VACCINES BEAT

VACCINES FOR ALL: PIONEERING STRATEGIES FOR SUSTAINABLE GLOBAL HEALTH

Dr. Jerome Kim shares his trajectory at the helm of the International Vaccine Institute

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

WORLD HEALTH ORGANIZATION

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Dr. Jerome Kim shares his trajectory at the helm of the International Vaccine Institute

Jerome H. Kim, M.D., serves as the Director General of the International Vaccine Institute (IVI) and is an international expert in vaccine development and evaluation.

Before joining IVI, Dr. Kim held several prominent positions, including Principal Deputy of the U.S. Military HIV Research Program and Chief of the Laboratory of Molecular Virology and Pathogenesis at the Walter Reed Army Institute of Research. He was also the U.S. Army Program Manager for HIV vaccines and led the Army's RV144 Phase III HIV vaccine trial, which demonstrated efficacy in preventing HIV-1.

Dr. Kim is an Adjunct Professor in the Department of Medicine at the Uniformed Services University of the Health Sciences in Bethesda, USA, and at the Graduate School of Public Health at Yonsei University in the Republic of Korea. He is also an Honorary Professor at the University of Rwanda and was named a Distinguished Visiting Professor at Seoul National University in 2022. He has authored over 350 publications.

A graduate of the University of Hawaii, Dr. Kim earned high honors in History and the highest honors in Biology. He received his M.D. from Yale University School of Medicine and completed his training in Internal Medicine and Infectious Diseases at Duke University Medical Center.

Full Bio

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LETTER FROM EDITORS

WELCOME TO THE 9TH ISSUE OF VACCINES BEAT

As we present our 9th issue, we reflect on a somber milestone: the fifth anniversary of the WHO's declaration of COVID-19 as a pandemic. With over 7 million lives lost, trillions of dollars in economic damage, and countless personal tragedies, we might expect the world to have learned critical lessons. Unfortunately, many governments and societies still fall short in their preparedness for future health threats.

In this issue's "Coffee with an Expert" section, we are excited to feature an interview with Prof. Jerome Kim, the Director General of the International Vaccine Institute (IVI). Based in South Korea, IVI has offices in Europe and Africa and branches across all five continents. In our candid and insightful discussion, Prof. Kim provides a historical perspective on IVI's role in advancing vaccines, both independently and in collaboration with various organizations and governments. He highlights IVI's contributions to the entire vaccine ecosystem—from education, R&D, and clinical development to regulation, manufacturing (including technology transfer to developing countries), and global implementation. Additionally, he shares IVI's future outlook, focusing on the development of new vaccines, innovative administration methods, and expanded global dissemination strategies.

In the "Editor's Corner," we explore the concerning resurgence of Pertussis, particularly the increase in cases following the replacement of whole-cell Pertussis (wP) vaccines with acellular Pertussis (aP) vaccines, spurred by fears of neurological side effects. We examine the implications of this shift on disease control and discuss strategies to address current challenges and shape future vaccination efforts.

Our "Best Practice" section emphasizes the importance of combination vaccines as a critical strategy for accelerating the elimination of vaccine-preventable diseases. Meanwhile, we thank renowned vaccine expert, Dr. Jeffrey J. Stoddard, for his insightful article in our "Guest Contributors" section, which highlights the vital role of physicians in the innovation of new medicinal products and health and wellness therapies.

Thank you for joining us in this important conversation.

Javier Casellas, M.D., Ph.D.
Chief Editor

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

Javier Casellas

Well-recognized Argentinian Pediatrician and Infectious Diseases Specialist with more than 17 years of experience on Medical Affairs & Clinical Research on Vaccines field within different multinatinational & recognized Pharmaceutical Companies. (GSK and Novartis Vaccines)

From 2005 to 2015 Dr. Casellas worked as Vaccines Medical Affairs / Clinical Research Director (GSK and Novartis vaccines in Latam Region) with experience on vaccine clinical research, medical affairs activities, vaccine pharmacovigilance, public & private vaccine market access, strong relationship with MoHs across Latam and supranational organizations (such as PAHO, and Sabin Institute), and has published several scientific papers and posters in international journals and meetings, among the most relevant medical activities.

Since 2016 Dr. Casellas became an Independent Vaccine Consultant. From 2016 to 2018, Dr. Casellas joined an NPO (FIDEC, Miami, FL, USA) as Medical Manager working on vaccine clinical trials along with Bill and Melinda Gates Foundation. Currently, Dr. Casellas works on global & regional Vaccine and Infectious Diseases (IDs) trials at IQVIA as Global Medical Director within the Infectious Diseases and Vaccines Team.

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.

He is an Overseas Fellow of the Royal Society of Medicine of the United Kingdom and a member of several international associations in Infectious Diseases. 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 a member of the Mexican Committee for the Elimination of Measles, Rubella, and Congenital Rubella, and the Scientific Committee on Health Issues of the Mexican Government in Baja-California. 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

VACCINES FOR ALL: PIONEERING STRATEGIES FOR SUSTAINABLE GLOBAL HEALTH

Dr. Jerome Kim shares his trajectory at the helm of the International Vaccine Institute

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Jerome H. Kim, M.D., serves as the Director General of the International Vaccine Institute (IVI) and is an international expert in vaccine development and evaluation.

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A graduate of the University of Hawaii, Dr. Kim earned high honors in History and the highest honors in Biology. He received his M.D. from Yale University School of Medicine and completed his training in Internal Medicine and Infectious Diseases at Duke University Medical Center.

As part of his achievements, Dr. Kim has received numerous awards, including the John Maher Award for Research Excellence from the Uniformed Services University (2013), the Department of the Army Research and Development Achievement Award for Technical Excellence (2013), the Asia Pacific Vaccine Excellence Lifetime Achievement Award (2021), and the Medal of Honor for Civil Merit from the Government of the Republic of Korea (2022).

https://www.ivi.int/who-we-are/leadership/jerome-h-kim/

The International Vaccine Institute (IVI)

Founded in 1997 as an initiative of the United Nations Development Program (UNDP), IVI's mission is to discover, develop, and deliver safe, effective, and affordable vaccines for global health.

Dr. Jerome Kim emphasizes the importance of this mission: "As a natural consequence of developing vaccines for countries and diseases that aren't common in the Global North, IVI is deeply committed to enabling countries and partners to establish vaccine security."

Before leading IVI in 2015, Dr. Kim was involved in technology transfer to enable the manufacturing of an HIV vaccine in Thailand. He reflects on IVI's accomplishments: "With a similar challenge to HIV, but now addressing other neglected disease vaccines, IVI has done remarkably well in its 27-year history."

For some countries, this means simply gaining access to vaccines, while in others—especially in the post-COVID-19 pandemic landscape—it's about ensuring vaccine security through local manufacturing and bolstering epidemiology, surveillance, discovery, development, and delivery.

"Although we work across the entire vaccine value chain—from epidemiology, to discovery, to delivery, to postmarketing surveillance and health economics—we do not manufacture vaccines ourselves. That's part of our establishment agreement," Dr. Kim asserts.

IVI's mission is critically relevant today, particularly in filling vaccine research and development gaps for neglected diseases that primarily affect low- and middle-income countries where major pharmaceutical companies often do not invest. Ironically, many neglected diseases are now emerging in high-income countries as well, necessitating a paradigm shift in global health.

Pharmaceutical companies are often driven by stockholder interests, and their revenues come from diseases affecting high-income countries," he emphasizes. "This situation places IVI in a unique position, as we understand the critical need to fill the gap and profound impact vaccines have on health, economic growth, pediatric development, cognitive development, and education."

IVI's portfolio

IVI's portfolio features an extensive array of vaccines in development. Collaborating with the World Health Organization (WHO), Gavi, National Immunization Technical Advisory Groups, and other organizations, IVI aims to create a compelling global health investment case, ensuring that vaccination can proceed smoothly once a safe and effective vaccine is available.

For example, technology transfers to several companies have resulted in the world's only stockpile of oral cholera vaccine, which previously held 70 million doses. However, demand for this vaccine has significantly outpaced manufacturing capacity, leaving the stockpile completely empty.

"We recently received funding to enter phase three testing for this technology-transferred oral cholera vaccine, which will be the first successful drug substance tech transfer to Africa since the 1930s. This is a testament not only to the capabilities of African manufacturers but also to our commitment to advancing vaccine technology to countries capable of achieving such technological feats," Dr. Kim proudly states. He also notes that IVI has developed a WHO pre-qualified typhoid conjugate vaccine.

