



VACCINES
BEAT

THE BRAIN BEHIND VACCINOLOGY

An in-depth conversation with **Prof. Ralf Clemens**
over investment, manufacturing, clinical
development, pharmacovigilance, regulatory
affairs and implementation of vaccines

October
2024

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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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One of the current top experts in the field of vaccinology, Prof. Ralf Clemens did not choose vaccinology as his lifelong career plan from the beginning. Rather, vaccinology chose him. Trained as a physician in Germany, Switzerland and the United States, he specialized in intensive and emergency care. He spent time in a refugee camp in Thailand with 100,000 refugees from Indochina, where he got interested in infectious and tropical diseases and worked with the Mahidol University, in Bangkok, where he was soon appointed visiting professor. His clinical and research interest was on the treatment of malaria and snake bites. Prof. Clemens has been working in the vaccine industry since 1988 in various senior scientific and business positions. He was global Head of GSK Biologicals' vaccine development, followed by his role as head of Global Vaccine Development at Novartis, and SVP and head of Development for the Global Vaccine Business Unit at Takeda. During these years, he and his teams developed and brought to licensure more than 25 different vaccines globally. Nowadays, Prof. Clemens, serves as Senior Advisor to the Bill & Melinda Gates Foundation and is on the managerial and scientific boards of various biotech startups.

INDEX

01

Letter from the Editors: Welcome to Issue 004

02

Coffee with the Expert: The brain behind vaccinology
An in-depth conversation with Prof. Ralf Clemens over investment, manufacturing, clinical development, pharmacovigilance, regulatory affairs and implementation of vaccines

03

News & Alerts: Most relevant monthly news on vaccination and emerging diseases & bibliographic alerts

04

Latest Scientific Publications: Latest published papers and commentaries from the chief editors

05

Editors Corner: “Sewage surveillance: a distinct field of science, and an essential tool for pandemic preparedness”

06

Best Practice: Novel pentavalent (Men5CV) for Africa

07

Vaccines Beat

08

Sponsors & Partners

LETTER FROM EDITORS

Welcome to the fourth issue of Vaccines Beat. We are excited to continue our mission of communicating, educating, and promoting knowledge in the fields of vaccinology and vaccination.

In our “Coffee with an Expert” section, we are deeply honored to feature an interview with Professor Ralf Clemens, a renowned global expert in vaccines. Prof. Clemens has been a key figure in the vaccine industry since 1988, holding various senior scientific and business roles, including Head of Vaccine Development at GSK Biologicals, leading global vaccine development at Novartis, and serving as Senior Vice President and Head of Development for Takeda’s Global Vaccine Business Unit. Over his distinguished career, he has successfully developed and licensed more than 25 vaccines worldwide. Currently, Prof. Clemens is Senior Vice President at GRID Rio (Global Research in Infectious Diseases), a senior advisor to the Bill & Melinda Gates Foundation, and a professor in the Master’s in Vaccinology and Drug Development program at the University of Siena, Italy. In this interview, Prof. Clemens provides invaluable insights into every aspect of a vaccine’s journey—from financing to implementation—covering key stages such as clinical development, manufacturing, pharmacovigilance, regulation, launch, and sustainability. He also shares his perspectives on the evolution of vaccine clinical development, the four pillars required to develop a vaccine against “Pathogen X” within 100 days, vaccine equity, and other critical issues in the field.

Our “Editor’s Corner” explains the basics of sewage surveillance and highlights its crucial role as an essential tool for the early detection of outbreaks, strengthening preparedness and response capabilities.

Our “Best Practice” section discusses the significant impact of introducing the pentavalent meningococcal conjugate vaccine (ACWYX) in the Sub-Saharan region, known as the “meningitis belt.” This decision marks a critical step in protecting public health in the area.

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

We hope you find this October issue informative and engaging, and we look forward to continuing this unique effort in support of a healthier planet.



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 multinational & 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.

Editorial disclaimers: "The author/s assumes no responsibility or liability for any errors or omissions in the content of this publication. The information contained in this publication is provided on an "as is" basis with no guarantees of completeness, accuracy, usefulness or timeliness. The purpose of this Vaccines Beat is purely academic, sponsors do not contribute to its content."

Coffee with the Expert

THE BRAIN BEHIND VACCINOLOGY

An in-depth conversation with Prof. Ralf Clemens over investment, manufacturing, clinical development, pharmacovigilance, regulatory affairs and implementation of vaccines

Authors:

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Enrique Chacon-Cruz, M.D., MSc

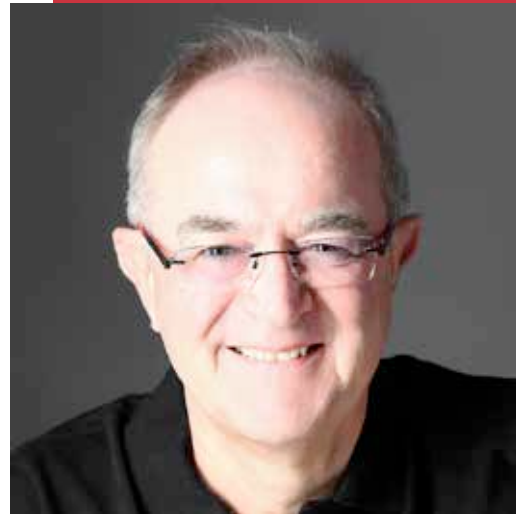
Felicitas Colombo, MPA

One of the current top experts in the field of vaccinology, Prof. Ralf Clemens did not choose vaccinology as his lifelong career plan from the beginning. Rather, vaccinology chose him.

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How it all started

Reflecting on the last 35 years, when the industry was starting to get serious about vaccine development, Prof. Clemens recalls that the change in vaccine R&D was not evolutionary but revolutionary. He recalls getting his first budget on a napkin big enough to provide all the information needed.

“At that time, there were very little processes and standards. Somebody knew somebody in the company who had some ideas on how to do clinical development and off we started. And then, the next years were determined by building processes, building a team, and implementing things such as IPDP [integrated product development plan], CDP [clinical development plan] and having the ‘end-in-mind’ approach which was mostly unheard of. And, of course, good clinical practices (GCP) and statistical standards became really very important and established a shift in mindset throughout the organization and the vaccine development environment,” says Prof. Clemens.

These initial gaps were obvious throughout the entire industry. Similarly, the regulatory environment was quite different. To give a bit of a flavor on how it all changed in the last decades in vaccine development, he shares that there was no EMA and a regulatory file included often far less than 10,000 subject's efficacy data, and post licensure commitments of a few thousand individuals. For newer vaccines, the prelicensure efficacy/safety package was close to 65,000 subjects, and post licensure commitments for HPV were up to 200,000 women over up to 10 years. Prof. Clemens

recalls that formal cost-effectiveness analyses were almost unheard of and not needed for inclusions in National Immunisation Programs (NIPs).

