

doi: <https://doi.org/10.3390/vaccines13121231>

Editorial comment: Personalized cancer vaccines represent a rapidly advancing frontier in oncology, leveraging the unique genetic and molecular features of each patient's tumor to generate highly targeted immune responses. This review summarizes the current landscape and emerging directions of neoantigen-based personalized cancer vaccines, including peptide, mRNA, DNA, autologous dendritic-cell, and viral or bacterial vector platforms.

13

Valentini S, Sota J, Fineschi I, Conticini E, Garcia-Gonzalez E, D'Ignazio E, Bardelli M, Gentileschi S, Fabbroni M, Bellisai F, et al. **Effectiveness and Safety of Recombinant Zoster Vaccine in Rheumatic Diseases: Real-World Evidence from a Single-Centre Italian Cohort.** *Vaccines.* 2025; 13(12):1227.

doi: <https://doi.org/10.3390/vaccines13121227>

Editorial comment: Patients with rheumatic diseases (RMDs) are at increased risk of herpes zoster (HZ), particularly when receiving immunosuppressive therapy. Although the recombinant zoster vaccine (RZV) has demonstrated high effectiveness in the general population, data in rheumatologic patients remain limited due to their exclusion from pivotal trials. This retrospective study evaluated 179 adults who received two doses of RZV between January 2021 and June 2025, including 114 patients with RMDs and 65 individuals from the general population. Vaccine effectiveness was assessed by prevention of HZ reactivation, and safety outcomes included any adverse events temporally associated with vaccination.

A statistically significant reduction in varicella-zoster virus (VZV) reactivation was observed following vaccination ($p < 0.001$). Among RMD patients, only one case of HZ recurrence occurred 14 weeks post-vaccination, with no significant difference compared with the general population cohort. These findings support the broader use of RZV as a safe and effective preventive strategy in individuals with rheumatic diseases.

14

Myer L, Wasserman E, Tabasum S, Shittu E, Liu Y, Jose L, Horne E, Moraba RS, Wilhase A, Zar HJ, et al. **Safety, Tolerability, and Immunogenicity of RSVpreF Vaccine in Pregnant Individuals Living with HIV.** *Vaccines.* 2025; 13(12):1218.

doi: <https://doi.org/10.3390/vaccines13121218>

Editorial comment: HIV-exposed uninfected (HEU) infants have higher rates of severe RSV lower respiratory tract illness (RSV-LRTI) than HIV-unexposed infants, yet data on maternal RSV vaccination in this population are limited. This phase 3 randomized, double-blind trial evaluated the safety and immunogenicity of the bivalent RSVpreF vaccine in pregnant women with HIV in South Africa and their infants. A total of 343 participants received RSVpreF ($n=172$) or placebo ($n=171$). Reactogenicity was mostly mild to moderate, and adverse events—including hypertensive disorders—occurred at similar frequencies across groups. Infant safety outcomes were also comparable, with no differences in adverse events, serious adverse events, or preterm birth. RSVpreF induced strong maternal neutralizing antibody responses to RSV-A and RSV-B, with efficient transplacental antibody transfer (GMRs vs placebo at birth: 7.8 for RSV-A and 6.8 for RSV-B).

15

Millar JR, Anglemeyer A, Werno A, Austin NC, Walls T. **Epidemiology of Infant Group B Streptococcus Infection in New Zealand: A 10-Year Retrospective Study.** *Pediatr Infect Dis J.* 2025 Dec 1;44(12):1209–1215.

doi: <https://doi.org/10.1097/INF.0000000000004908>

Editorial comment: This retrospective study (2012–2021) examined all infants under 180 days of age in New Zealand with invasive group B Streptococcus (GBS) infection. Clinical records from the National Collections dataset were linked to positive sterile-site GBS cultures or PCR results. Cases were classified as early-onset (≤ 2 days), late-onset (3–89 days), or ultra-late-onset (90–179 days), and incidence rates were estimated using Poisson regression.

Among 406 laboratory-confirmed and 224 clinically suspected cases, early-onset disease (EOGBS) incidence was higher than previously reported but showed no significant change over time ($P = 0.4$). Pacific infants had twice the EOGBS incidence of European infants, with elevated rates also observed among Māori infants. These findings underscore the urgent need for perinatal GBS vaccination to reduce disease burden and address inequities.

