VACCINES BEAT

TURNING SCIENCE INTO SCALE

Dr. Clarisse Ingabire's One Health journey from cattle herds to Global Policy

June
2026

ISSN 2997-2833

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Americas Health Foundation

"IMMUNIZATION IS A GLOBAL HEALTH AND DEVELOPMENT SUCCESS STORY SAVING MILLIONS OF LIVES EVERY YEAR"

WORLD HEALTH ORGANIZATION

Turning science into scale

Dr. Clarisse Ingabire's One Health journey from cattle herds to Global Policy

Dr. Clarisse Ingabire is a veterinarian, public health specialist, and international development expert with more than two decades of experience advancing animal health, food security, and sustainable livestock development across Africa and globally. She currently serves as Global Livestock Specialist at the World Bank, where she supports countries in strengthening livestock systems through investments in animal health, One Health, climate-smart agriculture, disease prevention, and sustainable food production.

Prior to joining the World Bank in 2023, Dr. Ingabire spent more than 11 years with the Food and Agriculture Organization of the United Nations (FAO), holding several leadership positions in animal health, emergency preparedness, and sustainable agricultural development. As Policy and Programme Specialist, she led sector analysis and policy advisory work for low-income countries, helping governments design evidence-based strategies to improve agricultural productivity, food security, nutrition, and resilience. Her contributions to FAO's global development agenda were recognized in 2019 when she was named among the organization's Top 100 Employees for her impact on the Zero Hunger programme.

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LETTER FROM EDITOR

Welcome to the **24th issue of Vaccines Beat**!

It is truly a pleasure to celebrate two consecutive years of publication and to have you as part of this growing global community dedicated to vaccines, vaccinology, and public health. Thank you for your continued support and engagement throughout this journey.

In our ***Coffee with the Expert*** section, we are honored to feature **Dr. Clarisse Ingabire**, Global Livestock Specialist at the World Bank. A veterinarian, public health specialist, and leading advocate for the One Health approach, Dr. Ingabire brings more than two decades of experience in animal health, food security, and sustainable livestock development. In this insightful interview, **"One Health: The Journey from Cattle Herds to Global Policy,"** she discusses the critical connections between animal health, vaccination, food security, economic development, and global public health.

In our ***Editor's Corner***, we explore **"Drones and Vaccines: Are We Ready to Rethink How We Deliver Life-Saving Immunization?"** As technology continues to reshape healthcare, drone-based vaccine delivery is emerging as a promising solution to overcome geographic and logistical barriers. The challenge is no longer whether drones can deliver vaccines effectively, but how quickly health systems can integrate this innovation to expand access and improve immunization equity worldwide.

Our ***Best Practice*** section examines **"Fractional Dosing in Vaccinology: From Emergency Strategy to Precision Public Health Tool."** Once considered primarily a response to vaccine shortages and outbreaks, fractional dosing is increasingly recognized as a valuable strategy to expand vaccine coverage, improve equity, optimize resource utilization, and maximize population-level impact.

In the ***Guest Contributor*** section, **Bruno Speder, MSc**, a bioengineer and health economist at **Aletheia Life Science**, discusses **"The Use of Prior Knowledge in Early Vaccine Development."** Drawing on his extensive experience in global regulatory affairs and vaccine development, including interactions with major regulatory agencies such as the FDA and EMA, Bruno highlights how existing scientific, clinical, and regulatory evidence can accelerate vaccine innovation, streamline development, and support more efficient decision-making.

As always, this issue also features carefully curated summaries of the **Latest Scientific Publications**, together with the most relevant and timely **News and Alerts** from the world of vaccines and infectious diseases.

We hope you find this **June 2026 Second Anniversary Issue** both informative and engaging. We look forward to continuing our shared commitment to advancing immunization, strengthening public health, and contributing to a healthier and more resilient world.

Sincerely,

Enrique Chacon-Cruz, M.D., MSc
Chief Editor, *Vaccines Beat*

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 and of the Health Equity Committees 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.

Coffee with the Expert

TURNING SCIENCE INTO SCALE

Dr. Clarisse Ingabire's One Health journey from cattle herds to Global Policy

Authors:

Felicitas Colombo
Dr. Enrique Chacon-Cruz

Dr. Clarisse Ingabire is a veterinarian, public health specialist, and international development expert with more than two decades of experience advancing animal health, food security, and sustainable livestock development across Africa and globally. She currently serves as **Global Livestock Specialist at the World Bank**, where she supports countries in strengthening livestock systems through investments in animal health, One Health, climate-smart agriculture, and sustainable livestock transformation.

Prior to joining the World Bank in 2023, Dr. Ingabire spent more than 11 years with the **Food and Agriculture Organization of the United Nations (FAO)**, holding several leadership positions in animal health, emergency preparedness, and sustainable agricultural development. As Animal Production and Health Officer, she led sector analysis and policy advisory work for low-income countries, helping to improve livestock productivity, efficiency and resilience. Her contributions to FAO's global development agenda were recognized in 2019 when she was named among the organization's **Top 100 Employees** for her impact on the Zero Hunger programme.

Born and raised in Rwanda, Dr. Ingabire earned her **Doctor of Veterinary Medicine** degree from Cheikh Anta Diop University in Dakar, Senegal, and later completed a **Master's degree in Veterinary Public Health**. Throughout her career, she has worked at the intersection of animal health, poverty reduction, disease control, climate resilience, and economic development, advocating for preventive approaches that protect both livelihoods and public health.

A passionate advocate for the One Health approach, Dr. Ingabire believes that healthy animals, healthy people, and healthy ecosystems are fundamentally interconnected. Her work continues to focus on building stronger veterinary systems, expanding access to vaccination, promoting sustainable livestock transformation, and helping countries unlock the economic and social benefits of resilient agricultural systems.

Where it all starts

When Dr. Clarisse Ingabire speaks about animal health, she does not start with vaccines, laboratories, or international development. She starts with cows.

Growing up in Rwanda, where cattle are deeply woven into culture and daily life, she

saw firsthand how animals support families, livelihoods, and communities. Today, as Global Livestock Specialist at the World Bank, she works at the intersection of animal health, food security, climate resilience, and economic development.

Over a ***Coffee with the Expert*** conversation with the editorial team of Vaccines Beat for its **second year anniversary issue**, Dr. Ingabire reflected on a career that began almost by chance and evolved into a mission to transform livestock systems worldwide through prevention, investment, and One Health collaboration.

"I actually came into veterinary medicine randomly," she laughs.

After receiving a scholarship to study abroad shortly after Rwanda's recovery from the 1994 genocide, Dr. Ingabire enrolled in veterinary medicine in Senegal. What began as curiosity soon became a calling.

"And you can imagine in the aftermath of the genocide and everything chaotic in the country, having a scholarship was such a great opportunity that no one can refuse. And so, there was some curiosity to understand what veterinary medicine was," she recalls.

Studying in a Pan-African veterinary school exposed her to livestock systems across West Africa and to the realities faced by rural farming communities. Unlike veterinary training focused primarily on companion animals, veterinary medicine in many parts of Africa centers on livestock as a source of income, jobs, nutrition, and resilience.

That experience eventually led her to public health, international development, and later to the FAO, where she spent more than a decade working on disease prevention and emergency response. In 2023, she joined the World Bank, where she now supports countries in strengthening livestock systems through sustainable investment and One Health approaches.

"I'm really committed and passionate about the livestock sector and what we can do to transform our lives. It remains at the core of what we do at the World Bank," she says.

Vaccination: One Health in Action

Central to Dr. Ingabire's work is the **One Health** concept, which recognizes that the health of animals, humans, and the environment are inseparably linked. Whether addressing zoonotic diseases such as rabies and avian influenza, combating antimicrobial resistance, or improving food security through healthier livestock systems, One Health promotes collaboration across sectors to prevent health threats before they emerge.

Dr. Ingabire has been a strong advocate for integrating animal health interventions –including vaccination, surveillance, and biosecurity– into broader development strategies, demonstrating how investments in prevention can generate benefits for public health, economic growth, and environmental sustainability alike.

For Dr. Ingabire, animal vaccination represents one of the clearest examples of One Health in practice.

"If an animal is healthy because it has been prevented from getting disease, that animal is going to be more productive, more profitable, and have a lower environmental impact," she claims.

The benefits extend far beyond individual farms. Vaccination reduces disease outbreaks that can devastate livelihoods, disrupt trade, and threaten food security. It also helps prevent zoonotic diseases that can spread from animals to humans. Rabies remains one of her favorite examples.

"If we vaccinate dogs against rabies, we tremendously reduce rabies in humans, especially among children," Dr. Ingabire says.

The lesson is simple: prevention saves lives, protects economies, and reduces suffering.

Why not Prevent

Despite the proven value of vaccination, scaling programs remains challenging, particularly in low- and middle-income countries. The obstacle, Dr. Ingabire explains, is rarely the vaccine itself.

"We already have the tools. We have manufacturers innovating every day. Financing remains the biggest constraint," she asserts.

Vaccination campaigns require transportation,

trained personnel, cold-chain systems, community engagement, and public awareness. In many rural areas, reaching livestock owners can be as challenging as producing the vaccine itself.

Trust is another critical factor. Just as vaccine hesitancy exists in human health, misconceptions can affect animal vaccination programs. Rumors linking vaccines to reproductive problems or other adverse outcomes can spread quickly and undermine years of progress.

Building confidence therefore requires more than science. It requires communication, local leadership, and sustained community engagement.

The hidden link between Vaccines and Climate Change

One of the most fascinating parts of the conversation was the connection between vaccination and climate resilience. At first glance, vaccines and climate change may seem unrelated. Dr. Ingabire argues the opposite.

She emphasizes the often-overlooked relationship between **vaccination and climate resilience**. Climate change is altering disease patterns, expanding the geographic range of animal pathogens and vectors, and increasing the vulnerability of livestock systems to outbreaks. By preventing disease, vaccination helps animals remain healthy and productive under increasingly stressful environmental conditions.

Healthier livestock produce more food with fewer resources, reducing the emissions intensity associated with meat, milk, and egg production. Vaccination therefore contributes not only to animal welfare and food security, but also to more sustainable and climate-smart livestock systems helping farmers adapt to climate change while protecting livelihoods, reducing losses, and supporting sustainable agricultural development.

She highlighted innovative approaches already being implemented, including integrated crop-livestock-forestry systems that improve soil health, enhance carbon sequestration, and increase productivity simultaneously.