Nowadays, of course, the landscape has drastically changed. Safety, alongside with efficacy, benefit-risk, and cost-benefit, is a key parameter and an essential part of the development of any novel vaccine.

“So, show me the benefits. Why should I invest in a vaccine compared to other public health measures? Why should I invest in a vaccine compared to safer cars or better roads? And is the incremental costs worth the incremental benefit of an improved existing vaccine as part of its life cycle management? This assessment was in the early days on some people’s radar screen, but not on many,” recalls Prof. Clemens.

He continues to emphasize that Good Clinical Practice (GCP), Standard Operating Procedures (SOPs), and Data and Safety Monitoring Boards (DSMBs) with the right composition and charter are critical to ensuring subject safety and the integrity of data without any doubt. However, one should also critically challenge SOPs and requirements, as they can seem bureaucratic and may increase development time and costs with questionable added value.

“Of course, one needs to ensure the highest level of safety for drugs and vaccines. And SOPs should focus on that, as well as data integrity. But sometimes I have the impression that SOPs are there just for the sake of bureaucratic perfection. Same with manuals – manuals try to predict all eventualities. Accept gaps which do not affect safety or integrity and it makes everybody’s life easier,” he continues.

Currently, to even start thinking about a new vaccine, a thorough development plan on how a vaccine is envisioned, from its inception to its commercialization and accessibility, needs to be meticulously outlined. This includes an assessment of the competitive environment in which the vaccine will, hopefully, enter the market.

“So, the huge change from the very beginning of vaccine development to now is this integrated approach that as soon as there is a research candidate, the entire value chain or development chain is included in decision making: CMC [Chemistry, Manufacturing, and Controls], translational and clinical

medicine, regulatory science, manufacturing, market access and policies.” he shares.

And along with it also came processes and documents.

“And I’m not the typical process person, but these processes and documents such as the IPDP, where each and every function has given the input including stage gate criteria, is the blueprint of vaccine and drug development. It’s a live document where periodically adjustments are made,” Prof. Clemens continues, adding that IPDPs should also demonstrate the societal benefit of the project.

He shares that, for each project, other essential documents include a target product profile (TPP) and a regulatory plan as basis for the CDP, along with a commercial plan that includes financials and a market access plan.

“If you don’t have those, you’re really fishing in the dark and you’re just doing development for development. You need to have the end in mind, and the how to get there. That’s my learning,” concludes Prof. Clemens, who has developed over 25 vaccines that were brought to licensure.

Challenging vaccines

When discussing the most challenging vaccines to develop and the lessons learned from those projects, Prof. Clemens’ answer is unequivocal: HIV, HIV, HIV. Next, tuberculosis (TB), dengue, malaria, and herpes simplex virus (HSV).

“When I was at GSK we did three efficacy trials for prophylactic or therapeutic HSV [Herpes Simplex Virus] and all failed. And GSK was not alone, the same happened to Chiron and others. GSK nevertheless did another efficacy trial and just a few weeks ago they announced that a new phase 2 HSV trial also failed, which led them to reconsider the entire program. May be an mRNA with longer persistence, such as self-amplifying mRNA, could have a chance as a therapeutic HSV vaccine,” he shares.

Prof. Clemens’ learnings: “My learning is I’m a huge fan of the protein and VLP [virus-like particle] technology because this is much more predictable. VLP [which enables high-density, multivalent display of antigens in a manner that closely resembles the structure of a virus have been shown to be highly effective, and safe. They can be produced at scale which reduces COGS [Cost of Goods Sold]. The downside is

that, as a biological process, it is not as quick as mRNA or vector-based technologies.”

He also reminds us to keep in mind mucosal vaccination, such as oral vaccines. Oral vaccines are attractive due to their ease of delivery. However, in low-middle income countries (LMICs), there is a high incidence of enteropathies that impact the effectiveness of oral vaccines. As a result, vaccine efficacy is often lower in LMICs compared to high-income countries.

Big failures: “Therapeutic vaccines. All big vaccine companies, including GSK, looked to develop therapeutic vaccines, especially using the novel adjuvant systems, but all failed. Ironically, the only vaccine that has therapeutic effects is the well-known BCG for bladder cancer. However, there is hope: the concept of personalized cancer treatment based on mRNA constructs combined with PD-1 inhibitors has recently shown impressive results: Moderna has reported success in melanoma, CureVac in glioblastoma, and BioNTech in melanoma and pancreatic cancer, with efficacy rates of 50% or more.”

However, the prevention of cancer by vaccines is long established. The HBV vaccine has dramatically reduced the incidence of hepatocellular carcinoma, and the HPV vaccine has done the same for cervical cancer. The HPV vaccines represent a success story: when we conducted our efficacy trial in Costa Rica in collaboration with the NIH, we used a three-dose schedule. From that trial, we demonstrated that women who were not compliant and received only two or even one dose had the same protection against cervical cancer as those who received the full three doses. This finding has since been confirmed by various other studies, leading SAGE (Strategic Advisory Group of Experts on Immunization) to recommend considering single-dose HPV vaccination two years ago.

Among Prof. Clemens’ wish list and based on what could be feasible, a TB vaccine would be the top one on his list.

“There are so many vaccines in late-stage development that we must ask ourselves: how do we get all these vaccines into the kids or adolescence or elderly? This is only doable if we focus again, as in the late nineties, on combination vaccines,” he suggests.

Viral vector vaccines against COVID-19

As part of the conversation with Prof. Clemens, it was unavoidable to discuss the thrombotic events associated with the viral vector COVID-19 vaccines. The 2 manufacturers of adenovirus-vector based Covid-19 vaccines exited the market this year as recommendation for use were restricted and sales plummeted.

“That’s a very important question, and I want to offer a bit of a broader answer. In the pandemic it was so important to have a vaccine quickly as the number of infections grew exponentially. Every Covid-19 vaccine platform – inactivated, vectored, mRNA – was safer than to be infected with COVID, specifically if you were in a risk group. ChadOx1 (Chadox) was one of the very first vaccines available and it saved well over 6 million lives, more than any other Covid-19 vaccine,” Prof. Clemens highlights. “The next biggest societal impact was with the inactivated vaccines, which saved 5.5 million lives, followed by mRNA vaccines.”

He underscores that whatever vaccine was available during the pandemic had a highly positive benefit-risk ratio.

