

Vaccines and Global Health: The Week in Review 06 September 2025 :: Issue 812 Center for Vaccine Ethics & Policy (CVEP)

This weekly digest targets news, events, announcements, articles and research in the vaccine and global health ethics and policy space and is aggregated from key governmental, NGO, international organization and industry sources, key peer-reviewed journals, and other media channels. This summary proceeds from the broad base of themes and issues monitored by the Center for Vaccine Ethics & Policy in its work: it is not intended to be exhaustive in its coverage.

Vaccines and Global Health: The Week in Review is published as a PDF and scheduled for release each Saturday [U.S.] at midnight [0000 GMT-5]. The PDF is posted at https://centerforvaccineethicsandpolicy.net. This blog allows full text searching of over 27,000 entries.

Comments and suggestions should be directed to

David R. Curry, MS

Editor and

Executive Director Center for Vaccine Ethics & Policy

david.r.curry@centerforvaccineethicsandpolicy.org

Request email delivery of the pdf: If you would like to receive the PDF of each edition via email [Constant Contact], please send your request to <u>david.r.curry@centerforvaccineethicsandpolicy.org</u>.

Support this knowledge-sharing service: Your financial support helps us cover our costs and to address a current shortfall in our annual operating budget. Click <u>here</u> to donate and thank you in advance for your contribution.

Contents [click to move among sections]

- :: Milestones, Perspectives
- :: <u>WHO</u>
- :: U.S. Immunization and Public Health Governance/Policy/Funding
- :: Organization Announcements
- :: Journal Watch
- :: Pre-Print Servers
- :: Think Tanks
- :: Public Consultations/Call for Inputs/Call for Papers

Milestones, Perspectives

WHO - Strategic Advisory Group of Experts on Immunization (SAGE) - September 2025 22 - 25 September 2025

This meeting for the Strategic Advisory Group of Experts on Immunization (SAGE) will be held from Monday to Thursday. Additional meeting materials, such as a provisional list of participants and background documents, will be provided in due course.

:: Draft agenda

:: Declaration on interests (as of 28 August)

:::::::

.....

New global collaboration uses experts and AI to spot the next pandemic CEPI News

OSLO, SEP 4 —Global health and pandemic experts are banding together to combine their AI programmes and infectious disease knowledge to more accurately rank the viruses that have the potential to cause the next deadly pandemic.

The new partnership will see the Coalition for Epidemic Preparedness Innovations (CEPI) and University of California, Davis (UC Davis) working with the Boston University-based Biothreats Emergence, Analysis and Communication Network (<u>BEACON project</u>) to integrate BEACON's open-source disease surveillance program with UC Davis's <u>Virus Intelligence & Strategic Threat Assessment (VISTA) project</u> (formerly "SpillOver 2.0").

VISTA aims to provide risk rankings in near real time through the use of AI-assisted tools along with expert oversight and curation. The combined intelligence will help to identify the viruses at greatest risk of spillover from animals to humans and those most likely to cause disease and death. This could include known culprit viruses like Nipah and Ebola, as well as a new or as-yet-identified pathogen with pandemic potential, known as Disease X. Rankings will be regularly updated through AI pulling through new virus data that then gets fed into the VISTA platform.

Integrating these tools along with expert insights will help inform scientists and research funders like CEPI on what new vaccines should be prioritised or considered for development to prepare for a likely pandemic threat and more rapidly and effectively respond to health emergencies. For example, the viral rankings, which will be made publicly available, will help CEPI's work building a vaccine library - a store of relevant virus knowledge, data and prototype versions of vaccines that could be rapidly adapted to help respond to a Disease X more quickly and stop a pandemic before it starts. This can help advance the 100 Days Mission, the ambitious goal spearheaded by CEPI and embraced by the G7 and G20 to develop a vaccine in 100 days from identification of a new virus.

CEPI is providing up to \$1 million to support the integration of data between BEACON and VISTA.

... Dr. Tim Endy, Disease X Programme Leader at CEPI, said, "Building on the success of the SpillOver and BEACON projects, VISTA will leverage AI to analyse more robust human,

animal and environmental data and help pinpoint the top viruses and viral families with pandemic potential that we should be directing our resources, time and attention towards."

The partnership is especially important as our globally connected world has made us vulnerable to the rapid spread of new pathogens. This risk is heightened by urbanisation and environmental changes which is expanding the range of disease-carrying insects, birds, and animals and increasing their interaction with people.

"The integration of AI and global expert networks into platforms like VISTA and BEACON marks a transformative shift in how we anticipate and respond to emerging infectious threats. By identifying high-risk viruses and providing assessments of their pandemic risk potential, we're not just reacting to pandemics—we're working to prevent them," said Dr. Angel Desai, Principal investigator and associate professor of infectious disease at UC Davis Health.

...Now rebranded as VISTA, the project will also leverage BEACON's advanced large language models (LLMs) and network of global experts to rapidly collect, analyse and disseminate information on emerging infectious diseases affecting humans, animals and the environment. BEACON is the first open-access infectious diseases surveillance system that pulls in data from disease-tracking websites and systems before using AI to sift through the data, assign a potential threat level and produce a written report summarizing the key details verified by a human.

"This partnership will allow us to continuously update the risk levels of zoonotic disease spillovers and, through BEACON, share this information more rapidly with the public. By providing timely and actionable insights, BEACON's mission is to empower communities and public health officials to take proactive measures, preventing outbreaks and mitigating the spread of diseases" said Dr. Nahid Bhadelia, Founding Director of BEACON and the Boston University Center on Emerging Infectious Diseases (CEID).

CEPI is committed to promoting the responsible development of AI for the 100 Days Mission through our Biosecurity Programme to prevent and prepare for future epidemics and pandemics.

::::::::

WHO updates list of essential medicines to include key cancer, diabetes treatments

5 September 2025 News release

Today, the World Health Organization (WHO) has released **updated editions of its Model Lists of Essential Medicines (EML) and Essential Medicines for Children (EMLc),** adding new treatments for various types of cancer and for diabetes with associated comorbidities such as obesity. Medicines for cystic fibrosis, psoriasis, haemophilia and blood-related disorders are among the other additions.

WHO EML and EMLc include medicines for priority health needs of populations. They are adopted in over 150 countries, serving as a basis for public sector procurement, supply of medicines and health insurance, reimbursement schemes. The revisions mark the 24th edition of WHO EML and 10th edition of EMLc.

"The new editions of essential medicines lists mark a significant step toward expanding access to new medicines with proven clinical benefits and with high potential for global public health impact," said Dr Yukiko Nakatani, Assistant Director-General for Health Systems, Access and Data.

Launched in 1977 largely to promote better access to medicines in developing countries, the WHO Model Lists have become a trusted global policy tool for decisions related to the selection and universal coverage of medicines within all health systems.

The WHO Expert Committee on the Selection and Use of Essential Medicines reviewed 59 applications, including 31 proposals for the addition of new medicines or medicine classes.

As a result, 20 new medicines were added to the EML and 15 to the EMLc, along with new use indications for seven already-listed products. The updated lists now include a total of 523 essential medicines for adults and 374 for children, reflecting the most pressing public health needs...

<u>The selection and use of essential medicines, 2025: WHO AWaRe (Access, Watch, Reserve) classification...</u>

5 September 2025

The selection and use of essential medicines, 2025: WHO Model List of Essential Medicines for Children, 10th List

5 September 2025

<u>The selection and use of essential medicines, 2025: WHO Model List of Essential Medicines, 24th list</u>

5 September 2025

5 September 2025

The selection and use of essential medicines, 2025: report of the 25th WHO Expert Committee on Selection...

:::::::

Polio - PHEIC

Polio this week [27 August 2025]

Headlines [Selected]

- :: GPEI stands with communities in Sudan, Afghanistan and Pakistan, amid devastating landslide, earthquake and floods
- :: Tribute to Professor Tony Adams

The Global Polio Eradication Initiative mourns the passing of Professor Tony Adams, whose leadership and dedication left an enduring mark on public health in Australia and globally.

Summary of new polioviruses this week, cases and positive environmental isolates:

Afghanistan: one WPV1 case
Pakistan: three WPV1 cases
Angola: two cVDPV2 cases
Chad: one cVDPV2 case
Nigeria: one cVDPV2 case

Papua New Guinea: one cVDPV2 case

......

mPox - PHEIC

Mpox Still a Continental Emergency, Africa CDC Advisory Group Recommends

Addis Ababa, Ethiopia | 4 September 2025 —

The Emergency Consultative Group (ECG), which advises the Director General of the Africa Centres for Disease Control and Prevention (Africa CDC) on mpox, has urged that the Public Health Emergency of Continental Security (PHECS) remain in place.

Meeting on 2 September 2025 to review the outbreak and assess whether the emergency status should be lifted, the Group concluded that maintaining the declaration is essential to preserve political will, mobilise resources, and keep countries on high alert.

Members warned that lifting the status prematurely could trigger complacency, reduce funding, and increase the risk of resurgence.

The Group's recommendation followed a detailed review of the mpox situation. Weekly confirmed cases declined by 52 per cent between weeks 17–22 and weeks 27–32 of 2025. Yet, surges emerged in Ghana, Liberia, Kenya, Zambia, and Tanzania, with fresh introductions of the virus reported in Malawi, Ethiopia, Senegal, Togo, The Gambia, and Mozambique...

The ECG also expressed concern over reduced international support, including the withdrawal of programmes such as PEPFAR. This shift leaves people living with HIV — among the most vulnerable to severe illness and death — at increased risk. Weaknesses in surveillance persist, as poor sample collection, preservation, and transport undermine effective response. In the Democratic Republic of the Congo, transport system collapse has prevented timely testing and follow-up.

To address these challenges, the ECG recommended strengthening sample collection and referral systems, including the **use of community-based surveillance and wastewater monitoring as early warning tools.** The Group also called for more rigorous investigation of mpox-related deaths, particularly among children, and for expanding vaccine access to under-12s in high-risk countries.

It further advised maintaining strong continental coordination, integrating the mpox response with other ongoing health emergencies such as cholera and circulating vaccine-derived polioviruses, and developing a scalable, tiered alert system to sustain vigilance without relying solely on a binary emergency declaration...

•••••
······
Contents [click to move among sections]
:: Milestones, Perspectives
:: WHO
:: U.S. Immunization and Public Health Governance/Policy/Funding
:: Organization Announcements
:: <u>Journal Watch</u>
:: Pre-Print Servers
:: <u>Think Tanks</u>
:: Public Consultations/Call for Inputs/Call for Papers

Selected News/Announcements/Statements

5 September 2025 News release

WHO updates list of essential medicines to include key cancer, diabetes treatments

3 September 2025 Departmental update

Bridging global guidance and local action for maternal and newborn health

2 September 2025 Departmental update

WHO releases new reports and estimates highlighting urgent gaps in mental health

2 September 2025 News release

Over a billion people living with mental health conditions – services require urgent scaleup

::::::

WHO Regional Offices

Selected Press Releases, Announcements

WHO African Region AFRO

No new digest content identified.

WHO Region of the Americas PAHO

:: 5 Sep 2025

PAHO launches award to recognize Caribbean leadership in the fight against superbugs

Nominations open until 30 September 2025Bridgetown, Barbados, 5 September 2025 (PAHO/WHO)

— The Pan American Health Organization (PAHO) has launched the Suzan McLennon-Miguel Caribbean Antimicrobial Resistance (AMR) Leadership Award, a new regional honor recognizing exceptional leadership in the fight against antimicrobial resistance—a growing...

:: 2 Sep 2025

<u>PAHO publishes first guidelines for the treatment of tungiasis, a neglected disease that</u> affects millions

Washington, D.C., 3 September 2025 (PAHO) – The Pan American Health Organization (PAHO) has released the world's first evidence-based guidelines for the treatment of tungiasis, a parasitic disease that affects millions of people in vulnerable communities across Latin America, the Caribbean, and sub-Saharan Africa. Tungiasis is a neglected tropical...

WHO South-East Asia Region SEARO

:: Cholera outbreak in Birgunj: WHO supporting scaling up response to save lives 29 August 2025

WHO European Region EURO

No new digest content identified.

WHO Eastern Mediterranean Region EMRO

:: <u>EU provides €22 million to WHO to keep health services running for over 6.5 million in Syria</u>

2 September 2025

WHO Western Pacific Region

:: 5 September 2025

Samoa mobilizes dengue outbreak response with support from WHO and partners

:: 3 September 2025 News release

WHO Regional Director Visits Jiwaka to Support School-Based Vaccinations and Strengthen He...

::::::

WHO - Emergency situation reports

Latest WHO official reports for emergency situations. Latest WHO official reports for emergency situations.

No new digest content identified.

::::::

Disease Outbreak News (DONs)

Latest WHO Disease Outbreak News (DONs), providing information on confirmed acute public health events or potential events of concern.

5 September 2025 | Ebola virus disease - Democratic Republic of the Congo

:::::::

Weekly Epidemiological Record

Vol. 100, No. 36, pp. 347–364 5 September 2025 https://www.who.int/publications/journals/weekly-epidemiological-record :: Cholera, 2024

::::::

New WHO Publications

https://www.who.int/publications

Selected

5 September 2025

The selection and use of essential medicines, 2025: WHO AWaRe (Access, Watch, Reserve) classification...

5 September 2025

The selection and use of essential medicines, 2025: WHO Model List of Essential Medicines for Children,...

5 September 2025

The selection and use of essential medicines, 2025: WHO Model List of Essential Medicines, 24th list

5 September 2025

The selection and use of essential medicines, 2025: report of the 25th WHO Expert Committee on Selection...

4 September 2025

Green spaces: sectoral solutions for air pollution and health

4 September 2025

Household air pollution and related health impacts

4 September 2025

Understanding the health impacts of sand and dust storms

2 September 2025

Standard case definitions of acute bacterial meningitis and invasive meningococcal disease for routine...

2 September 2025

Tailoring event-based surveillance using open sources: practical guide for mass gatherings

Africa

Africa CDC [06 Sep 2025]

https://africacdc.org/

Press Releases, Statements [Selected]

New Ebola Outbreak Confirmed in the Democratic Republic of Congo

4 September 2025

Press Releases

Mpox Still a Continental Emergency, Africa CDC Advisory Group Recommends

Addis Ababa, Ethiopia | 4 September 2025 — The Emergency Consultative Group (ECG), which advises the Director General of the Africa Centres for Disease Control and Prevention (Africa CDC) on mpox, has urged that the Public Health Emergency of Continental Security (PHECS) remain in place.

Meeting on 2 September 2025 to review the outbreak and assess whether the emergency status should be lifted, the Group concluded that maintaining the declaration is essential to preserve political will, mobilise resources, and keep countries on high alert. Members warned that lifting the status prematurely could trigger complacency, reduce funding, and increase the risk of resurgence...

::::::

China - CDC+

http://www.chinacdc.cn/en/

National Health Commission of the People's Republic of China [06 Sep 2025]

http://en.nhc.gov.cn/

News

No new digest content identified.

National Medical Products Administration – PRC [06 Sep 2025]

http://english.nmpa.gov.cn/

News

No new digest content identified.

China CDC

CCDC Weekly Reports: Current Volume (7)

2025-09-05 / No. 36 ENVIRONMENTAL HEALTH ISSUE

PDF of this issue

- :: <u>Perspectives: From Evaluation to Practice: Bridging the Gap Between Air Pollution Health Risk Assessment and Policy-Making in China</u>
- :: <u>Methods and Applications: Wastewater-Based Monitoring of Dengue Fever at Community Level Guangzhou City, Guangdong Province, China, May 2024</u>

::::::

Europe

European Centre for Disease Prevention and Control

https://www.ecdc.europa.eu/en News/Updates/Reports/Publications [Selected] Surveillance and monitoring

Communicable disease threats report, 30 August - 5 September 2025, week 36

5 Sep 2025

This issue of the ECDC Communicable Disease Threats Report (CDTR) covers the period 30 August - 5 September 2025 and includes updates on Salmonella Strathcona, West Nile virus infection, dengue, chikungunya, Crimean-Congo haemorrhagic fever, Ebola, MERS-CoV and respiratory viruses.