For Dr. Ingabire, investing in animal health is ultimately an investment in resilience.

"Vaccination is a resilience tool," she says. "It helps producers protect their animals and adapt to increasing pressures."

Addressing Anti-Microbial Resistance before it starts

The conversation also explored one of the most pressing global health threats: antimicrobial resistance (AMR). Dr. Ingabire views vaccination as a powerful and ambitious intervention.

"Vaccination sits upstream. It addresses risks before they begin," she claims.

Dr. Ingabire is a strong advocate for vaccination as a critical tool in the fight against **AMR,** one of the most pressing global health threats of our time. By preventing infectious diseases before they occur, vaccines reduce the need for antibiotics and other antimicrobial treatments in both animals and humans.

In livestock systems, effective vaccination programmes help farmers avoid disease outbreaks that would otherwise lead to widespread antimicrobial use, thereby slowing the emergence and spread of resistant pathogens.

"This preventive approach not only protects animal health and productivity but also safeguards the effectiveness of life-saving medicines for future generations, Dr. Ingabire points out.

Preventing disease reduces the need for antibiotics, helping slow the emergence of drug-resistant pathogens in both animals and humans. But vaccines alone are not enough.

Effective surveillance, stronger veterinary services, diagnostic capacity, biosecurity measures, and education all play critical roles in reducing inappropriate antimicrobial use. For Dr. Ingabire, the future lies in integrated systems that combine prevention, detection, and response across sectors.

"As part of a broader One Health strategy, vaccination -alongside improved biosecurity, surveillance, diagnostics, and veterinary services- plays a vital role in reducing the burden of AMR while supporting sustainable food production and public health," she says.

The World Bank's role: turning Science into Scale

As scientific organizations generate evidence and technical guidance, the World Bank brings a different strength to the table: scale.

While organizations such as the World Organisation for Animal Health (WOAH), FAO, WHO, universities, and research institutions generate scientific evidence, technical standards, and innovative solutions, the World Bank helps countries translate and implement these advances into high impact strategies through policy dialogue, financing, and investment.

"We have a catalytic role. We are able to scale," asserts Dr. Ingabire.

By supporting governments in strengthening veterinary services, disease surveillance systems, laboratory networks, regulatory frameworks, and vaccination programmes, the World Bank creates the enabling environment needed for sustainable change.

The bank's investments can help scale proven interventions across entire regions and countries, ensuring that scientific knowledge reaches farmers, communities, and livestock systems where it can deliver tangible benefits for food security, public health, economic growth, and climate resilience.

"That means supporting governments to strengthen veterinary services, improve disease surveillance, invest in laboratories, enhance regulatory frameworks, and create conditions that attract private-sector investment," she comments.

It also means helping countries see livestock not simply as an agricultural sector, but as a driver of jobs, nutrition, food security, and economic growth.

Partnerships: the path forward

As the discussion drew to a close, one message emerged repeatedly: no single institution can solve these challenges alone.

Whether addressing zoonotic diseases, antimicrobial resistance, climate change, or food security, success depends on collaboration among governments, international organizations, researchers, manufacturers, veterinarians, producers, and communities.

For Dr. Ingabire, the future is not about proving that vaccination works. The evidence is already there. She asserts the challenge now is building the integrated systems, partnerships, and investments that allow vaccination to deliver its full potential for animals, people, and the planet.

"The key to success has always been partnership," she concludes. "And that may be one of the most important One Health opportunities of our time."

Animal vaccination may very well be a test to assess how smart we are in public health.

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.

NCDC reports 190 deaths from Lassa fever in 2026, with rising fatality rate.
The Nigeria Centre for Disease Control and Prevention (NCDC) don report say 190 people don die from Lassa fever so far for 2026. According to the latest Lassa Fever Situation Report covering 20 to 26 April, the case fatality rate (CFR) don rise to 25.2 percent, higher than 19.1 percent wey dem record for same period last year.
Published: May 12, 2026.
https://killbait.com/en/ncdc-reports-190-deaths-from-lassa-fever-in-2026-with-rising-fatality-rate/

WHO: Epidemic of Ebola Disease caused by Bundibugyo virus in the Democratic Republic of the Congo and Uganda determined a public health emergency of international concern.
Determination of a public health emergency of international concern, including a pandemic emergency of the International Health Regulations (2005) (IHR), the Director-General of the World Health Organization (WHO), after having consulted the States Parties where the event is known to be currently occurring, is hereby determining that the Ebola disease caused by Bundibugyo virus in the Democratic Republic of the Congo and Uganda constitutes a public health emergency of international concern (PHEIC), but does not meet the criteria of pandemic emergency, as defined in the IHR.
Published: May 17, 2026.
https://www.who.int/news/item/17-05-2026-epidemic-of-ebola-disease-in-the-democratic-republic-of-the-congo-and-uganda-determined-a-public-health-emergency-of-international-concern

Venezuela reports a rise in cases of malaria in 2026 when compared to the same period in 2025 (in Spanish).
The Venezuelan Ministry of Popular Power for Health (MPPS) reported that from epidemiological week (EW) 1 through EW16 of 2026, a total of 33,955 new and imported malaria cases were recorded, representing a 5.9% increase compared with the same period of the previous year (31,568 cases).
Published: May 19, 2026.
https://lawebdelasalud.com/venezuela-reporta-incremento-de-casos-de-malaria-en-2026-en-comparacion-con-el-mismo-periodo-de-2025/

The Ebola Outbreak and the Need for Stronger Global Health Governance.
On 17 May 2026, the World Health Organization (WHO) declared the Ebol outbreak in the Democratic Republic of the Congo (DRC) and Uganda a public health emergency of international concern (PHEIC), noting that while the overall global risk remains low, national and regional risks are elevated due to ongoing transmission, population movement, weak health infrastructure, and the outbreak's emergence in conflict-affected areas. Although Ebola virus disease (EVD) outbreaks occurred periodically over the past several decades,

the current Ebola outbreak in the DRC and Uganda is exposing persistent vulnerabilities within emergency financing, emergency preparedness and coordination at national, regional and global health security systems. It is transpiring in a global context defined by constrained humanitarian financing, geopolitical fragmentation, conflict, and growing pressure on already overstretched health systems.
Published: June 4, 2026.
https://mecouncil.org/publication/the-ebola-outbreak-and-the-need-for-stronger-global-health-governance/

Graham F. Daily briefing: What it will take to stop the spiralling Ebola outbreak.
Nature. 2026 Jun 1. doi: 10.1038/d41586-026-01782-4.
Published: June 1, 2026.
https://www.nature.com/articles/d41586-026-01782-4

MTBVACN3 advances phase 3 tuberculosis vaccine trial and strengthens African research capacity.
The MTBVACN3 project is advancing the phase 3 clinical development of MTBVAC, a novel tuberculosis (TB) vaccine candidate for newborns in sub-Saharan Africa. The project aims to position MTBVAC as a potential replacement for BCG, which provides only partial protection against pulmonary TB.
Published: June 2026.
https://www.edctp.org/project/mtbvacn3-advances-phase-3-tuberculosis-vaccine-trial-and-strengthens-african-research-capacity/

Inside - and outside - Namibia's fight to stop polio before it strikes.
The threat of polio is back, and as the government races to protect the vulnerable, some are more at risk than others.
Published: May 21, 2026.
https://www.gavi.org/vaccineswork/inside-and-outside-namibias-fight-stop-polio-it-strikes

Experimental mRNA vaccine shows promise against multiple Ebola strains.
Scientists from China have developed a new broad-spectrum mRNA vaccine that could provide long-term protection against the most lethal family of Ebola viruses, including the Bundibugyo strain behind the current outbreak in the Democratic Republic of Congo and Uganda.
Published: May 25, 2026.
https://medicalxpress.com/news/2026-05-experimental-mrna-vaccine-multiple-ebola.html

Lilly to buy three vaccine developers for nearly $4 billion in infectious disease push.
Eli Lilly said on Tuesday it will buy three vaccine developers in deals worth up to $3.8 billion in combined value, signaling its push into infectious disease prevention. The U.S. drugmaker said it had agreed to acquire Curevo, LimmaTech Biologics and Vaccine Company.
Pubished: May 26, 2026.
https://www.reuters.com/legal/transactional/lilly-acquire-three-vaccine-developers-4-billion-2026-05-26/

Statement on vaccine efforts relating to the Bundibugyo Ebolavirus outbreak in the DRC.
In response to the current Bundibugyo Ebolavirus outbreak in the Democratic Republic of the Congo, the Oxford Vaccine Group (OVG) is working urgently with Oxford's own Clinical BioManufacturing Facility and the Serum Institute of India Pvt. Ltd. (SIIPL), to rapidly produce and scale doses of our ChAdOx-based monovalent Bundibugyo Ebolavirus candidate vaccine, ChAdOx1 BDBV.
Published: May 22, 2026.
https://www.ox.ac.uk/news/2026-05-22-statement-on-vaccine-efforts-relating-to-the-bundibugyo-ebolavirus-outbreak-in-the

In Mali, one year in, hybrid malaria vaccine programme shows early results.
Health workers say they are seeing encouraging signs of the vaccine's impact, even as the programme's steepest challenge comes into focus: bringing families back for every last dose.
Published: May 20, 2026.
https://www.gavi.org/vaccineswork/mali-one-year-in-hybrid-malaria-vaccine-programme-shows-early-results

WHO: Experts convened by WHO advise on candidate treatments and vaccines for Ebola disease caused by Bundibugyo virus.
In response to the current outbreak of Ebola disease caused by Bundibugyo virus occurring in the Democratic Republic of the Congo, with cases also reported in Uganda, WHO convened several of its expert and advisory groups. These groups

assessed potential vaccines and therapeutics for both prevention and treatment of Bundibugyo virus disease (BVD). The WHO advisory groups recommended that all the products identified and considered be used exclusively within clinical trials to generate robust data and ensure safe, ethical, and effective research.
Published: May 28, 2026.
https://www.who.int/news/item/28-05-2026-experts-convened-by-who-advise-on-candidate-treatments-and-vaccines-for-ebola-disease-caused-by-bundibugyo-virus

No more needles? Six technologies that could transform how we get vaccinated.
From vaccine patches to sprays, research is accelerating on a number of new ways of delivering protection against the world's deadliest diseases.
Published: May 26, 2026.
https://www.gavi.org/vaccineswork/no-more-needles-six-technologies-could-transform-how-we-get-vaccinated