“Of course, when you vaccinate millions and millions you might detect events which you could not identify during clinical development which include, for most vaccines, about 35–45,000 subjects because they are so rare. The thrombotic events following Chadox fall into that category,” says Prof. Clemens, who refers to [publications](#) from the UK and elsewhere which show an attributable risk for Cerebral Venous Thrombosis (CVT) of 16 per million doses in younger adults and 3 per million doses in older adults, with the risk being higher in females compared to males.

While an increased risk for Cerebral Venous Thrombosis (CVT) has not been observed after vaccination with mRNA vaccines, Prof. Clemens believes that the myocarditis events occurring after mRNA vaccination are being significantly downplayed. According to a passive surveillance study by the CDC involving 196 million people, and based on VAERS safety reporting, the risk for myocarditis following mRNA vaccination with either the Moderna or BioNTech vaccine increased in young men from an expected incidence of about 0.5 per million doses to up to 70 per million doses—an increase by a factor of approximately 140. The risk increase was higher after the second dose compared to the first, generally

more pronounced in males than in females, and was most significant in young men up to the age of about 40 years ([Oster M, et al. JAMA 2022;327\(4\): 331-40. doi:10.1001/jama.2021.24110; Table 2](#)). There was no material difference between the Moderna and BioNTech mRNA vaccines.

“But what is the consequence of a vaccine induced myocarditis? While the acute impact is manageable and generally benign in most cases, myocarditis can be an important factor for arrhythmias later in life. We need to remain vigilant, but we should also avoid overstressing these findings,” warns Prof. Clemens, adding that neither individuals nor society benefit from exaggerating these concerns.

Vaccines within 100 days

Recently, CEPI launched the 100 Days Moonshot Initiative to make vaccines available within 100 days during a pandemic, while it took close to one year in the COVID pandemic from the availability of the genome sequence to the first licensing and vaccination. Typically, it takes 5 to 10 years to develop a vaccine. Although developing a vaccine in 100 days may seem almost impossible, Prof. Clemens believes there are no limits to improvements in processes.

“Traditionally, you do the development steps sequentially. In a pandemic, you must do the development in parallel,” he illustrates, adding that the most important consideration is to define what day zero is.

“Day zero is not when you hear for the first time about the pathogen and then a couple of weeks later you get the sequence and then you start your development. The entire concept is based on a pre-pandemic phase and a pandemic phase,” he explains.

In the **pre-pandemic phase**, **five pillars** must be established to ensure readiness when an outbreak poses a risk of becoming a pandemic. According to Prof. Clemens, the **first and most important pillar is to build libraries of viral vaccines**, as the next pandemic is likely to be viral.

“The concept is to build libraries of vaccines for virus families by picking one or two prototypes of that family. You then test this prototype to find out what immune response is needed to neutralize or kill that virus, which vaccine platform is best suited, what are the best animal models, what are the best immune read out tests. You do a clinical phase I or

even II study and then put this prototype on hold in the library. One does this for the virus families with the highest risk and likelihood of outbreaks. Cumbersome, costly, but doable,” he highlights.

The second most important pillar in the pre-pandemic phase of development is to **improve surveillance and data sharing**. Surveillance is a field that is chronically underfunded and underrated. Prof. Clemens is a strong advocate of wastewater surveillance because it can detect viruses much earlier than waiting for clinical cases. However, considering the risk that tourism might decline, there can be hesitation, complacency, and even a conscious withholding of surveillance data.

The third pillar is for **clinical trial sites to have the capacity to conduct large-scale efficacy trials across various geographies, especially in LMICs**. He emphasizes the importance of keeping these sites “warm” and proposes mechanisms to ensure they remain active and funded.

The fourth pillar, which he believes is not as critical until later in a pandemic when improvements to a vaccine are needed, is **identifying potential surrogates of protection**. And **final pillar is global manufacturing**, which introduces a host of challenges.

Prof. Clemens proposes implementing transparent technology transfer agreements in stages. First, he emphasizes the importance of establishing a reliable fill-finish process in LMICs before transferring upstream technologies.

However, a manufacturing site is not a stand-alone solution. The country must have a functional national regulatory agency, and the manufacturer needs to be capable of executing trials, preparing regulatory files, and conducting adequate pharmacovigilance.

Additionally, issues of trust and cost are intrinsic to this conversation. The cost of manufacturing in LMICs is likely to be higher than sourcing from established mass producers. Therefore, would Gavi or UNICEF be willing to pay the incremental cost for this approach? Prof. Clemens recommends developing a realistic plan that starts with the end goals and works up the value chain.

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.

“California Confirms Fourth Human Case of Bird Flu”

Published: October 10, 2024.

<https://www.usnews.com/news/top-news/articles/2024-10-10/california-confirms-fourth-human-case-of-bird-flu#:~:text=The%20four%20people%20who%20tested,two%20additional%20possible%20human%20cases>

“The Nobel Prize of Medicine to Victor Ambros and Gary Ruvkun for the discovery of microRNA and its role in post-transcriptional gene regulation”.

Published: October 7, 2024.

<https://www.nobelprize.org/prizes/medicine/2024/press-release/>

“Sabin Vaccine Institute Delivers Marburg Vaccines to Combat Outbreak in Rwanda.”

Currently, there are no licensed vaccines or treatments for Marburg, which has a



mortality rate of up to 88%. Sabin’s single-dose vaccine, based on the cAd3 platform, is in Phase 2 trials in Uganda and Kenya with no safety concerns reported to date. Results from Phase 1 clinical trials and nonclinical studies indicate that the vaccine is safe and elicits rapid, robust immune responses.

Published: October 5, 2024.

<https://www.sabin.org/resources/sabin-vaccine-institute-delivers-marburg-vaccines-to-combat-outbreak-in-rwanda/>

“WHO appeal: Marburg virus disease outbreak Rwanda 2024”

Published: October 2024.

<https://www.who.int/publications/m/item/who-appeal--marburg-virus-disease-outbreak-rwanda-2024>.

“WHO News, October 2024.”

- COVID-19 vaccine considerations.
- HPV vaccine as a single dose.
- Mpox vaccination.
- Mpox diagnostic test.
- Pandemic preparedness cooperation between

the WHO, the World Bank Group, and the International Monetary Fund.
<https://www.who.int/news>

“WHO recognizes healthy, innovative cities across Asia”

Published: September 25, 2024.

<https://www.who.int/westernpacific/news/item/25-09-2024-who-recognizes-healthy--innovative-cities-across-asia>

“Strategic Advisory Group of Experts on Immunization (SAGE) - September 2024”

Published: Reunions held from September 23rd to 26th, 2024.