Surveillance and monitoring

Seasonal surveillance of dengue in the EU/EEA

5 Sep 2025

Update providing weekly overview of the countries and areas where dengue cases have been reported.

Surveillance and monitoring

Seasonal surveillance for chikungunya virus disease in the EU/EEA for 2025

5 Sep 2025

Update providing weekly overview of the countries and areas where chikungunya virus disease cases have been reported.

European Medicines Agency [EMA]

https://www.ema.europa.eu/en/news

News & Press Releases

EMA and WHO mark ten years of collaboration to advance global access to medicines

Key partnership leverages EMA's scientific expertise and WHO's mandate to improve access to safe and effective medicines worldwide

1 September 2025

U.S. Immunization and Public Health Governance/Policy/Funding

Given the continuing extraordinary situation in the U.S., we are establishing a separate section of the digest to capture and organize key content. Please note that we will selectively include external analysis and comment, indenting this content under the relevant organization. We recognize that despite the volume of content in this section, this summary is indicative and not exhaustive.

<u>Presidential Actions – Executive Orders; Memoranda; Proclamations</u> No new digest content identified.

HHS

News

HHS Secretary Kennedy Testifies on Health Care Agenda, Part 1
HHS Secretary Kennedy Testifies on Health Care Agenda, Part 2

September 4, 2025 CSPAN Video

Health and Human Services Secretary Robert F. Kennedy Jr. fielded questions from Democrats and Republicans on oversight of his agency and President Donald Trump's health care agenda before the Senate Finance Committee.

5 Takeaways From RFK Jr.'s Senate Hearing

During often tense exchanges, Health Secretary Robert F. Kennedy Jr. defended his positions on Covid vaccines, the Centers for Disease Control and Prevention and autism.

By Apoorva Mandavilli, Dani Blum, Christina Jewett and Reed Abelson

The New York Times, Sept. 4, 2025

HHS Reinforces Religious and Conscience Exemptions from Childhood Vaccine Mandates September 4, 2025 Press Release

The U.S. Department of Health and Human Services' (HHS) Office for Civil Rights (OCR) today issued a letter notifying state awardees of the Vaccines for Children Program (VCP) that participating immunization programs and program-registered providers must respect state religious and conscience exemptions from vaccine mandates.

"Today's letter makes clear that providers must respect state laws protecting religious and conscience-based exemptions to vaccine mandates," said HHS Secretary Robert F. Kennedy, Jr. "States have the authority to balance public health goals with individual freedom, and honoring those decisions builds trust. Protecting both public health and personal liberty is how we restore faith in our institutions and Make America Healthy Again."

Participation in the VCP, which provides reduced cost, public-purchased vaccines for eligible children, requires compliance with state religious and other exemptions from vaccination laws. HHS provides operational funding to 61 state, local, and territorial immunization programs to implement and oversee their VCPs. State or local boards of education may administer or receive funds through the VCP.

"VCP providers should be aware that in addition to explicit religious exemptions, state religious freedom laws may limit vaccine mandates that substantially burden religious exercise," said Paula M. Stannard, OCR Director. "Some individuals with religious or moral objections don't oppose vaccination itself. They may have specific concerns that focus on the development or manufacturing of particular vaccines. For example, parents may object to immunizing their children with vaccines historically derived from aborted fetal cell lines, based on their sincere and deeply held beliefs about the sanctity of life."

In the letter, OCR offers states and participating providers assistance and support in their good faith efforts to operate VCP programs in compliance with the law. OCR is responsible for enforcing the Federal condition of the VCP that requires provider compliance with applicable state law, including laws regarding religious exemptions to compulsory vaccination.

Today's nationwide letter is part of a <u>larger effort</u> by HHS to strengthen enforcement of laws protecting conscience and religious exercise. It follows a similar recent <u>letter to West Virginia health departments</u> [PDF, 214 KB] that reminded them that they are obligated to recognize West Virginia's laws promoting religious freedom as a condition of participating in the VCP.

The Dear Colleague letter on the VCP may be found at: https://www.hhs.gov/sites/default/files/ocr-nationwide-vaccine-letter.pdf [PDF, 140 KB].

RFK Jr.: We're Restoring Public Trust in the CDC

September 2, 2025 Op-Ed, Wall Street Journal

NIH [06 Sep 2025] http://www.nih.gov/ News Releases No new digest content identified

FDA

<u>Press Announcements</u> No new digest content identified

FDA CBER

<u>Latest News</u> No new digest content identified

CDC/ACIP [06 Sep 2025]
http://www.cdc.gov/media/index.html
Latest News

No relevant media releases identified.

RFK Jr.'s Operation Warped Memory

The health secretary can't keep his vaccine story straight. by The Editorial Board

Wall Street Journal - Opinion

Review & Outlook

Sept. 4, 2025 6:39 pm ET

Is Robert F. Kennedy Jr. suffering from long Covid? His memory was foggy during a Senate hearing on Thursday, in which the Health and Human Services Secretary hailed as "genius" President Trump's Operation Warp Speed, which produced Covid vaccines in record time. Mr. Trump must have liked hearing that.

But these are the same vaccines that RFK has also called "a crime against humanity." So which is it, Mr. Kennedy: Was Mr. Trump's vaccine operation a triumph or a government catastrophe?

Mr. Kennedy has lambasted the mRNA technology that underlies the <u>Moderna</u> and <u>Pfizer</u> Covid vaccines as unsafe and ineffective, never mind that they have saved millions of lives around the world. He has called the Covid jabs the "deadliest vaccine ever made." Last month he moved to end \$500 million in contracts for other mRNA vaccine development.

Louisiana GOP Sen. Bill Cassidy on Thursday asked the slippery Mr. Kennedy if he agreed with Pfizer CEO Albert Bourla's statement this week that Mr. Trump deserved a Nobel Peace Prize for Operation Warp Speed.

Mr. Kennedy concurred, saying that the project rapidly "got the vaccine to market that was perfectly matched to the virus at that time, when it was badly needed because there was low natural immunity and/or people getting very badly injured by COVID." Yes, and the reason for the vaccines' rapid development was mRNA technology, which Mr. Kennedy wants to abandon.

The secretary has stacked an official vaccine advisory panel with people who share his skepticism of vaccines. One concern is that they could change vaccine recommendations to limit access, which Susan Monarez, the former director of the Centers for Disease Control and Prevention, says that she tried to stop before she was pushed out last week.

Mr. Kennedy came under fire at Thursday's hearing from both Democrats and Republicans over his moves to undermine vaccines. "In your confirmation hearings, you promised to uphold the highest standards for vaccines," Wyoming GOP Sen. John Barrasso said. "Since then, I've grown deeply concerned." Mr. Kennedy struggled to defend his inconsistencies.

Vice President <u>JD Vance</u> tried to ride to Mr. Kennedy's defense. "When I see all these senators trying to lecture and 'gotcha' Bobby Kennedy today," Mr. Vance wrote on social media, "all I can think is: You all support off-label, untested, and irreversible hormonal 'therapies' for children, mutilating our kids and enriching big pharma. You're full of sh— and everyone knows it." Classy, as ever, Mr. Vice President.

None of this is true of Dr. Cassidy, Dr. Barrasso, and other Senators, and the Vice President knows it. Mr. Vance is trying to rally Republicans to RFK's side by framing this dispute in a polarized partisan framework, either/or, us/them. That may serve his political purposes as he courts RFK's supporters with 2028 in mind, but it won't win over anyone paying attention to the health secretary's contradictions as he attacks life-saving vaccines.

Robert F. Kennedy Jr.: We're Restoring Public Trust in the CDC

The agency's Covid failures stem from politicized science, bureaucratic inertia and mission creep.

By Robert F. Kennedy Jr.

Wall Street Journal, Opinion - Commentary
Sept. 2, 2025 [paywall]

Robert F. Kennedy Jr., the CDC and Me

*I was fired after 29 days because I held the line and insisted on rigorous scientific review.*By Susan Monarez

Wall Street Journal, Opinion - Commentary

Sept. 4, 2025 8:00 am ET

I served for 29 days as director of the Centers for Disease Control and Prevention. The Senate confirmed me to ensure that unbiased evidence serves our nation's health, and for doing that, I lost my job. America's children could lose far more.

During my first week as CDC director, a gunman opened fire on our Atlanta headquarters on Aug. 8. Investigators recovered more than 500 shell casings at the scene and more than 180 rounds struck CDC campus buildings. Officer David Rose was killed.

Investigators found documents in which the gunman expressed his discontent with Covid vaccines, indicating his actions were driven by vaccine distrust. Amid the trauma, hundreds of CDC employees told me the same thing: We need to take immediate steps to rebuild public trust. That's the CDC I know: service before self.

Just as we began to recover, I was confronted with another challenge—pressure to compromise science itself.

Reporters have focused on the Aug. 25 meeting where my boss, Health and Human Services Secretary Robert F. Kennedy Jr., pressured me to resign or face termination. But that meeting revealed that it wasn't about one person or my job. It was one of the more public aspects of a deliberate effort to weaken America's public-health system and vaccine protections.

I'm gone now, but that effort continues. One of the troubling directives from that meeting more than a week ago: I was told to preapprove the recommendations of a vaccine advisory panel newly filled with people who have publicly expressed antivaccine rhetoric. That panel's next meeting is scheduled for Sept. 18-19. It is imperative that the panel's recommendations aren't rubber-stamped but instead are rigorously and scientifically reviewed before being accepted or rejected.

For three decades, I have worked at the intersection of public health, science and technology innovation—always challenging the status quo and welcoming discovery and change. Real science evolves with evidence.

As President Trump recently wrote on social media: "It is very important that the Drug Companies justify the success of their various Covid Drugs. Many people think they are a miracle that saved Millions of lives." Mr. Trump is right to call for proof. We should always demand evidence—exactly what I was doing when I insisted all CDC recommendations be based on credible data, not ideology or preordained outcomes.

The CDC can't fulfill its obligation to the American people if its leader can't demand proof in decision-making. If discarding evidence for ideology becomes the norm, why should parents, physicians or the public trust the CDC's guidance?

This week, HHS leadership published a vision that mirrors the priorities I laid out during my Senate confirmation hearing and had already advanced during my brief tenure at CDC. But since Aug. 25 I have had serious concerns.

Those seeking to undermine vaccines use a familiar playbook: discredit research, weaken advisory committees, and use manipulated outcomes to unravel protections that generations of families have relied on to keep deadly diseases at bay. Once trusted experts are removed and advisory bodies are stacked, the results are predetermined. That isn't reform. It is sabotage.

Public health shouldn't be partisan. Vaccines have saved millions of lives under administrations of both parties. Parents deserve a CDC they can trust to put children above politics, evidence above ideology and facts above fear.

I was fired for holding that line. But the line doesn't disappear with me. It runs through every parent deciding whether to vaccinate a child, every physician counseling patients, and every American who demands accountability.

If we stay silent, preventable diseases will return—as we saw with the largest measles outbreak in more than 30 years, which tragically killed two children. If we act, the facts can still prevail.

Dr. Monarez served as CDC director (2025) and deputy director of the federal Advanced Research Projects Agency for Health (2023-25).

We Ran the C.D.C.: Kennedy Is Endangering Every American's Health

By William Foege, William Roper, David Satcher, Jeffrey Koplan, Richard Besser, Tom Frieden, Anne Schuchat, Rochelle P. Walensky and Mandy K. Cohen

The New York Times, Opinion

Sept. 1, 2025

Guest Essay

The authors previously led in the C.D.C., as directors or acting directors under Republican and Democratic administrations.

We have each had the honor and privilege of serving as director of the Centers for Disease Control and Prevention, either in a permanent or an acting capacity, dating back to 1977. Collectively, we spent more than 100 years working at the C.D.C., the world's pre-eminent public health agency. We served under multiple Republican and Democratic administrations — every president from Jimmy Carter to Donald Trump — alongside thousands of dedicated staff members who shared our commitment to saving lives and improving health.

What the health and human services secretary, Robert F. Kennedy Jr., has done to the C.D.C. and to our nation's public health system over the past several months — culminating in his decision to fire Dr. Susan Monarez as C.D.C. director days ago — is unlike anything we had ever seen at the agency and unlike anything our country had ever experienced.

Mr. Kennedy has fired thousands of federal health workers and <u>severely weakened</u> programs designed to protect Americans from cancer, heart attacks, strokes, lead poisoning, injury, violence and more. Amid the largest measles outbreak in the United States in a generation, he's <u>focused on</u> unproven treatments while downplaying vaccines. He <u>canceled</u> investments in promising medical research that will leave us ill-prepared for future health emergencies. He <u>replaced</u> experts on federal health advisory committees with unqualified individuals who share his dangerous and unscientific views. He announced the end of U.S. support for global

vaccination programs that protect millions of children and keep Americans safe, <u>citing</u> flawed research and making inaccurate statements. And he <u>championed</u> federal legislation that will cause millions of people with health insurance through Medicaid to <u>lose</u> their coverage. Firing Dr. Monarez — which led to the resignations of top C.D.C. officials — adds considerable fuel to this raging fire.

We are worried about the wide-ranging impact that all these decisions will have on America's health security. Residents of rural communities and people with disabilities will have even more limited access to health care. Families with low incomes who rely most heavily on community health clinics and support from state and local health departments will have fewer resources available to them. Children risk losing access to lifesaving vaccines because of the cost.

This is unacceptable, and it should alarm every American, regardless of political leanings. The C.D.C. is an agency under Health and Human Services. During our C.D.C. tenures, we did not always agree with our leaders, but they never gave us reason to doubt that they would rely on data-driven insights for our protection or that they would support public health workers. We need only look to Operation Warp Speed during the first Trump administration — which produced highly effective and safe vaccines that saved millions of lives during the Covid-19 pandemic — as a shining example of what Health and Human Services can accomplish when health and science are at the forefront of its mission.

The current department leadership, however, operates under a very different set of rules. When Mr. Kennedy administered the oath of office to Dr. Monarez on July 31, he <u>called</u> her "a public health expert with unimpeachable scientific credentials." But when she refused weeks later to rubber-stamp his <u>dangerous and unfounded</u> vaccine recommendations or heed his demand to fire senior C.D.C. staff members, he decided she was expendable.

These are not typical requests from a health secretary to a C.D.C. director. Not even close. None of us would have agreed to the secretary's demands, and we applaud Dr. Monarez for standing up for the agency and the health of our communities.

When the C.D.C. was created in 1946, the average life expectancy in the United States was around <u>66 years</u>. Today it is <u>more than 78 years</u>. While medical advances have helped, it is public health that has played the <u>biggest role</u> in improving both the length and the quality of life in our nation. The C.D.C. has led efforts to <u>eradicate</u> smallpox, increase access to <u>lifesaving vaccinations</u> and <u>significantly reduce</u> smoking rates. The agency is also on the front lines in communities across the country, delivering crucial but often less visible wins — such as <u>containing</u> an outbreak of H.I.V. cases in Scott County, Ind., and <u>protecting</u> residents in East Palestine, Ohio, from toxic chemical exposure.

The C.D.C. is not perfect. What institution is? But over its history, regardless of which party has controlled the White House or Congress, the agency has not wavered from its mission. To those on the C.D.C. staff who continue to perform their jobs heroically in the face of the excruciating circumstances, we offer our sincere thanks and appreciation. Their ongoing dedication is a model for all of us. But it's clear that the agency is hurting badly. The loss of Dr. Monarez and other top leaders will make it far more difficult for the C.D.C. to do what it has done for about 80 years: work around the clock to protect Americans from threats to their lives and health.

We have a message for the rest of the nation as well. This is a time to rally to protect the health of every American. Congress must exercise its oversight authority over Health and Human Services. State and local governments must fill funding gaps where they can. Philanthropy and the private sector must step up their community investments. Medical groups must continue to stand up for science and truth. Physicians must continue to support their patients with sound guidance and empathy.