Before any impact on public health can be realized, IVI provides cost-effectiveness data to ministries of health and finance, which will ultimately support the implementation of vaccination programs.

"In global health, when developing a cholera or typhoid vaccine, we must not only demonstrate that the vaccine is safe and effective but also provide the necessary economic and health justification for its use. We are well accustomed to this challenge," claims Dr. Kim.

IVI in Africa

Headquartered in Seoul, South Korea, IVI is increasingly focusing its efforts in Africa, supported significantly by the Bill & Melinda Gates Foundation's commitment to vaccine development in the region and other funders including CEPI. Rwanda hosts the IVI Africa

Regional Office, serving as the primary footprint for partner engagements. IVI's "Advancing Vaccine End-to-End Capabilities (AVEC)" program based in Kenya works toward sustainable vaccine manufacturing on the continent. IVI reaches more than 20 countries across Africa, aiming to secure grants that enhance the ecosystem by facilitating the transfer of capabilities to governments, academia, and manufacturers.

Currently, less than 1% of the vaccines used in Africa are manufactured locally, prompting countries to commit USD 5 billion to boost vaccine manufacturing. IVI is working to strengthen this relatively weak ecosystem to enable capabilities across the entire value chain. For context, South Korea improved its self-sufficiency in vaccine manufacturing from 20% in 2010 to about 50% in 2025, with a target of reaching 80% by 2030.

IVI takes vaccines from the laboratory to the clinic, collaborating with manufacturers to facilitate production and navigate regulatory approval for WHO pre-qualification. The organization also partners with regional authorities and WHO to make recommendations for vaccine use and works with Gavi to establish mechanisms for purchasing the vaccines. Through initiatives like Advancing Vaccine End-to-End Capabilities (AVEC), IVI serves as the project management agency to ensure successful execution.

"Africa has now developed solutions on its own. Gavi is committed to the African Vaccine Manufacturing Accelerator (AVMA), which enables them to purchase African-manufactured vaccines at a slightly higher cost. However, the broader ecosystem is still not fully established," Dr. Kim notes, emphasizing the importance of public-private partnerships.

Vaccines as a commodity

While vaccines are highly specialized and unique, Dr. Kim notes that they are often treated as commodities in the global trade arena. Vaccines have become standardized, fungible goods purchased in large quantities from the lowest bidder in the market.

This has led to significant efficiency and consolidation in vaccine manufacturing in the Global North, where market forces largely dictate pricing. However, this model falls short when it comes to equitable allocation of vaccines. Dr. Kim argues that national security interests often overshadow market dynamics.

So how do these models fit into the broader landscape of global health? Some countries are advocating for private ownership, while others rely on state and international funding to advance vaccine production. Many nations recognize the necessity of paying a bit more for local manufacturing security, understanding that without their purchases, companies may cease to exist. With the development of local manufacturing capacity comes the expectation of higher vaccine costs.

However, the high efficiency and quality of vaccines produced by major pharmaceutical companies make it challenging for smaller manufacturers to compete, especially as new vaccines are introduced.

"Actually, the largest burden of unvaccinated children is in middle-income countries, which do not benefit from Gavi's revolving fund and its dollar-a-dose vaccines. These countries often lack the birth cohorts large enough to negotiate effectively with manufacturers and do not have local industries capable of fill-and-finish operations," Dr. Kim points out.

Currently, a model exists for countries willing to pay a bit more for vaccine security through regional agreements that allow for equitable distribution during pandemics, negotiated in advance of outbreaks.

"It's a complicated issue and somewhat counterintuitive. It highlights the failures of markets and the difficulties countries face in purchasing vaccines," he concludes. This situation challenges the conventional notion of free markets and their efficiency.

The future at IVI

IVI engages across the comprehensive vaccine research and development lifecycle that encompasses education, manufacturing, clinical development across all phases, regulation—including collaboration with WHO—and

implementation. In addition to traditional vaccine development, IVI is currently exploring innovative methods of vaccine delivery to complement conventional needle, syringe and oral routes.

"We have begun funding initial work on the development of patches for vaccine delivery, which we refer to as microarray patches or Multiple Antigen Presenting systems (MAPs). This remarkable technology includes a specific patch that will enter human clinical trials next month. You apply it, and within five minutes, it delivers more than 80% of the drug into the dermis," Dr. Kim explains.

When this technology becomes available, it could revolutionize the administration of essential vaccines, allowing for delivery without the need for a specialist. Moreover, newer versions of the patch, provided they can freeze-dry or lyophilize the product, have the potential to hold multiple vaccines.

"Currently, there is work underway on a pentavalent version of the patch. We know that we can incorporate mRNA into a patch, and preliminary results in animals show that it produces levels comparable to those achieved through injection. This could be the next significant advancement," he shares enthusiastically.

"I believe that the model of innovation to advance global health goals is crucial and will make a substantial difference in the long term. At a small international organization like IVI, we are committed to creating benefits not only for the global community but also for the countries that support us," Dr. Kim concludes.

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.

"On the fifth anniversary of COVID-19, the world must reassess the global tragedy—over 7 million lives lost, trillions of dollars in economic damage, the persistent burden of long COVID, and, most critically, our preparedness for the next pandemic, an ever-present global threat. Yet, nations appear more inclined to invest in warfare than in healthcare prevention, despite the fact that pandemics have historically claimed more lives and caused far greater societal and economic devastation. Moreover, despite the fact that vaccines and vaccination were instrumental in restoring normalcy, anti-science and anti-vaccine movements are expanding at an alarming rate, inflicting immense harm with potentially even deadlier consequences. Have we truly learned from our past?"
https://www.reuters.com/business/healthcare-pharmaceuticals/five-years-economic-impact-covid-19-lingers-2025-03-08/

https://time.com/7266503/covid-19-pandemic-5-years/

https://www.scientificamerican.com/article/on-covids-fifth-anniversary-scientists-reflect-on-mistakes-and-successes/

"Summary of WHO Position Papers - Recommendations for Routine Immunization, updated January 2025".
https://cdn.who.int/media/docs/default-source/immunization/immunization_schedules/table_1_january_2025_web_english.pdf?sfvrsn=2e112cea_10&download=true

"Kingdom of Saudi Arabia confirms US$ 500 million commitment to global polio eradication effort".
Published: February 24, 2025.
Critical funds will be immediately disbursed to the Global Polio Eradication Initiative to help end wild polio in Pakistan and Afghanistan and stop outbreaks of variant polio.

https://polioeradication.org/news/kingdom-of-saudi-arabia-confirms-us-500-million-commitment-to-global-polio-eradication-effort/

"CDC: Measles Cases and Outbreaks in the US".
Updated to: March 15, 2025.
As of March 15, 2025, the US has reported 301 cases of measles:

Ages:

- Under 5 years: 103 (34%)
- 5-19 years: 126 (42%)
- 20+ years: 63 (21%)
- Age unknown: 9 (3%)
- Vaccination Status
- Unvaccinated or Unknown: 95%
- One MMR dose: 3%
- Two MMR doses: 2%

Of the 301 reported cases, 259 (86%) originated in West Texas, primarily within a Mennonite

community, before spreading to New Mexico, other U.S. states, and even Mexico. Among these cases, 50 (17%) required hospitalization, and tragically, two individuals—one child and one adult, both unimmunized—have died.

https://www.cdc.gov/measles/data-research/index.html

https://www.dshs.texas.gov/news-alerts/measles-outbreak-2025

"Weekly Special Press Briefing on the Mpox Outbreak and other Health Emergencies in Africa".
Published: February 24, 2025.
https://africacdc.org/news-item/weekly-special-press-briefing-on-the-mpox-outbreak-and-other-health-emergencies-in-africa-17/

"TBE cases, United Kingdom, 2015-2023".
Published: February 2025.
https://tbenews.com/tbe/tbe-cases-united-kingdom-2015-2023/

"Ixchiq - opinion on variation to marketing authorisation".
Published: February 28, 2025.
Comment: On 27 February 2025, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending a change to the terms of the marketing authorisation for the medicinal product Ixchiq. The marketing authorisation holder for this medicinal product is Valneva Austria GmbH. The CHMP adopted an extension to the existing indication to include active immunisation of children from 12 years of age.