This meeting of the Strategic Advisory Group of Experts on Immunization (SAGE) was held from Monday to Thursday inclusive at WHO HQ.

It covered the following items:

- Global Reports
- Immunization Agenda 2030 and regional updates
- Respiratory syncytial virus
- Rubella and congenital rubella syndrome prevention
- Poliomyelitis
- COVID-19 vaccines
- Cholera
- Mpox and H5N1 updates

https://www.who.int/news-room/events/detail/2024/09/23/default-calendar/sage_meeting_september_2024

“Prevention Strategies for Mpox, including Vaccinating People at Risk via Sexual Exposure, for U.S. Travelers Visiting Countries with Clade I Mpox Outbreaks (CDC)”

Published: September 23, 2024.

<https://emergency.cdc.gov/han/2024/han00516.asp>

“FDA Approves Nasal Spray Influenza Vaccine for Self- or Caregiver-Administration”

Note: Still, this live attenuated influenza vaccine could only be used in persons >18 years of age, and a prescription will be required.

Published: September 20, 2024.

<https://www.fda.gov/news-events/press-announcements/fda-approves->

[nasal-spray-influenza-vaccine-self-or-caregiver-administration](#)

“Governments progress on negotiations for a pandemic agreement to boost global preparedness for future emergencies”

Published: September 20, 2024.

<https://www.who.int/news/item/20-09-2024-governments-progress-on-negotiations-for-a-pandemic-agreement-to-boost-global-preparedness-for-future-emergencies>

“Disease Outbreak News (DONs)”

Published: Up to September 20, 2024.

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

“The silent invaders: Oropouche and Melao viruses, causes of increased public health risks for the Americas”

Published: Infectious Diseases, 1–6.

<https://doi.org/10.1080/23744235.2024.2403712>

“COVID pandemic started in Wuhan market animals after all, suggests latest study (nature.com)”

Published: Nature News 20 September 2024

doi: <https://doi.org/10.1038/d41586-024-03026-9>

“Public Health Confirms the Third Case of Locally Acquired Dengue in California.”

Published: September 9, 2024.

<http://publichealth.lacounty.gov/phcommon/public/media/mediapubhpdetail.cfm?prid=4811#:~:text=It%20is%20the%20third%20case,and%20Pasadena%20in%20fall%202023.>

“CDC Confirms Human H5 Bird Flu Case in Missouri”

Published: September 6, 2024.

<https://www.cdc.gov/media/releases/2024/s0906-birdflu-case-missouri.html>

“Introducing World’s Meningitis Day: October 5th”

Published: September 2024.

<https://www.meningitis.org/blogs/introducing-world-meningitis-day>

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

“Characteristics of children with invasive pneumococcal disease eligible for the 1+1 compared with the 2+1 PCV13 infant immunisation schedule in England: a prospective national observational surveillance study”.

Published: Lancet Child & Adolescent Health. September 24/2024; [https://doi.org/10.1016/S2352-4642\(24\)00193-7](https://doi.org/10.1016/S2352-4642(24)00193-7)

Editorial comment: Three years ago, the United Kingdom introduced a 1+1 schedule for vaccinating children with the 13-valent pneumococcal conjugate vaccine (PCV13). This study demonstrates that with robust surveillance and high vaccination coverage, there has been no significant increase in the incidence of invasive pneumococcal disease. However, continued—and potentially enhanced—surveillance remains necessary.

02

“Evaluation of a Quadrivalent Shigella flexneri Serotype 2a, 3a, 6, and Shigella sonnei O-Specific Polysaccharide and IpaB MAPS Vaccine”.

Published: Vaccines. September 20/2024; 12(10): 1091. <https://doi.org/10.3390/vaccines12101091>

Editorial comment: A Shigella vaccine is crucial, especially in regions with limited access to clean drinking water. This animal study shows promising results for a quadrivalent Shigella vaccine utilizing Multiple Antigen-Presenting System (MAPS) technology. However, further clinical trials are necessary to confirm its efficacy.

03

“Wastewater Surveillance for Influenza A Virus and H5 Subtype Concurrent with the Highly Pathogenic Avian Influenza A(H5N1) Virus Outbreak in Cattle and Poultry and Associated Human Cases — United States, May 12–July 13, 2024”

Published: Weekly / September 19, 2024 / 73(37);804–809 DOI: <http://dx.doi.org/10.15585/mmwr.mm7337a1>

Editorial Comment: Wastewater surveillance can detect influenza A virus and the H5 subtype, although current testing does not distinguish between human and animal sources.

During May 12–July 13, 2024, high influenza A virus levels were detected in wastewater in four states, including three states with seasonal human influenza virus activity noted during this time. The H5 subtype was detected in wastewater in nine states; follow-up investigations in many of these states revealed likely animal-related sources, including those related to milk processing.

Early work to interpret influenza A virus and H5 subtype detections in wastewater can help with public health preparedness and response for the upcoming respiratory illness season.

04

“Humanly Possible”: Geographies, Metrics and Methods to Address Immunization Inequalities”

Published: *Vaccines*. September 18/2024; 12(9): 1062. <https://doi.org/10.3390/vaccines12091062>

Editorial comment: The year 2024 marks the 50th anniversary of the World Health Organization’s (WHO) Expanded Program on Immunization (EPI). WHO Director General Dr. Tedros Adhanom Ghebreyesus has recognized the EPI’s remarkable success, highlighting what is ‘humanly possible.’ This Special Issue explores various contexts where inequalities in immunization arise and how they are being addressed.

The contributions provide compelling evidence that transformation is ‘humanly possible’ in two keyways. First, they reveal that immunization inequalities stem from structural factors such as maternal education, gender inequality, societal norms, and global financing. While these factors contribute to inequities, they are also changeable, underscoring both the possibility and responsibility for human intervention to mitigate them. Second, methodological advancements—such as improved measurement of ‘zero dose’ (ZD), standardization of indicators, and the integration of diverse data sources and analytical approaches—demonstrate our ability to refine analyses, identify gaps, and advance toward greater equity.

05

“Chikungunya Virus Vaccines: A Review of IXCHIQ and PXVX0317 from Pre-Clinical Evaluation to Licensure”

Published: *BioDrugs* . 2024 Sep 18th DOI: <https://doi.org/10.1007/s40259-024-00677-y>

Editorial Comment: The European Medicine Agency is considering accelerated assessment review of PXVX0317, with potential for approval by both agencies in 2025. In this review, authors summarize published data from pre-clinical and clinical trials for the IXCHIQ and PXVX0317 vaccines.