And each of us must do what public health does best: look out for one another.

The men and women who have joined the C.D.C. across generations have done so not for prestige or power but because they believe deeply in the call to service. They deserve a health

and human services secretary who stands up for health, supports science and has their back. So, too, does our country.

ACIP Meetings [06 Sep 2025]

Future ACIP Meetings

:: October 22-23

:: <u>September 18, 19, 2025</u>

[Docket No. CDC-2025-0454]

SUMMARY: In accordance with the Federal Advisory Committee Act, the Centers for Disease Control and Prevention (CDC) announces the following meeting of the Advisory Committee on Immunization Practices (ACIP). Time will be available for public comment.

DATES: The meeting will be held on September 18, 2025, from 10 a.m. to 5 p.m., EDT, and September 19, 2025, from 8 a.m. to 4 p.m., EDT (times subject to change; see the ACIP website for updates: https://www.cdc.gov/vaccines/acip/index.html). The meeting is expected to be held at the Centers for Disease Control and Prevention, with a virtual option. Written comments must be received between September 2-13, 2025.

Matters to be Considered: The agenda will include discussions on COVID-19 vaccines; Hepatitis B vaccine; measles, mumps, rubella, varicella (MMRV) vaccine; and Respiratory Syncytial Virus (RSV). The agenda will include updates on ACIP Workgroups. Recommendation votes may be scheduled for COVID-19 vaccines, Hepatitis B vaccine, MMRV vaccine, and RSV. Vaccines for Children (VFC) may be scheduled for COVID-19 vaccines, Hepatitis B vaccine, MMRV vaccine, and RSV. Agenda items are subject to change as priorities dictate.

[Full agenda not yet posted on ACIP site]

FDA VRBPAC [Vaccines and Related Biological Products Advisory Committee]

Advisory Committee Calendar

Advisory Committee Calendar has no meetings posted for this Advisory Committee

RFK Jr critic Paul Offit removed from FDA vaccine advisory committee

Offit, long-serving vaccine scientist, says he was not given a reason for dismissal after initially being offered extension

Melody Schreiber

The Guardian, Tue 2 Sep 2025 18.21 EDT

Paul Offit, a vocal critic of <u>Robert F Kennedy Jr</u>, has been removed from the advisory committee on vaccines for the US Food and Drug Administration (FDA), as Kennedy continues undercutting scientific expertise at federal agencies.

Offit has said that Americans can <u>no longer trust</u> the US Centers for Disease Control and Prevention because of the <u>decisions</u> taken by Kennedy as secretary of the US Department of Health and Human Services. Offit has also <u>warned</u> that Kennedy, a longtime anti-vaccine activist, is attempting to sow doubt and confusion about vaccines in particular in order to drive down vaccination rates across the country...

FDA Pediatric Advisory Committee Meeting

Advisory Committee Calendar

Advisory Committee Calendar has no meetings posted for this Advisory Committee

National Vaccine Program Committee (NVAC)

https://www.hhs.gov/vaccines/about/index.html
Upcoming Meetings/Latest Updates

No 2025 meeting dates posted.

Advisory Commission on Childhood Vaccines (ACCV)

https://www.hrsa.gov/advisory-committees/vaccines/meetings

Next ACCV Meeting - TBD [To be re-scheduled from original date January 29, 2025]

MMWR Weekly

https://www.cdc.gov/mmwr/index2025.html

September 4, 2025 / No. 33

PDF of this issue

:: <u>Highly Pathogenic Avian Influenza A(H5N1) Virus Infection in a Child with No Known Exposure — San Francisco, California, December 2024–January 2025</u>

::::::::

U.S. Congress

House of Representatives

No new actions, announcements identified.

U.S. Senate

Senate Finance Committee

HHS Secretary Kennedy Testifies on Health Care Agenda, Part 1
HHS Secretary Kennedy Testifies on Health Care Agenda, Part 2

September 4, 2025 CSPAN Video

Health and Human Services Secretary Robert F. Kennedy Jr. fielded questions from Democrats and Republicans on oversight of his agency and President Donald Trump's health care agenda before the Senate Finance Committee.

::::::::

Supreme Court, Federal Appellate Courts

No new cases, rulings, announcements identified.

:::::::

U.S. States

<u>California, Oregon, and Washington to launch new West Coast Health Alliance to uphold scientific integrity in public health as Trump destroys CDC's credibility</u>

Mecia Release, Sep 3, 2025 [Posted on CA Governor website]

What you need to know: In response to recent federal actions that have undermined the independence of the CDC and raised concerns about the politicization of science, California, Oregon, and Washington are beginning the process to provide evidence-based <u>unified recommendations</u> to their residents regarding who should receive immunizations and to help ensure the public has access and credible information for confidence in vaccine safety and efficacy.

SACRAMENTO — Today, California Governor Gavin Newsom, Oregon Governor Tina Kotek, and Washington Governor Bob Ferguson announced they will launch a new West Coast Health Alliance to ensure residents remain protected by science, not politics. The alliance represents a unified regional response to the Trump Administration's destruction of the U.S. CDC's credibility and scientific integrity.

"President Trump's mass firing of CDC doctors and scientists — and his blatant politicization of the agency — is a direct assault on the health and safety of the American people. The CDC has become a political tool that increasingly peddles ideology instead of science, ideology that will lead to severe health consequences. California, Oregon, and Washington will not allow the people of our states to be put at risk."

Joint statement from Governors Newsom, Kotek, and Ferguson

"The dismantling of public health and dismissal of experienced and respected health leaders and advisors, along with the lack of using science, data, and evidence to improve our nation's health are placing lives at risk," said Erica Pan, MD, MPH, FIDSA, FAAP, Director and State Public Health Officer, California Department of Public Health. "California stands together with our public health and medical professional colleagues to uphold integrity and support our mission to protect the health of our communities."

"Our communities deserve clear and transparent communication about vaccines — communication grounded in science, not ideology," said Sejal Hathi, MD, MBA, Director, Oregon Health Authority. "Vaccines are among the most powerful tools in modern medicine; they have indisputably saved millions of lives. But when guidance about their use becomes inconsistent or politicized, it undermines public trust at precisely the moment we need it most. That is why Oregon is committed, alongside California and Washington, to leading with science and delivering evidence-based recommendations that protect health, save lives, and restore confidence in our public health system."

"When federal agencies abandon evidence-based recommendations in favor of ideology, we cannot continue down that same path," said Dennis Worsham, Secretary of Health, Washington State Department of Health. "Washington State will not compromise when it comes to our values: science drives our public health policy. Public health at its core is about prevention — preventing illness, preventing the spread of disease, and preventing early, avoidable deaths.

We stand firmly with trusted medical professionals and organizations like the American Academy of Pediatrics and the American College of Obstetricians and Gynecologists, as well as fellow West Coast health agencies — whose guidance remains rooted in rigorous research and clinical expertise. Our commitment is to the health and safety of our communities, protecting lives through prevention, and not yielding to unsubstantiated theories that dismiss decades of proven public health practice."

Details about this new Alliance

Our three states share a commitment to ensuring that public health recommendations are guided by safety, efficacy, transparency, access, and trust. The Alliance will help safeguard scientific expertise by ensuring that public health policies in California, Oregon, and Washington are informed by trusted scientists, clinicians, and other public health leaders. **Through this partnership, the three states will start coordinating health guidelines by aligning immunization recommendations informed by respected national medical organizations.** This will allow residents to receive consistent, science-based recommendations they can rely on — regardless of shifting federal actions.

In the coming weeks, the Alliance will finalize shared principles to strengthen public confidence in vaccines and in public health. While each state will independently pursue strategies shaped by their unique laws, geographies, histories, and peoples, these shared principles will form the foundations of the Alliance. Importantly, the three states affirm and respect Tribal sovereignty, recognizing that Tribes maintain their sovereign authority over vaccine services.

Since its founding, the CDC has been central to protecting Americans from disease. But recent leadership changes, reduced transparency, and the sidelining of long-trusted advisory bodies have impaired the agency's capacity to prepare the nation for respiratory virus season and other public health challenges. In a vacuum of clear, evidence-based vaccine guidance, manufacturers lack reliable information to plan production, health care providers struggle to provide consistent plans of care, and families face uncertainty about access and coverage.

In June, California, Oregon, and Washington condemned Secretary Robert F. Kennedy Jr.'s removal of all 17 members of the CDC's Advisory Committee on Immunization Practices. Today, we reaffirm our commitment to science-driven decision-making. We will continue to provide clear, evidence-based guidance to people living in our states, look to scientific experts in trusted medical professional organizations for recommendations, and work with public health leaders across the country to ensure all Americans are protected. The absence of consistent, science-based federal leadership poses a direct threat to our nation's health security. To protect the health of our communities, the West Coast Health Alliance will continue to ensure that our public health strategies

:::::::

Northeastern states consider regional approach to vaccine guidance after CDC changes

Shifting national vaccine policy under Health Secretary Robert F. Kennedy Jr. has Massachusetts and other states exploring a regional approach.

By Malcolm Johnson • Published August 22, 2025 • Updated on August 22, 2025 at 7:44 pm ...Health officials from Massachusetts, Maine, Vermont, Connecticut, Rhode Island, New York, New Jersey and Pennsylvania met this week to consider coordinating their own vaccine recommendations, separate from the federal government...

......

U.S. Medical Societies, Health Organizations

are based on best available science.

Leading Physician Organizations Say Turmoil at the CDC Puts Lives at Risk

WASHINGTON September 3, 2025— Our organizations believe that the turmoil that occurred at the Centers for Disease Control and Prevention (CDC) last week will have harmful consequences for the health of the American public. The firing of Director Monarez and the resignation of multiple senior officials are alarming, threatening our nation's public health infrastructure. Leadership and oversight from Congress are needed now to ensure that our nation's public health is protected.

As physicians, we are extremely worried that this latest action takes place at the critical start of the flu and respiratory illness season, at a time when we should be increasing access to vaccines and encouraging their use. Instead, we receive confusing, often contradictory recommendations that are counter to the best-available evidence regarding vaccine use and infection mitigation that are already leading to additional restrictions on access. The consequences of this confusion will be harmful to the well-being of our patients. We are deeply concerned that this portends future attempts to impose restrictions on vaccines and other public health measures supported by sound scientific evidence.

Adding preventable stress to our already overburdened health care system, which has little to no capacity to absorb additional emergency department, outpatient, inpatient, and intensive care unit capacity is unacceptable. We need the CDC and other federal public health agencies to make decisions based on the best-available scientific evidence, guided by qualified experts in these fields and

supported by the resources they need. We need strong congressional oversight to enable these agencies to correct course and ensure they can protect the health of Americans.

American Academy of Family Physicians

American Academy of Pediatrics

American College of Emergency Physicians

American College of Physicians

American College of Obstetricians and Gynecologists

The American College of Obstetricians and Gynecologists (ACOG)

American Osteopathic Association (AOA)

American Psychiatric Association

Society of General Internal Medicine

.....

American Academy of Pediatrics (AAP)

https://www.aap.org/en/news-room/news-releases-from-the-aap/ (Accessed 04 Sep 2025)

News

AAP Says Decision to Limit Children's Access to Vaccines is Deeply Troubling

August 27, 2025

"Today's announcement from U.S. Department of Health and Human Services Secretary Robert F. Kennedy, Jr., proposing to limit the availability of COVID-19 vaccines for children and young adults is deeply troubling. ... "The AAP recommends the COVID-19 vaccine for all children ages 6 months through 23 months. Beyond age 2, we recommend annual shots for children and teens with health conditions that make COVID-19 especially risky. Any parent who wants their child vaccinated should have access to this vaccine; today's unprecedented action from HHS not only prevents this option for many families, but adds further confusion and stress for parents trying to make the best choices for their children. Parents and pediatricians, together, make the best decisions to protect children's long-term health. We urge the Administration to allow these choices to remain with medical experts and families."

American College of Physicians (ACP)

https://www.acponline.org/more-acp-news

(Accessed 04 Sep 2025)

ACP News

Leading physician organizations say turmoil at the CDC puts lives at risk

09/03/25

Infectious Diseases Society of America (IDSA)

https://www.idsociety.org/

(Accessed 04 Sep 2025)

News

Joint statement calling for Secretary Kennedy resignation

Last Updated - September 03, 2025

As national medical, scientific, public health and patient organizations, we call for the resignation of HHS Secretary Robert F. Kennedy Jr. to ensure the health of the American people.

Forcing high-level CDC expert leaders to turn their back on decades of sound science to meet Kennedy's agenda puts us all at risk. This final exclamation point on a term defined by repeated efforts to undermine science and public health definitively leaves Americans less safe in a multitude of ways...

American Public Health Association (APHA)

https://www.apha.org/news-and-media/news-

releases?sortFieldName=ItemDate&sortDisplayName=Newest&sortMode=desc

(Accessed 04 Sep 2025)

News Releases

Kennedy's attack on public health must be stopped

August 27, 2025

The abrupt attempt to oust Dr. Susan Monarez, the CDC's director just weeks after her Senate confirmation, is yet another glaring sign of Secretary Kennedy's failed leadership and reckless mismanagement.

Society for Maternal-Fetal Medicine (SMFM)

https://www.smfm.org/ (Accessed 04 Sep 2025)

Research

[No new digest content identified]

Massachusetts Public Health Alliance (MPHA)

https://mapublichealth.org/press-room/

(Accessed 04 Sep 2025)

Press Room

[No new digest content identified]

American Medical Association (AMA)

https://www.ama-assn.org/press-center

(Accessed 04 Sep 2025)

Press Center

AMA statement on Florida ending all vaccine mandates

Sep 3, 2025 |

The following statement is attributable to: <u>Sandra Adamson Fryhofer, MD</u>, Trustee, American Medical Association

"The American Medical Association strongly opposes Florida's plan to end all vaccine mandates, including those required for school attendance. This unprecedented rollback would undermine decades of public health progress and place children and communities at increased risk for diseases such as measles, mumps, polio, and chickenpox resulting in serious illness, disability, and even death. While there is still time, we urge Florida to reconsider this change to help prevent a rise of infectious disease outbreaks that put health and lives at risk."

American Academy of Family Physicians (AAFP)

https://www.aafp.org/news/media-center.html

(Accessed 04 Sep 2025)

Statements, Releases

[No new digest content identified]

American Geriatrics Society (AGS)

https://www.americangeriatrics.org/media-center

(Accessed 04 Sep 2025)

Recent Press Releases

<u>American Geriatrics Society Calls on the Administration to Ensure that Vaccine Policy in the United States Remains Evidence-Based</u>

New York (August 5, 2025)

American Osteopathic Association (AOA)

https://osteopathic.org/news/
(Accessed 04 Sep 2025)

Latest News
[No new digest content identified]

National Medical Association (NMA)

https://nmanet.org/blog/ (Accessed 04 Sep 2025) Latest News [No new digest content identified]

National Foundation for Infectious Diseases (NFID)

https://www.nfid.org/news-updates/ (Accessed 04 Sep 2025) News and Updates August 30, 2025

Staying on Track: Evidence-Based Vaccine Recommendations

Looking for trusted vaccine guidance? Read on for evidence-based immunization recommendations from professional medical groups and trusted NFID partners ...

:::::::

Civil Society Organizations

Center for Vaccine Ethics & Policy – GE2P2 Global Foundation

<u>Expression of Solidarity :: American Academy of Pediatricians (AAP) and American College of Obstetricians and Gynecologists (ACOG) – Issuance of Independent, Evidence-based Immunization Recommendations</u>

Issued 05 September 2025

The GE2P2 Global Foundation issues this expression of solidarity with AAP and ACOG as they continue to inform citizens of their respective immunization recommendations based on scientific evidence, rigorous analysis, and medical judgment.