https://www.ema.europa.eu/en/medicines/human/variation/ixchiq

"Cluster of community deaths in Basankusu, Equateur- Democratic Republic of the Congo".
Published: March 3, 2025
Comment: On 9 February 2025, officials in the Democratic Republic of the Congo reported to regional health authorities a cluster of 24 unexplained community deaths in a single village in Ekoto health area, Basankusu health zone, Equateur province. As of 25 February, a total of 53 deaths have been reported, with the last death occurring on 22 February. Deaths have occurred in all age groups, but adolescents and young adults, particularly males, appeared to be disproportionately affected in the initial cluster reported. Disease progression appeared to be fast, with a median time from onset of symptoms to death of one day. Given the rapid decline in the incidence of reported deaths, their geographic clustering, the age profile of deaths and the rapid disease progression in the initial cluster, working hypotheses include chemical poisoning or a rapid onset bacterial meningitis cluster, on a background of malaria and other infectious illnesses endemic in the region. The definitive cause of illness remains undetermined, with initial samples testing negative for Ebola and Marburg viruses.

https://www.who.int/emergencies/disease-outbreak-news/item/2025-DON557

"France's Next Chikungunya Outbreak".
Published: March 6, 2025.
Comment: On March 5, 2025, a Mamoudzou resident returned from visiting La Reunion Island, another of France's overseas departments. These departments are separated by the island of Madagascar and the Mozambique Channel. Following this identification, the ARS of Mayotte immediately implemented vector control actions to identify larval breeding sites around the person's home. Local health professionals and emergency services have been informed of the situation.No indigenous case has been reported in Mayotte to date. Generally, a single, travel-related Chikungunya case does not generate significant actions. However, since late August 2024, La Reunion has been facing a Chikungunya epidemic, with 3,390 cases recorded. In mainland France, 25 travel-related cases were reported in 2024. And, for the first time, Ile de France (Paris) reported a locally acquired Chikungunya case. The World Health Organization says Chikungunya transmissions have occurred frequently in about 110 countries.

https://www.vax-before-travel.com/2025/03/06/frances-next-chikungunya-outbreak

"The world should prepare now for a potential H5N1 flu pandemic, experts warn".
Published: March 6, 2025.
Comment: In a letter to the journal Science, CEPI's Executive Director for Preparedness and Response Dr Nicole Lurie and six other experts said the bird flu virus – known as H5N1 and known to be very severe in some human cases—had in recent years crossed species from birds to mammals, including dairy cattle, and was now causing widespread exposure and sporadic human infections in the U.S. and beyond. At least one person has died from H5N1 infection in the U.S., and a teenager in Canada suffered critical illness before eventually recovering. "Pandemic preparedness initiatives should be urgently resourced and implemented," they wrote. "Enhancing readiness now can save lives and reduce societal and economic disruption if H5N1 or another outbreak becomes a pandemic."

https://cepi.net/world-should-prepare-now-potential-h5n1-flu-pandemic-experts-warn

"Europe's Chikungunya Cases Come From India and the Caribbean Islands".
Published: March 10, 2025.
With international travel accelerating in 2025, a recent study offers an overview of Chikungunya infections in mainland Europe over the past two decades. This research article provides this mosquito-transmitted disease's epidemiological characteristics, diversity, and clinical manifestations.

https://www.vax-before-travel.com/europes-chikungunya-cases-come-india-and-caribbean-islands-2025-03-09

"Africa CDC website."
https://africacdc.org/

"Disease Outbreak News: Sudan virus disease - Uganda, 8 March 2025".
Since the outbreak of Sudan virus disease (SVD) was declared in Uganda on 30 January 2025, and as of 5 March 2025, a total of 14 cases (including 12 confirmed cases and two probable cases) including four deaths (two confirmed and two probable) have been reported.

https://reliefweb.int/report/uganda/disease-outbreak-news-sudan-virus-disease-uganda-8-march-2025

"Chikungunya epidemic in Reunion Island"
The mobilisation of all stakeholders and the population is necessary to avoid a large-scale chikungunya epidemic in Reunion Island.

https://lnkd.in/eqfynutP 23FEB25

"DRC Fever Cases Investigation" Special Briefing on Mpox & other Health Emergencies || March 6, 2025
Video: Special Briefing on Mpox & other Health Emergencies || March 6, 2025

"Middle East respiratory syndrome coronavirus - Kingdom of Saudi Arabia"
Published: March 13, 2025.
Middle East respiratory syndrome coronavirus - Kingdom of Saudi Arabia

Between 6 September 2024 and 28 February 2025, the Ministry of Health (MoH) of the Kingdom of Saudi Arabia (KSA) reported four cases of Middle East respiratory syndrome coronavirus (MERS-CoV) infection, including two deaths, with the last case being reported on 4 February 2025. The cases were reported from the Hail (2), Riyadh (1) and the Eastern (1) Provinces of the KSA (Figure 1). Laboratory confirmation of the cases was performed by real-time polymerase chain reaction (RT-PCR) between 8 November 2024 and 4 February 2025.

All cases involved males aged between 27 and 78 years, and all presented with comorbidities. None were health workers, and from investigations only one was found to have indirect contact with dromedary camels (hosts of MERS-CoV) and their raw products (milk).

Two cases, with symptoms onset in November 2024, were identified within the same hospital. The first case was confirmed on 11 November through RT-PCR testing, and follow-up on close contacts revealed a secondary case that shared the same hospital room and developed symptoms subsequently. Neither of the two patients had direct or indirect contact with dromedary camels,

including consumption of raw camel milk in the 14 days prior to the onset of symptoms.

Since the first report of MERS-CoV in KSA in 2012, a total 2618 laboratory-confirmed cases of MERS-CoV infection, with 945 associated deaths (CFR 36%), have been reported to WHO from 27 countries, across all six WHO regions. The majority of cases (2209; 84%), have been reported from KSA, including these newly reported cases. Since 2019, no MERS-CoV infections have been reported from countries outside the Middle East.

"Tanzania declares end of Marburg virus disease outbreak"
Published: March 13, 2025.
Since the last Disease Outbreak News on this event, published on 14 February 2025, no new confirmed cases of Marburg virus disease (MVD) have been reported in the United Republic of Tanzania.

As of 12 March 2025, 10 cases have been reported including two confirmed and eight probable cases. All cases resulted in deaths, including eight who died before the confirmation of the outbreak and were classified as probable cases, resulting in a case fatality ratio of 100%.

The first identified case, an adult female, had symptom onset on 9 December and died on 16 December 2024. The last confirmed case died on 28 January, and a safe and dignified burial was performed. No new confirmed or probable cases have been reported following this burial. All 10 cases were reported from Biharamulo district in Kagera region; the median age of cases was 30 years (range: 1 to 75 years) and the majority of cases (70%, 7) were females.

Cumulatively, 108 suspected cases were reported between 20 January and 11 March, of which 106 tested negative for MVD.

As of 12 March 2025, 281 contacts had been listed, including nine who were subsequently classified as probable and confirmed cases and 272 contacts who completed 21 days of follow-up.

On 13 March 2025, after two consecutive incubation periods (a total of 42 days) without a new confirmed case being reported after the last confirmed case died on 28 January 2025, the Ministry of Health of the United Republic of Tanzania declared the end of the MVD outbreak, as per WHO recommendations.

https://www.afro.who.int/countries/united-republic-of-tanzania/news/tanzania-declares-end-marburg-virus-disease-outbreak

"Human Cases of Highly Pathogenic Avian Influenza A(H5N1) — California, September–December 2024"
Published: Weekly / March 13, 2025 / 74(8);127–133
During September 30–December 24, 2024, a total of 38 persons received a positive test result for HPAI A(H5N1) viruses in California; 37 were dairy farm workers with occupational exposure to sick cows. One, a person aged <18 years with an undetermined exposure, was the first pediatric patient detected with influenza A(H5) infection in the United States.

What are the implications for public health practice?

Public health agencies should investigate influenza-like illness or conjunctivitis in workers with occupational exposure to animals infected with HPAI A(H5N1) virus. Thorough investigations of all human HPAI A(H5N1) virus infections are necessary to identify potential exposure sources, including monitoring the virus for concerning genetic changes that indicate the potential for person-to-person transmission.