16

Saxena K, Dempsey A, Verma RP, Martinez R, Schmier JK, Zimet GD. **Parental acceptance of HPV vaccinations at ages 9–10 in the United States.** *Hum Vaccin Immunother.* 2025 Dec;21(1):2592432.

doi: <https://doi.org/10.1080/21645515.2025.2592432>

Editorial comment: This survey of 250 parents assessed attitudes toward HPV vaccination at ages 9–10. Most supported vaccination by age 10 (72% for boys; 77% for girls). Among parents whose children were vaccinated at 11–12 years, 90% said they would have accepted earlier vaccination.

Perceived benefits of starting at 9–10 included greater confidence in completing the series before sexual activity, fewer injections at later visits, and reduced concern about triggering sexual behavior. Reported barriers included separating HPV from other 11–12-year vaccines, challenges involving children in decision-making, and discomfort discussing sexuality at younger ages.

Overall, parental acceptance of HPV vaccination at ages 9–10 was high—both among those who had been offered early vaccination and those who had not.

17

Abbasi TN, Khan MS, Siddiqui E, Zaheer MA, Tabassum A, Zainab N, Waafira A. **Exploring the safety and immunogenicity of the VLA15 vaccine among healthy or high-risk population: a systematic review and meta-analysis of randomized controlled trials.** *Ther Adv Vaccines Immunother.* 2025 Oct 28;13:25151355251387927.

doi: <https://doi.org/10.1177/25151355251387927>

Editorial comment: This PROSPERO-registered systematic review and meta-analysis (CRD420251058818) included three RCTs with 5,907 participants (4,500 VLA15; 1,407 placebo). VLA15 was associated with higher rates of mild-to-moderate adverse events—fever, headache, fatigue, and arthralgia (all $p < 0.0001$), with a dose-response trend for arthralgia at higher doses. Nausea and severe unsolicited AEs did not differ significantly from placebo. Immunogenicity outcomes consistently favored VLA15, with higher IgG levels, GMTs, and seroconversion. Overall, VLA15 demonstrates strong immunogenicity and an acceptable safety profile despite increased reactogenicity.

18

Liedes O, Reinholm A, Ekström N, Haveri A, Solastie A, Vara S, Rijnink WF, Bestebroer TM, Richard M, de Vries RD, Jalkanen P, Lindh E, Ikonen N, Grifoni A, Sette A, Laaksonen T, Holopainen R, Kakkola L, Lappalainen M, Syrjänen RK, Kolehmainen P, Julkunen I, Nohynek H, Melin M. **Influenza A(H5N8) vaccine induces humoral and cell-mediated immunity against highly pathogenic avian influenza clade 2.3.4.4b A(H5N1) viruses in at-risk individuals.** *Nat Microbiol.* 2025 Dec 5.

doi: <https://doi.org/10.1038/s41564-025-02183-5>

Editorial comment: Finland's 2023 outbreak of clade 2.3.4.4b A(H5N1) avian influenza prompted vaccination of high-risk workers in June 2024 with the MF59-adjuvanted A(H5N8) vaccine (Seqirus). In this observational phase IV study, researchers evaluated immune responses in at-risk individuals. Among those without prior avian influenza vaccination, two doses produced high seroprotection: 83% by microneutralization and 97% by haemagglutination inhibition. Previously vaccinated individuals achieved seroprotection after a single dose. The vaccine also generated measurable A(H5N8)-specific memory CD4⁺ T-cell responses, with ~5-fold increases in IFN γ after two doses. Overall, the findings indicate likely cross-protection against circulating clade 2.3.4.4b H5 viruses.



Editor's Corner

WHY EVERY NEWBORN NEEDS THE HEPATITIS B VACCINE AT BIRTH—AND THE DANGERS OF NOT VACCINATING



Introduction:

Hepatitis B virus (HBV) is the leading cause of chronic viral hepatitis and is a major contributor to acute and chronic liver disease worldwide. It is transmitted through blood exposure, sexual contact, and—critically—through vertical transmission from mother to child.

In 2022, an estimated 304 million people were living with chronic hepatitis B or C globally, with HBV accounting for over 80% of the burden. Despite the availability of effective prevention tools and therapies, viral hepatitis caused 1.3 million deaths—around 3,500 deaths every day. More than 60 countries report hepatitis mortality rates exceeding 20 per 100,000 people, double the 2025 target. The Western Pacific and African regions bear the greatest burden.