As the largest World Cup ever kicks off, health officials are focused on more than Ebola.
The largest World Cup ever is putting public health systems on alert, though experts say the risk of Ebola remains low because it is not as transmissible as other diseases. (US) Officials and experts are more concerned about highly contagious diseases like measles and respiratory viruses, which can spread quickly through large, fast-moving crowds.
Published: June 5, 2026.
https://www.cnbc.com/amp/2026/06/04/world-cup-2026-health-officials-focused-on-ebola-measles.html

Mass Sloth Deaths in Florida Show Why the Wildlife Trade Is a Pandemic Risk.
When pathologists cut open dead sloths from a planned Florida tourist attraction, they found a plethora of pathogens. Parasites, bacteria and viruses were all lurking in animals weakened by grueling international transport and stressful conditions at the warehouse that received them, according to necropsy records and a state inspection report obtained by Inside Climate News through an open records request. The sloths had distended stomachs, diarrhea matted into fur and lungs congested with pneumonia.
Published: June 7, 2026.
https://www.sej.org/headlines/mass-sloth-deaths-florida-show-why-wildlife-trade-pandemic-risk

World Cup creates perfect conditions for infectious diseases to spread – here are the biggest threats health experts are watching for.
Ebola is indeed a threat, however, COVID-19, measles, and influenza by far much more important.
Published: June 7, 2026.
https://theconversation.com/world-cup-creates-perfect-conditions-for-infectious-diseases-to-spread-here-are-the-biggest-threats-health-experts-are-watching-for-284700

Health experts to screen US wastewater for disease outbreaks during World Cup.
Epidemiologists will be busy this summer shifting through sewage and social media with the goal of keeping soccer fans and the public safe from severe illness during the World Cup, one of the largest and most globally diverse mass gatherings ever anticipated. A public health squad based in Washington, D.C., plans to monitor wastewater and internet chatter to detect and track infectious diseases should they emerge in any of the U.S. or Canadian cities hosting World Cup players, their matches, and millions of spectators, organizers said.
Published: June 8, 2026.
https://www.reuters.com/business/healthcare-pharmaceuticals/health-experts-screen-us-wastewater-disease-outbreaks-during-world-cup-2026-06-08/

A strong El Niño is coming: could it lead to more disease outbreaks?
Climate experts warn that we should expect "hotter than normal" temperatures worldwide from June to August this year. Infectious disease specialists say we need to start preparing now.
Published: June 4, 2026.
https://www.gavi.org/vaccineswork/strong-el-nino-coming-could-it-lead-more-disease-outbreaks

Cholera Outbreak: 74 dead, over 7,800 cases strain Borno (Nigeria) facilities.
Médecins Sans Frontières (MSF), also known as Doctors Without Borders, said

the outbreak had spread across 14 local government areas and 50 wards, citing figures from the Borno State Ministry of Health.
Published: June 10, 2026.
https://www.premiumtimesng.com/news/top-news/886540-cholera-outbreak-74-dead-over-7800-cases-strain-borno-facilities.html

CEPI awards Public Health Vaccines US$1.9m to accelerate Bundibugyo ebolavirus vaccine.
CEPI has partnered with Public Health Vaccines, LLC. (PHV) to rapidly advance early-stage development of a vaccine candidate against the Bundibugyo ebolavirus in response to the ongoing epidemic in the Democratic Republic of the Congo (DRC) and neighbouring Uganda that has been declared both a continental and global health emergency. CEPI is providing $1.9 million funding to long-standing partner PHV to quickly generate starting vaccine research material, known as Master Viral Seed (MVS) stock*, needed to advance the company's investigational Bundibugyo virus vaccine into clinical testing.
Published: June 9, 2026.
https://cepi.net/cepi-awards-public-health-vaccines-us19m-accelerate-bundibugyo-ebolavirus-vaccine?blaid=8697010.

One World Against Dengue. June 15 is World Dengue Day.
As dengue expands into both longaffected regions and entirely new geographies, the need for coordinated, forwardlooking action has never been greater. A global threat needs a global day: on June 15, World Dengue Day aligns the world's awareness, inspiring every day to act as One World Against Dengue.
Published: June 2026.
https://www.dengueday.org/.

AI-designed universal coronavirus DNA vaccine advances pandemic preparedness with successful first human trial.
A novel AI-designed universal coronavirus DNA vaccine has successfully completed its first human trial, demonstrating a favorable safety profile and broad immune responses. Developed by researchers at the University of Cambridge and DIOSynVax, the vaccine is designed to protect not only against SARS-CoV-2 and SARS, but also against related bat coronaviruses with pandemic potential. Unlike conventional vaccines that target a single virus, artificial intelligence was used to create a synthetic "super-antigen" capable of inducing immunity across the entire Sarbecovirus family. Delivered as a needle-free DNA vaccine using microfluidic jet technology, the candidate generated immune responses against multiple coronaviruses in 39 healthy volunteers without significant adverse effects. While larger Phase 2 studies are still needed, this innovative DNA vaccine platform represents a potentially transformative step toward pandemic preparedness by providing broad protection against future coronavirus threats before they emerge.
Published: June 11, 2026.
https://scitechdaily.com/this-ai-designed-universal-vaccine-could-stop-future-pandemics-before-they-start/

One Health in a Fractured World: Why Global Health Governance Must Adapt to Geopolitical Fragmentation.
The COVID-19 pandemic exposed weaknesses in global health systems and underscored how interconnected drivers such as changes in land usage, urbanization, and climate amplify zoonotic disease threats. One Health, an integrated approach linking human, animal, and ecosystem health, has gained institutional traction via global governance approaches, yet faces persistent structural challenges, including siloed mandates, funding misalignment, and limited enforcement.
Published: June 5, 2026.
https://gjia.georgetown.edu/science-technology/one-health-in-a-fractured-world-why-global-health-governance-must-adapt-to-geopolitical-fragmentation/

Nachega JB, Mbala-Kingebeni P, Mulangu S, Ndembi N, Preiser W, Skinner D, Sam-Agudu NA, Ntoumi F, Tegally H, Baxter C, Oliveira T, Bosa HK, Kaleebu P, Kallay O, Uthman OA, Mills EJ, Rosenthal PJ, Zumla A, Muyembe-Tamfum JJ. Ebola outbreak caused by Bundibugyo virus: challenges and priorities for epidemic preparedness and response. ***Lancet*****. 2026 Jun 9:S0140-6736(26)01141-4.**
Editorial comment: As of June 3, 2026, the ongoing Bundibugyo ebolavirus (BDBV) outbreak had resulted in 344 laboratory-confirmed cases and 60 deaths in the Democratic Republic of the Congo, and 15 confirmed cases with one death

in Uganda, highlighting the continuing threat posed by emerging ebolaviruses. The absence of a licensed BDBV-specific vaccine or therapy, coupled with limited access to rapid and reliable diagnostics, underscores persistent gaps in outbreak preparedness and response. Beyond its immediate health impact, the outbreak exposes weaknesses in surveillance systems, laboratory capacity, healthcare infrastructure, and outbreak response capabilities that can facilitate sustained transmission and cross-border spread. These events reinforce the urgent need for broadly protective Ebola vaccines, improved diagnostics, effective therapeutics, and stronger global preparedness systems to prevent future outbreaks from escalating into larger regional or international public health emergencies.
doi: 10.1016/S0140-6736(26)01141-4.

The World's Game, the World's Pathogens: Infection Prevention at the FIFA World Cup 2026.

The 2026 edition (running June 11 through July 19 across the US, Mexico, and Canada) is historic in scale: 48 nations, 104 matches, 39 days, and 11 US host cities stretching from Boston to Los Angeles and Seattle to Miami. It is anticipated that between 3 and 5 million domestic and international visitors will descend on these cities, some arriving from countries with meaningfully different infectious disease landscapes than the cities hosting them. For infection preventionists (IPs), hospital epidemiologists, and public health practitioners working in or near any of these host cities, this is not a background event. This is a clinical and operational reality that, if we're being honest, is probably already giving you a bit of heartburn.
Published: June 10, 2026.
https://www.infectioncontroltoday.com/view/world-s-game-world-s-pathogens-infection-prevention-fifa-world-cup-2026

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

Gaythorpe KAM, Li X, Shankar M, Hartner AM, Gibney Z, Abbas K, Abeysuriya R, Alam C, Auzenbergs M, Azman AS, Barasa E, Costello A, Ferrari MJ, Fraser K, Fu H, Haile L, Kakaï RG, Karachaliou-Prasinou A, Lee EC, Katama EN, Kim JH, Jit M, Liu Y, Malinga J, Moore S, Nayagam S, Nedjati-Gilani G, Okell LC, Onifade AA, Papadopoulos T, Penny MA, Perkins TA, Pitzer VE, Portnoy A, Procter SR, Saraswati CM, Scott N, Seaman C, Shattock AJ, Sim SY, Tran Q, Vynnycky E, Winter AK, Hinsley W, Ferguson NM, Trotter CL. **Quantifying relative health impact across Gavi, the Vaccine Alliance's portfolio in 117 countries at the subregional level: a modelling study.** *Lancet.* 2026 May 16;407(10542):1941-1952.
doi: https://doi.org/10.1016/S0140-6736(26)00555-6

Editorial comment: This large modeling analysis from the Vaccine Impact Modelling Consortium highlights the enormous public health value of vaccination across 117 low- and middle-income countries. Among 14 Gavi-supported vaccines, HPV and measles vaccines demonstrated the greatest impact in terms of deaths averted per 1,000 vaccinations. The study emphasizes the growing importance of robust comparative metrics as countries face increasing budgetary constraints and difficult immunization-prioritization decisions. These findings reinforce that investment in vaccination remains one of the most cost-effective and life-saving public health interventions globally, while also supporting more evidence-based allocation of limited immunization resources.