"Chad officials seal schools as measles epidemic hits poor district".
Published: February 15, 2025.

https://www.voanews.com/a/chad-officials-seal-schools-as-measles-epidemic-hits-poor-district/7976693.html

Latest Relevant Publications

LATEST PUBLISHED PAPERS AND COMMENTARIES FROM THE CHIEF EDITORS

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

"Maternal RSVpreF and Infant Nirsevimab Immunizations Uptake During Respiratory Syncytial Virus Season"

Published: JAMA Network 2025; 8(2): e2460729. https://doi.org/10.1001/jamanetworkopen.2024.60729

Editorial comment: This retrospective cohort study included pregnant individuals, and their infants delivered between September 1, 2023, and January 31, 2024, at an urban academic center in Boston, MA. During the study period, 1,899 pregnant patients (median [IQR] age: 33.9 [30.9-36.8] years) were admitted for childbirth. Overall, 20.5% of mothers and 35.0% of infants received RSV immunizations, aligning with previous CDC reports but lower than the 35% maternal vaccination rate reported in a New York health system. Future research should explore systemic factors contributing to non-vaccination, particularly among pregnant women.

02

"Transplacental Antibodies: Role of Maternal Vaccines and Immunity"

Published: Clin Perinatol 2025; 52: 101-13. https://doi.org/10.1016/j.clp.2024.10.007

Editorial comment: A compelling, comprehensive, and practical review of maternal vertical protection to the newborn through the placenta, highlighting the numerous protective benefits of maternal immunization, particularly during the third trimester.

03

"WHO defeating meningitis symposium, 3rd international symposium on Streptococcus agalactiae disease (ISSAD) in Rio de Janeiro, Brazil: State-of-the-art overview of S. agalactiae meningitis"

Published: Vaccine 2025; 52: 126895. https://doi.org/10.1016/j.vaccine.2025.126895

Editorial comment: The World Health Organization (WHO) Defeating Meningitis Symposium was held as part of the 3rd International Symposium on Streptococcus agalactiae Disease (ISSAD) conference, which took place in Rio de Janeiro, Brazil, from October 16–18, 2023. The symposium highlighted WHO's Defeating Meningitis by 2030 global roadmap, with a particular focus on Group B Streptococcus (GBS) meningitis. It provided an overview of the disease burden and the key challenges in combating meningitis across the Americas, Africa, and Asia.

04

"Exploration of a GMMA-Based Bivalent Vaccine Against Klebsiella pneumoniae"
Published: Vaccines 2025; 13: 226. https://doi.org/10.3390/vaccines13030226

Editorial comment: Klebsiella pneumoniae is a bacterium responsible for thousands of local and systemic infections, often associated with multidrug resistance (MDR), particularly in vulnerable populations such as hospitalized patients, immunocompromised individuals, and the elderly. Vaccination against this potentially lethal pathogen is a priority for many health organizations. This study evaluates the initial efficacy and safety of a recombinant strain developed using Generalized Modules for Membrane Antigens (GMMA) technology in animal models—an encouraging candidate for further investigation in human clinical trials.

05

"Prevalence, clinical management, and outcomes of adults hospitalized with endemic arbovirus illness in southeast Europe (MERMAIDS-ARBO): a prospective observational study"
Published: Lancet 2025: https://doi.org/10.1016/S1473-3099(24)00655-8

Editorial comment: In this prospective observational study (MERMAIDS-ARBO), the authors enrolled adults hospitalised with an arbovirus-compatible disease syndrome within 21 days of symptom onset across 21 hospitals in seven countries in southeast Europe over four arbovirus seasons (May 1–Oct 31, during 2016–19). The primary outcome was the proportion of participants with confirmed or probable acute infections with West Nile virus (WNV), tick-borne encephalitis virus (TBEV), Crimean–Congo haemorrhagic fever virus (CCHFV), or Toscana virus (TOSV), per reference laboratory criteria. Of 847 participants with a reference laboratory sample who met full eligibility criteria for analysis, 110 (13%) were diagnosed with 114 confirmed or probable acute arbovirus infections (four had coinfections or cross-reactivity): one (<1%) with CCHFV, 16 (2%) with TBEV, 44 (5%) with TOSV, and 53 (6%) with WNV. There was one death (<1%) of an individual with WNV. Of the 110 participants, 49 (45%) had a local clinician-attributed arbovirus discharge diagnosis. These data highlight the need to strengthen arbovirus surveillance systems for the early detection of emerging and re-emerging outbreaks, including investments to increase awareness of arbovirus infections among clinicians, to improve access to specialist diagnostics, and to develop effective and accessible vaccines and treatments to protect populations and health systems in southeast Europe.

06

"Associations of COVID-19 vaccination with risks for post-infectious cardiovascular complications: an international cohort study in cancer patients with SARS-CoV-2 infection."
Published: Lancet Regional Health - Americas 2025; 44: 101038. https://doi.org/10.1016/j.lana.2025.101038

Editorial comment: A retrospective cohort study showing that COVID-19 vaccination was associated with a reduced risk of cardiac complications and cardiovascular events by 34% and 24%, respectively, after SARS-CoV-2 infection in patients with cancer.

07

"Next-generation seasonal influenza virus vaccines need a neuraminidase component"
Published: Vaccine 2025; 54: 126994.

Editorial comment: This insightful commentary highlights the potential need to incorporate neuraminidase components into future influenza vaccines. The rationale behind this approach is that relying solely on hemagglutinin antigens increases the risk of inadequate coverage against antigenic drift and limits cross-protection, particularly in the face of a potential influenza pandemic, among other public health issues.

08

"Cost-effectiveness analysis of 21-valent pneumococcal conjugated vaccine among adults in Canada"
Published: Vaccine 2025; 54: 126126985. https://doi.org/10.1016/j.vaccine.2025.126985

Editorial comment: In this pharmacoeconomic study, by using a static cohort model to estimate lifetime incremental cost-effectiveness ratios (ICERs), in 2023 Canadian dollars per quality-adjusted life year (QALY), PCV21 was cost-effective at a $50,000 per QALY threshold and dominated PCV20 in most scenarios when PCV21 serotypes were more prevalent.

09

"Antibody Response to Pertussis Vaccine Among Children and Adolescents in Croatia: A Cross-Sectional Prevalence Study."

Published: Vaccines 2025; 13: 228. https://doi.org/10.3390/vaccines13030288

Editorial comment: The current national vaccination program does not completely control the transmission of Bordetella pertussis in Croatia. This cross-sectional seroprevalence study aimed to measure the prevalence of IgG antibodies to pertussis toxin (IgG-anti-PT) in regularly vaccinated Croatian children of 6–18 years of age and to estimate the duration of pertussis vaccine-induced immunity elicited by the National Immunization Program (NIP) with respect to the transition from a mixed acellular pertussis (DTaP) and whole-cell pertussis (DTwP) vaccine regimen to a DTaP regimen. Single-serum IgG-anti-PT concentrations were measured using a commercial enzyme-linked immunosorbent assay (ELISA) and analyzed in twelve age groups from 2020 to 2023. According to the manufacturer's classification, IgG-anti-PT concentrations of <40 IU/mL were considered to be negative (no protection). Most subjects had an IgG-anti-PT concentration < 40 IU/mL (95.1%). Although introducing a booster pertussis vaccine could be suitable for young adolescents to strengthen their immunity, before such a recommendation, it would be useful to initiate further research to complement the results obtained in this study, perhaps not to remove the booster dose with DTwP.

10

"A journey worth taking: global eradication of measles, rubella and congenital rubella syndrome"

Published: Review of Vaccines, 24(1), 173–174. https://doi.org/10.1080/14760584.2025.2476535

Editorial Comment: Yet because of inaction, measles and rubella continue to kill and maim children. The opportunity to rid the world of measles and congenital rubella syndrome, therefore, must be seized without delay.

11

"Effectiveness of nirsevimab in reducing hospitalizations in emergency departments due to bronchiolitis among infants under 3 months: a retrospective study"

Published: Eur J Pediatr 184, 229 (2025). https://doi.org/10.1007/s00431-025-06050-7

Editorial Comment: What is New:

• Nirsevimab showed 53.5% (95% CI 34.1–67.3) adjusted effectiveness in reducing hospitalizations for all-cause bronchiolitis in infants aged < 3 months in emergency departments.

• Analyses included social deprivation and highlighted potential disparities in immunization access.