06

“The greatest Dengue epidemic in Brazil: Surveillance, Prevention, and Control”

Published: *I Rev. Soc. Bras. Med. Trop.* 57 • 2024 • <https://doi.org/10.1590/0037-8682-0113-2024>

Editorial Comment: Increasing tetravalent vaccination coverage and the implementation of a novel *Aedes aegypti* infection control technologies could reduce the number of dengue cases in Brazil in the coming years. Community engagement through activities such as home cleaning and elimination of potential mosquito breeding sites, facilitated by social media and health education initiatives, must continue to achieve this reduction. Ultimately, a multisectoral approach encompassing sanitary improvements, mosquito control, vaccination, and community mobilization is crucial in the fight against dengue epidemics.

07

“AAP Recommendations for the Prevention of RSV Disease in Infants and Children”

Published: Last Updated 09/03/2024 Source: American Academy of Pediatrics Respiratory Syncytial Virus (RSV) Prevention (aap.org)

Editorial Comment: Please read the recently released AAP RSV recommendations for prevention of this terrible disease causing a high morbidity and mortality in infants worldwide.

08

“mRNA-based HIV-1 vaccines”

Published: *Virology*;17 July 2024 DOI: <https://doi.org/10.1128/cmr.00041-24>

Editorial Comment: Recently, attempts to address some of these challenges have led to multiple studies that manufactured, optimized, and tested, in different animal models, mRNA-based HIV-1 vaccines. Several clinical trials have also been initiated or are planned to start soon. Here, we have a nice review of the current strategies applied to HIV-1 mRNA vaccines, discussion about different targeting approaches, and a summary of the latest findings, offering insights into the challenges and future of HIV-1 mRNA vaccines.

09

“T-Cell Immune Responses to SARS-CoV-2 Infection and Vaccination”

Published: *Vaccines* 2024; 12 (10): 1126. <https://doi.org/10.3390/vaccines12101126>

Editorial comment: The authors described the main features of SARS-CoV-2-specific CD4+ and CD8+ T cells, including cross-reactive T cells, generated in patients with different degrees of COVID-19 severity, and of Spike-specific CD4+ and CD8+ T cells induced by vaccines. Finally, they discussed T-cell responses to SARS-CoV-2 variants and hybrid immunity and concluded by highlighting possible strategies to improve the efficacy of COVID-19 vaccination.

10

“Report from the World Health Organization’s immunization and vaccines-related implementation research advisory committee (IVIR-AC) ad hoc meeting, 28 June – 1 July 2024”.

Published: *Vaccine* 42(26): 126307. <https://doi.org/10.1016/j.vaccine.2024.126307>

Editorial comment: The World Health Organization’s Immunization and Vaccines-related Implementation Research Advisory Committee (IVIR-AC) provides independent reviews and evaluations of vaccine-related research to optimize the impact of vaccination programs. From June 28 to July 1, 2024, IVIR-AC convened for an ad hoc meeting to discuss new evidence regarding criteria for rubella vaccine introduction and the risk of congenital rubella syndrome. This report summarizes the background on rubella virus transmission and the burden of congenital rubella syndrome, along with the meeting structure, presentations, discussions, and recommendations.

11

“National recommendations for adult pneumococcal vaccination in countries of the WHO regions of Americas, Africa, Eastern Mediterranean, South East Asia, and Western Pacific”

Published: *Vaccine* 2024; 42(26): 126390. <https://doi.org/10.1016/j.vaccine.2024.126390>

Editorial comment: In this study the authors gathered national guidelines for adult pneumococcal immunization from 161 countries across the World Health Organization (WHO) regions, including the Americas (excluding Canada and the United States), Africa, Eastern Mediterranean, South-East Asia, and Western Pacific. Data were sourced from official country websites and documents, the WHO portal, as well as through direct contact with public health officials, relevant governmental sources, and local vaccination experts.

12

“Recent advances in the influenza virus vaccine landscape: a comprehensive overview of technologies and trials”.

Published: *Clin Microbiol Rev* 2024; Oct 3:30002524. <https://doi.org/10.1128/cmr.00025-24>

Editorial comment: This review aimed to summarize advances in the influenza virus vaccine landscape by describing all the different technologies that are currently in use in the United Kingdom and elsewhere.

13

“Tracking the spread of avian influenza A(H5N1) with alternative surveillance methods: the example of wastewater data”.

Published: *Lancet* 2024; 24(10): E604-5. [https://doi.org/10.1016/S1473-3099\(24\)00498-5](https://doi.org/10.1016/S1473-3099(24)00498-5)

Editorial comment: In this correspondence the authors demonstrate the potential of wastewater monitoring as a complementary tool in avian influenza surveillance. Integrating this information with other sources of epidemiological data could substantially improve our ability to detect emerging avian influenza threats early and respond effectively.

14

“Early onset of protection of the TAK-003 dengue vaccine: Data from the DEN-301 clinical trial”.

Published: *Vaccine* 2024; 42(26): 126309. <https://doi.org/10.1016/j.vaccine.2024.126309>

Editorial comment: Data from this phase 3 study shows that a single dose of TAK-003 provides 82.1% efficacy 14 days after administration, with protection lasting at least 3 months, making it a suitable option for travelers.

15

“Anticipated Effects of Higher-valency Pneumococcal Conjugate Vaccines on Colonization and Acute Otitis Media”.

Published: *Pediatr Infect Dis J* 2024; 43(10): 1004-10. <https://doi.org/10.1097/INF.0000000000004413>.

Editorial comment: From September 2021 to September 2023 in Rochester, New York, 825 nasopharyngeal (NP) and middle ear fluid (MEF) samples were collected from 301 children aged 6 to 36 months. Most *Streptococcus pneumoniae* isolates in young children were non-PCV15 and non-PCV20 serotypes, with serotype 35B being particularly prevalent. As a result, the impact of higher-valency PCVs in reducing pneumococcal colonization or acute otitis media (AOM) is expected to be limited.

16

“Mosquito-borne diseases are surging in Europe — how worried are scientists?”.

Published: *Nature* 2024; 633: 749. <https://doi.org/10.1038/d41586-024-03031-y>

Editorial comment: A must-read paper that explores how diseases like West Nile virus and dengue are becoming more prevalent as the insects that transmit them migrate north. It discusses the potential consequences of this trend and the actions that may need to be taken in response.

17

“The Recent Research Progress of the Tumor mRNA Vaccine”.

Published: *Vaccines* 2024; 12(10): 1167. <https://doi.org/10.3390/vaccines12101167>

Editorial comment: This review aims to provide a comprehensive overview of the defining characteristics of mRNA vaccines and recent research advancements in the rapidly evolving field of tumor (cancer) immunotherapy.