02

Morton C, Ouyang D, Schwartz D et al. **Partisan differences in childhood measles vaccination and general refusals: a retrospective cohort study of electronic health records in the United States, 1988–2024.***The Lancet Regional Health – Americas.* 2026; 60: 101495.
doi: https://doi.org/10.1016/j.lana.2026.101495

Editorial comment: This nationwide U.S. study highlights the growing political polarization surrounding childhood vaccination, particularly measles vaccination. Over the past two decades—and especially during and after the COVID-19 pandemic—Republican parents were increasingly more likely than Democratic parents to refuse childhood vaccines, delay MMR vaccination, and have lower on-time measles vaccine coverage for their children. The polarization was even greater in states allowing non-medical vaccine exemptions. These findings are particularly concerning in the context of recent measles outbreaks in the United States, where declining vaccine confidence and refusal among some Republican communities may contribute to the resurgence of a disease once considered eliminated. The study underscores how political identity is increasingly influencing public health decisions, representing a major challenge for measles prevention and vaccine confidence efforts in the U.S.

03

Lenglart L, Levy C, Cahn-Sellem F, Zouari M, Frederic H, Béchet S, Boulhol M, Kramer R, Rybak A, Ouldali N, Cohen R. **Impact of nirsevimab implementation on the mid-term burden of bronchiolitis in the outpatient setting: results from the prospective OURSYN study.** *J Pediatric Infect Dis Soc.* 2026 May 18:piag035.
doi: https://doi.org/10.1093/jpids/piag035

Editorial comment: This large prospective French study provides important real-world evidence supporting the benefits of nirsevimab implementation against RSV in infants. Beyond reducing RSV-related bronchiolitis cases, the study suggests meaningful improvements in mid-term outcomes, including shorter daycare absences, reduced persistent symptoms, better quality of life, and lower parental work absenteeism. These findings reinforce the growing public health value of RSV prevention strategies in early infancy and highlight how monoclonal antibody immunization may reduce not only healthcare burden, but also the broader social and economic impact of RSV disease on families.

04

Turcinovic J, Fenton KA, Agans KN, Borisevich V, Deer DJ, Geisbert JB, O'Toole R, Abelson D, Dobias NS, Prasad AN, Woolsey C, Connor JH, Albariño CG, Geisbert TW, Cross RW. **Recombinant Bombali ebolavirus in cynomolgus macaques as a survival model of Ebola virus disease.** *Nat Commun.* 2026 Jun 2.
doi: https://doi.org/10.1038/s41467-026-73405-5

Editorial comment: This study provides the first experimental evidence that the recently discovered Bombali ebolavirus (BOMV), identified in bats across several African countries, can infect non-human primates and produce clinical features consistent with Ebola virus disease. However, unlike more pathogenic ebolaviruses such as Ebola, Sudan, or Bundibugyo viruses, all infected macaques survived and developed strong immune responses, suggesting that BOMV may cause a substantially milder disease phenotype. These findings are reassuring from a public health perspective but underscore the importance of continued surveillance of emerging ebolaviruses, as well as ongoing research to better understand their zoonotic and pandemic potential.

05

Zainal HM, Guimarães RS, Al Owesie A, Ribeiro LS, Roman-Pimentel A, Sharma T, de Godoy VN, Mendes RB. **Impact of Wolbachia-infected Aedes aegypti on dengue incidence in endemic regions: a systematic review and meta-analysis.** *Trans R Soc Trop Med Hyg.* 2026 May 29:trag063.
doi: https://doi.org/10.1093/trstmh/trag063

Editorial comment: This systematic review and meta-analysis provides strong evidence that the release of *Wolbachia*-infected *Aedes aegypti* mosquitoes is a highly effective strategy for dengue control. Across more than 8 million individuals in dengue-endemic regions, *Wolbachia* deployments were associated with an estimated 85% reduction in dengue incidence, with the greatest impact observed in areas achieving full population coverage. These findings position *Wolbachia* as one of the most promising complementary interventions to traditional vector-control measures and highlight its potential to substantially reduce the growing global burden of dengue, particularly in highly endemic settings.

06

O'Leary ST, Danchin M. **Childhood Vaccine Hesitancy.** *N Engl J Med.* 2026 Jun 4;394(21):2134-2145.
doi: https://doi.org/10.1056/NEJMcp2516616

Editorial comment: This review emphasizes that vaccine hesitancy is often driven not by opposition to vaccination, but by parental concerns about vaccine safety and a desire to protect their children. The authors highlight the critical role of healthcare professionals as the most trusted source of vaccine information and demonstrate that clear, confident vaccine recommendations are strongly associated with higher vaccine uptake. Empathetic, patient-centered communication strategies—including motivational interviewing—can effectively address concerns, counter misinformation, and build trust, reinforcing the importance of strong clinician–parent relationships in maintaining and improving childhood immunization coverage.

07

Priante E, Baraldi E. **Protecting infants from RSV: cost-effectiveness of nirsevimab in a real-world study from Chile.** *Lancet Reg Health Am.* 2026 May 25;59:101506.
doi: https://doi.org/10.1016/j.lana.2026.101506

Editorial comment: This editorial highlights the transformative impact of new RSV prevention strategies, including maternal vaccination and long-acting monoclonal antibodies such as nirsevimab. Real-world data from Chile demonstrate substantial reductions in RSV-related disease burden and healthcare costs, reinforcing findings from clinical trials. However, achieving the full public health potential of these interventions will require equitable global access, continued surveillance, monitoring for breakthrough infections and resistance, and further evaluation of their long-term effects on respiratory outcomes such as recurrent wheezing and asthma. Together, these advances represent a historic opportunity to dramatically reduce RSV-related infant morbidity and mortality worldwide.

08

Dvorkin J, Pico M, Guiñazú G, Crespi MS, Lee S, Merlino R, Palau J, Samaruga C, Esposto S, Pichinenda M, Regalado A, Torre V, Fenelli GS, Ossorio MF, Sbruzzi A, Souto SM, Ferrero F, Losada JV, Graziano A, Ojeda MN, Lugo S, Geli G, Schpilberg M, Eymann A, Busaniche J, Caballero MT. **Residual burden of severe RSV disease in infants during the first season of maternal RSVpreF immunization in Argentina: A hospital-based, multicentre, retrospective cohort study.** *Vaccine.* 2026 May 29;87:128773.
doi: https://doi.org/10.1016/j.vaccine.2026.128773

Editorial comment: This real-world study from Argentina demonstrates that maternal RSV vaccination has substantially reduced the burden of infant RSV hospitalizations, with more than 90% of hospitalized infants born to unvaccinated mothers. However, a significant residual burden of severe disease remains, particularly among infants born before the vaccination campaign and high-risk preterm infants. These findings highlight both the success and limitations of maternal immunization alone and support the need for complementary strategies, such as long-acting monoclonal antibodies, to achieve broader and more equitable protection against RSV in early infancy.

09

Härmä V, Palsola M, Kuusipalo A, Lindh E, Melin M, Nohynek H. **Lessons from the 2024 avian influenza vaccination campaign in Finland: a qualitative inquiry.** *Vaccine.* 2026 May 21;86:128736.
doi: https://doi.org/10.1016/j.vaccine.2026.128736

Editorial comment: This study highlights a critical challenge for future pandemic preparedness: vaccine availability alone does not guarantee vaccine uptake. Despite being the first country to offer pre-pandemic H5N1 vaccination to high-risk occupational groups, Finland achieved low coverage among fur and poultry workers. The main barriers included logistical challenges, low perceived personal risk, and distrust of public health authorities. These findings underscore the importance of integrating behavioral science, community engagement, and effective risk communication into future avian influenza vaccination strategies to ensure that those at highest risk are adequately protected.

10

Sinha D, Coquant G, Yuan X, Paul S, Longet S. **Postpandemic adjuvants to tailor vaccine-induced immunity.** *Trends Immunol.* 2026 May;47(5):423-435.
doi: https://doi.org/10.1016/j.it.2026.01.001

Editorial comment: This review highlights the pivotal role of next-generation adjuvants in addressing some of vaccinology's most important unmet needs, including durable immunity, broad variant protection, and strong mucosal immune responses. Emerging adjuvants targeting specific immune pathways have shown promise in enhancing humoral, cellular, and mucosal immunity across different age groups, including children and older adults. As the world enters the post-pandemic era, these innovative adjuvant technologies may become key components of future vaccine platforms, improving protection against both existing and emerging infectious threats.

11

Song S, Hitchings MDT, Yang Y, Longini IM Jr; N3C consortium. **Improving Assessment of Vaccine Effectiveness by Coupling Test-negative Design Studies with Survival Models.** *Epidemiology.* 2026 Jul 1;37(4):417-426.
doi: https://doi.org/10.1097/EDE.0000000000001972

Editorial comment: This methodological study challenges the traditional view of the test-negative design (TND), one of the most widely used approaches for evaluating vaccine effectiveness. The authors demonstrate that TND can be analyzed as a cohort study and introduce a novel statistical model that better accounts for recurrent infections and changing vaccination status over time. Applied to real-world COVID-19 data, the approach provided more robust estimates of vaccine effectiveness against both primary infection and reinfection. These findings may improve the accuracy of future vaccine effectiveness studies and strengthen the evidence used to guide immunization policies.

12

Bähner F, Faust SN, Davies LRL, Blokhina O, Brandon DM, Smith WB, Chatterjee VKK, Hassanin H, Babu TM, Zuiani A, Steinhauser S, Poran A, Brittain C, Mucker E, Hooper JW, van der Most RG, Alonso PL, Türeci Ö, Mensa FJ, Şahin U. **Safety and immunogenicity of mRNA-based mpox vaccine candidate BNT166a: an open-label, dose-escalation, first-in-human trial.** *Lancet Infect Dis.* 2026 Jun 3:S1473-3099(26)00177-5.
doi: https://doi.org/10.1016/S1473-3099(26)00177-5

Editorial comment: This first-in-human phase 1 study demonstrates that the quadrivalent mRNA mpox vaccine candidate BNT166a has a favorable safety profile and induces strong antibody responses against multiple monkeypox virus antigens. The vaccine generated durable binding antibodies for at least 12 months and elicited neutralizing activity against both mpox and vaccinia viruses, supporting broad orthopoxvirus protection. Although neutralizing antibody levels declined over time, the overall immunogenicity and safety results support further clinical development and highlight the growing potential of mRNA technology beyond COVID-19 for addressing emerging infectious disease threats such as mpox.