Further, we call on these medical societies and all "liaison organizations" who have historically contributed to ACIP/CDC immunization recommendations over decades to stay engaged in the vaccines recommendations process and to challenge HHS processes and decisions wherever they are not scientifically rigorous and evidence-driven, or are otherwise politicized.

Expression of Concern :: U.S. Centers for Disease Control and Prevention [CDC] Bars Liaison Organizations from ACIP [Advisory Committee on Immunization Practice] Work Groups - 31 July 2025

Issued 05 September 2025

- :: Barring credentialed volunteer experts vetted for conflicts-of-interest from contributing to ACIP [Advisory Committee on Immunization Practice] work groups compromises critical scientific evidence review and vaccine recommendation processes
- :: This action damages the integrity of the well-grounded process to develop science-based immunization recommendations to protect public health from vaccine-preventable diseases

The GE2P2 Global Foundation calls on CDC leadership and the ACIP Secretariat to immediately restore Liaison Organization representatives to all current ACIP work groups and continue to integrate such representatives in future work groups.

::::::::

CIDRAP – Vaccine Integrity Project [UMinn]

https://www.cidrap.umn.edu/vaccine-integrity-project [Accessed 06 Sep2025] No new digest content identified.

::::::

Contents [click to move among sections]

:: Milestones, Perspectives

:: <u>WHO</u>

:: Organization Announcements

:: Journal Watch

:: Pre-Print Servers

::::::

Organization Announcements

Paul G. Allen Frontiers Group [06 Sep 2025]

https://alleninstitute.org/news-press/ Recent News No new digest content identified.

BMGF - Gates Foundation [06 Sep 2025]

https://www.gatesfoundation.org/ideas/media-center Press Releases & Statements No new digest content identified.

CARB-X [06 Sep 2025]

https://carb-x.org/ News

09.03.2025 |

CARB-X to support lower respiratory tract infection diagnostic by Zeteo

CARB-X has awarded Zeteo Tech, Inc. US\$1M to execute a workplan for its noninvasive diagnostic platform that aims to evaluate whether exhaled breath can diagnose lower respiratory tract infections (LRTIs) in high-risk populations within critical care environments, including intubated patients with mechanical ventilation.

Chan Zuckerberg Initiative [06 Sep 2025]

https://chanzuckerberg.com/newsroom/

Newsroom

No new digest content identified.

CEPI – Coalition for Epidemic Preparedness Innovations [06 Sep 2025]

http://cepi.net/

CEPI News, Blog

News

New global collaboration uses experts and AI to spot the next pandemic

Combining AI programmes and disease knowledge can help more accurately rank the viruses that have the potential to cause the next pandemic.

3 Sep 2025

CIOMS - COUNCIL FOR INTERNATIONAL ORGANIZATIONS OF MEDICAL SCIENCES [to 06

Sep 2025]

https://cioms.ch/

News; Publications; Events

CIOMS Benefit-risk balance webinar

Online September 10, 2025

In May 2025, the Council for International Organizations of Medical Sciences (CIOMS) published its consensus report on Benefit-risk balance for medicinal products. This webinar introduces and explains the main concepts of the report...

DARPA – Defense Advanced Research Projects Agency [U.S.] [06 Sep 2025]

https://www.darpa.mil/news

News

No new digest content identified.

DNDI – Drugs for Neglected Diseases initiative [06 Sep 2025]

https://dndi.org/press/press-releases/

Press Releases

No new digest content identified.

Duke Global Health Innovation Center [06 Sep 2025]

https://dukeghic.org/

News

No new digest content identified.

EDCTP [06 Sep 2025]

http://www.edctp.org/

The European & Developing Countries Clinical Trials Partnership (EDCTP) aims to accelerate the development of new or improved drugs, vaccines, microbicides and diagnostics against HIV/AIDS, tuberculosis and malaria as well as other poverty-related and neglected infectious diseases in sub-Saharan Africa, with a focus on phase II and III clinical trials

News

No new digest content identified.

Emory Vaccine Center [06 Sep 2025]

http://www.vaccines.emory.edu/

Vaccine Center News

No new digest content identified.

European Vaccine Initiative [06 Sep 2025]

http://www.euvaccine.eu/

Latest News, Events

Naobios, Nuvonis and European Vaccine Initiative collaborate on manufacturing influenza challenge agent

Working with the Inno4Vac consortium coordinated by European Vaccine Initiative, Naobios will leverage Nuvonis's Vero Cell Bank to...

Fondation Merieux [06 Sep 2025]

http://www.fondation-merieux.org/

News, Events

No new digest content identified.

Gates Medical Research Institute [06 Sep 2025]

https://www.gatesmri.org/news

The Gates Medical Research Institute is a non-profit organization dedicated to the discovery, development and effective use of novel biomedical interventions addressing substantial global health concerns, for which investment incentives are limited.

News: Articles and Publications No new digest content identified.

Gavi [06 Sep 2025] https://www.gavi.org/ Press Releases

26 August 2025

Gavi welcomes renewed commitments to health equity and security made at TICAD9

- :: Prime Minister of Japan H.E. Shigeru Ishiba announces Japan's contribution of up to US\$ 550 million to Gavi's next strategic period at TICAD9
- :: Gavi and the African Union Commission renew commitment to advance universal health coverage and health security in Africa through immunisation, innovation, and co-created solutions

25 August 2025

Gavi expands US\$ 28 million Health Facility Solarisation Project with inauguration of first facility in Zambia

- :: Zambia is the first of four Health Facility Electrification (HFSE) implementors alongside Pakistan, Ethiopia, and Uganda to inaugurate a solarised facility
- :: Over 250 remote healthcare facilities across Zambia will be powered with solar energy, benefitting an estimated 1.3 million people
- :: Backed by Gavi funding, this initiative is designed to enhance the functionality of vaccine supply chains, power essential medical equipment, support staff housing and improve maternal and primary health services

GE2P2 Global Foundation [06 Sep 2025]

www.ge2p2.org

News/Analysis/Publications-Digests/Statements

<u>Expression of Solidarity :: American Academy of Pediatricians (AAP) and American College of Obstetricians and Gynecologists (ACOG) – Issuance of Independent, Evidence-based</u>

Immunization Recommendations

Issued 05 September 2025

Expression of Concern :: U.S. Centers for Disease Control and Prevention [CDC] Bars
Liaison Organizations from ACIP [Advisory Committee on Immunization Practice] Work
Groups - 31 July 2025

Issued 05 September 2025

Digests

- :: Vaccines and Global Health: The Week in Review Current edition
- :: Informed Consent: A Monthly Review May 2025
- :: Public Consultations Watch :: Global Calls for Input/Public Comment 28 Aug 2025
- :: Genomics :: Governance, Ethics, Policy, Practice A Monthly Digest May 2025

GHIT Fund [06 Sep 2025]

https://www.ghitfund.org/newsroom/press Press Releases No new digest content identified.

Global Fund [06 Sep 2025]

https://www.theglobalfund.org/en/news/ News Releases 27 August 2025

Global Fund Warmly Welcomes Australia's Pledge to the Eighth Replenishment

The Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund) warmly welcomes Australia's early pledge of AUD 266 million to the Eighth Replenishment, reinforcing Australia's commitment to ending the three epidemics as public health threa...

Global Research Collaboration for Infectious Disease Preparedness [GloPID-R] [06 Sep 2025]

https://www.glopid-r.org/

GloPID-R Launches First Coordinated Funding Call to Boost Clinical Trial Readiness in LMICs

September 4, 2025

... The Call 1 theme—strengthening the clinical research ecosystem in low- and middle-income countries (LMICs) to improve good clinical practices—was chosen by the GloPID-R members in recognition of their pivotal role in building coordinated, equitable clinical trial capacity worldwide

The call seeks to directly advance the World Health Organization's (WHO) Global Action Plan for Clinical Trial Ecosystem Strengthening (GAP-CTS) which delivers the commitments outlined by the World Health Assembly Resolution 75.8 and operationalizing the goals and principles of the GloPID-R Funders Living Roadmap for Clinical Trial Coordination....

Hilleman Laboratories [06 Sep 2025]

http://www.hilleman-labs.org/ News & Insights No new digest content identified.

HHMI - Howard Hughes Medical Institute [06 Sep 2025]

https://www.hhmi.org/news

Press Room

No new digest content identified.

Human Immunome Project [nee Human Vaccines Project] [06 Sep 2025]

https://www.humanimmunomeproject.org/

News

No new digest content identified.

IAVI [06 Sep 2025] https://www.iavi.org/ Press Releases, Features No new digest content identified.

INSERM [06 Sep 2025]

https://www.inserm.fr/en/home/

Press Releases

No new digest content identified.

International Coalition of Medicines Regulatory Authorities [ICMRA]

http://www.icmra.info/drupal/en/news Selected Statements, Press Releases, Research No new digest content identified.

ICH [International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use] [06 Sep 2025]

https://www.ich.org/

News/Pubs/Press Releases [Selected]

7 August 2025

ICH Q3E Draft Guideline is Available Now on the ICH Website

The ICH Q3E draft "Guideline for Extractables and Leachables" and supporting document has reached Step 2b of the ICH Process on 1 August 2025 and entered the Step 3 public consultation period.

On	Ongoing Public Consultations		
>	M13B EWG	Bioequivalence for Immediate-Release Solid Oral Dosage Forms	
>	Q1 EWG	Stability Testing of Drug Substances and Drug Products	
> M4Q(R2) EWG Revision of M4Q(R1)			
>	E21 EWG	Inclusion of Pregnant and Breastfeeding Individuals in Clinical Trials	
>	Q3E EWG	Guideline for Extractables and Leachables	
~	E20 EWG	Adaptive Designs for Clinical Trials	

https://www.ich.org/page/public-consultations

E20 EWG Adaptive Designs for Clinical Trials

The E20 EWG is working on the development of a new E20 Guideline on "Adaptive Clinical Trials" on the design, conduct, analysis, and interpretation of adaptive clinical trials that provides a transparent and harmonized set of principles for the regulatory review of these studies in a global drug development program. These principles should also provide the flexibility to evaluate / discuss innovative approaches to clinical trial design throughout the development process.

Following MC approval in June 2025 the E20 Guideline title was changed to "Adaptive Designs for Clinical Trials"

Rapporteur: Dr. Gregory Levin (FDA, United States) Regulatory Chair: Dr. Christian Roes (EC, Europe) Date of Step 2b: 25 June 2025 Status: Step 3

Public consultation dates:

ANMAT, Argentina - Deadline for comments by 8 October 2025 EC, Europe - Deadline for comments by 30 November 2025 Health Canada, Canada - Deadline for comments by 25 September 2025 MHRA, UK - Deadline for comments by 30 November 2025 Swissmedic, Switzerland - Deadline for comments by 30 November 2025 TFDA, Chinese Taipei - Deadline for comments by 13 October 2025

ICRC [06 Sep 2025]

https://www.icrc.org/en/news

News

<u>Israel and the occupied territories: ICRC reiterates call to release hostages after release of distressing video</u>

Statement 05-09-2025

Afghanistan: Swift response needed to help those hit by devastating earthquake

News release 02-09-2025

IFFIm [06 Sep 2025] http://www.iffim.org/ Press Releases/Announcements No new digest content identified.

IFRC [to 06 Sep 2025]

http://media.ifrc.org/ifrc/news/press-releases/

Press releases

Press release 05/09/2025

IFRC: Acting before disasters strike is key to saving lives and protecting human development progress in South America

Press release 03/09/2025

Pakistan floods: Escalating humanitarian crisis amid climate extremes

Press release 01/09/2025

Afghanistan earthquake: IFRC responds to devastating quake in southeastern provinces

IPPS - International Pandemic Preparedness Secretariat [06 Sep 2025]

https://ippsecretariat.org/news/

News

No new digest content identified.

Institut Pasteur [06 Sep 2025]

https://www.pasteur.fr/en/press-area

Press Documents

No new digest content identified.

ISC / International Science Council [06 Sep 2025]

https://council.science/current/

ISC is a non-governmental organization with a unique global membership that brings together 40 international scientific Unions and Associations and over 140 national and regional scientific organizations including Academies and Research Councils.

Latest Updates

No new digest content identified.

International Union of Immunological Societies (IUIS)

https://iuis.org/

News/Events [Selected]

19th Vaccine Congress

Sunday 7th September 2025 at Kyoto International Conference Center

Organized by <u>Vaccine</u>, the premier journal for those interested in vaccine science, the congress will bring together leading experts from all over the world to share the latest cutting-edge discoveries in the field.

IVAC [06 Sep 2025]

https://www.jhsph.edu/research/centers-and-institutes/ivac/index.html

Updates; Events

No new digest content identified.

IVI [06 Sep 2025]

http://www.ivi.int/

IVI News & Announcements

The Zambia National Public Health Institute and International Vaccine Institute sign MoU

September 4, 2025, LUSAKA, Zambia — The Zambia National Public Health Institute (ZNPHI) and International Vaccine Institute (IVI) signed a landmark Memorandum of Understanding (MoU) to strengthen Zambia's end-to-end capacity for vaccine and therapeutic innovation. The collaboration positions Zambia as a regional leader in sustainable vaccine production and health security...

<u>Strengthening Adult Immunization Policy in APEC – Regional Alignment and Global Engagement</u>

September 15, 2025 (Monday), 16:30–18:30 KST, as part of the APEC High-Level Meeting on Health and the Economy (HLMHE) & World Bio Summit 2025.

IVI is leading global efforts to prioritize adult immunization on the policy agenda. Hosted by IVI and sponsored by Moderna, this free in-person and live-streamed forum will bring together government officials, policymakers, industry experts, and civil society to discuss strategies for advancing adult

immunization across APEC economies.

Johns Hopkins Center for Health Security [06 Sep 2025]

https://centerforhealthsecurity.org/newsroom
Center News [Selected]
No new digest content identified.

MSF/Médecins Sans Frontières [06 Sep 2025]

http://www.msf.org/ Latest [Selected Announcements] About MSF

Dr Javid Abdelmoneim starts as new MSF International President

Press Release 3 Sep 2025

National Academy of Medicine - USA [06 Sep 2025]

https://nam.edu/programs/ News, Stories, Insights No new digest content identified.

National Academies-Sciences-Engineering-Medicine [NASEM]- USA [to 06 Sep 2025]

https://www.nationalacademies.org/newsroom

News

New Report Identifies Policy Options to Improve Federal Research Regulations, Bolster U.S. Scientific Competitiveness

The U.S. scientific enterprise has produced significant advances in technologies and medicines for the nation but is being held back by uncoordinated regulations and policies. A new National Academies report examines the landscape of federal regulations and outlines policy options to alleviate administrative and regulatory burden.

Date 2025-09-03 Type News Release

PATH [06 Sep 2025] https://www.path.org/media-center/ Newsroom [Selected] No new digest content identified.

Sabin Vaccine Institute [06 Sep 2025]

https://www.sabin.org/press/ Latest News & Press Releases No new digest content identified.

UNAIDS [06 Sep 2025] http://www.unaids.org/en News, Stories, Updates Press Release

<u>UNAIDS</u> welcomes US announcement to expand access to medicine to prevent HIV and urges greater global ambition to reach all in need

GENEVA, 5 September 2025—UNAIDS welcomes the announcement by the US State Department that the President's Emergency Plan for AIDS Relief (PEPFAR) will be supporting an initiative by the Global Fund to Fight AIDS, TB and Malaria to provide lenacapavir to up to 2 million people in countries with high burdens of HIV...

UNICEF [to 06 Sep 2025]

https://www.unicef.org/media/press-releases

Latest press releases, news notes and statements [Selected]

Remarks 04 September 2025

The unthinkable in Gaza City has already begun

AL MAWASI, GAZA, 4 September 2025 –, "Gaza City, the last refuge for families in the northern Gaza Strip, is fast becoming a place where childhood cannot survive. It is a city of fear, flight and funerals. "The world is sounding the alarm about what an intensified military offensive in Gaza City could bring - a ca...