18

“5-year vaccine protection following a single dose of Vi-tetanus toxoid conjugate vaccine in Bangladeshi children (TyVOID): a cluster randomised trial”.

Published: *Lancet* 2024; 404(10461): 1419-29. [https://doi.org/10.1016/S0140-6736\(24\)01494-6](https://doi.org/10.1016/S0140-6736(24)01494-6)

Editorial comment: This extended follow-up study of a cluster-randomized controlled trial in Bangladesh evaluated the protection provided by a single dose of the Typhoid-Fever Conjugate Vaccine (TCV) in children aged 9 months to 15 years, over a period of 3–5 years post-vaccination. The study found a decline in vaccine effectiveness during this period, with an estimated effectiveness of 50% (95% CI: -13 to 78) at 3–5 years. Additionally, the authors noted that vaccine effectiveness waned more significantly in children vaccinated under the age of 2, dropping from 85% to 24%.

19

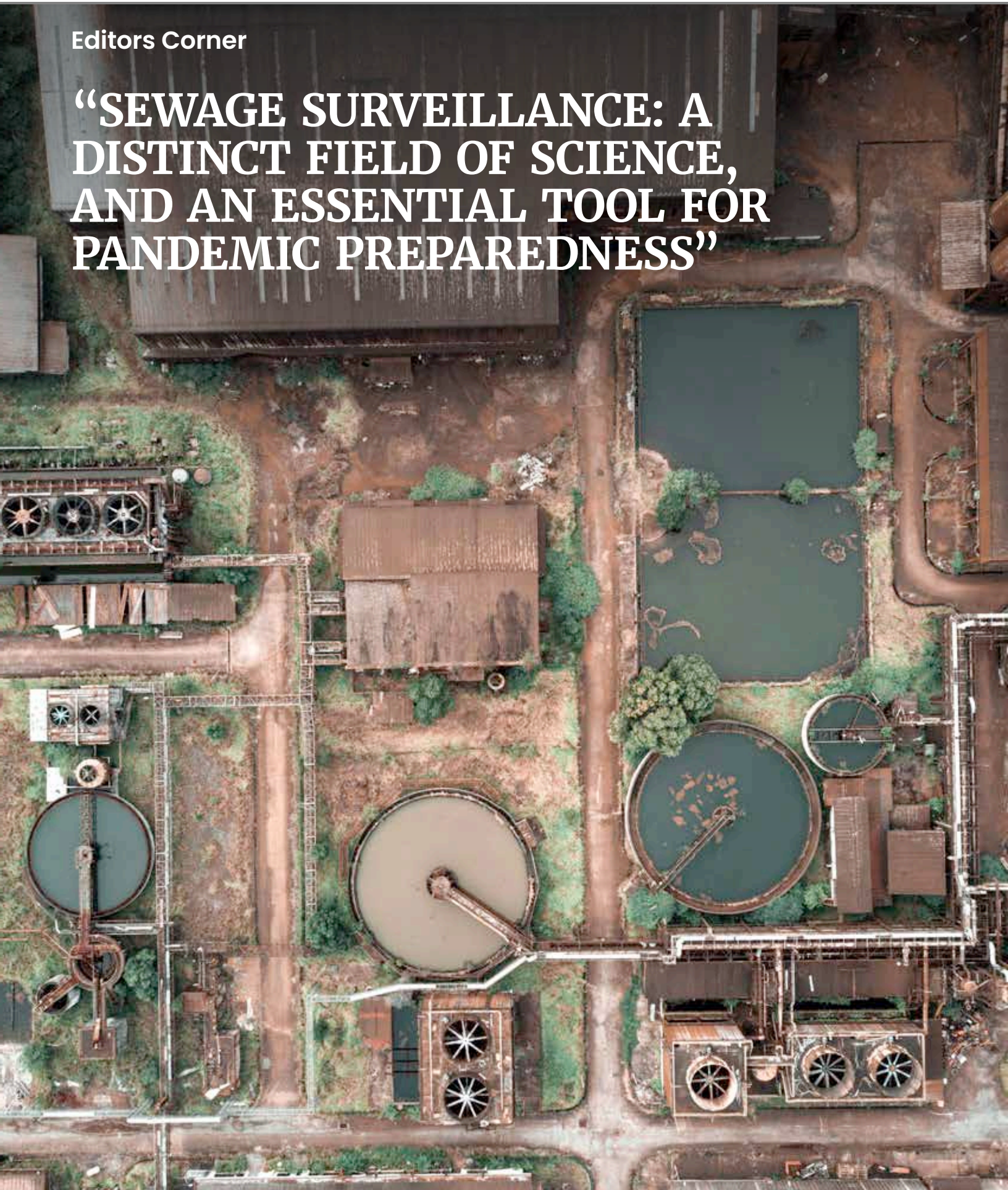
“Pooled safety evaluation for a new single-shot live-attenuated chikungunya vaccine”.

Published: *J Travel Med* 2024; taae133: <https://doi.org/10.1093/jtm/taae133>

Editorial comment: In this phase 3 clinical trial, the live-attenuated Chikungunya vaccine VLA1553 demonstrated excellent local tolerability and a strong overall safety profile in both adults aged 18–64 and those over 65, consistent with expectations for a live-attenuated vaccine.

Editors Corner

**“SEWAGE SURVEILLANCE: A
DISTINCT FIELD OF SCIENCE,
AND AN ESSENTIAL TOOL FOR
PANDEMIC PREPAREDNESS”**



Public health surveillance has traditionally focused on actual cases, either retrospectively through passive surveillance or prospectively through active surveillance. While sewage surveillance has historically been used to monitor toxic substances, in 1939 South Carolina successfully implemented active surveillance for poliovirus in wastewater. This marked the first evidence that poliovirus, excreted in stools, could be detected in wastewater, proving it to be an essential tool for anticipating potential polio outbreaks.

From a public health standpoint, diseases that are under-reported by traditional surveillance systems and result in widespread negative health outcomes (e.g. surveillance for flaccid paralysis in polio) should be prioritized in wastewater monitoring programs. These include illnesses with nonspecific symptoms, such as polio, influenza, and viral gastroenteritis, as well as those where patients often delay seeking care until symptoms become severe. Wastewater monitoring is also valuable for diseases where current diagnostic tests are inadequate, inaccessible, or costly, providing data that could inform vaccine campaigns or other interventions to improve health outcomes.

Among the various biomarkers and chemicals measurable in sewage to assess public health, viruses have shown the most promise. Additionally, growing evidence suggests that wastewater may be an ideal environment for detecting antimicrobial-resistant pathogens — a rising global public health threat.