12

"Chikungunya virus in Europe: A retrospective epidemiology study from 2007 to 2023"

Published: PLoS Negl Trop Dis 19(3): e0012904. https://doi.org/10.1371/journal.pntd.0012904

Editorial Comment: This study provides the first overview of chikungunya infections in mainland Europe in the time period 2007–2023. The 4730 chikungunya cases were reported in 22 countries, predominantly affecting females aged 45–64 years. The United Kingdom had the highest number of cases (21.9%), followed by France (19.6%), Germany (14.5%), and Italy (13.6%). Bubble plot illustrating the dynamics of age-standardized incidence rates by country per year showed significant variation. The majority of chikungunya infections in humans were travel-related, with most cases originating from India (11.7%), Dominican Republic (9.0%), Guadeloupe (8.7%), and Thailand (7.8%). Chikungunya cases in Europe showed a seasonal pattern with peaks mainly associated with summer vacation. Two genotypes were identified based on genome sequencing, with the II-ECSA genotype being predominant. Common symptoms included fever (97.6%), joint pain (94.3%), and fatigue (63.5%).

13

"Novel strategy for whole-genome sequencing of hepatitis A virus using NGS illumina technology and phylogenetic comparison with partial VP1/2A genomic region"
Published: Sci Rep 15, 6375 (2025). https://doi.org/10.1038/s41598-025-91116-7

Editorial Comment: HEPATITIS A OUTBREAK IN ARGENTINA: The study of partial VP1/2A regions (mainly the 1084 bp fragment) would constitute useful alternatives for outbreak investigation and surveillance when WGS could not be performed.

14

"Increase in Hepatitis A Cases in Argentina" (Spanish Version)
Published: comunicacion_epidemiologica-hepatitis_vf.pdf 19 FEB2025

Editorial Comment: In the context of epidemiological surveillance, a variation in the incidence of hepatitis A has been observed in recent years. During the five-year period 2019-2023, an average of 31 cases were reported annually, with a minimum of 10 in 2021 and a maximum of 55 in 2022. In 2024, 69 cases were confirmed, exceeding the alert threshold starting in week 39. Since the beginning of 2025, the number of confirmed cases reported has been higher than expected.

15

"Effective communication strategies and practices for dengue and other arboviral diseases: Systematic review"
Published: 2024-12-17 - Document Number: PAHO/CDE/VT/24-0017

Editorial Comment: This work proposes to adopt a unified and coherent government approach to communication strategic and operational, involving partners and allies from the non-governmental sector. This involves defining and implement a system that guarantees the coherence of messages between the national government and the local health authorities, as well as developing content guides aimed at obtaining messages unified and define protocols for the release of public information in emergency situations health, such as the spread of dengue and other diseases caused by arboviruses. In summary, we are looking for comprehensive, coordinated and evidence-based communication to effectively confront the emergency of public health represented by arboviral diseases.

16

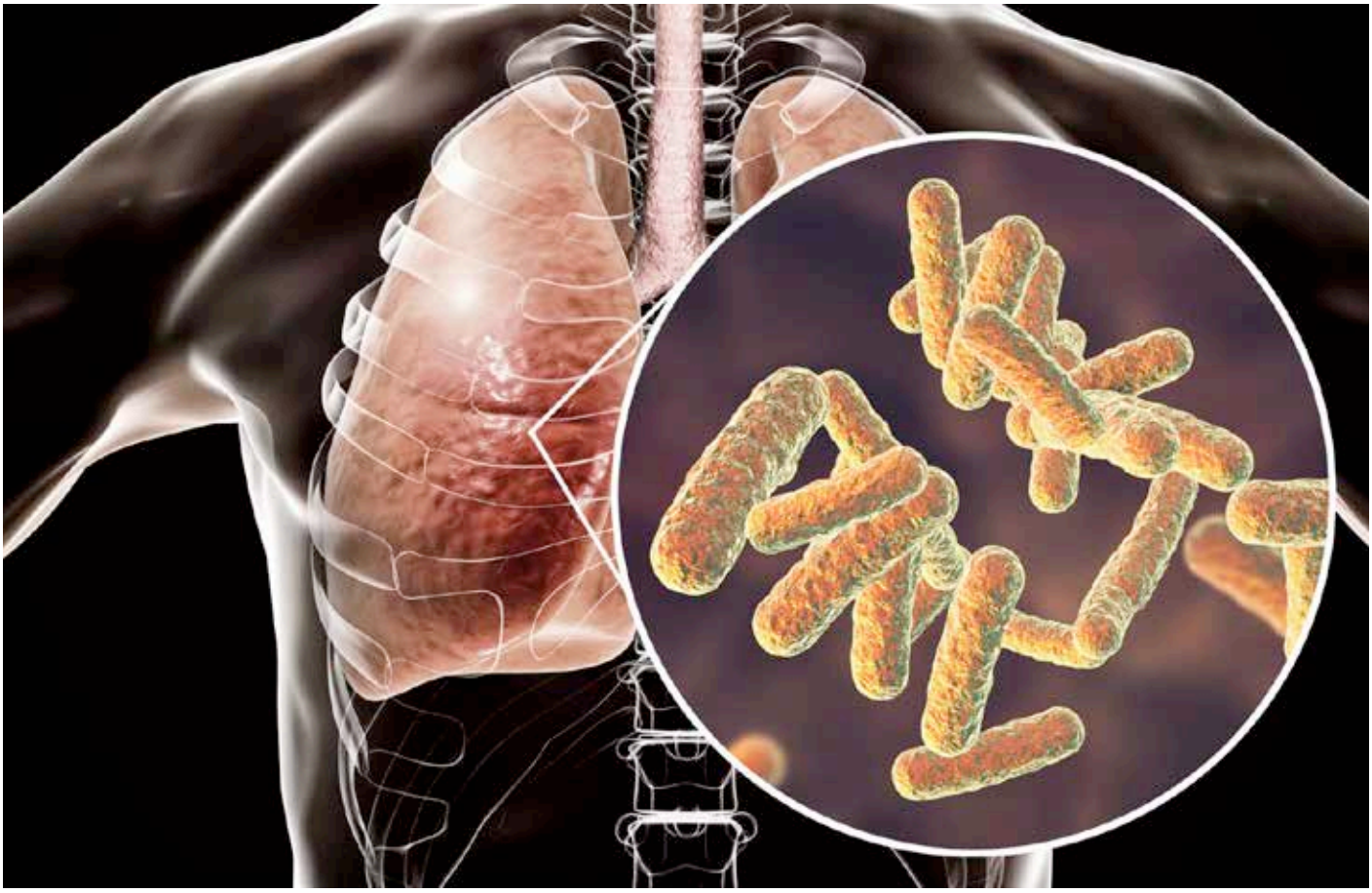
"The research and development landscape of mpox vaccines"
Published: Lancet Infect Dis 2025 (February). https://doi.org/10.1016/S1473-3099(25)00115-X

Editorial comment: A concise summary of the three licensed mpox vaccines, the five currently in clinical development, and the fifteen in either the investigational new drug (IND) approval process or pre-IND stage. Additionally, an insightful overview of the various platforms and targets being utilized, ranging from attenuated vaccinia viruses and poxvirus-based approaches to mRNA and novel mpox-specific platforms.

Editors Corner

THE FUTURE OF PERTUSSIS VACCINATION

What Comes After Acellular and Whole-Cell Vaccines?



Pertussis is a highly infectious respiratory disease, and even though vaccination has been globally implemented since the 1940s, we are far from elimination, and even still suffering from many outbreaks throughout the world.

1. Vaccination with whole cell Pertussis (wP) vaccine, a success: The establishment of the Expanded Program on Immunization (EPI) in 1974 significantly improved pertussis vaccination coverage. By the early 1980s, widespread vaccination efforts led to a dramatic reduction in the morbidity and mortality associated with the disease.

2. Safety Concerns, discontinuation of wP vaccine, and resurgence of Pertussis. In the 1980s, as the risks of pertussis markedly declined, public attention shifted from the dangers of the disease to concerns over vaccine side effects. Doubts regarding the safety of wP vaccines led to decreased public acceptance, and

in some countries, their use was completely discontinued. For example, in the United Kingdom and the United States, media coverage, including reports in newspapers and television programs, heightened fears about vaccine safety, contributing to declining vaccination rates. The reactogenicity of wP vaccines was extensively studied. The pertussis component—specifically the lipooligosaccharide—was identified as the primary factor responsible for vaccine-associated toxicity. Reported adverse reactions ranged from local effects such as redness, swelling, and pain at the injection site to systemic effects including fever (ranging from mild to high), persistent crying, irritability, and, in rare cases, seizures and encephalopathy.