Press release 02 September 2025

<u>Global funding cuts could force 6 million more children out of school in the coming year – UNICEF</u>

NEW YORK, 3 September 2025, – As global education funding faces steep cuts, an estimated 6 million additional children could be out of school by the end of 2026, around one-third of them in humanitarian settings, UNICEF warned in a new analysis released today. Official Development Assistance (ODA) for education is...

Remarks 02 September 2025

<u>UNICEF Executive Director Catherine Russell remarks at the second regular session of the UNICEF Executive Board</u>

NEW YORK, 2 September 2025, — "Excellencies, distinguished delegates, colleagues and friends ... "It is my pleasure to welcome you to this second regular session of the UNICEF Executive Board for 2025. I begin by extending my sincere gratitude to Ambassador Hikmat, President of the Executive Board, and to the entire...

Statement 01 September 2025

Thousands of children at risk after devastating earthquake hits eastern Afghanistan

KABUL, 1 September 2025 – , "A powerful 6.0-magnitude earthquake struck eastern Afghanistan late last night, with its epicentre near Jalalabad in Nangarhar province. Early reports indicate a significant loss of life, including many children, with hundreds of fatalities and thousands injured, alongside widespread d...

Unitaid [06 Sep 2025] https://unitaid.org/ Press Releases No new digest announcements identified.

Vaccine Equity Cooperative [nee Initiative] [06 Sep 2025]

https://vaccineequitycooperative.org/news/

News

No new digest content identified.

Vaccine Confidence Project [06 Sep 2025]

http://www.vaccineconfidence.org/ News, Research and Reports No new digest content identified.

Vaccine Education Center – Children's Hospital of Philadelphia [06 Sep 2025]

http://www.chop.edu/centers-programs/vaccine-education-center
News

<u>September 2025 — Cutting through the Confusion on COVID-19 Vaccination of Young</u> Children in Fall 2025

In this short video, Dr. Paul Offit addresses the confusion surrounding COVID-19 vaccination in young children. You'll also find resources related to measles and to aluminum in vaccines.

Wellcome Trust [06 Sep 2025]

https://wellcome.org/news/all News. Opinion, Reports No new digest content identified.

The Wistar Institute [to 06 Sep

2025]

https://www.wistar.org/news/press-

releases *Press Releases*

September 4, 2025

<u>The Wistar Institute Appoints Katherine Aird, Ph.D., to Ellen and Ronald Caplan Cancer</u> Center

The Wistar Institute announces the appointment of Katherine Aird, Ph.D., as co-leader and professor in the Molecular and Cellular Oncogenesis Program of the Ellen and Ronald Caplan Cancer Center.

World Bank [06 Sep 2025]

http://www.worldbank.org/en/news/all

All News [Selected]

No new digest announcements identified.

WFPHA: World Federation of Public Health Associations [06 Sep 2025]

https://www.wfpha.org/

Blog, Events

No new digest content identified.

World Medical Association [WMA] [06 Sep 2025]

https://www.wma.net/news-press/press-releases/

Press Releases

WMA Opens Recruitment for New Secretary General

02.09.2025

World Organisation for Animal Health [OIE] [06 Sep 2025]

https://www.oie.int/ Press Releases, Statements No new digest announcements identified.

::::::

ARM [Alliance for Regenerative Medicine] [06 Sep 2025]

https://alliancerm.org/press-releases/ Selected Press Releases No new digest announcements identified.

BIO [06 Sep 2025] https://www.bio.org/press-releases Press Releases No new digest announcements identified.

DCVMN – Developing Country Vaccine Manufacturers Network [06 Sep 2025]

http://www.dcvmn.org/ News; Upcoming events

DCVMN Annual General Meeting 2025

October 29 - 31, 2025 Bali, Indonesia

ICBA – International Council of Biotechnology Associations [06 Sep 2025]

https://internationalbiotech.org/news/

News

No new digest announcements identified.

IFPMA [06 Sep 2025]

https://ifpma.org/ News, Statements [Selected] Statement 5 Sep 2025

Statement on the publication of the 24th WHO Model List of Essential Medicines

Responding to the publication of the updated WHO Model List of Essential Medicines (EML), IFPMA Director General, Dr. David Reddy said: "The inclusion of innovative medicines on the updated EML highlights how scientific advances are transforming how we prevent, treat and cure disease, and reinforces the importance of ensuring patients everywhere can benefit from them...

"We welcome the opportunity to contribute our expertise to the EML process, to help ensure that decisions are informed by the most current and robust evidence, while maintaining the policies and IP framework that sustains the innovation our companies deliver for patients."

International Alliance of Patients' Organizations – IAPO [06 Sep 2025]

https://www.iapo.org.uk/news Press and media [Selected]

International Generic and Biosimilar Medicines Association [IGBA]

https://www.igbamedicines.org/

News

No new digest announcements identified.

PhRMA [06 Sep 2025]

http://www.phrma.org/

Press Releases

No new digest announcements identified.

::::::

Vaccines/Therapeutics/Medicines - Selected Developer/Manufacturer Announcements

We recognize that this listing is indicative but certainly not exhaustive. We invite nomination of other vaccine developers for potential addition to those monitored below.

AstraZeneca

Press Releases - No new digest announcements identified.

Bavarian Nordic

<u>Latest News</u> - No new digest announcements identified.

BioCubaFarma – Cuba

<u>Últimas Noticias</u> - No new digest announcements identified.

Biological E

<u>News</u> - No new digest announcements identified.

BioNTech

<u>Press Releases</u> - No new digest announcements identified.

Boehringer

<u>Press Releases</u> - No new digest announcements identified.

CanSinoBIO

<u>News</u> - Website not responding at inquiry.

CIGB

<u>Latest News</u> - No new digest announcements identified.

CinnaGen

Recent News - No new digest announcements identified.

Clover Biopharmaceuticals – China

News - No new digest announcements identified.

Curevac

News - No new digest announcements identified.

Gamaleya National Center/Sputnik

<u>Latest News and Events</u> - No new digest announcements identified [Last: 09 Nov 2020] <u>https://sputnikvaccine.com/</u> - No new digest announcements identified [Last: 31 Aug 2022]

GSK

Press releases for media - No new digest announcements identified.

EuBiologics, S Korea

<u>News</u> - No new digest announcements identified.

IMBCAMS, China

Home - Website not responding at inquiry.

JNJ Innovative Medicine [Janssen]

<u>Press Releases</u> - No new digest announcements identified.

Merck

News releases - No new digest announcements identified.

Nanogen

News - No new digest announcements identified.

Novartis

<u>News</u> - No new digest announcements identified.

Novavax

Press Releases

Nuvaxovid® Now Approved in Japan Triggering Takeda Milestone Payment

GAITHERSBURG, Md., Sept. 4, 2025 /PRNewswire/ -- Novavax, Inc. (Nasdaq: NVAX) today announced a milestone payment* from Takeda has been triggered by regulatory approval for Novavax's COVID-19 vaccine Nuvaxovid® Intramuscular Injection 1 mL formulated to target SARS-CoV-2 Omicron LP.8.1 as an initial immunization (first and second vaccination) for those aged six years or older and a booster immunization (after the third vaccination) for those aged 12 years or older...

Novavax Statement on Publicly Available COVID-19 Vaccine Data

September 3, 2025

Novavax is a U.S.-based biotechnology company that is proud to have successfully developed a COVID-19 vaccine as part of President Trump's Operation Warp Speed. Under President Trump's leadership, this program enabled the ingenuity of the American scientific community to come together to solve the most pressing public health issue of our lifetime. For Novavax, this resulted in the development of the only non-mRNA, protein-based COVID-19 vaccine available in the U.S. and many markets around the world.

We applaud President Trump's call for available data, and consistent with that, we have shared clinical and preclinical data, and real-world evidence for Novavax's COVID-19 vaccine via publication, at medical meetings, on our website and/or via press release. Additionally, we have made these data available to the U.S. Food and Drug Administration, the U.S. Centers for Disease Control and Prevention, dozens of regulatory bodies around the world and scientific and medical experts in public health. A list of publicly available information is at the link here and we will continue to add additional information here.

Novavax's COVID-19 vaccine is based on a well-established, protein-based technology platform that includes our proprietary Matrix-M® adjuvant. Through Operation Warp Speed and President Trump's leadership, Americans have been given an important tool to protect themselves and ensure that they have choice in doing so

Pfizer

Recent Press Releases - No new digest announcements identified.

R-Pharm

https://rpharm-us.com/index.php
[No news or media page identified]

Sanofi Pasteur

Press Releases

ERS: new data across Sanofi's immunology pipeline reinforce leadership in respiratory diseases

September 4, 2025

Serum Institute

News & Announcements - No new digest announcements identified.

Sinopharm/WIBPBIBP

News - No new digest announcements identified.

Sinovac

<u>Press Releases</u> - No new digest announcements identified.

SK Biosciences

Press Releases

SK bioscience Submits IND for Phase 3 Clinical Trial of 2-Dose Varicella Vaccine

- :: Approximately 800 children aged 12 months to 12 years in Korea and abroad, aiming for completion by 2027
- :: Rising demand for 2-dose regimen as international standards amid projected global market growth to USD 6.3 billion by 2034
- :: SKBS continues strategic R&D to enhance global vaccine competitiveness of its vaccine pipelines 2025.09.02

Takeda

Newsroom - No new digest announcements identified.

Valneva

Press Releases

September 3, 2025

<u>Valneva Reports Further Positive Phase 2 Safety and Immunogenicity Results for Lyme Disease Vaccine Candidate</u>

WestVac Biopharma

Media - No new digest announcements identified.

Zhifei Longcom, China

[Anhui Zhifei Longcom Biologic Pharmacy Co., Ltd.] <u>Website</u> [No News/Announcements page identified]

::::::

Contents [click to move among sections]

:: Milestones, Perspectives

:: <u>WHO</u>

:: Organization Announcements

:: <u>Journal Watch</u>

:: Pre-Print Servers

::::::

Journal Watch

Vaccines and Global Health: The Week in Review continues its weekly scanning of key peer-reviewed journals to identify and cite articles, commentary and editorials, books reviews and other content supporting our focus on vaccine ethics and policy. Journal Watch is not intended to be exhaustive, but indicative of themes and issues the Center is actively tracking. We selectively provide full text of some editorial and comment articles that are specifically relevant to our work. Successful access to some of the links provided may require subscription or other access arrangement unique to the publisher.

If you would like to suggest other journal titles to include in this service, please contact David Curry at: david.r.curry@centerforvaccineethicsandpolicy.org

AJOB Empirical Bioethics

Volume 16, 2025 Issue 3 https://www.tandfonline.com/toc/uabr21/current [Reviewed earlier]

AMA Journal of Ethics

Volume 27, Number 8: E541-627

https://journalofethics.ama-assn.org/issue/existential-health-care-ethics

Existential Health Care Ethics

The American Medical Association declares that physicians will address "natural and man-made assaults on the health and wellbeing of humankind," and that "[h]umanity is our patient." The World Medical Association likewise pledges physicians "to the service of humanity." This theme issue considers that, if these are to be more than mere assertions, we must think more powerfully than we have in the past about what continued human existence requires of global and domestic health care.

As an emerging area of moral philosophical inquiry concerned with human extinction, existential health care ethics considers the nature and scope of what health professionals and health professions are obliged to do—as individuals and collectives—to orient us to threats that undermine humanity's survival. Such threats include familiar ones like critical resource depletion and weapons of mass destruction proliferation and less familiar ones like planetary-scale anthropogenic disequilibrium of Earth systems and dual (military and civilian) use of technology applications.

American Journal of Human Genetics

Aug 07, 2025 Volume 112Issue 8 p1733-1980 https://www.cell.com/ajhg/current
This month in *The Journal*Paul W. Hook,vSara B. Cullinan

The use of genomic testing for diagnostic purposes has increased as the cost of sequencing has decreased. However, genomic testing has been deployed mostly in pediatric settings with information on how it can benefit adult populations lacking. In this issue, Gold et al. assess the utility of sequencing for diagnostic purposes in a young adult (ages 18–40) population admitted to the intensive care unit (ICU). Through whole-exome sequencing, the authors discovered 24.4% of the 365 individuals in the cohort had a diagnostic variant.

American Journal of Infection Control

August 2025 Volume 53 Issue 8 p809-918 http://www.ajicjournal.org/current [Reviewed earlier]

American Journal of Preventive Medicine

August 2025 Volume 69 Issue 2 https://www.ajpmonline.org/current [Reviewed earlier]

American Journal of Public Health

August 2025 115(8) http://ajph.aphapublications.org/toc/ajph/current [Reviewed earlier]

American Journal of Tropical Medicine and Hygiene

Volume 113 (2025): Issue 2 (Aug 2025) https://www.ajtmh.org/view/journals/tpmd/113/1/tpmd.113.issue-2.xml [Reviewed earlier]

Annals of Internal Medicine

August 2025 Volume 178, Issue 8 https://www.acpjournals.org/toc/aim/current [Reviewed earlier]

Artificial Intelligence – An International Journal

Volume 345 August 2025 https://www.sciencedirect.com/journal/artificial-intelligence/vol/345/suppl/C [Reviewed earlier]

BMC Cost Effectiveness and Resource Allocation

http://resource-allocation.biomedcentral.com/ (Accessed 06 Sep 2025) [No new digest content identified]

BMC Health Services Research

http://www.biomedcentral.com/bmchealthservres/content

(Accessed 06 Sep 2025 [No new digest content identified]

BMC Infectious Diseases

http://www.biomedcentral.com/bmcinfectdis/content (Accessed 06 Sep 2025) [No new digest content identified]

BMC Medical Ethics

http://www.biomedcentral.com/bmcmedethics/content (Accessed 06 Sep 2025) [No new digest content identified]

BMC Medicine

http://www.biomedcentral.com/bmcmed/content (Accessed 06 Sep 2025) No new digest content identified]

BMC Pregnancy and Childbirth

http://www.biomedcentral.com/bmcpregnancychildbirth/content (Accessed 06 Sep 2025) No new digest content identified]

BMC Public Health

http://bmcpublichealth.biomedcentral.com/articles

(Accessed 06 Sep 2025)

<u>Assessing immunization coverage in Southern togo: implications for perennial malaria chemoprevention delivery</u>

Malaria remains a major health challenge in sub-Saharan Africa, especially for children under five. The World Health Organization (WHO) recommends perennial malaria chemoprevention (PMC) to children in areas o...

Authors: Shino Arikawa, Martin Kouame Tchankoni, Fifonsi Gbeasor-Komlanvi, Somiabalo P. Atekpe, Tinah Atcha-Oubou, Antía Figueroa-Romero, Joanna Orne-Gliemann, Clara Menendez, Raquel Gonzalez,

Valérie Briand and Didier Ekouevi

Citation: BMC Public Health 2025 25:3035

Content type: Research Published on: 2 September 2025

Explanatory spatial modeling of COVID-19 vaccine coverage in Thailand: policy implications for equitable distribution

The COVID-19 pandemic posed significant challenges globally, with vaccine distribution being a critical factor for recovery. Despite achieving vaccination targets, Thailand faced disparities in vaccine coverag...

Authors: Kittipong Sornlorm and Sarayu Muntaphan

Citation: BMC Public Health 2025 25:3028

Content type: Research Published on: 2 September 2025

Assessing the impact of childhood pneumococcal vaccination on pneumonia mortality in Colombia: a 14-year analysis

The 10-valent pneumococcal conjugate vaccine (PCV10) has been offered to all infants through Colombia's National Immunization Program (NIP) since 2012, with catch-up vaccination until age 5. However, pneumococ...