13

Zane GK, Dimitrov D, Levin CE, Khosropour CM, Duerr A. **Evaluating the potential health and economic impacts of chlamydia vaccination strategies in the United States: a mathematical modeling and cost-effectiveness simulation study.** *The Lancet Regional Health – Americas.* 2026;60: 101502 Published Online xxx.
doi: https://doi.org/10.1016/j.lana.2026.101502

Editorial comment: This modeling study suggests that a future chlamydia vaccine could have a major public health impact in the United States, substantially reducing infections, complications, and healthcare costs. Under realistic assumptions, vaccination could reduce chlamydia incidence by up to 52% by 2075, with sex-neutral vaccination providing the greatest benefit. Importantly, all vaccination strategies were projected to be cost-saving, highlighting the considerable potential of chlamydia vaccines as a transformative tool for the prevention of one of the world's most common sexually transmitted infections.

14

Minhaj FS, Mandra A, Nguete BU, Likafi T, Kokola G, Tran S, Kennedy JL, Monroe B, Hughes CM, Joseph T, Person MK, Townsend MB, Satheshkumar PS, Kabamba J, Reynolds MG, Rao AK, Kasongo D, Yu PA, Yu Y, Shongo Lushima R, Kaba D, Petersen B, McCollum AM. **Safety of MVA-BN vaccine in health-care personnel in DR Congo: a prospective cohort study.** *Lancet Infect Dis.* 2026 Jun;26(6):561-570.
doi: https://doi.org/10.1016/S1473-3099(25)00779-0

Editorial comment: This large prospective study from the Democratic Republic of the Congo provides important real-world evidence supporting the safety of the MVA-BN (JYNNEOS) mpox vaccine in an African population at increased risk of exposure. Both liquid and lyophilized formulations demonstrated favorable safety profiles, with no vaccine-related serious adverse events identified during two years of follow-up. These findings strengthen confidence in the use of MVA-BN as a key tool for controlling current and future mpox outbreaks, particularly in endemic African settings where the disease burden remains highest.

15

Hossain MJ, Secka F, Sanyang LC, Taiwo R, Okoh EC, Olubiyi OA, Drammeh M, Richard EU, Balami AD, Drammeh M, Jallow SJ, Sonko B, Ezedimbu-Michael P, Obiaduo J, Secka O, Kaim J, Sjöstrand B, Lissmats A, Carlin N, D'Alessandro U, Svennerholm AM, Wierzba TF. **Efficacy of ETVAX, a vaccine against enterotoxigenic Escherichia coli-positive diarrhoea in Gambian children: a double-blind, randomised, placebo-controlled, phase 2b trial**. *Lancet Infect Dis.* 2026 Jun;26(6):627-637.
doi: https://doi.org/10.1016/S1473-3099(25)00774-1

Editorial comment: This phase 2b trial in Gambian children demonstrated that the oral ETEC vaccine candidate ETVAX is safe and immunogenic, inducing strong antibody responses against key ETEC antigens. Although the primary efficacy endpoint was not met, secondary analyses showed meaningful protection against moderate-to-severe ETEC diarrhea, particularly when vaccination was initiated before 9 months of age. Given the substantial global burden of ETEC-associated childhood diarrhea and mortality, these encouraging findings support continued clinical development of ETVAX and advancement to phase 3 evaluation.

16

De Coster I, AbdelGhany M, Sarakinou E, Fineschi C, Marchetti E, La Gaetana R, Nigro S, Carducci M, Massai L, Conti V, Rossi O, Luna Cilio G, Serry-Bangura A, Tessitore P, Van Damme P, Withanage K, Micoli F, Berlanda Scorza F, Rondini S, Nakakana UN, Kumar Arora A. **Safety and immunogenicity of a conjugate vaccine candidate against Salmonella enterica serovars Typhi and Paratyphi A in healthy adults in Europe: a phase 1 randomised controlled trial.** *Lancet Infect Dis.* 2026 Jun;26(6):638-650. doi: 10.1016/S1473-3099(25)00730-3. Epub 2026 Jan 23. Erratum in: Lancet Infect Dis. 2026 Apr;26(4):e214.
doi: https://doi.org/10.1016/S1473-3099(26)00066-6

Editorial comment: This phase 1 trial provides encouraging early evidence for a novel bivalent conjugate vaccine targeting both *Salmonella Typhi* and *Salmonella Paratyphi A*, addressing a major unmet need in enteric fever prevention. The vaccine demonstrated a favorable safety profile and induced strong immune responses against both pathogens after a single dose, with no significant safety concerns identified. Given the absence of licensed vaccines against *S. Paratyphi A*, these findings represent an important step toward broader protection against enteric fever and support further evaluation of this candidate in endemic populations, particularly children.

17

The Lancet Infectious Diseases. **How are vaccine recommendations made?** *Lancet Infect Dis.* 2026 May;26(5):439.
doi: https://doi.org/10.1016/S1473-3099(26)00189-1

Editorial comment: This commentary highlights how meningococcal outbreaks can expose gaps in vaccine policy. Although effective MenB vaccines have been available for years, their use in adolescents remains limited in many countries due largely to cost-effectiveness considerations rather than concerns about safety or efficacy. The authors argue that vaccine recommendations should consider not only economic models but also the severe consequences of meningitis, health equity, public confidence in vaccination, and the broader societal benefits of disease prevention. The recent UK outbreak serves as a reminder that vaccine policy decisions can have profound public health implications.

18

Sparling AC, Florsheim EB, Sullivan ZA. **Scaling immunity: sickness as a host defense strategy.** *Trends Immunol.* 2026 Apr 30:S1471-4906(26)00076-1.
doi: https://doi.org/10.1016/j.it.2026.03.015

Editorial comment: This thought-provoking review proposes that "sickness behavior"—including fever, fatigue, anorexia, and social withdrawal—should be viewed as a form of organismal immunity, representing an adaptive host-defense strategy coordinated through interactions between the immune system and the brain. The authors suggest that these responses can enhance pathogen resistance, promote tolerance to infection, and even reduce transmission, while also being tailored to specific pathogens. Importantly, dysregulation of these protective mechanisms may contribute to chronic inflammatory conditions, depression, Long COVID, and chronic fatigue syndromes. This emerging framework broadens our understanding of host defense beyond traditional immune responses and highlights the critical role of the brain–immune axis in health and disease.

19

Ortiz, J.R., Kurup, D., Kaufman, A.C. *et al.* **Adjuvanted inactivated rabies virus-vectored Lassa virus vaccine in healthy adults: a phase 1 trial**. *Nat Med*, 2026 June:
doi: https://doi.org/10.1038/s41591-026-04429-z

Editorial comment: This phase 1 trial provides encouraging early evidence for LASSARAB, a novel rabies virus-vectored vaccine against Lassa fever, a major but often neglected cause of hemorrhagic fever in West Africa. The vaccine demonstrated a favorable safety profile and induced robust immune responses, with 100% of recipients developing antibodies against Lassa virus after two doses. Notably, the platform also generated protective immunity against rabies, highlighting its potential as a dual-purpose vaccine. These promising results support further clinical development and represent an important step toward addressing a longstanding unmet need in global health.

20

Edwards KM, Rathore MH. **Resurgence of Tetanus-Reasons Why the Vaccine Remains Instrumental.** *JAMA*. 2026 Jun 8.
doi: https://doi.org/10.1001/jama.2026.9347

Editorial Comment: The resurgence of tetanus cases in North America serves as a reminder that vaccine-preventable diseases can quickly re-emerge when immunization coverage declines. This concerning trend appears to be driven largely by inadequate vaccination and booster uptake, compounded by growing vaccine hesitancy and a loss of public confidence in vaccines. Strengthening public awareness, restoring trust in immunization programs, and ensuring timely administration of tetanus-containing vaccines are essential to prevent the return of a disease that is entirely preventable yet potentially fatal.

21

Rodriguez-Morales AJ, Rodríguez-Sabogal IA, Porras-Pedroza BE, Faccini-Martínez ÁA, Grisales-Nieto D, Escarrá F, Quispe-Torrez PP, Membrillo FJ, Orduna T, Lloveras S, Chaves TSS, Cabada MM, Perret C, Echavarría R, Ribeiro AF, Tanabe M, Bazzino F, Ramirez M, Diaz B, Morejón KML, Daly K, Rosas R, Lopez MB, Miranda C, Fernandez ML, Özsürekçi Y, Matsee W, Carrero Y, Biscayart C, Cimerman S, Avila-Aguero ML, Debbag R, Brea J, Risquez A, Acosta-España JD, Ulloa-Gutierrez R, Espinal C, Torres-Martinez CN, González-Sanz M, Abbara A, Weatherhead J, Masana M. **The 2026 FIFA World Cup: Communicable disease risks and advice for visitors to Canada, the United States, and Mexico**. *Travel Med Infect Dis*. 2026 May 28:102995.
doi: https://doi.org/10.1016/j.tmaid.2026.102995

Editorial comment: This mini-review highlights the infectious disease risks associated with travel to Mexico, the United States, and Canada, with particular emphasis on vaccine-preventable diseases. Special attention is given to infections currently causing outbreaks in the region, including measles and pertussis, underscoring the importance of ensuring travelers are adequately vaccinated before departure and remain up to date with recommended immunizations.

22

Tscherne A, Halwe NJ, Krammer F. **Vaccines and therapeutics for Andes hantavirus.** *Npj Viruses*. 2026 Jun 9;4(1):29.
doi: https://doi.org/10.1038/s44298-026-00200-w

Editorial comment: This review highlights the significant progress in the development of vaccines against Andes hantavirus (ANDV), for which no licensed human vaccine currently exists. While older inactivated hantavirus vaccines used in Asia have shown limited and short-lived protection, several next-generation ANDV vaccine candidates—including viral-vectored, DNA, mRNA, and nanoparticle-based platforms—have demonstrated promising immunogenicity and protection in preclinical models. Notably, a DNA vaccine encoding the ANDV glycoprotein has successfully completed a Phase 1 clinical trial, showing a favorable safety profile and inducing neutralizing antibodies in healthy volunteers. These advances bring the field closer to an effective vaccine against a highly lethal emerging pathogen and may also provide cross-protection against other hantaviruses.

23

Pley C, Jeffries D, Kanteh E et al. **Yellow fever vaccination in healthy Gambian children of different ages to establish safety and immunogenicity of a booster dose: a open-label, non-randomised, single-site, phase 3 vaccine trial.** *The Lancet Infectious Diseases.*, 2026 Jun; 0.
doi: https://doi.org/10.1016/S1473-3099(26)00193-3

Editorial comment: This study provides important evidence that immunity following primary yellow fever vaccination in infancy may wane over time in children living in endemic regions. In Gambian children previously vaccinated at 9–12 months of age, a booster dose was safe and induced strong neutralizing antibody responses, with nearly all children achieving seroprotection. The greatest immune boosting was observed among children aged 4–9 years, suggesting that booster vaccination during childhood could help maintain long-term protection. These findings may have important implications for yellow fever vaccination policies in endemic countries, where optimizing the timing of booster doses could strengthen population immunity and reduce the risk of future outbreaks.