Diagnosis and treatment rates remain far below global targets. As of 2022, only 13% of people with hepatitis B and 36% of those with hepatitis C were diagnosed. Treatment rates were even lower—3% for HBV and 20% for HCV—far from the 2025 goals of 60% diagnosed and 50% treated.

Vertical Transmission of HBV:

Definition, Timing, and Risk:

Vertical (mother-to-child) transmission of HBV is highly efficient. In the absence of preventive interventions, transmission rates range from:

- 70–90% for HBeAg-positive mothers
- 10–40% for HBeAg-negative mothers

Contributing factors include:

- Mode of delivery
- Amniocentesis and invasive obstetric procedures
- Breastfeeding

Prevention of Vertical Transmission: Management at Birth:

1. Neonatal Immunoprophylaxis: The Birth Dose

Post-exposure immunoprophylaxis—consisting of immediate HBV vaccination, with or without HBV immunoglobulin (HBIG)—is the most effective strategy to prevent vertical transmission.

- Administering the first HBV vaccine dose

within 12 hours of life, followed by at least two additional doses over 6–12 months, is 90–95% effective in preventing infection.

- Delaying vaccination beyond 24–48 hours significantly reduces efficacy.
- WHO recommends providing the birth dose as soon as possible, ideally within 24 hours, even in low-endemicity settings.

2. Combined Vaccine + HBIG Approach

Adding HBIG at birth further decreases transmission—especially in infants born to mothers with high viral loads—to below 5%. However, HBIG access remains limited in many low- and middle-income countries due to cost, refrigeration needs, and short shelf life.

Elimination of Mother-to-Child

Transmission: Global Progress:

Preventing mother-to-child transmission is central to HBV elimination.

- 129 countries have adopted antenatal HBV screening policies.
- 147 countries administer universal or targeted birth-dose vaccination.
- Global birth-dose coverage remains low at 43%, and only 17% in the African region.
- Just over half of WHO Member States have achieved ≥90% coverage for the full infant HBV vaccine series.

Strategic Planning and Service Integration, as of 2025:

- 123 countries have national hepatitis strategic plans.
- 80 countries have integrated hepatitis testing/treatment into primary health care.

Gaps and Priorities Toward 2030:

Major challenges include:

- Persistently high mortality in Africa and the Western Pacific
- Extremely low diagnosis and treatment rates
- Large disparities in access and medicine pricing
- Significant data gaps affecting national planning

Priority actions for 2030 focus on:

- Expanding access to testing, vaccination, and treatment
- Strengthening service integration
- Addressing pricing and intellectual property barriers
- Increasing political and financial commitment
- Improving surveillance and data systems

Conclusions and remarks:

- 1. Infant HBV transmission occurs primarily from mother to baby during pregnancy or childbirth.**
- 2. Adults and infants respond very differently to Hepatitis B infection.**
- 3. In adults, most infections are silent: symptoms are uncommon, but individuals remain contagious.**
- 4. In newborns, the consequences are far more severe:**
Nine out of ten infected infants develop chronic hepatitis B, which can later lead to:
 - cirrhosis
 - liver failure
 - liver cancer
- 5. Many mothers may unknowingly be infected.**
In the U.S., an estimated 3–5% of women of reproductive age have Hepatitis B without being aware of it.
This means **any newborn is potentially at risk**, even when the mother shows no symptoms.
- 6. The Hepatitis B birth dose saves lives.**
The U.S. has administered the first Hepatitis B vaccine dose within 24 hours of birth since 1994.
As a result: **approximately 90,100 infant deaths have been prevented.**
The birth dose is the *only* intervention that protects the baby immediately—even if maternal infection has not yet been detected.
- 7. What would happen if we stopped vaccinating at birth?**
Projections indicate that **18,000–20,000 infants per year** in the U.S. would be born infected.
Most would develop chronic hepatitis B, facing lifelong risks of cirrhosis and liver cancer.
- 8. HBV vaccination at birth must be protected, strengthened, and expanded worldwide—never discontinued.**

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Best Practice

VACCINATION GUIDELINES AND CONSIDERATIONS FOR ADULTS LIVING WITH HIV

**Introduction:**

Acquired immunodeficiency syndrome (AIDS) is caused by two lentiviruses—human immunodeficiency virus types 1 and 2 (HIV-1 and HIV-2)—both originating from multiple cross-species transmissions

of simian immunodeficiency viruses (SIVs) naturally infecting African primates. While most of these transmissions led to limited human spread, one event involving *SIVcpz* from chimpanzees in southeastern Cameroon gave rise to HIV-1 group M, the principal driver of the global AIDS pandemic.