Authors: C. I. Parellada, L. F. Reyes, J. Urrego-Reyes, J. L. Webster, P. C. Pungartnik, A C Dos Santos,

M. Rojas and F. de la Hoz

Citation: BMC Public Health 2025 25:2990

Content type: Research Published on: 1 September 2025

BMC Research Notes

http://www.biomedcentral.com/bmcresnotes/content (Accessed 06 Sep 2025) [No new digest content identified]

BMJ Evidence-Based Medicine

August 2025 - Volume 30 - 4 https://ebm.bmj.com/content/30/4 [Reviewed earlier]

BMJ Global Health

August 2025 - Volume 10 - Suppl 5 https://gh.bmj.com/content/10/Suppl 5 [Reviewed earlier]

Bulletin of the Atomic Scientists

DIGITAL MAGAZINE - July 2025 https://thebulletin.org/magazine/2025-07/ [Reviewed earlier]

Bulletin of the World Health Organization

Volume 103, Number 8, August 2025, 465-516 https://www.who.int/publications/journals/bulletin/ [Reviewed earlier]

Cell

Aug 21, 2025 Volume 188 Issue 17 p4475-4810 https://www.cell.com/cell/current [Reviewed earlier]

Cell and Gene Therapy Insights

May 2025 Issue Volume 11 Issue 4 https://www.insights.bio/cell-and-gene-therapy-insights/journal/250/volume-11-issue-4 [Reviewed earlier]

Child Care, Health and Development

Volume 51, Issue 5 September 2025 https://onlinelibrary.wiley.com/toc/13652214/current RESEARCH ARTICLE

<u>Looped Audiovisual Health Education Talk Reduces Vaccine Clinic Wait Time in Nigeria</u>
Rosena O. Oluwafemi, Bukola Ajayi, Eneida A. Mendonca, Paul Biondich, Osayame A. Ekhaguere

e70152

First Published: 04 August 2025

Clinical Pharmacology & Therapeutics

Volume 118, Issue 3 Pages: 521-745 September 2025 https://ascpt.onlinelibrary.wiley.com/toc/15326535/current [Reviewed earlier]

Clinical Therapeutics

August 2025 Volume 47Issue 8 p533-662 http://www.clinicaltherapeutics.com/current [Reviewed earlier]

Clinical Trials

Volume 22 Issue 4, August 2025 https://journals.sagepub.com/toc/ctja/22/4 [Reviewed earlier]

Conflict and Health

http://www.conflictandhealth.com/ [Accessed 06 Sep 2025] [No new digest content identified]

Contemporary Clinical Trials

Volume 155 August 2025 https://www.sciencedirect.com/journal/contemporary-clinical-trials/vol/155/suppl/C [Reviewed earlier]

The CRISPR Journal

Volume 8, Issue 4 / August 2025 https://www.liebertpub.com/toc/crispr/8/4 [Reviewed earlier]

Current Genetic Medicine Reports

Volume 13, Issue 1 December 2025 https://link.springer.com/journal/40142/volumes-and-issues/13-1 [Reviewed earlier]

Current Medical Research and Opinion

Volume 41, Issue 3 2025 https://www.tandfonline.com/toc/icmo20/current [Reviewed earlier]

Current Opinion in Infectious Diseases

August 2025 - Volume 38 - Issue 4 https://journals.lww.com/co-infectiousdiseases/pages/currenttoc.aspx [Reviewed earlier]

Current Protocols in Human Genetics

https://currentprotocols.onlinelibrary.wiley.com/journal/19348258 [Accessed 06 Sep 2025] [No new digest content identified]

Cytotherapy

September 2025 Volume 27 Issue 9 p1031-1150 https://www.isct-cytotherapy.org/current SHORT REPORT / Perspectives

<u>Cellular gene therapy access in Africa: a multifactorial feasibility analysis for implementation</u>

<u>Cynthia C. Obiozor cynthia.obiozor@gmail.com</u> · <u>Lukejohn W. Day</u> · <u>Bukhosi Dube</u> · ... · <u>Carl H. June</u> · <u>Bruce L. Levine levinebl@pennmedicine.upenn.edu</u> · <u>Stephen M. Sammut</u> ... Show more <u>Abstract</u>

Cutting-edge therapeutics, such as cellular and gene therapies, can address critical health care access gaps, improving outcomes for diseases that disproportionately affect individuals living in Africa. Despite the potential to transform health care, financial and clinical infrastructure factors have limited their use. With the potential for better survival rates, improved quality of life, and fewer side effects, is it time to prioritize the development of innovative therapies in Africa? Using CAR T-cell therapies as an exemplar, this study examines whether implementing these therapies is feasible and what strategic shifts are required to make them viable across the continent. With proper clinical infrastructure and expertise, introducing these therapies could drive a medical "leapfrog" phenomenon in African health care, similar to how the telecommunications and mobile banking sectors have rapidly accelerated the continent's development.

Developing World Bioethics

Volume 25, Issue 3 Pages: 165-252 September 2025 https://onlinelibrary.wiley.com/toc/14718847/current ORIGINAL ARTICLES

<u>Adults aged 65 years and older in South Africa have a responsibility to vaccinate against</u> influenza

Ruach Sarangarajan, Cornelius Ewuoso

Pages: 228-238

First Published: 18 November 2024

Development in Practice

Volume 35, Issue 5, 2025 https://www.tandfonline.com/toc/cdip20/35/5?nav=tocList [Reviewed earlier]

Development Policy Review

Volume 43, Issue 5 September 2025 https://www.tandfonline.com/toc/cdip20/35/5?nav=tocList [Reviewed earlier]

Disaster Medicine and Public Health Preparedness

Volume 19 - 2025

https://www.cambridge.org/core/journals/disaster-medicine-and-public-health-preparedness/latest-

<u>issue</u>

[Reviewed earlier]

Disasters

Volume 49, Issue 4 October 2025

https://onlinelibrary.wiley.com/toc/14677717/current

Future of humanitarian and development aid

Humanitarian reform in 2025: why this time has to be different

Samir Elhawary

e70008

First Published: 21 August 2025

Lack of accountability, not budget cuts, is the real humanitarian crisis

Mohamed Hassan Mohamud

e70005

First Published: 29 August 2025

A post-social question

<u>Juliano Fiori</u>

e70007

First Published: 05 September 2025

The unbearable lightness of humanitarian reform: Reflections on calls for change in the sector

Sherine El Taraboulsi-McCarthy DPhil

e70006

First Published: 05 September 2025

eBioMedicine

Volume 117 July 2025

https://www.sciencedirect.com/journal/ebiomedicine/vol/117/suppl/C

[Reviewed earlier]

EMBO Reports

Volume 26 Issue 16 22 August 2025

https://www.embopress.org/toc/14693178/current [Reviewed earlier]

Emerging Infectious Diseases

Volume 31, Number 9—September 2025 http://wwwnc.cdc.gov/eid/ Perspective

Chagas Disease, an Endemic Disease in the United States

N. L. Beatty et al.

Epidemics

Volume 51 June 2025 https://www.sciencedirect.com/journal/epidemics/vol/51/suppl/C [Reviewed earlier]

Epidemiology and Infection

Volume 153 - 2025 https://www.cambridge.org/core/journals/epidemiology-and-infection/latest-issue [Reviewed earlier]

Ethics & Human Research

Volume 47, Issue 4 Pages: 1-17 July-August 2025 https://onlinelibrary.wiley.com/toc/25782363/current Sharing aggregate results :: Consent and health data

[Reviewed earlier]

Ethics & International Affairs

Volume 39 - Issue 1 - Spring 2025 https://www.cambridge.org/core/journals/ethics-and-international-affairs/latest-issue [Reviewed earlier]

Ethics, Medicine and Public Health

Volume 32 2024

https://www.sciencedirect.com/journal/ethics-medicine-and-public-health/vol/32/suppl/Cc [Reviewed earlier]

The European Journal of Public Health

Volume 35, Issue 3, June 2025 https://academic.oup.com/eurpub/issue/35/3 [Reviewed earlier]

Expert Review of Vaccines

Volume 24, 2025 Issue 1 https://www.tandfonline.com/toc/ierv20/current

[Reviewed earlier]

Foreign Affairs

July/August 2025 Volume 104, Number 4 https://www.foreignaffairs.com/issues/2025/104/4 [Reviewed earlier]

Forum for Development Studies

Volume 52, 2025 - Issue 2

http://www.tandfonline.com/toc/sfds20/current

The Rebirth of the Global South: Geopolitics, Imageries, and Developmental Realities [Reviewed earlier]

Frontiers in Genetics

https://www.frontiersin.org/journals/genetics [Accessed 06 Sep 2025] [No new digest content identified]

Frontiers in Genome Editing

https://www.frontiersin.org/journals/genome-editing [Accessed 06 Sep 2025] [No new digest content identified]

Frontiers in Medicine

https://www.frontiersin.org/journals/medicine/volumes?volume-id=1463 [Accessed 06 Sep 2025] [No new digest content identified]

Gene Therapy – Nature

Volume 32 Issue 4, July 2025 https://www.nature.com/gt/volumes/32/issues/4 [Reviewed earlier]

Genetics in Medicines

Volume 27, Issue 6 June 2025 https://www.sciencedirect.com/journal/genetics-in-medicine/vol/27/issue/65 [Reviewed earlier]

Genome Medicine

https://genomemedicine.biomedcentral.com/articles [Accessed 06 Sep 2025] [No new digest content identified]

Global Health Action

Volume 18, Issue 1 (2025) https://www.tandfonline.com/toc/zgha20/current?nav=tocList [Reviewed earlier]

Global Health: Science and Practice (GHSP)

August 2025 | Volume 13 | Number 1 http://www.ghspjournal.org/content/current [Reviewed earlier]

Global Legal Monitor & Legal Reports – Library of Congress/USA

https://www.loc.gov/collections/global-legal-monitor/ https://www.loc.gov/books/?q=legal+reports&fa=partof%3Alegal+reports+%28publications+of+the+law+library+of+congress%29&sb=date_desc

[Accessed 06 Sep 2025]

[No new digest content identified]

Global Public Health

Volume 20, Issue 1 (2025) http://www.tandfonline.com/toc/rgph20/current [Reviewed earlier]

Globalization and Health

http://www.globalizationandhealth.com/ [Accessed 06 Sep 2025] [No new digest content identified]

Health and Human Rights

Volume 26, Issue 2, December 2024 https://www.hhrjournal.org/volume-26-issue-2-december-2024/ **Special Section: Distress Migration and the Right to Health** [Reviewed earlier]

Health Economics, Policy and Law

Volume 20 - Issue 2 - April 2025 https://www.cambridge.org/core/journals/health-economics-policy-and-law/latest-issue **Special issue on Managed Competition** [Reviewed earlier]

Health Policy and Planning

Volume 40, Issue 6, July 2025 https://academic.oup.com/heapol/issue/40/6 [Reviewed earlier]

Health Research Policy and Systems

http://www.health-policy-systems.com/content

[Accessed 06 Sep 2025]

Implementation context and stakeholder perspectives on routine immunization data among lower-level private for-profit providers in an urban setting: experiences from Kampala, Uganda

Lower-level private for-profit health service providers form part of the pluralistic health systems delivering immunization services in urban areas of sub-Saharan Africa. However, their operational context is ...

Authors: Eric Ssegujja, Paul Kiggundu, Sarah Zalwango Karen and Elizeus Rutebemberwa

Citation: Health Research Policy and Systems 2025 23:112 Content type: Research Published on: 2 September 2025

Human Gene Therapy

Volume 36, Issue 15-16 / August 2025

https://www.liebertpub.com/toc/hum/36/15-16

Special Issue on Gene Therapy for Diseases of the Respiratory System

[New issue; No digest content identified]

Humanitarian Practice Network

https://odihpn.ora/ [Accessed 06 Sep 2025] Featured Publications

The humanitarian—development—peace nexus and UN 2.0: a field practitioner's perspective on bridging silos for humanitarian impact

September 3, 2025

Hama Amadou Oumarou

Human Vaccines & Immunotherapeutics (formerly Human Vaccines)

Volume 21 Issue 1, 2025 https://www.tandfonline.com/toc/khvi20/21/1?nav=tocList Selected Content [Reviewed earlier]

Immunity

Jul 08, 2025 Volume 58 Issue 7 p1615-1870 https://www.cell.com/immunity/current [Reviewed earlier]

Infectious Agents and Cancer

http://www.infectagentscancer.com/ [Accessed 06 Sep 2025] [No new digest content identified]

Infectious Diseases of Poverty

http://www.idpjournal.com/content]

[Accessed 06 Sep 2025]
[No new digest content identified]

International Health

Volume 17, Issue 4, July 2025 https://academic.oup.com/inthealth/issue/17/4 [Reviewed earlier]

International Human Rights Law Review

Volume 14 (2025): Issue 1 (Jun 2025) https://brill.com/view/journals/hrlr/14/1/hrlr.14.issue-1.xml [Reviewed earlier]

International Journal of Community Medicine and Public Health

Vol. 12 No. 9 (2025): September 2025 https://www.ijcmph.com/index.php/ijcmph/issue/view/128 [Reviewed earlier]

International Journal of Epidemiology

Volume 54, Issue 3, June 2025 https://academic.oup.com/ije/issue/54/3 [Reviewed earlier]

International Journal of Human Rights in Healthcare

Volume 18 Issue 2 2025 https://www.emerald.com/ijhrh/issue/18/3 Table of contents [Reviewed earlier]

JAMA

September 2, 2025, Vol 334, No. 9, Pages 751-838 https://jamanetwork.com/journals/jama/currentissue Perspective
AI in Medicine

Ethical Obligations to Inform Patients About Use of AI Tools

Michelle M. Mello, JD, PhD, MPhil; Danton Char, MD, MAS; Sonnet H. Xu JAMA. 2025;334(9):767-770. doi:10.1001/jama.2025.11417

This Perspective discusses the use of artificial intelligence (AI) tools in health care and offers a framework for deciding what patients should be told about AI tools.

JAMA Health Forum

August 2025, Vol 6, No. 8 https://jamanetwork.com/journals/jama-health-forum/issue [Reviewed earlier]

JAMA Pediatrics

August 2025, Vol 179, No. 8, Pages 814-932 https://jamanetwork.com/journals/jamapediatrics/currentissue [Reviewed earlier]

JBI Evidence Synthesis

August 2025 - Volume 23 - Issue 8 https://journals.lww.com/jbisrir/Pages/currenttoc.aspx [New issue; No digest content identified]

Journal of Adolescent Health

August 2025 Volume 77 Issue 2 p173-338 https://www.jahonline.org/current [Reviewed earlier]

Journal of Artificial Intelligence Research

Vol. 83 (2025) https://www.jair.org/index.php/jair [Reviewed earlier]

Journal of Bioethical Inquiry

Volume 22, Issue 1 March 2025 https://link.springer.com/journal/11673/volumes-and-issues/22-1 [Reviewed earlier]

Journal of Community Health

Volume 50, Issue 3 June 2025 https://link.springer.com/journal/10900/volumes-and-issues/50-3 [Reviewed earlier]

Journal of Current Medical Research and Opinion

...a peer-reviewed, international journal for the rapid publication of original research on new and existing drugs and therapies, and post-marketing investigations. Equivalence, safety and efficacy/effectiveness studies are especially encouraged.