24

Koopmans M, Brechot C, Bruzzone R, Hotez P, et al. **Andes Virus on a Cruise Ship, what it Tells us About the Global Pandemic Preparedness Agenda.** *The Lancet Regional Health – Europe.* 2026 Jun, 101755.
doi: https://doi.org/10.1016/j.lanepe.2026.101755

Editorial comment: The recent Andes virus outbreak linked to a cruise ship serves as a powerful reminder that emerging zoonotic diseases can rapidly transcend geographic boundaries in an increasingly interconnected world. While Andes hantavirus remains a relatively rare pathogen, its documented person-to-person transmission and ability to spread through international travel highlight vulnerabilities in global surveillance, outbreak detection, and response systems. This event underscores the importance of strengthening pandemic preparedness through enhanced surveillance, rapid diagnostics, international collaboration, and investment in vaccines and therapeutics for emerging infectious diseases before they become larger public health threats.

25

Tejada CE, Aizenberg M, Cucunubá Z, Rodríguez WC, Bazán JD, Terrón FAG, Gutiérrez G, Cuentas AL, Casapia Morales M, Núñez JGM, Rico-Restrepo M, et al. **Bridging the Gaps in Dengue Control in Latin America: Multisectoral Strategies from an Expert Panel.** *Vaccines.* 2026; 14(6):488.
doi: https://doi.org/10.3390/vaccines14060488

Editorial comment: Dengue continues to pose a major public health challenge across Latin America, driven by increasing transmission, insecticide resistance, underreporting, fragmented surveillance systems, and persistent socioeconomic and environmental factors. Experts from the Latin America Dengue Task Force highlighted the urgent need for a more integrated regional strategy that combines enhanced surveillance, improved diagnostics, effective vaccination programs, innovative vector control approaches, and stronger political commitment. Their recommendations underscore that sustainable dengue control will require coordinated action across sectors and countries, embracing a comprehensive One Health approach to reduce the growing burden of disease in the region.

Editor's Corner

DRONES AND VACCINES: ARE WE READY TO RETHINK HOW WE DELIVER LIFE-SAVING IMMUNIZATION?

Introduction: The Innovation Gap We Can No Longer Ignore

Vaccines save millions of lives every year—yet millions still miss them. Not because we lack vaccines, but because we fail to deliver them. The "last mile" remains one of the most persistent and inequitable barriers in global health.

In an era of unprecedented technological advancement, it is no longer acceptable that geography, poor infrastructure, or fragile logistics determine who gets vaccinated and who does not. Drone technology (unmanned aerial vehicles, UAVs) challenges this paradigm. The question is no longer whether drones *can* deliver

vaccines—but whether we are willing to fully integrate them into health systems at scale.

Breaking the Tyranny of Distance:

For decades, vaccine delivery has depended on roads that do not exist, vehicles that break down, and supply chains that fail under pressure. In many low- and middle-income countries (LMICs), reaching remote communities can take hours—or days.

Drones fundamentally disrupt this model. They bypass terrain, deliver directly, and operate on demand. Countries such as Ghana and Rwanda have demonstrated that national drone delivery networks are not futuristic concepts—they are operational realities. These systems have already delivered millions of medical products, including vaccines, to previously hard-to-reach populations.

If we can deliver packages across continents overnight, why are we still unable to reliably deliver vaccines within our own countries?

From Stockouts to Precision Delivery:

One of the most overlooked failures in immunization programs is not vaccine hesitancy—it is vaccine absence. Stockouts at peripheral health facilities remain a major driver of missed opportunities for vaccination.

Drone-enabled systems allow for real-time, on-demand resupply, reducing dependence on periodic distribution cycles. This transforms vaccine logistics from a "push" system to a responsive, data-driven "pull" system, indeed more pragmatic. Evidence shows that drone delivery can significantly reduce stockout duration and improve availability of essential vaccines.

Moreover, smaller, more frequent deliveries reduce the need for large local storage, minimizing wastage and improving cold chain integrity—particularly critical for temperature-sensitive vaccines.

Equity Is a Logistics Problem, but Why?

Global vaccination inequities are often framed as issues of access, demand, or policy. But at their core, they are also logistics failures.

Drones offer a powerful tool to address these inequities. By reaching remote, rural, and underserved populations, they help close the gap between urban and rural health services. Modeling studies suggest that drone-supported supply chains can increase vaccine availability and coverage in geographically challenging settings.

In this sense, drones are not just a technological innovation—they are an equity intervention.

Speed Matters: Outbreaks, Emergencies, and Lives Saved (not only "Micro Science"):

In outbreak scenarios, time is everything. Delays in vaccine delivery translate directly into preventable infections and deaths.

Drones can deliver vaccines and medical supplies in minutes rather than hours, enabling rapid response to emerging health threats. Their independence from road infrastructure makes them particularly valuable in disaster zones, conflict settings, and during epidemics.

If pandemic preparedness is truly a global priority, then drone logistics must be part of the conversation—not an afterthought.

Vaccines, Climate Change, and Sustainable Health Systems:

Ironically, the same systems that struggle to deliver vaccines are also vulnerable to climate change. Floods, extreme weather, and environmental degradation increasingly disrupt traditional supply chains.

Drone delivery systems—often electric and low-emission—offer a more resilient and environmentally sustainable alternative. By reducing reliance on ground transport, they can lower carbon emissions while maintaining continuity of care.

This aligns with the growing need for climate-smart health systems, where innovation supports both health outcomes and environmental sustainability.

Cost: Barrier or Excuse?

A common argument against drone deployment is cost. However, this perspective often reflects short-term thinking.

While initial investments may be significant, evidence suggests that drone delivery can be cost-effective at scale, particularly when accounting for reduced wastage, improved efficiency, and avoided health system costs.

The real question is not whether we can afford drones—but whether we can afford not to invest in systems that prevent missed vaccinations and save lives.

The Real Barriers: Policy, Perception, and Prioritization, a Political Concern (?):

Despite strong evidence and successful implementations, drone adoption remains uneven. The barriers are rarely technological; they are political, regulatory, and perceptual.

- Fragmented regulatory frameworks
- Limited integration into national immunization strategies
- Perception of drones as "pilot projects" rather than core infrastructure
- Uncertain financing and procurement mechanisms

In other words, the challenge is not innovation, it is implementation at scale.

Conclusion: From Innovation to Standard of Care:

Drone technology has moved beyond proof of concept. It is already saving time, improving access, and strengthening health systems. Yet its full potential remains underutilized.

If we are serious about achieving equitable immunization coverage, strengthening pandemic preparedness, and building resilient health systems, we must move drones from the margins to the mainstream.

The future of vaccine delivery will not be defined by what we can invent—but by what we choose to implement.

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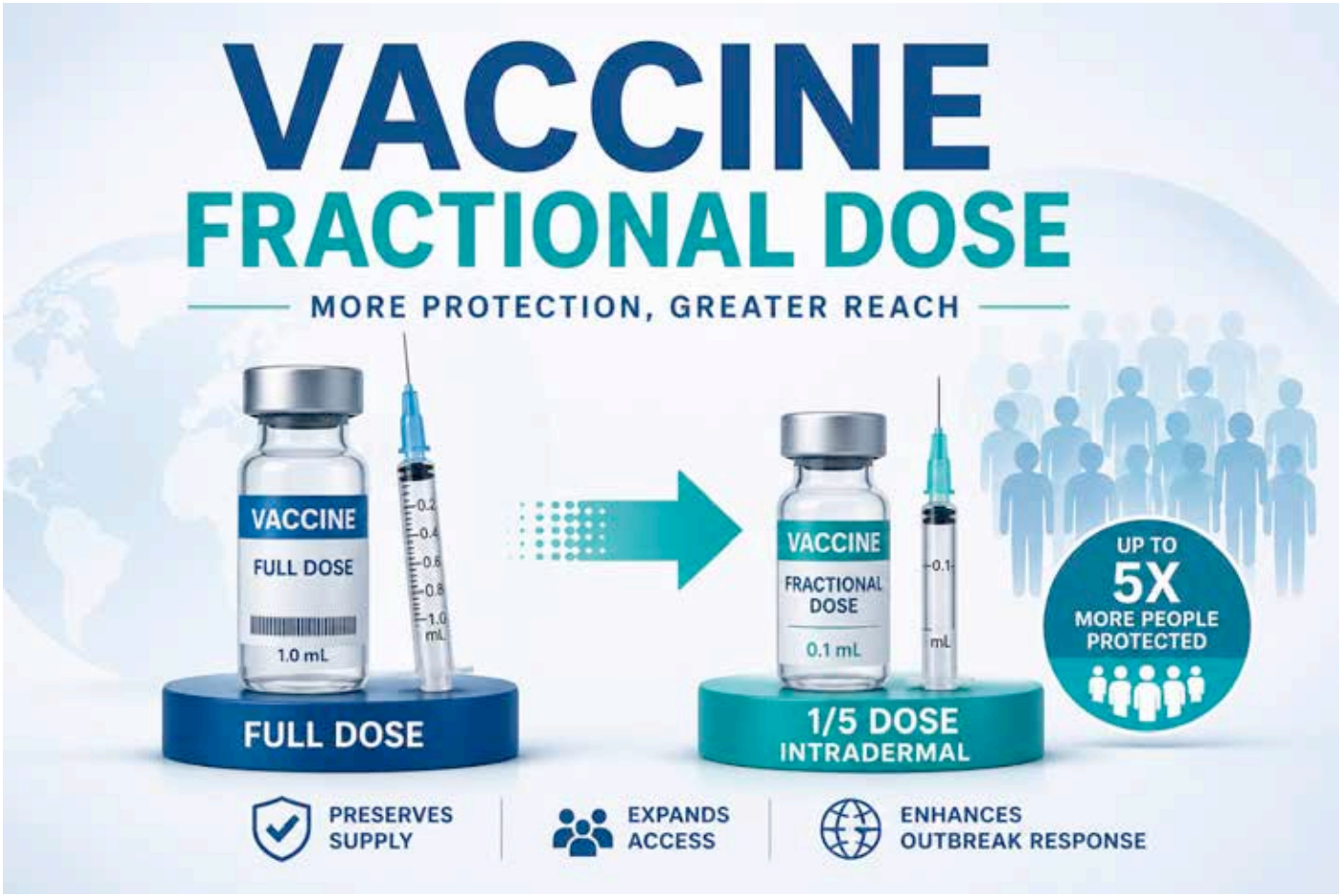
Best Practice

FRACTIONAL DOSING IN VACCINOLOGY: FROM EMERGENCY STRATEGY TO PRECISION PUBLIC HEALTH TOOL



Introduction:
Fractional dosing—defined as the administration of a reduced quantity of antigen compared to the standard licensed dose—has evolved from a contingency approach into a credible, evidence-based public health strategy. Initially deployed during vaccine shortages, it is now increasingly recognized as a tool to expand coverage, improve equity, and optimize population-level impact.