It is important to highlight that several viral respiratory infections are also excreted through feces, making the investigation of these viruses in wastewater both practical and essential.

Why is sewage surveillance an essential tool for anticipating clinical cases? The outcome of exposure to a virus (or any other pathogen) can be categorized into three scenarios:

1. **No Infection:** The individual shows no colonization.
2. **Subclinical Infection:** The individual is colonized (either transiently or permanently) but does not exhibit clinical symptoms.
3. **Clinical Infection:** The individual is infected and manifests the disease.

In scenarios 1 and 2, neither passive nor active surveillance can detect pathogens circulating in the environment, meaning that circulation may be occurring without detection, potentially leading to a latent outbreak.

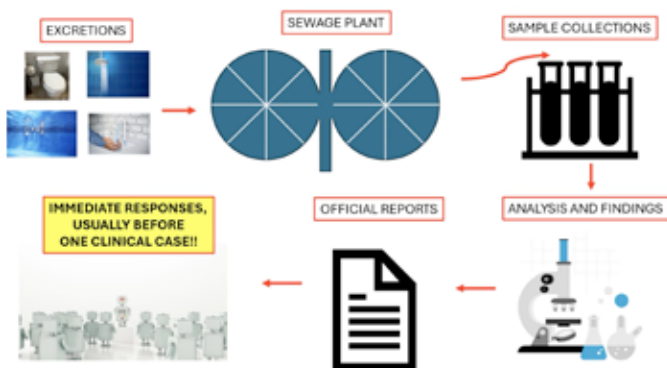
Sewage surveillance enables us to proactively identify pathogens before any individuals develop the disease—such as the recent polio case in Gaza—and implement preventive measures. These measures can include mass vaccination, enhanced clinical surveillance, strengthening healthcare facilities, and educating healthcare workers, among others.

In addition, monitoring human pathogens in sewage is even more feasible because they can be excreted through various bodily fluids other than feces: skin, and hair during active infection. These materials enter sewage systems through waste elimination processes such as toilet flushing and personal hygiene activities like bathing and hand washing. Additionally, pathogens can be introduced into the sewage system through indoor cleaning (e.g., floor mopping, kitchen sink use) and outdoor activities (e.g., car washing, driveway cleaning, stormwater runoff). As a result, sewer systems collect pathogens from a wide area and transport them to a central facility for processing. This process can be effectively understood as outlined in the accompanying figures:

CLINICAL SURVEILLANCE:



SEWAGE SURVEILLANCE:



Over the past 30 years, numerous studies have demonstrated that wastewater testing offers an accurate population-level view of disease. Recent research further confirms that trends in wastewater concentrations of SARS-CoV-2 strongly predict clinical case counts.

However, several challenges remain for large-scale implementation, which have been thoroughly described by Drs. Aparna Keshaviah, Ruchir N. Karmali, Divya Vohra, Tessa Huffman, Xindi C. Hu, and Megan B. Diamond (“The Role of Wastewater Data in Pandemic Management” Washington, DC: Mathematica, 2022):

Barriers to implementation (United States):

1. Only 7% of local agencies that had not yet monitored wastewater possess the necessary resources to initiate this process.
2. The most common barrier to implementing wastewater surveillance is a lack of internal staff capacity.
3. Additionally, rural agencies reported more barriers to implementation compared to their non-rural counterparts.

Again, a global effort:

In the United States, the situation is already challenging; however, worldwide sewage surveillance faces even greater obstacles. These include the complexities of collecting wastewater from septic tanks in many developing countries, the willingness of sewage plants to share wastewater data, the budget and personnel required to collect large volumes of samples, and establish both regional and national laboratories, among other issues. Indeed, sewage surveillance is a distinct field of science that requires the harmonious integration of various factors, including political support, private sector involvement, and scientific expertise. This collaboration is essential for effectively detecting current and future outbreaks and pandemics, enabling prompt and effective responses.

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Best Practice

NOVEL MENINGOCOCCAL PENTAVALENT VACCINE (MEN5CV) FOR AFRICA

Meningitis is one of the leading causes of mortality and morbidity, especially in the meningitis belt of sub-Saharan Africa, with a recorded disease burden of over 2.5 million cases globally and children under five disproportionately impacted. (see map below)

(Meningitis is a leading cause of mortality and morbidity, particularly in the meningitis belt of sub-Saharan Africa. Globally, the disease burden exceeds 2.5 million cases, with children under five being disproportionately affected. (See map below).)

In 2021, WHO launched a global road map to “defeat meningitis by 2030”, after its approval by the World Health Assembly at its Seventy-third session in November 2020.