3. Debunking the Myth: Encephalopathy and Seizures Associated with the Whole-Cell Pertussis Vaccine: In 1994, Jale G. et al. conducted a population-based case-control study involving 424 confirmed cases of neurological illness identified through statewide active surveillance over a 12-month period. The study population consisted of 218,000 children aged 1 to 24 months living in Washington and Oregon, who received an estimated 368,000 DTP immunizations. The odds ratios (OR) for specific neurological diagnoses within seven days of vaccination varied, but all confidence intervals (CI) included 1, indicating no significant association. Furthermore, no elevated risk of nonfebrile seizures was observed. In 2001, Barlow W.E. et al. assessed the relative risks (RR) of febrile and nonfebrile seizures among 679,942 children after receiving 340,386 DTP vaccinations. The study found no increased risk of nonfebrile seizures following pertussis vaccination. Additionally, children who experienced febrile seizures after vaccination were not at higher risk of subsequent seizures or neurodevelopmental disabilities compared to children with febrile seizures unrelated to vaccination. At least three additional studies reported similar findings, providing no evidence of a link between WP vaccination and seizures or encephalopathy. However, variations in vaccine manufacturing processes may contribute to higher reactogenicity in some WP vaccines.

4. Concerns with acellular Pertussis (aP) vaccines:

a. Reduced duration of immunity compared to wP vaccines. Numerous studies indicate that immune protection against pertussis lasts between 10 and 20 years following natural infection and up to 12 years after whole-cell pertussis (wP) vaccination. In contrast, immunity from acellular pertussis (aP) vaccines typically wanes within 3 to 5 years, increasing susceptibility among school-aged children and necessitating booster doses at younger ages. Furthermore, cohort-based efficacy studies conducted in several European countries and Senegal, involving infants and toddlers who received three- or four-dose pertussis vaccine series, demonstrated that immunity waned more rapidly following aP vaccination compared to wP vaccination.

b. Reduced mucosal immunity compared to wP vaccines. Warfel, Merkel, et al. analyzed T-cell phenotypes in infant baboons before and after challenge infection with Bordetella pertussis and following wP or aP vaccination. As expected, Bordetella pertussis infection induced a predominantly TH17 immune response. Similarly, wP vaccination elicited a primarily TH17 response, accompanied by a lesser TH1 response, resulting in the production of both IgG and IgA antibodies. In contrast, baboons vaccinated with aP exhibited only TH2 responses, characterized mainly by IgE antibody production, which is unlikely to provide effective mucosal protection.

c. Reduced nasopharyngeal carriage and indirect (herd) immunity compared to wP vaccines. For both wP and aP vaccines, studies assessing nasopharyngeal (NP) carriage or colonization reduction were not conducted during late-phase 3 clinical trials or phase 4 cohort studies. Consequently, the impact of vaccination on indirect (herd) immunity remained unclear until recently. Research conducted in baboons by Warfel et al. demonstrated that wP vaccines, but not aP vaccines, reduce nasopharyngeal colonization, thereby contributing to indirect immunity. Supporting this finding in humans, a 2003 longitudinal study conducted in Senegal observed secondary attack rates among vaccine failures. The results showed that wP vaccination reduced secondary infections by 86%, compared to only 6% among individuals vaccinated with aP.

Acellular Pertussis vaccine implementation related to the increased number of Pertussis cases in developed countries. The licensure of aP was first started in 1991 as 4th and 5th doses only, followed by recommendation for all five doses in childhood by 1996-1997, as DTaP. Accordingly,

FIGURE 1
Trends of Pertussis incidence in the US, Australia, England/ Wales, and the Republic of Ireland. 1992 - 2012
Taken from Gil GJ, et al,28.

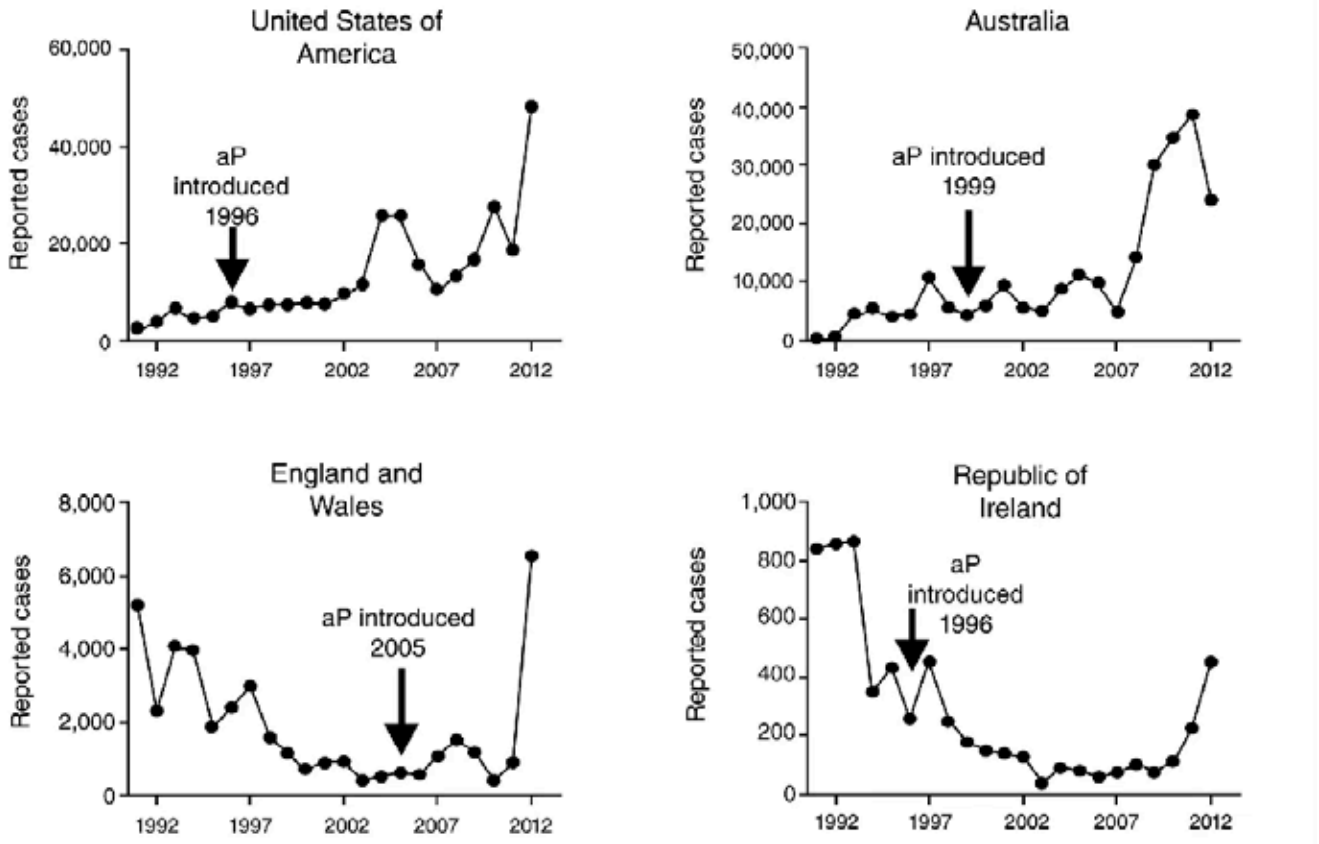


Figure adapted from Mills KHG et al, Trends in Microbiological Sciences, 2014 22(2): 49-52.

- US data from The Center for Disease Control and Prevention, Atlanta, GA, USA (http://www.cdc.gov/pertussis/fast-facts.html);
- Australia data from the National Notifiable Diseases Surveillance System, Office of Health Protection, Department of Health and Ageing, Canberra, Australia (http://www9.health.gov.au/cda/source/rpt_2_sel.cfm);
- UK data from The Health Protection Agency, London, UK; http://www.hpa.org.uk/hpr/archives/2013/hpr14-1713.pdf);
- Ireland data from The Health Protection, Surveillance Centre, Dublin, Ireland (http://www.hpsc.ie/hpsc/A-Z/VaccinePreventable/PertussisWhoopingCough/)-

a rise in Pertussis cases rose significantly in 2005, and was markedly increased by 2010. Similar trends occurred also in Australia, the Republic of Ireland, and England/Wales, with reemergence of Pertussis cases between 3 to 6 years of aP vaccine introduction (see Figure 1).