AIDS was first recognized in 1981, when increasing numbers of young men who have sex with men developed unusual opportunistic infections and rare malignancies, revealing a previously unknown immune deficiency syndrome.

Despite major advances in antiretroviral therapy that have transformed HIV infection into a manageable chronic disease, the epidemic remains ongoing worldwide. Both high-income and low- and middle-income countries continue to be affected, with the greatest burden in the latter due to limited access to healthcare and treatment. In the absence of an effective preventive vaccine, HIV/AIDS remains a major global public health challenge, carrying profound human, social, and economic consequences.

Global HIV statistics up to 2024:

- 40.8 million [37.0 million–45.6 million] people globally were living with HIV in 2024.
- 1.3 million [1 million–1.7 million] people became newly infected with HIV in 2024.
- 630 000 [490 000–820 000] people died from AIDS-related illnesses in 2024.
- 31.6 million people [27.8–32.9 million] were accessing antiretroviral therapy in 2024.
- 91.4 million [73.4 million–116.4 million] people have become infected with HIV since the start of the epidemic.
- At the end of 2024, US\$ 18.7 billion was available for the AIDS response in low- and middle-income countries—17% below the US\$ 21.9 billion needed annually by 2030 to stay on track to end AIDS as a public health threat.

General recommendations:

Human immunodeficiency virus (HIV) disrupts immune function primarily by depleting CD4 T lymphocytes, compromising both humoral and cellular immunity. Although combination antiretroviral therapy (cART) has transformed HIV care, enabling most patients to achieve undetectable viral loads and adequate CD4 counts, significant immune function differences persist. Immune recovery can be incomplete in patients with low nadir CD4 counts or delayed initiation of cART, due to inadequate CD4 cell reconstitution and additional defects in cell-mediated and humoral immunity.

Immunizations are a critical component for people living with HIV (PWH), as immunodeficiency increases susceptibility to vaccine-preventable diseases and the risk of severe outcomes. However, HIV-related immune suppression may reduce the ability to mount or sustain adequate vaccine-induced immunity, and live vaccines can pose safety concerns in this population.

Vaccine responses are often diminished in individuals with advanced HIV infection, particularly those with CD4 counts <200 cells/mm³ or HIV RNA levels ≥200 copies/mL and may wane more rapidly than in individuals without HIV. Monitoring immunogenicity and determining the need for booster doses remain important aspects of vaccine management in people with HIV.

Inactivated vaccines are generally safe, though rare adverse effects cannot be completely excluded. In contrast, live attenuated vaccines are relatively contraindicated for patients with CD4 counts <200 cells/mm³ due to the risk of severe reactions. For those with CD4 counts ≥200 cells/mm³, inactivated formulations—such as for polio, influenza, typhoid, and zoster—are preferred. Live vaccines should be used only when no inactivated alternative exists and when the benefit of protection outweighs the potential risk.

Given the unique immunologic and clinical characteristics of PWH, vaccination guidelines differ in several important ways from those established for the general population. This section summarizes the most recent updates to these recommendations, integrates emerging data on vaccine safety, immunogenicity, and effectiveness in PWH, and discusses persisting gaps in knowledge that warrant further investigation.

Accordingly, vaccine recommendations for PWH differ from those for the general population regarding timing, dosing, and the need for serologic response monitoring. In addition, newly available vaccines are now recommended for PWH to prevent invasive pneumococcal disease, respiratory syncytial virus (RSV), COVID-19, mpox, Herpes Zoster, and hepatitis B virus (HBV).

Vaccination in Low Resource Settings:

In low-resource settings, PWH should receive

routine and recommended vaccinations like the annual flu shot and Tdap vaccine, along with the Hepatitis A, Hepatitis B, and Pneumococcal vaccines, prioritizing those that are most effective and accessible. Specific recommendations may be adjusted based on individual risk factors, immune status, and vaccine availability, which requires a collaborative decision with a healthcare provider.