This approach is grounded in a key immunological principle: vaccine dose–response relationships are often nonlinear. In many cases, a substantial proportion of the maximal immune response

can be achieved at doses lower than the standard formulation. This creates an opportunity to trade small reductions in individual immunogenicity for large gains in population coverage, particularly critical in outbreak settings and supply-constrained environments.

Evidence Base: Where Fractional Dosing Works:

The most compelling evidence comes from Yellow Fever vaccination. Randomized trials and observational studies have consistently shown that administration of one-fifth of the standard 17D vaccine dose induces non-inferior neutralizing antibody responses in healthy adults.

Crucially, this evidence has been translated into real-world impact. During the 2016 Yellow Fever outbreak in Democratic Republic of the Congo, fractional dosing was implemented in Kinshasa as part of a mass vaccination campaign. Faced with limited global vaccine stockpiles, authorities used one-fifth doses to immunize millions of people in a short period. This strategy was instrumental in controlling the outbreak and is widely regarded as a landmark example of adaptive vaccinology in practice.

Similarly, fractional dosing has been used in outbreak responses in Angola during the same epidemic, further reinforcing its operational feasibility and public health value.

Long-term follow-up studies suggest that fractional doses can induce durable immunity, with high seroprotection rates reported up to 8–10 years. However, these data remain limited to specific populations and contexts and should be interpreted cautiously when extrapolating to broader use.

Beyond Yellow Fever, fractional dosing has been explored in:

- Inactivated poliovirus vaccine (IPV).
- Mpox (MVA-BN) vaccine during recent outbreaks.
- Influenza and rabies vaccines.
- COVID-19 vaccines (immunogenicity and modeling studies).
- Malaria - RTS, S /AS01(E) vaccine.

Across these platforms, a consistent pattern emerges: fractional dosing can preserve immunogenicity, particularly when paired with optimized delivery routes such as intradermal administration.

The Immunological Rationale:

The dermis is highly enriched with antigen-presenting cells, particularly dendritic cells, making intradermal delivery especially efficient. This allows smaller quantities of antigen to generate robust immune responses.

In addition, correlates of protection—such as neutralizing antibody titers—often plateau at relatively low antigen doses. Modeling studies suggest that even modest reductions in individual-level protection may be outweighed by the benefits of increased population coverage, particularly during rapidly evolving outbreaks.

Programmatic Advantages:

Fractional dosing offers several strategic advantages:

1. Rapid expansion of coverage:
   Reducing the dose per vial can multiply available doses by 3–5 times, enabling rapid scale-up during outbreaks.
2. Equity and access:
   This approach is particularly relevant for LMICs, where vaccine supply constraints remain a persistent challenge.
3. Cost-effectiveness:
   Lower antigen requirements reduce costs per immunized individual, improving sustainability.
4. Pandemic preparedness:
   Fractional dosing may play a critical role in early outbreak response, when supply is limited and speed is essential.

Limitations and Risks:

Despite its promise, fractional dosing is not universally applicable and carries important limitations:

1. Uncertainty in long-term protection:
   While Yellow Fever data are reassuring, the duration of immunity after fractional dosing

remains insufficiently characterized for many vaccines. In outbreak settings, the primary goal is rapid short-term protection; however, there is a legitimate risk that reduced doses may not confer the same longevity of immunity as full-dose schedules. This raises important considerations for future booster strategies and long-term disease control.

2. Population variability:
Most evidence is derived from healthy adult populations. Data in infants, older adults, and immunocompromised individuals remain limited.

3. Regulatory constraints:
Fractional dosing is often implemented under emergency use frameworks rather than routine licensure.

4. Operational complexity:
Intradermal administration requires training and precision, increasing the risk of administration errors.

5. Perception and communication challenges:
Reduced-dose strategies may be perceived as inferior, potentially affecting public confidence if not communicated effectively.

When Should Fractional Dosing Be Used?

A rational framework for implementation includes:

1. Evidence threshold:

- Demonstrated non-inferior immunogenicity.
- Preferably supported by clinical trials or robust real-world data.

2. Epidemiologic context:

- Active outbreak or high transmission risk.
- Clear mismatch between supply and demand.

3. Target population:

- Prioritize groups with strongest evidence (typically healthy adults).
- Exercise caution in high-risk populations.

4. Delivery strategy:

- Consider intradermal administration when supported by evidence.
- Ensure adequate training of healthcare workers.

5. Regulatory alignment:

- Coordinate with national authorities and WHO guidance.

6. Communication strategy:

- Clearly explain the rationale to maintain trust.

7. Exit strategy:

- Plan for potential boosters if long-term protection is uncertain.

From Emergency Tool to Strategic Policy:

The success of fractional dosing in Yellow Fever outbreaks has demonstrated that this approach is not merely theoretical, but operationally feasible at scale.

The next challenge is determining whether fractional dosing should remain an emergency measure or evolve into a proactive, evidence-based strategy within routine immunization and pandemic preparedness frameworks.

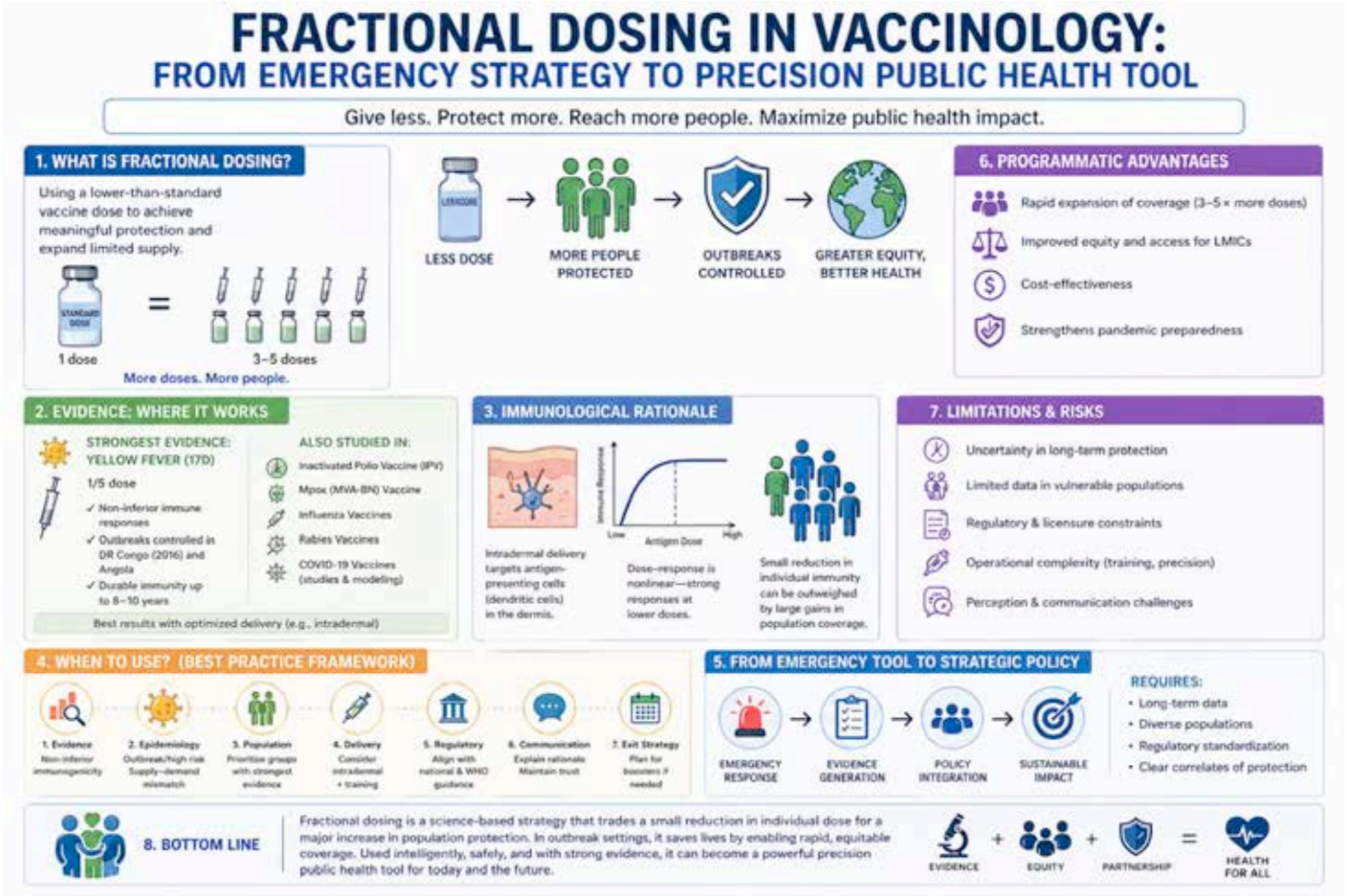
This will require:

- Expanded long-term immunogenicity data.
- Inclusion of diverse populations.
- Regulatory standardization.
- Clear correlates of protection.

Conclusions:

Fractional dosing represents a shift in vaccinology—from a scarcity-driven compromise to a potentially optimized strategy for maximizing population health impact.

However, its use must remain context-specific and evidence-driven. In outbreak settings, the benefits of rapid, expanded coverage are clearly



demonstrated in Yellow Fever epidemics. Yet, the potential trade-off in long-term immunity underscores the need for careful planning, follow-up strategies, and ongoing research.

In a world of constrained resources and emerging threats, the critical question is not whether fractional dosing works—but how to deploy it intelligently, safely, and sustainably.