Proposed guidelines for Pertussis vaccination in infants and toddlers:

a. Countries using only WP vaccines. The World Health Organization (WHO) recommends a 3-dose primary series, with the first dose administered as early as 6 weeks of age; subsequent doses should be given 4–8 weeks apart, at age 10–14 weeks and 14–18 weeks. The last dose of the recommended primary series should ideally be completed by 6 months of age with either wP or aP vaccines.

b. Countries with mixed aP and wP vaccines schedules. No accepted serological correlate of protection after vaccination with either wP- or aP-containing vaccines has been established, although various parameters have been suggested, hence, interchangeability between wP and aP vaccines is difficult to assess in a non-large clinical trial. Nonetheless, few studies have addressed this issue, as an example, a novel liquid hexavalent DTwP-containing vaccine (EasySix, Panacea Biotec®)

was compared with Pentavac® + inactivated poliovirus (IPV) in a small study of around 300 infants in India, and it was reported that the immunogenicity would be similar. The lack of robust data resulted in a general recommendation from the WHO not to interchange wP or aP vaccines from different manufacturers during the primary series,45, though this recommendation is not universally followed.

c. Countries only using aP vaccines. Most developed countries use solely aP vaccines for primary immunization in infants. Returning to wP vaccines is not feasible since it would most likely carry out significant criticism by the media, and, particularly, antivaccination groups. Both the Pertussis Global Initiative and the WHO strongly recommend high vaccination coverages and enhancing surveillance.

d. Vaccination in adolescents, adults, and during pregnancy. Indeed, aP vaccines are currently the only option for these populations, and we strongly advocate for their use to enhance overall protection, as demonstrated by numerous studies. Specifically, for pregnant women, preventing pertussis in both the mother and the infant is crucial for ensuring optimal health outcomes.

Next steps:

a. Improve coverage.

b. Better surveillance.

c. New vaccine platforms: Recently, results from a phase 2/3 randomized-controlled clinical trial evaluating a monovalent pertussis vaccine containing recombinant, genetically inactivated pertussis toxin (aPgen®), either alone or as DTaPgen®, were published. These were compared to a chemically detoxified comparator vaccine (DTaPchem®). Three years post-vaccination, seroconversion rates for PT-neutralizing antibodies were 65.0% (95% CI 44.1–85.9) for aPgen® recipients and 55.0% (95% CI 33.2–76.8) for DTaPgen® recipients. Based on these results, the genetically detoxified aPgen® and DTaPgen® vaccines are expected to provide longer-lasting protection than chemically inactivated DTaP vaccines, although larger clinical trials are needed to confirm these findings. Mucosal (nasal) vaccines represent the ideal approach to immunization, as delivering immunogens via the natural route of infection could potentially induce stronger mucosal immunity and reduce nasopharyngeal colonization compared to intramuscular vaccines. This could result in better indirect (herd) immunity and a greater overall impact. Nasal vaccines are currently under development, with several animal studies completed and some human clinical trials in early stages. Examples of these platforms include live attenuated vaccines, aP vaccines with adjuvants, and nasal wP vaccines with outer membrane vesicle pertussis vaccines. We must await the results of phase 3 clinical trials to assess their efficacy.

Conclusions:

Despite being a vaccine-preventable disease, pertussis remains far from eradication in many regions worldwide. In a landscape where both whole-cell and acellular pertussis vaccines are in use, adherence to established vaccination guidelines is crucial to optimizing protection and safety for all populations. While prioritizing the immunization of young infants is essential, it is equally important to strongly recommend vaccination for adolescents and adults.

Guidelines from reputable organizations like the Global Pertussis Alliance and the World Health Organization emphasize the need to strengthen surveillance systems and pharmacovigilance efforts. Additionally, investing resources in the clinical development of novel and improved vaccines is key to addressing the evolving challenges of pertussis.

Ongoing medical education on pertussis and its vaccines, along with raising societal awareness about this potentially deadly disease, is of utmost importance. Such collective efforts are essential to maintaining a global, comprehensive approach to the prevention and control of pertussis.

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Best Practice

COMBINATION VACCINES

A Key Strategy for Accelerating the Elimination of Vaccine-Preventable Diseases

The core function of a vaccine is to trigger immune responses that specifically target a particular pathogen. Historically, vaccines were designed, developed, registered, recommended, procured, and administered as monopathogen formulations. However, the control and elimination of numerous diseases were only achieved after several previously separate vaccines were combined into single formulations.

Combination vaccines are numerous, with the measles-mumps-rubella (MMR) and diphtheria-tetanus-pertussis (DTP or DTaP) vaccines being among the most common. However, various other tetravalent, pentavalent, and hexavalent vaccines, which include DTP/DTaP alongside additional components such as *Haemophilus influenzae* type b (Hib), hepatitis B, inactivated polio vaccine (IPV), varicella, and others, are also used in different regions.

Additionally, combination vaccines for respiratory viruses, including influenza, SARS-CoV-2, and Respiratory Syncytial Virus (RSV), are expected to become available soon, as the development pipelines show great promise.

Finally, it is important to highlight combination vaccines targeting multiple serotypes of a single pathogen, such as multivalent pneumococcal and meningococcal vaccines.

Potential Value of Combination Vaccines vs. Coadministration of Separate Antigens

Vaccine Delivery

Potential Advantages

- Improved timeliness of vaccination, with greater acceptance from both end users and healthcare providers.
- Higher and more equitable vaccination coverage.

Potential Challenges

- Ensuring compatibility between vaccination schedules and administration routes for each component.

Health Impact

Potential Advantages

- Greater and more equitable health impact.
- Enables targeting of less prevalent but still significant pathogens.
- Provides the possibility of a syndromic combination—targeting pathogens that cause the same clinical syndrome.

Potential Challenges

- Demonstrating the incremental health and economic benefits of the combination compared to standalone components.
- More challenging to attribute safety signals to a specific component.

Vaccine Administration Efficiency and Cost

Potential Advantages

- Fewer syringes and reduced packaging disposal need.
- Less cold-chain storage and transportation space are required.
- Shorter administration time, with fewer errors.
- Reduced number of needlestick injuries, improving safety for vaccinators.

Potential Challenges

- Combination vaccines could be more expensive to procure than individual components, despite potentially lower delivery costs.
- Some available combinations may contain more vaccines than countries are willing to introduce.

Vaccine Design, Development, and Supply

Potential Advantages

- Greater demand for combination vaccines than for individual components, potentially leading to economies of scale and reduced cost of goods.

Potential Challenges

- Lack of guidance or recommendations from the public health community regarding combination composition or usage preferences.
- Higher risk of failure due to immunological interference or unacceptable reactogenicity.
- A more complex, lengthy, and costly clinical development pathway, driven by current regulatory guidelines.
- Need to develop and validate additional assays to accurately characterize components within complex mixtures.
- Limited competition if only a few developers have access to all necessary components or must engage in complex intellectual property agreements.
- Without guidance on preferred combinations, the market could become fragmented, resulting in numerous competing, overlapping, and commercially unviable combinations, ultimately increasing costs.

Conclusions

In July 2024, the World Health Organization (WHO) published a call for experts to join the WHO Technical Advisory Group on COVID-19 Vaccine Composition (TAG-CO-VAC).

While there are numerous challenges, the benefits of investing in the manufacturing and implementation of combination vaccines far outweigh those of using monopathogen vaccine deliveries. This approach offers significant advantages for both developed and developing countries, leading to substantial, long-term benefits.

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Guest Contributors

ROLES OF THE PHYSICIAN IN MEDICINAL PRODUCT INNOVATION

Varied, But Still Vital

By Jeffrey J. Stoddard, MD

Overview

The role of the physician in innovation of new medicinal products and other health and wellness therapies is central. The specific roles and specific tasks for medically trained experts varies across the spectrum of innovation, and it is worth some time to consider these varied functions physicians play. These roles have been described in detail (1). In early pre-clinical strategic planning, pharmaceutical companies and biotech firms typically rely very heavily upon physician experts to help them identify areas of unmet medical need. Most of the work in the discovery phase of researh is in the hands of the basic scientists, but those hands are guided at the outset by physicians who recognize where innovation is most sorely needed; i.e. where there are gaps in the therapeutic armentarium. In early stage clinical trials (Phase I for example), physicians closely and carefully monitor the safety and tolerability of investigational early stage products, often in specialized research units. In Phase II dose-ranging studies and proof-of-concept studies, physicians have critical roles in assessing and analyzing the safety and efficacy data. In Phase III registration trials, including large, pivotal safety & efficacy studies, physicians have a critical role initially in designing the studies, drafting the study protocols, then in the execution or conduct of the studies, and finally in the analysis and interpretation of safety and efficacy results. Few Phase III studies of important new medicines have had their primary endpoints defined without the central input of medical doctors working within clinical development departments. Moreover, the clinical relevance of multiple observations seen during the conduct of clinical research requires interpretation of medically trained personnel. Upon completion of Phase III trials, analysis of primary, secondary and exploratory endpoints often requires careful clinical assessment by physicians who bring their clinical experience to bear on the process of interpretation of the results. Post licensure Phase IV studies as well as label extension studies (Phase IIIB) require physicians to again design and conduct these studies in order to assess risks and benefits of real world use of newly approved products. This article will look in turn at each of these roles and review some of the most critical roles that physicians play along the spectrum in the development and commercialization of new pharmacologic agents.