Considerations for low-resource settings

- **Prioritize based on risk:** Focus on the most critical and accessible vaccines, such as influenza and pneumococcal vaccines, which are vital for protecting people with HIV from severe illness.
- **Address specific needs:** Consider travel to endemic areas, which may require additional vaccinations like the Hepatitis A and yellow fever vaccines.
- **Ensure access:** Work with healthcare providers to ensure timely access to routine and urgent medical care and vaccines, including through patient-centered approaches and low-barrier models like telehealth or mobile clinics.
- **Manage immune status:** When considering live attenuated vaccines like MMR or varicella, carefully assess a patient's immune status, prioritizing those with higher CD4 counts and stable viral loads.
- **Consider cost and logistics:** Adjust vaccination schedules based on the availability and affordability of different vaccines in the local context. For example, the double-dose Hepatitis B vaccine regimen may improve immunogenicity and seroconversion rates.

Travel and Vaccination Considerations for PWH:

All travelers should be up to date with routine immunizations before departure, regardless of destination. For those planning international travel, additional vaccines may be indicated based on regional disease risk, such as cholera, yellow fever, typhoid, or Japanese encephalitis.

For individuals living with HIV, pre-travel consultation with a healthcare provider experienced in immunization of immunocompromised patients is essential. Most travel-related vaccines are safe for people with HIV, although vaccine efficacy may be reduced, particularly among those with advanced immunosuppression. In such cases, clinicians may recommend serologic testing to assess post-vaccination immunity or suggest additional doses or alternative preventive measures to ensure adequate protection.

Certain travel vaccines are live-attenuated and generally contraindicated in individuals with CD4 counts <200 cells/mm³ due to the risk of vaccine-associated complications. However, in specific high-risk travel situations, the benefit of protection may outweigh potential risks. Decisions regarding live vaccines should be individualized, balancing disease exposure risk, immune status, and availability of alternative protective measures.

Conclusions:

The HIV/AIDS epidemic is approaching its fifth decade. Advances in combination antiretroviral therapy (cART) in high-resource settings have transformed HIV infection into a chronic, manageable condition. However, despite achieving viral suppression and normal CD4+ T-cell counts, people with HIV (PWH) often experience persistent immune dysregulation and incomplete immune restoration.

In the absence of a preventive HIV vaccine in the short to mid-term, tailored vaccination strategies for this unique population—now exceeding 40 million individuals globally—are essential. Moreover, many PWH in low- and middle-income countries (LMICs) remain without access to cART, leaving them highly vulnerable to both opportunistic and non-opportunistic infections. A sustained global effort is urgently needed to expand treatment access and, concurrently, to strengthen and promote immunization programs specifically designed for this population.

Summary of Vaccine Considerations for Adults with HIV (PWH)
 (modified and adapted from Gispen F, Marks K. *Curr HIV/AIDS Rep.* 2025 Feb 20;22(1):17. doi: [10.1007/s11904-025-00731-6](https://doi.org/10.1007/s11904-025-00731-6)).

Vaccine	Incidence / Severity in PWH	Vaccine Immunogenicity in PWH	Whom to Vaccinate	Serological Monitoring	Notes
Pneumococcal	↑ incidence	↓	19–64 yrs w/ risk factors; all ≥65 yrs	No	Complete one dose of PCV20 or PCV21 at any point
Meningococcal	↑ incidence	↓ / ↔	MenACWY & MenB: with risk factors	No	Possible efficacy of 4CMenB in gonorrhea
Mpox	↑ incidence and severity	↓	Adults with potential exposure	No	Vaccine effectiveness may be reduced
HBV	↑ incidence and severity	↓ (conventional); ↔ (TLR-9 adjuvanted)	HBV-nonimmune (anti-HBs <10 mIU/mL)	Yes	HepB–CpG adjuvanted preferred for PWH
HAV	↑ severity	↓	Adults at increased risk; all HAV-nonimmune	Yes	
HPV	↑ persistent infection and related diseases	↓	All ≤26 yrs; shared decision up to 45 yrs	No	3-dose schedule recommended
VZV – “Shingles”	↑ incidence and severity	↔	>18 yrs	No	Preferably used only the recombinant VZV-adjuvanted vaccine
RSV	Minimal data	Minimal data	Pregnant (32–36 wks); 60–74 yrs w/ risk factors; ≥75 yrs	No	Also approved for high-risk adults 50–59
COVID-19	↑ severity if CD4 <350	↓	All adults	No	mRNA vaccines noted for reactogenicity
Influenza	Possible ↑ severity	↓	All adults	No	Live attenuated vaccine contraindicated