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Guest Contributors

THE USE OF PRIOR KNOWLEDGE IN EARLY VACCINE DEVELOPMENT

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Introduction

During the development of the COVID-19 vaccines, regulatory agencies accepted reliance on already existing data from vaccines based on the same technology.[1] This leveraging of existing data, the so-called 'prior knowledge', was not new in vaccine development. For example, seasonal influenza vaccines' reliance on related authorised strains minimises data required for annual updates.[2]

In a 2018 Joint Biologics Working Party (BWP)/ Quality Working Party (QWP) workshop, the European Medicines Agency (EMA) defined 'prior knowledge' as 'including company knowledge from development and manufacturing experience (e.g. experience based on similar compounds, products and processes) as well as reference to scientific and technical publications or application of established scientific principles e.g. within chemistry'.[3]

A particular subset of prior knowledge is the 'platform approach', a term which is used throughout the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and EMA guidance, but is described in more detail in the ICH Q11 guideline as the 'development of a production strategy for a new drug starting from manufacturing processes similar to those used by the same applicant to manufacture other drugs of the same type (e.g., as in the production of monoclonal antibodies using predefined host cell, cell culture, and purification processes, for which there already exists considerable experience)'.[4]

The World Health Organization (WHO) defines platform technology as 'a group of technologies used as a base upon which other applications, processes or technologies are developed.'[5]

Platform approaches are also referred to as 'platform manufacturing' and 'platform technology' in the framework of manufacturing and are sometimes used interchangeably.

The use of prior knowledge and platform approaches is 'traditionally' linked with marketing authorisation applications (MAA). However, it can also be used in early stages of development, in particular in vaccines that are based on a common technology.

Non-clinical development

An early step in the development of vaccines is the evaluation of nonclinical safety. For general toxicology studies, a single repeated dose toxicology (RDT) in one species, according to the 'N+1' principle, is usually sufficient for vaccines. In principle, this study needs to be repeated for every new vaccine candidate.[6] Depending on the type of vaccines, other safety toxicology studies may also be required, including biodistribution studies and neurovirulence studies. Safety toxicology studies should be performed under good laboratory practice (GLP) conditions.

In general, there is an ethical consideration to reduce the number of animal studies based on the 3R (replacement, reduction, refinement) principle.[7]

When leveraging safety toxicology data, it is very important to assess which elements of the product are the 'drivers' of safety toxicology and if these drivers are linked to the platform or product-specific variations. For mRNA vaccines formulated in Lipid Nanoparticles (LNP), the driver of the potential toxicity is the LNP composition and, to a lesser extent, the biologic activity of the expressed antigens of the mRNA vaccine. For DNA vaccines that are based on a common backbone like, for instance,

a Yellow Fever-based viral vector, the toxicity is mainly driven by the backbone itself and less by the inserted antigen. This is particularly true if the antigen used is well-known and has an already characterised safety profile.

A careful case-by-case assessment is therefore required to establish the nonclinical risk/benefit profile.

For mRNA vaccines, the leveraging of existing nonclinical data of products based on the mRNA platform is discussed in the WHO guidance on mRNA vaccines.5 As an example, the EMA accepted a non-GLP repeated dose toxicity (RDT) study for Spikevax (Moderna mRNA Covid-19 vaccine)[8] and, for mRESVIA (Moderna mRNA RSV vaccine), accepted the omission of a recovery group[9] in the RDT study, based on existing non-clinical GLP data with different vaccines based on the same platform.

In DNA vaccines, where the gene of interest is inserted into a plasmid vector, it could be conceived that a full RDT study with a single vaccine could form the basis of a 'platform toxicology program', as the main toxicity driver would be the vector.

As an example, in a RDT study, one antigen could be sufficient to initiate early clinical trials of a vaccine based on the same platform, but with a different antigen inserted. This will, of course, be dependent on several conditions, such as the same route of administration, the same (or less) number of doses, the same dosing regimen, the same or lower doses. Additionally, the 'new' antigen should have a better or similar safety profile then the antigen that has already been included in the 'platform' toxicology trial.

For plasmid DNA vaccines, a biodistribution/ persistence study to assesses the presence of plasmid collected from a panel of tissues at multiple time points is required.[10] Until recently, there was a requirement to perform a biodistribution study for each novel DNA vaccine. As studies examining plasmid biodistribution/ persistence indicate that DNA vaccines prepared from a common plasmid vector but encoding different antigens behave similarly, biodistribution studies may be waived for DNA vaccines based on platform data from vaccines with the same plasmid vector, but with a different gene inserted.

For vaccines based on a Yellow Fever-derived vector, a nonclinical study is required to assess the neurovirulence.[11,12] As the potential risk for neurotropism is derived from the Yellow Fever vector and not from the inserted gene, performing such a study could be omitted if neurovirulence data from vaccines based on the same Yellow Fever vector are available.

Chemistry, manufacturing and controls

Also, during the chemistry, manufacturing and controls (CMC) development, the leveraging of existing data is possible. This can be considered in a wide range of manufacturing aspects, including process and formulation development, development of analytical procedures, specification setting, stability, and characterisation of impurities, for example.

The use of prior knowledge has been accepted previously by the EMA during the COVID-19 pandemic, for example. for Jcovden (Janssen COVID-19 Vaccine) where, based on experience with the Ad26 vaccine platform products, critical quality attributes (CQA), critical material attributes (CMA) and critical process parameters (CPP) were assigned. A process control strategy was also developed based on extensive platform experience.[13] It is also important to take into consideration that, at the time of initial marketing authorisation, Jcovden was granted 'conditional marketing authorisation' by the EMA.

More recently, during the approval of mRESVIA,9 the EMA also accepted prior knowledge for the development of analytical procedures.

Both the WHO[14] and the EMA[15] reference the possibility of using prior knowledge in their updated guidance on mRNA vaccines. The ICH Q2(R2) and ICH Q14[16,17] guidance of analytical method development also allows the use of prior knowledge.

The EMA toolbox guidance on quality data packages for PRIME applications offers a good framework where prior knowledge can be extrapolated in early development.[18]

It is also possible to leverage existing analytical methods developed for other vaccines based on the same platform. When an established platform analytical procedure is used for a new purpose, validation testing can be abbreviated, if scientifically justified. In certain cases, an analytical procedure can be applied to multiple

products with little or no modification of measurement conditions. For a new application of such platform analytical procedures, the subsequent development can be abbreviated, and certain validation tests can be omitted based on a science- and risk-based justification.

The validation package for methods can also be leveraged between different products based on the same platform, where appropriate.

When establishing the shelf-life claim of a novel vaccine, this could be supported by existing stability data of other vaccines based on the same platform. Different parameters would need to be considered to evaluate if making extrapolations is possible, including already tested stability conditions (including stress and accelerated testing conditions), similarity of degradation profiles, potential impact of novel antigen on stability, changes in manufacturing process between the different vaccines and comparability of batch analysis data, for example.

Shelf-life extrapolation would be particularly useful in the early development of vaccines, as it would avoid having to relabel clinical supplies during early clinical trials. This would be particularly true in cases where the first-in-human studies are performed in patients.

Performance of confirmatory stability studies would still be required for novel vaccines based on the same platform, but existing stability data would also support the rational design of this stability. Based on the existing experience, one could assess which release criteria remain stable over time and therefore should not be assessed at each timepoint.

When leveraging CMC data between products, it is important to have an in-depth understanding of parameters that are dependent on the platform, compared with which parameters are product specific. Conclusive risk assessments in case product-specific data are reduced or omitted as prior knowledge will be required. It will therefore be a case-by-case decision as to whether the use of existing data will be considered acceptable.

Integrating prior knowledge in early clinical trials

The extent to which prior knowledge/platform approaches can be used in regulatory submissions depends on the degree of similarity between the structural composition, intended effect, manufacturing process and product quality, and proposed context of use between the different vaccines based on the same platform.

The approach of using prior knowledge can, in principle, be applied to all types of biologicals, including, for example, mAbs and other therapeutic proteins, vaccines, viral vectors, cell therapy products and vaccines. However, it is acknowledged that the principle will be difficult to apply to other groups of products and formulations where data are unavailable (for example, data from mAbs is unlikely to apply in general to other types of recombinant products). For complex products in particular, the prior knowledge is expected to be based on very similar products (for example, same viral vector with a similar genetic construct carrying a different gene of similar size).

The leveraging of clinical data with other similar products can support the dose selection (including the selection of starting dose based on existing safety data), as well as the proposed dosing schedule on trials with new products. It can also support other elements of trial design, such as the selection of relevant timepoints.

Platform designations

The FDA established a Platform Designation Program in 2024.[19] This designation needs to be formally requested by the pharmaceutical company to the FDA and is subject to several eligibility criteria. One of the criteria for this designation is that it needs to be incorporated within, or used by, an approved drug product (NDA/ANDA) or licensed biologic (BLA), which limits its use for early stage biotech companies who are developing multiple products based on the same platform.[20] It is recommended that organisations engage in formal discussions with the FDA before applying for the platform designation.

In the EU, there is currently no equivalent for the FDA Platform Designation Program. However, the newly proposed EU pharmaceutical legislation[21] proposal contains provisions for 'platform technology', which it defines as a technology or collection of technologies that is comprehensive, well-characterised, reproducible and used to support the development, manufacturing process, quality control, or testing of medicinal products or their components that rely on

prior knowledge and that are established under the same underlying scientific principles.

It also introduces the notion of a 'platform technology master file' prepared by the owner of the platform technology. This would contain data of a platform technology for which the underlying scientific principles, under which the platform technology is established, have reasonable scientific certainty to remain unchanged across products and to apply regardless of components added to the platform for a medicinal product.

Future development

The expansion of the use of prior knowledge is currently being discussed in the framework of pandemic preparedness and in the framework of accelerated development of products for which there is a high unmet medical need.[22,23] The establishment of a regulatory framework for the use of prior knowledge could be supportive in the development of these products.

Conclusion

The use of 'prior knowledge' and/or 'platform approach' is already an established practice in vaccine development at the time of marketing authorisation. However, the same principles can be applied in the early development of vaccines. It is currently accepted by regulators on a case-by-case basis, depending on the relevance and robustness of the data with similar products. Importantly, it creates a positive environment to help accelerate the development of new medicinal products, in emergency situations such as a pandemic.

Timely interaction with regulators is nevertheless essential, to ensure the acceptance of existing data of other products based on the same platform.

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VACCINES BEAT

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