Vol. 8 No. 01 (2025)

https://www.cmro.in/index.php/jcmro/issue/view/91

[Reviewed earlier]

Journal of Development Economics

Volume 176 September 2025 https://www.sciencedirect.com/journal/journal-of-development-economics/vol/176/suppl/C [Reviewed earlier]

Journal of Empirical Research on Human Research Ethics

Volume 20 Issue 3, July 2025 http://journals.sagepub.com/toc/jre/current [Reviewed earlier]

Journal of Epidemiology & Community Health

July 2025 - Volume 79 - 7 https://jech.bmj.com/content/79/6 [Reviewed earlier]

Journal of Evidence-Based Medicine

Volume 18, Issue 2 June 2025 https://onlinelibrary.wiley.com/toc/17565391/current [Reviewed earlier]

Journal of Global Ethics

Volume 21, Issue 2 (2025) http://www.tandfonline.com/toc/rjge20/current [Reviewed earlier]

Journal of Health Care for the Poor and Underserved (JHCPU)

Volume 36, Number 2, May 2025 https://muse.jhu.edu/issue/54734 Table of Contents [Reviewed earlier]

Journal of Immigrant and Minority Health

Volume 27, Issue 4 August 2025 https://link.springer.com/journal/10903/volumes-and-issues/27-4 [Reviewed earlier]

Journal of Immigrant & Refugee Studies

Volume 23, Issue 3 (2025) https://www.tandfonline.com/toc/wimm20/current [New issue; No digest content identified]

Journal of International Development

Volume 37, Issue 6 Pages: 1-1404 August 2025 https://onlinelibrary.wiley.com/toc/10991328/current [Reviewed earlier]

Journal of Medical Ethics

September 2025 - Volume 51 - 9 http://jme.bmj.com/content/current

Journal of Patient-Centered Research and Reviews

Volume 12, Issue 3 (2025)
https://institutionalrepository.aah.org/jpcrr/
[Reviewed earlier]

The Journal of Pediatrics

Volume 282 July 2025 https://www.sciencedirect.com/journal/the-journal-of-pediatrics/vol/282/suppl/C [Reviewed earlier]

Journal of Pharmaceutical Policy and Practice

Volume 18, 2025 Issue 1 https://www.tandfonline.com/toc/jppp20/18/1?nav=tocList [Reviewed earlier]

Journal of Public Health Management & Practice

July/August 2025 - Volume 31 - Issue 4 https://journals.lww.com/jphmp/pages/currenttoc.aspx [Reviewed earlier]

Journal of Public Health Policy

Volume 46, Issue 2 June 2025 https://link.springer.com/journal/41271/volumes-and-issues/46-2 [Reviewed earlier]

Journal of the Royal Society - Interface

August 2025 Volume 22 Issue 229 https://royalsocietypublishing.org/toc/rsif/current [Reviewed earlier]

Journal of Travel Medicine

Volume 32, Issue 5, July 2025 https://academic.oup.com/jtm/issue [Reviewed earlier]

Journal of Virology

Volume 99 • Number 6 • June 2025 http://jvi.asm.org/content/current [Reviewed earlier]

The Lancet

Sep 06, 2025 Volume 406 Number 10507 p979-1062 https://www.thelancet.com/journals/lancet/issue/current

<u>Influenza vaccination to improve outcomes for patients with acute heart failure (PANDA II): a multiregional, seasonal, hospital-based, cluster-randomised, controlled trial in China Craig S Anderson, et al.</u>

The Lancet Child & Adolescent Health

Aug 2025 Volume 9 Number 8 p519-612, e16 https://www.thelancet.com/journals/lanchi/issue/current [Reviewed earlier]

Lancet Digital Health

Aug 2025 Volume 7 Number 8 https://www.thelancet.com/journals/landig/issue/current Comment

Artificial intelligence and clinical trials: a framework for effective adoption

Bilal A Mateen, Vasee Moorthy, Alain Labrique, Jeremy Farrar

Lancet Global Health

Sep 2025 Volume 13 Number 9 e1489-e1653 https://www.thelancet.com/journals/langlo/issue/current [Reviewed earlier]

Lancet Infectious Diseases

Aug 2025 Volume 25 Number 8 p827-946, e439-e490 https://www.thelancet.com/journals/laninf/issue/current [Reviewed earlier]

Lancet Public Health

Sep 2025 Volume 10 Number 9 e722-e803 https://www.thelancet.com/journals/lanpub/issue/current [Reviewed earlier]

Lancet Respiratory Medicine

Sep 2025 Volume 13 Number 9 p769-856, e45-e52 https://www.thelancet.com/journals/lanres/issue/current [Reviewed earlier]

Maternal and Child Health Journal

Volume 29, Issue 6 June 2025 https://link.springer.com/journal/10995/volumes-and-issues/29-6 [Reviewed earlier]

Medical Decision Making (MDM)

Volume 45 Issue 5, July 2025 http://mdm.sagepub.com/content/current [Reviewed earlier]

The Milbank Quarterly

A Multidisciplinary Journal of Population Health and Health Policy Volume 103, Issue 2 Pages: 243-637 June 2025 https://onlinelibrary.wiley.com/toc/14680009/current [Reviewed earlier]

Molecular Therapy

Aug 06, 2025 Volume 33 Issue 8 p3453-4008 https://www.cell.com/molecular-therapy/current [Reviewed earlier]

Nature

Volume 645 Issue 8079, 4 September 2025 https://www.nature.com/nature/volumes/644/issues/8079 News 22 Aug 2025

FK Jr demanded a vaccine study be retracted — the journal said no

In a rare move for a US public official, health secretary Robert F. Kennedy Jr called for a Danish paper finding no link between aluminium in vaccines and disease to be retracted. Rachel Fieldhouse

Nature Biotechnology

Volume 43 Issue 7, July 2025 https://www.nature.com/nbt/volumes/43/issues/7 [Reviewed earlier]

Nature Communications

https://www.nature.com/subjects/health-sciences/ncomms (Accessed 06 Sep 2025) [Reviewed earlier]

Nature Genetics

Volume 57 Issue 8, August 2025 https://www.nature.com/ng/volumes/57/issues/8 [Reviewed earlier]

Nature Human Behaviour

Volume 9 Issue 8, August 2025 https://www.nature.com/nathumbehav/volumes/9/issues/8 [Reviewed earlier]

Nature Medicine

Volume 31 Issue 8, August 2025 https://www.nature.com/nm/volumes/31/issues/8 [Reviewed earlier]

Nature Reviews Drug Discovery

Volume 24 Issue 8, August 2025 https://www.nature.com/nrd/volumes/24/issues/8 [Reviewed earlier]

Nature Reviews Genetics

Volume 26 Issue 8, August 2025 https://www.nature.com/nrg/volumes/26/issues/8 [Reviewed earlier]

Nature Reviews Immunology

Volume 25 Issue 8, August 2025 https://www.nature.com/nri/volumes/25/issues/8 [Reviewed earlier]

New England Journal of Medicine Volume

Volume 393 No. 9 September 4, 2025 https://www.nejm.org/toc/nejm/medical-journal [New issue; No digest content identified]

NEJM Evidence

Volume 4 No. 7 July 2025 https://evidence.nejm.org/toc/evid/current

NEJM Evidence, a new monthly digital journal from NEJM Group, presents innovative original research and fresh, bold ideas in clinical trial design and clinical decision-making.

[Reviewed earlier]

njp Vaccines

https://www.nature.com/npjvaccines/ [Accessed 06 Sep 2025] [No new digest content identified]

Pediatrics

Volume 156, Issue 2 August 2025 https://publications.aap.org/pediatrics/issue/156/2 [Reviewed earlier]

PharmacoEconomics

Volume 43, Issue 8 August 2025 https://link.springer.com/journal/40273/volumes-and-issues/43-8 [Reviewed earlier]

PLoS Biology

https://journals.plos.org/plosbiology/ (Accessed 06 Sep 2025) [No new digest content identified]

PLoS Genetics

https://journals.plos.org/plosgenetics/ (Accessed 06 Sep 2025) [No new digest content identified]

PLoS Global Public Health

https://journals.plos.org/globalpublichealth/search?sortOrder=DATE_NEWEST_FIRST&filterStartDate=2 021-10-01&filterJournals=PLOSGlobalPublicHealth&q=&resultsPerPage=60 (Accessed 06 Sep 2025)

<u>Perceptions on vaccines, vaccine communication and information needs of healthcare professionals involved in older adult vaccination: A cross-country interview study</u>

Manuela Dominique Wennekes, Freek De Haan, Renske Eilers, Antonella Caputo, Francesco Nicoli, Dávid Nagy, Mart L. Stein, Amandine Gagneux-Brunon, Riccardo Gavioli, Zoltán Vokó, Aura Timen, on behalf of the VITAL Consortium

Research Article | published 02 Sep 2025 PLOS Global Public Health https://doi.org/10.1371/journal.pgph.0004928

PLoS Medicine

https://journals.plos.org/plosmedicine/

(Accessed 06 Sep 2025)

<u>Vaccination strategies to achieve outbreak control for MPXV Clade I with a one-time mass campaign in sub-Saharan Africa: A scenario-based modelling study</u>

Shihui Jin, Toshiaki R. Asakura, Hiroaki Murayama, David Niyukuri, Diafuka Saila-Ngita, Jue Tao Lim, Akira Endo, Borame L. Dickens

Research Article | published 05 Sep 2025 PLOS Medicine

https://doi.org/10.1371/journal.pmed.1004726

PLoS Neglected Tropical Diseases

http://www.plosntds.org/ (Accessed 06 Sep 2025) [No new digest content identified]

PLoS One

http://www.plosone.org/ [Accessed 06 Sep 2025]

<u>Human papilloma virus vaccination uptake and associated factors among adolescent girls in Merab Abaya district, Gamo zone, Southern Ethiopia: Mixed methods</u>

Zenebe Debena Den'o, Wondimagegn Paulos, Desta Markos, Woldetsadik Oshine Oche, Tamirat Mathewos Milkano

Research Article | published 05 Sep 2025 PLOS ONE

https://doi.org/10.1371/journal.pone.0330760

<u>Human papilloma virus vaccination uptake and associated factors among adolescent girls in Merab Abaya district, Gamo zone, Southern Ethiopia: Mixed methods</u>

Zenebe Debena Den'o, Wondimagegn Paulos, Desta Markos, Woldetsadik Oshine Oche, Tamirat Mathewos Milkano

Research Article | published 05 Sep 2025 PLOS ONE

https://doi.org/10.1371/journal.pone.0330760

Nurses' attitudes about RSV vaccination for pregnant women and infants: Evidence from a cross-sectional survey

Filip Viskupič, David L. Wiltse, Thomas E. Stenvig Research Article | published 02 Sep 2025 PLOS ONE https://doi.org/10.1371/journal.pone.0331326

PLoS Pathogens

http://journals.plos.org/plospathoge ns/ [Accessed 06 Sep 2025] [No new digest content identified]

PNAS - Proceedings of the National Academy of Sciences of the United States

September 2, 2025 vol. 122 no. 35 https://www.pnas.org/toc/pnas/122/35 [New issue; No digest content identified]

PNAS Nexus

Volume 4, Issue 8, August 2025 https://academic.oup.com/pnasnexus/issue/4/8 [Reviewed earlier]

Prehospital & Disaster Medicine

Volume 40 - Issue 3 - June 2025 https://www.cambridge.org/core/journals/prehospital-and-disaster-medicine/latest-issue [Reviewed earlier]

Preventive Medicine

Volume 197 August 2025 https://www.sciencedirect.com/journal/preventive-medicine/vol/197/suppl/C [Reviewed earlier]

Proceedings of the Royal Society B

August 2025 Volume 292 Issue 2053 https://royalsocietypublishing.org/toc/rspb/current Table of Contents

Special feature: The other 1%: Showcasing science and scientists from the Global South and indigenous communities

The other 1%: Showcasing science and scientists from the Global South and indigenous communities. Guest edited by Sarah Brosnan, Stephanie Meirmans, Maurine Neiman, Guadalupe Peralta and Shalene Singh-Shepherd.

Public Health

Volume 245 August 2025 https://www.sciencedirect.com/journal/public-health/vol/245/suppl/C [Reviewed earlier]

Public Health Ethics

Volume 18, Issue 2, July 2025 http://phe.oxfordjournals.org/content/current [Reviewed earlier]

Public Health Genomics

2025, Vol. 28, No. 1 https://karger.com/phg/issue/28/1 [Reviewed earlier]

Public Health Reports

Volume 140 Issue 2-3, March-April/May-June 2025 https://journals.sagepub.com/toc/phrg/140/2-3 [Reviewed earlier]

Qualitative Health Research

Volume 35 Issue 9, August 2025 https://journals.sagepub.com/toc/QHR/current [Reviewed earlier]

Research Ethics

Volume 21 Issue 3, July 2025 http://journals.sagepub.com/toc/reab/current [Reviewed earlier]

Reproductive Health

http://www.reproductive-health-journal.com/content [Accessed 06 Sep 2025] [No new digest content identified]

Revista Panamericana de Salud Pública/Pan American Journal of Public Health (RPSP/PAJPH)

https://www.paho.org/journal/en Latest Articles [No new digest content identified]

Risk Analysis

Volume 45, Issue 7 Pages: 1597-2068 July 2025 https://onlinelibrary.wiley.com/toc/15396924/current [Reviewed earlier]

Risk Management and Healthcare Policy

https://www.dovepress.com/risk-management-and-healthcare-policy-archive56 [Accessed 06 Sep 2025] [No new digest content identified]

Royal Society Open Science

August 2025 Volume 12 Issue 8 https://royalsocietypublishing.org/toc/rsos/current [Reviewed earlier]

Science

Volume 389| Issue 6764| 4 Sep 2025 https://www.science.org/toc/science/current Editorial

Improve the stewardship of federal research funds

BY Jennifer Lodge, Richard Stanton 04 Sep 202

Science and Engineering Ethics

Volume 31, Issue 4 August 2025 https://link.springer.com/journal/11948/volumes-and-issues/31-4 [Reviewed earlier]

Science Translational Medicine

Volume 17| Issue 814| 3 Sep 2025 https://www.science.org/toc/stm/current Research Resources

<u>Comprehensive analysis of microbial content in whole-genome sequencing samples from The Cancer Genome Atlas project</u>

BY Yuchen Ge, et al.

03 Sep 2025

An analysis of TCGA whole-genome sequencing samples yields a comprehensive resource for investigating the role of microbes in cancer.

Scientific Reports

https://www.nature.com/srep/articles?type=article [Accessed 06 Sep 2025] [No new digest content identified]

Social Science & Medicine

Volume 380 September 2025 https://www.sciencedirect.com/journal/social-science-and-medicine/vol/380/suppl/C [Reviewed earlier]

Systematic Reviews

https://systematicreviewsjournal.biomedcentral.com/articles [Accessed 06 Sep 2025] [No new digest content identified]

Theoretical Medicine and Bioethics

Volume 46, Issue 3 June 2025 https://link.springer.com/journal/11017/volumes-and-issues/46-3 [Reviewed earlier]

Travel Medicine and Infectious Diseases

Volume 66 July–August 2025 https://www.sciencedirect.com/journal/travel-medicine-and-infectious-disease/vol/66/suppl/C [Reviewed earlier]

Tropical Medicine & International Health

Volume 30, Issue 8 Pages: 749-864 August 2025 https://onlinelibrary.wiley.com/toc/13653156/current [Reviewed earlier]

Vaccine

Volume 61 13 August 2025 https://www.sciencedirect.com/journal/vaccine/vol/61/suppl/C [Reviewed earlier]

Vaccines

https://www.mdpi.com/journal/vaccines

[Accessed 06 Sep 2025] Open Access Article

<u>Challenges in Expanding Access to the HPV Vaccine Among Schooling Girls: A Mixed-</u> Methods Study from Indonesia

by Jacqueline Yap, Fauzi Budi Satria, Ivana Alona, Indo Mora Siregar, Shu Chen, Chee Fu Yung, Courtney Davis, Inke Nadia Diniyanti Lubis and Shenglan Tang Vaccines 2025, 13(9), 948; https://doi.org/10.3390/vaccines13090948 - 4 Sep 2025 Abstract Background: Indonesia launched a nationwide school-based HPV immunization program in August 2023. Despite this, regional disparities in vaccine uptake persist. Therefore, we undertook a study in North Sumatra Province to assess HPV vaccination coverage and analyze the main factors affecting the uptake of [...]

Open Access Article

<u>Trust in Information Sources and Parents' Knowledge, Attitudes, and Practices (KAP) of Children's PCV13 Vaccination in the Yangtze River Delta Region, China</u>

by Zhangyang Pan, Fan Liang and Shenglan Tang

Vaccines 2025, 13(9), 947; https://doi.org/10.3390/vaccines13090947 - 4 Sep 2025

Abstract

Background: Trust in information sources is essential to enhance an individual's understanding of the message and boost their willingness to change or act on specific health behavior, including vaccine uptake. This study explores the association between trust in information sources and parents' knowledge, [...