Research & Development

While most preclinical research is conducted by PhD research scientists with backgrounds in molecular biology, genetics, pharmacology, physiology and other basic science fields, physicians play a critical role in the initial designation of areas of high unmet medical need. Medical doctors are well aware of the diseases for which there is no adequate therapeutic intervention. It is this absence that indeed spurs many physicians to come to work in the health sciences industry, which is to a very high degree where innovation occurs. When drugs, vaccines or biologic agents come out of pre-clinical research (with abundant non-human animal model data behind them) and are ready to go into clinical trials, the first in human (FIH) Phase I studies (which involve healthy adult volunteers) typically come first. Specialized Phase I research units involve exceptionally close monitoring of patients exposed to the novel, investigational therapeutic agents and any signs or signals of adverse events are carefully scrutinized. If the novel drug, biologic, or vaccine is deemed to be

safe and well tolerated in Phase I trials, it can then move to Phase II for proof of concept, and for dose-ranging. Phase II trial design nearly always involves physicians integrally in the drafting of the study protocol and the overall design of the study. Certainly, statisticians, regulatory experts and other technical personnel are heavily involved, but it is the physicians in development departments that routinely dictate primary endpoints for safety and efficacy in Phase II trials. Phase III trials (larger, more robust, and designed to provide pivotal efficacy and safety data), require heavy input from clinical development physicians. The physicians nearly uniformly are responsible for drafting the study protocols, defining all primary, secondary and exploratory, endpoints, defining inclusion and exclusion, criteria, and monitoring the research subjects' experiences over the course of the trial.

Safety and Pharmacovigilance

The roles of experts in safety and pharmacoigilance have grown exponentially in recent years in their complexity, and in their importance. No longer are safety and pharmacovigilance personnel simply assigned to process adverse event reports in accordance to regulatory-driven "clocks". In 2025, drug safety and pharmacovigilance personnel, in teams usually led by physicians, and comprised heavily of physicians, are responsible for proactive and multifaceted analysis of a host of data sources, all with the purpose of determining the safety of the investigational or the newly approved medicinal product. Large scale databases comprised of real world evidence (RWE) such as electronic health records (HER) are utilized in the immediate postmarketing launch phase of products to assess safety in real time and in actual use. Rapid cycle analysis (RCA) is now utilized routinely when new vaccines, biologics and drugs are launched. Rapid cycle analysis allows for expedited analysis of safety signals based upon existing data-gathering infrastructure, relying upon real world evidence all outside of clinical trials. Certainly epidemiologists, statisticians and other experts in population-based methodology and data science are involved in these analysis; however, physicians with a deep clinical understanding based on their clinical expertise are crucial in the in the interpretation of these large scale, analytic efforts.

Medical Affairs

During the course of conduct of the Phase III safety & efficacy trial designed to garner licensure of a new drug, biologic or vaccine, most sponsors will forge a medical affairs team to support the product launch. This medical affairs team must understand fully the requirements for a successful new product launch. Facilitation of adoption by prescribers and reimbursement by payers is entirely dependent upon the success of the work conducted by the medical affairs team. Medical affairs personnel, usually comprised of, and certainly led by physicians, understand the requirements for adoption into medical use of new medicinal products. Safety and efficacy data from the phase III trial may very well be adequate to attain licensure for the product, but rarely will such data allow for all of the requirements of a successful introduction of a new medicine to be met. One need only think about the various stakeholders that come into play when a new medicinal product is launched, and then to ask 'what data do they require in order to adopt that product?' Certainly payors are paramount in this equation, and will insist upon having credible value evidence in hand, weighing benefit risk and cost-effectiveness of the new product. Certainly payors will also require comparative information regarding the therapeutic class in which the new product enters. Is the new product equally efficacious more efficacious or less efficacious than its competitor drugs? What are the safety and tolerability considerations compared with other therapies in the therapeutic class? What about other considerations such as dosing regimens, ease of use, tolerability, and accessibility, supply & pricing? Payors will want to know the answers to all of these questions, and they will expect the sponsor to bring credible data to them to assess the competitive landscape. Prescribers, separately, will immediately look up upon a new product in through a comparative and/or competitive lens. Prescribers will want to know relative efficacy; i.e. is the new drug superior, equivalent, or is it inferior in comparison to other agents in that class? Is it equivalent to other therapies in terms of ease of use, route of administration, frequency of dosing, etc? And how does the safety profile of the new product compare with more 'tried and true' – albeit older - products? Is the safety dataset available at launch large enough to fully understand the safety profile of the new product? Are there important dosing, administration, supply, accessibility or other convenience factors that bear on a decision as to which product to prescribe? Finally, but perhaps most

importantly, consumers will be very interested in understanding the product profile from the standpoint of the outcomes that consumers most care about. Whereas regulators may define primary efficacy endpoints in an arcane manner, consumers will often have very clear and very cogent appreciation for the outcomes that matter most in their eyes. So, patient reported outcomes (PROs) become very important in the assessment of new medicinal products, especially for patients and consumers. Finally, it is often the role of the medical affairs physicians in a company to pull all of these threads together and to weave from them a coherent narrative as to the optimal place in the therapeutic armamentarium of the new drug, biologic or vaccine. Some executives in some pharma companies will expect physicians to bring only very narrow technical expertise to bear on questions such as what clinical advantages might exist for company A's product versus company B's product. However, very importantly, physicians will understand better than anyone else within the company that not all data points, and not all lines of evidence are of equal importance. For example, if a newly launched product is less safe and less available due to manufacturing problems, is at best only equivalent in efficacy, but it offers some modest advantage with respect to dosing interval or half life, any physician will quickly conclude that such a product is, overall, markedly inferior to its competition, and unlikely to attain a top place (or potentially even an important share) within the therapeutic armamentarium. As a senior medical affairs executive in one major Pharma company, I was asked repeatedly to provide narrow technical expertise on singular advantages of the dosing regimen and the persistence of efficacy of a vaccine that had the following disadvantages clearly demonstrated:

-safety (serious adverse events of a certain type were uniquely attributed to the product at hand);

-efficacy (based upon respective dosing regimens tested in Phase III trials, point estimates of efficacy favored the competitor vaccines),

-supply and availability (manufacturing and supply chain problems hampered the product's availability relative to the competitor vaccines which remained readily available);

-expert recommendations (most national expert panels afforded preferential recommendations to the competitor vaccines).

"Just put on blinders to the issues other than where our product might have advantages, and focus on those advantages exclusively, and create a medical narrative to drive use" -- these were my marching orders. I found them to be untenable. The logic behind them was fundamentally flawed.

From this experience, and similar experiences, my own view is that physicians ought to have – and indeed need to have -- a positioning within pharmaceutical companies and other healthcare industry firms where they're allowed and encouraged to speak the truth as product profiles emerge through their development and commercialization cycles. If physicians in a pharma company are treated in the same way as sales personnel, marketing executives or other business functions, then such individuals are not likely to adhere to the Hippocratic Oath which they took, nor are they likely to speak up regarding the true picture of the company's drug relative to the full context/full array of therapeutic modalities available (2,3). Physicians, in my opinion, need to always remember first and foremost their duty to patients and to consumers of the medicinal products that they develop in whatever capacity they find themselves positioned within the healthcare industry. At its core, this is the critical aspect of medical professionalism and medical professional ethics that has always been expected of medical doctors(4). This special set of expectations may face new pressures as technological innovations advance and business upsides evolve, but it fundamentally should not change.

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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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