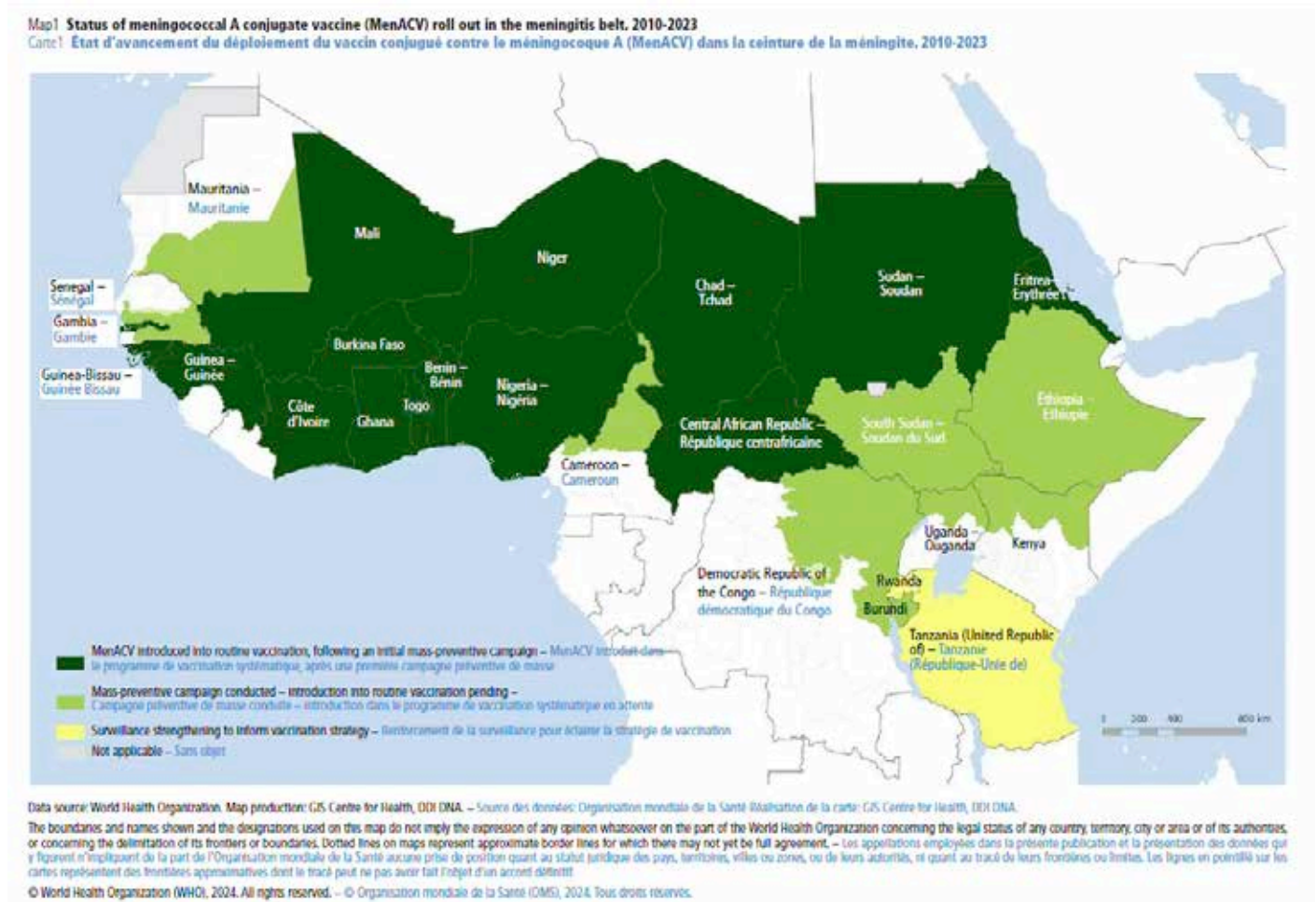
The road map addresses the 4 main causes of acute bacterial meningitis: *Streptococcus pneumoniae*, *Haemophilus influenzae*, *Neisseria meningitidis* and *Streptococcus agalactiae*, as well as the sequelae and after-effects that can occur from meningitis of any cause (as well as the potential sequelae and lasting effects that can result from meningitis, regardless of the cause.)

The 3(three) visionary goals to be achieved by 2030 are:

- (1) elimination of bacterial meningitis epidemics.
- (2) reduction by 50% in the number of cases and by 70% in the number of deaths from vaccine-preventable meningitis.
- (3) And a reduction in disability and an improvement in the quality of life after meningitis of any cause.

The recent development and introduction of novel pentavalent (Men5CV) meningococcal conjugate vaccine will be discussed here under.





Recurrent meningitis outbreaks across the meningitis belt have resulted in significant mortality over decades. A great turning point in the fight against the serogroup A epidemic was the deployment of MenAfriVac, which resulted in declining cases of Men A. Anyway, the bad news are that serogroups C, W, and X continue to generate epidemic problems (Unfortunately, serogroups C, W, and X continue to cause epidemic challenges.)

To circumvent the limitations of the monovalent MenAfriVac (serogroup A) vaccine and logistic challenges with integrating quadrivalent vaccines (A, C, W, and Y), researchers explored pentavalent options. The outcome of these efforts is the development and rollout of the Men5CV vaccine, which holds immense potential for further mitigating the burden of meningitis. The conjugate meningitis vaccine Men5CV is

the product of a 13-year collaborative effort between PATH and the Serum Institute of India Pvt. Ltd (SIIPL), a research project funded by the WHO and the UK government's Foreign, Commonwealth and Development Office (FCDO).

Men5CV vaccine has emerged as a remarkable advancement in the fight against meningitis, with its safety and effectiveness against a variety of serogroups, including the elusive serogroup X, demonstrated in clinical trials. Its prequalification by the World Health Organization (WHO), and subsequent recommendation for incorporation into routine immunization programs issued a new era with the potential for meningitis eradication. Nigeria now sets a benchmark for other nations in the meningitis zone (belt), becoming the first country in the world to roll out the new Men5CV vaccines. Funding from organizations like Gavi, the Vaccine Alliance,

highlights the importance of coordinated international efforts aligned with the WHO's roadmap for meningitis elimination by 2030.

The first pentavalent meningococcal ACWYX conjugate Men5CV, the only vaccine to include Nm X, was prequalified by WHO in July 2023. The development and prequalification of this affordable vaccine marks a significant milestone in the fight against meningitis. In September 2023, the Strategic Advisory Group of Experts on immunization (SAGE) reviewed the evidence and issued recommendations on use of Men5CV in the meningitis belt. The recommendations were adopted by WHO and published in January 2024 as an addendum to the WHO position paper on meningococcal vaccines.

WHO recommends that all countries in the African meningitis belt introduce Men5CV into their routine immunization programs in a single-dose schedule for infants and young children aged 9–18 months.

In high-risk countries and countries with high-risk districts, a one-off mass preventive campaign with Men5CV should also be conducted at the time of Men5CV introduction, targeting all individuals aged 1–19 years or 2–19 years (depending on age groups covered by routine immunization programs).

The recommendation states that countries that have already introduced MenACV into their routine immunization programs should switch to use of Men5CV and that countries that have not yet introduced MenACV should do so as soon as possible to avoid the risk of a resurgence of Nm A (The recommendation advises that countries already using MenACV in their routine immunization programs should transition to

Men5CV. Additionally, countries that have not yet introduced MenACV are urged to do so as soon as possible to prevent the risk of a resurgence of Nm A.). The recommendations also include updates on outbreak response vaccination strategies.

Notably, they advocate for reactive vaccination in high-risk areas that neighbor epidemic areas (regions) and for extension of reactive vaccination to areas (geographic zones) at increased risk of an outbreak during the upcoming epidemic season.

The aim of these updates is to create a cohesive strategy that bridges the reactive and preventive uses of vaccines, maximizing their public health impact across the African meningitis belt.

Stakeholder involvement, extensive immunization campaigns, and a strong healthcare infrastructure are all practical (essential) recommendations for public health integration.

The global road map for “Defeating meningitis by 2030” sets a path for improving diagnostic and surveillance capacity in the African Region and worldwide, as well as strengthening advocacy, engagement, epidemic prevention and control, treatment, support and care for people affected by meningitis. The African Region continues to take important steps, with regional strategic plans and support to countries in developing national plans to defeat meningitis.

As engagement continues towards achieving the goals of the global road map, (improved) surveillance, monitoring, and evaluation should be supported in at-risk countries in all regions. This will enable public health policies and actions at national, regional and global levels towards a world free of meningitis.

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VACCINES BEAT

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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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