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Guest Contributors

WHY IMMUNIZATION COMMITTEES ARE ESSENTIAL FOR MEDICAL SOCIETIES

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The presence of an Immunization Committee within a specialized medical association is a fundamental pillar to guarantee the quality, relevance and scientific rigor of the recommendations issued in the field of vaccination. Vaccines represent, historically and currently, the most effective and cost-efficient public health intervention for the prevention of

infectious diseases, the reduction of complications and the reduction of infant mortality. I

In this sense, the existence of a formal, structured and competent collegiate body is essential to conduct, supervise and strengthen all the activities related to immunizations that the Association undertakes. At the international

level, organizations related to public health and the prevention of infectious diseases have consolidated immunization committees, which today are recognized for their technical and academic leadership. These committees not only participate in the generation of scientific recommendations, but also contribute to continuous training, the development of research projects and the development of public positions regarding emerging issues in vaccinology.

This structure ensures active, scientific and global participation in the development of vaccine-related policies and knowledge. The members of the Immunization Committee must have a solid background in pediatric infectious diseases, vaccinology and epidemiology, as well as a genuine, sustained and demonstrated interest in the study, analysis and dissemination of scientific knowledge in immunizations. Be professionals with opinion leadership at the national level and international academic participation. The selection of members must obey criteria of merit, ethics, professional integrity and institutional commitment. The role of the Committee on Immunizations within organizations is broad and strategic. Among its main activities are: the continuous analysis of the available scientific evidence; the development of technical recommendations based on epidemiological and clinical principles; advising the Board of Directors and members regarding national and international vaccination programs; participation in processes of academic updating of health personnel; and the generation of formal positions during epidemiological contingencies, incorporation of new vaccines or modifications in immunization schedules. Likewise, this committee has a central role in the development of courses, workshops, training modules and academic materials that strengthen knowledge in vaccinology among pediatricians and infectologists.

In a global context where misinformation and

anti-vaccine movements represent real threats, the Committee on Immunizations serves as a reliable and technically specialized entity. Their role is to communicate clear, up-to-date, and scientifically sound evidence that helps strengthen confidence in vaccination programs.

Finally, the presence of this committee strengthens the capacity of associations to establish links with national and international organizations, participate in public health decision-making processes, and contribute significantly to the country's vaccination policies. Similarly, the committee promotes the academic development of its members through the systematic review of literature, participation in high-level forums and interaction with world-renowned experts.

Official Terms of Reference for the Immunization Committee:

1. Continuously analyze the updated scientific evidence related to vaccines, preventable diseases and immunization programs.
2. Prepare, review and update technical recommendations aimed at health professionals, medical institutions and government agencies.
3. Issue official AMIP positions regarding emerging issues in vaccinology, including outbreaks, new vaccines, changes in guidelines, and relevant epidemiological situations.
4. Advise the Board of Directors in making decisions related to internal policies and academic activities related to immunizations.
5. Design, coordinate, and execute continuing medical education activities, such as workshops, courses, academic modules, and conferences on vaccination.



VACCINES BEAT

Who we are

At Vaccines Beat, we understand that vaccines and immunization have become a crucial topic of discussion at the center of any public health analysis. Therefore, timely, relevant, accessible, and well-curated information for all vaccine preventable diseases is key to advancing better health policies.

For this reason, a team of passionate vaccine professionals has created Vaccines Beat and each month diligently works to share with the healthcare ecosystem information, knowledge, and insights to improve global health.

Vision

Vaccines Beat aims to become the beacon of insight in the public health ecosystem through its distinctive monthly newsletter. With an in-depth 360 perspective, carefully curated information and expert analysis, this novel platform fosters collaboration among a diverse global network of stakeholders.

Mission

Vaccines Beat's main task is to inform through the review of the most recent developments in vaccines, immunization, and vaccine preventable diseases. Our mission extends to sharing best practices from successful initiatives worldwide while building bridges through editorial collaboration with regional and international stakeholders.

Vaccines Beat highlights the importance of information sharing & collaborative efforts within the public health community to boost vaccination campaigns, R&D, public policy, access, awareness, and equity.

Vaccines Beat encourages stakeholders to take action and promote sustainable commitment with continued support through multi-stakeholder synergies.

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