Value in Health

August 2025 Volume 28 Issue 8 p1141-1304 https://www.valueinhealthjournal.com/current [Reviewed earlier]

World Development

Volume 192 August 2025 https://www.sciencedirect.com/journal/world-development/vol/192/suppl/C [Reviewed earlier]

::::::

Contents [click to move among sections]

- :: Milestones, Perspectives
- :: <u>WHO</u>
- :: Organization Announcements
- :: Journal Watch
- :: Pre-Print Servers

::::::

Pre-Print Servers

arxiv

https://arxiv.org/

[Accessed 06 Sep 2025]

[Filters: Emerging Technologies; Neural and Evolutionary Computing; Computers and Society; Genomics; Neurons and Cognition; Populations and Evolution; Other Quantitative Biology; General Economics]

[No new digest content identified]

Gates Open Research

https://gatesopenresearch.org/browse/articles [Accessed 06 Sep 2025] [No new digest content identified]

medRxiv

https://www.medrxiv.org/content/about-medrxiv

[Accessed 06 Sep 2025]

<u>Development of a COVID-19 Vaccination Anxiety Scale to measure COVID-19 vaccine anxiety in Japanese adults</u>

Time Fukuda, Ranno Haruyama, Yuto Tanaka, Shuma Natori, Kohei Koiwa, Koubun Wakashima medRxiv 2025.09.03.25332753; doi: https://doi.org/10.1101/2025.09.03.25332753

<u>Predicting COVID-19 Infection Among Older Syrian Refugees in Lebanon to inform outbreak preparedness: A Multi-Wave Survey</u>

Berthe Abi Zeid, Tanya El Khoury, Sawsan R Abdulrahim, Hala Ghattas, Stephen J McCall medRxiv 2024.01.17.24301436; doi: https://doi.org/10.1101/2024.01.17.24301436 Revision

The global return-on-investment of COVID-19 vaccines in the first year of the vaccination programme

Hallie Benjamin, Gregory Barnsley, Oliver John Watson, Mark Jit medRxiv 2025.09.02.25334932; doi: https://doi.org/10.1101/2025.09.02.25334932

<u>Effectiveness of 2024–2025 COVID-19 Vaccination Against COVID-19 Hospitalization and Severe In-Hospital Outcomes — IVY Network, 26 Hospitals, September 1, 2024–April 30, 2025</u>

Kevin C. Ma, Alexander Webber, Adam S. Lauring, Emily Bendall, Leigh K. Papalambros, Basmah Safdar, Adit A. Ginde, Ithan D. Peltan, Samuel M. Brown, Manjusha Gaglani, Shekhar Ghamande, Cristie Columbus, Nicholas M. Mohr, Kevin W. Gibbs, David N. Hager, Matthew E. Prekker, Michelle N. Gong, Amira Mohamed, Nicholas J. Johnson, Akram Khan, Catherine L. Hough, Abhijit Duggal, Jennifer G. Wilson, Nida Qadir, Steven Y. Chang, Christopher Mallow, Laurence W. Busse, Jennie H. Kwon, Matthew C. Exline, Ivana A. Vaughn, Mayur Ramesh, Jarrod M. Mosier, Aleda M. Leis, Estelle S. Harris, Adrienne Baughman, Sydney A. Cornelison, Paul W. Blair, Cassandra A. Johnson, Nathaniel M. Lewis, Sascha Ellington, Todd W. Rice, Carlos G. Grijalva, H. Keipp Talbot, Jonathan D. Casey, Natasha Halasa, James D. Chappell, Yuwei Zhu, Wesley H. Self, Fatimah S. Dawood, Diya Surie medRxiv 2025.08.29.25334612; doi: https://doi.org/10.1101/2025.08.29.25334612

Annual rehospitalization rates due to COVID-19 reinfection in Rio de Janeiro: the role of vaccination and associated factors

Ranna Kíssia Alves das Neves, Luiz Max Carvalho, Leonardo Soares Bastos, Daniel Antunes Maciel Villela, Valeria Saraceni, Débora Medeiros de Oliveira Cruz, Antonio Guilherme Pacheco medRxiv 2025.08.31.25334798; doi: https://doi.org/10.1101/2025.08.31.25334798

A comparison of alternative vaccination strategies for protecting those vulnerable to illness, hospitalization, or death upon infection with SARS-CoV-2: A metapopulation modeling study

Zhilan Feng, Troy Day, John W Glasser

medRxiv 2025.08.30.25334767; doi: https://doi.org/10.1101/2025.08.30.25334767

The Potential Public Health Impact of the mRNA-based Respiratory Syncytial Virus Vaccine, mRNA-1345, Under Extended Vaccination Campaigns Among Older Adults in the United Kingdom: A Modelling Study

Mariia Dronova, Anna Tytula, Zuzanna Janusz, Parinaz Ghaswalla, Stuart Carroll, Orsolya Balogh, Keya Joshi

medRxiv 2025.08.29.25334673; doi: https://doi.org/10.1101/2025.08.29.25334673

OSF Pre-prints

https://osf.io/preprints/discover?provider=OSF&subject=bepress%7 CLife%20Sciences
[Provider Filter: OSF Pre-prints Subject filters: Medicine and Health Sciences Format Filter: Pre-prints]
[No new digest content identified]

Wellcome Open Research

https://wellcomeopenresearch.org/browse/articles [Accessed 06 Sep 2025]
Review Open Access

<u>Ethical Challenges in Clinical Trials Involving Older Adults in India: A Bioethical and Public</u> Health Perspective

[version 1; peer review: awaiting peer review]
Jaya Kshatri, et al.

Abstract

India's aging population is growing rapidly, necessitating increased clinical research to address their healthcare needs. However, older adults remain underrepresented in clinical trials, leading to limited evidence-based treatment guidelines. Ethical complexities such as informed consent challenges, riskbenefit assessments, and participant selection make recruitment in geriatric trials particularly difficult. Cognitive impairments, sensory deficits, and socioeconomic barriers further hinder meaningful participation. Additionally, the absence of tailored ethical guidelines and inadequate oversight exacerbate these challenges. This paper explores key ethical concerns in conducting clinical trials among older adults in India, focusing on informed consent processes, the role of ethics committees, and the necessity for geriatric-specific risk assessment frameworks. We highlight issues of coercion, cultural influences on decision-making, and financial constraints affecting trial participation. Governance frameworks, including ethics committee capacity-building and improved insurance coverage for trial participants, are also discussed. To ensure ethical and inclusive research, we recommend strengthening regulatory oversight, integrating clinical trials within public health programs, and fostering community engagement to enhance trust in research. A systematic approach incorporating bioethics, public health priorities, and equitable participant selection is essential for ensuring that clinical trials among older adults uphold ethical principles while contributing to improved healthcare outcomes.

* * * *

Think Tanks

Brookings [06 Sep 2025] http://www.brookings.edu/ Reports, Events No new digest content identified. https://www.cgd ev.org/ All Research No new digest content identified.

Chatham House [06 Sep 2025] https://www.chathamhouse.org/ Selected Analysis, Comment, Events No new digest content identified.

Council on Foreign Relations [06 Sep 2025]

https://www.cfr.org/media/news-releases
New Releases [Selected]
No new digest content identified.

CSIS [06 Sep 2025] https://www.csis.org/ Reports [Selected] No new digest content identified.

Kaiser Family Foundation/KFF [06 Sep 2025]

https://www.kff.org/search/?post_type=press-release

Newsroom

Global COVID-19 Tracker

Sep 2, 2025

This tracker provides data on global COVID-19 cases and deaths by country, region, and incomelevel. Additionally, the tracker reports current closure, economic, and health system policy responses to the COVID-19 pandemic globally. This tracker will be updated as new data are available.

Poll Finding

KFF Tracking Poll on Health Information and Trust: COVID-19 Vaccine Update

Authors: <u>Grace Sparks</u>, <u>Julian Montalvo III</u>, <u>Shannon Schumacher</u>, <u>Ashley Kirzinger</u>, and <u>Liz Hamel</u> Published: Aug 1, 2025

Key Findings

- :: Amid ongoing news from federal agencies about changing COVID-19 vaccine recommendations, the replacement of the Centers for Disease Control and Prevention's vaccine advisory committee members (ACIP), and re-examination of the federal childhood vaccine schedule, **there is confusion among the public about U.S. vaccine policy**. While half of the public thinks Department of Health and Human Services (HHS) Secretary Robert F. Kennedy Jr. has made "major" (26%) or "minor" (26%) changes to vaccine policy in the U.S., the other half either say they "don't know enough to say" (40%) or say no changes have been made (7%). At least three in ten adults across demographic groups and party identification say they don't know enough about the recent changes from Kennedy to vaccine policy to describe them. In addition, half (48%) of parents are not sure if federal health agencies are currently recommending that healthy children receive a COVID-19 vaccine this fall or not.
- :: Once told about the changes to U.S. vaccine policy, the public is divided by partisanship in whether they think these changes will make people safer or less safe. About two in ten adults, including 41% of Republicans, think these changes will make people safer while about one-third of adults, including most Democrats (62%) and four in ten independents (41%) say they will make people less safe. Another third of adults (31%) say they "don't know enough to say" as to whether the

recent changes to U.S. vaccine policy will make people safer or not, and about one in ten say the changes won't make a difference.

- :: Most of the public (59%) say they will either "definitely not" or "probably not" get the COVID-19 vaccine this fall including about six in ten Republicans who say they will "definitely not" get the vaccine. Older adults and Democrats are much more likely to report that they will get the COVID-19 vaccine. About four in ten Black adults and Hispanic adults say they plan to get the COVID-19 vaccine as do 37% of White adults.
- :: With most of the public reporting that they will not get a COVID-19 vaccine this fall, few are worried about the availability of the vaccine or whether it will be covered by insurance. One-third (33%) of adults are concerned that COVID-19 vaccines won't be available to them this fall, while a third (34%) of insured adults are also worried that their insurance won't cover a shot. Concern about availability and coverage are tied to vaccine intention, with those who plan to get the vaccine much more likely to be concerned that it might not be available to them (66%), including specific demographic groups who are more likely to get vaccinated such as older adults and Democrats.
- **::** Personal doctors or health care providers remain the most trusted source for information about vaccines among asked sources, with eight in ten (83%) adults who say they trust their own doctor at least "a fair amount." Smaller shares of the public, but still majorities trust their local public health department and the U.S. Centers for Disease Control and Prevention, or CDC, to provide information on vaccines, though the share who say so has been steadily in decline since September 2023. Fewer continue to say they trust HHS Secretary Robert F. Kennedy Jr. to provide information on vaccines, with about four in ten (37%) saying they trust him at least a fair amount, unchanged since his appointment in April of this year.
- **::** About half of the public have confidence in agencies like the CDC and Food and Drug Administration (FDA) to ensure the safety and effectiveness of vaccines approved for use in the U.S. (49%), while less than half say they have at least some confidence in the agencies to make decisions based on science rather than the personal views of agency officials (42%), or act independently, without interference from outside interests (37%). Democrats continue to be more confident in federal health agencies than Republicans to ensure the safety and effectiveness of vaccines.

McKinsey Global Institute [06 Sep 2025] https://www.mckinsey.com/mgi/overview

No new digest content identified.

ODI [Overseas Development Institute] [06 Sep

2025] https://odi.org/en/publications/
Publications [Selected]
No new digest content identified.

Pew Research Center [06 Sep 2025]

https://www.pewresearch.org/ Latest Publications [Selected] Short reads Sep 5, 2025

United Nations seen favorably by many across 25 countries

A median of 61% of adults across the surveyed countries have a favorable view of the UN, and 32% have an unfavorable view.

https://www.rand.org/pubs.html Published Research [Selected] No new digest content identified.

Urban Institute [06 Sep 2025] https://www.urban.org/publications New Research Publications - Selected

World Economic Forum [06 Sep 2025]

https://agenda.weforum.org/press/ Media [Selected] No new digest content identified.

::::::

Public Consultations/Call for Inputs/Call for Papers

<u>Agency Information Collection Activities; Proposed Collection; Comment Request;</u>
<u>Emergency Use Authorization of Medical Products</u>

A Notice by the Food and Drug Administration on 07/14/2025 **Comment period ends 09/12/2025.**

OMB Control Number 0910-0595—Extension SUPPLEMENTARY INFORMATION:

This information collection helps support implementation of Agency policies applicable to the authorization for medical products for use in emergencies under sections 564, 564A, and 564B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360bbb-3, 360bbb-3a, and 360bbb-3b). For more information regarding emergency use authorization (EUA), visit our website at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

The FD&C Act permits the Commissioner of Food and Drugs (the Commissioner) to authorize the use of unapproved medical products for humans and animals, or unapproved uses of approved medical products for humans and animals, during an emergency declared under section 564 of the FD&C Act. The data to support issuance of an EUA must demonstrate that, based on the totality of the scientific evidence available to the Commissioner, including data from adequate and well-controlled clinical trials (if available), it is reasonable to believe that the product may be effective in diagnosing, treating, or preventing a serious or life-threatening disease or condition (21 U.S.C. 360bbb-3(c)).

Also, under section 564 of the FD&C Act, the Commissioner may establish conditions on issuing an authorization that may be necessary or appropriate to protect the public health...

<u>ICH - E21 Inclusion of Pregnant and Breastfeeding Women in Clinical Trials; International Council for Harmonisation; Draft Guidance for Industry; Availability</u>

A Notice by the Food and Drug Administration on 07/21/2025 **Comment period ends 09/19/2025** *SUMMARY:*

...The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "E21 Inclusion of Pregnant and Breastfeeding Women in Clinical Trials." The draft guidance was prepared under the auspices of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). The draft guidance is intended to provide general principles on the conduct of clinical trials that include pregnant and breastfeeding

women to inform evidence-based decisions on safe and effective use of medicinal products by these populations.

The draft guidance includes approaches to generating data that support informed decision-making on the safety, dosing, and efficacy of medicinal products during pregnancy and breastfeeding. Additionally, the draft guidance includes recommendations for recruiting and retaining pregnant and breastfeeding women in clinical trials, while reducing burden and harm on these participants. *Background*

...The recommendations found in this draft guidance are the product of the Efficacy Working Group of the ICH. Comments about this draft will be considered by FDA and the Efficacy Expert Working Group.

The draft guidance outlines strategies and considerations for developing and implementing clinical studies that include pregnant or breastfeeding women. This draft guidance includes approaches to plan, collect data, evaluate outcomes, and monitor safety of pregnant and breastfeeding women participating in clinical trials safely and ethically. Additionally, the draft guidance includes recommendations for recruiting and retaining pregnant and breastfeeding women in clinical trials. The draft guidance also emphasizes reduction of burden on pregnant and breastfeeding women participating in these trials.

This draft guidance has been left in the original ICH format. The final guidance will be reformatted and edited to conform with FDA's good guidance practices regulation (21 CFR 10.115) and style before publication.

<u>Call for Public Comment - WHO Classification of Digital Health Interventions v1.0</u> WHO 1 September 2022 **Deadline for comments: 30 September 2022, 23:59 (CEST)**Call for consultation

The World Health Organization (WHO) would like to issue a public call for comments to update v1.0 of the <u>Classification of Digital Health Interventions (CDHI)</u>. This will take the form of two public calls: Primary feedback: Call to receive public stakeholders' comments to update the Classification of Digital Health Interventions v1.0.

The WHO CDHI v1.0 was created in 2018 to provide a common digital health vocabulary for diverse stakeholders from numerous backgrounds and areas of expertise. It has since been used by stakeholders of digital health projects with a particular focus on Low and Middle-Income Countries (LMICs). As opposed to previous frameworks that provide highly technical terminology that is mainly intended for computer scientists and software developers in health, the CDHI constitutes a key bridging language between technology-oriented audiences and those in health to facilitate consistent ways of articulating needs and functionalities represented in digital health system implementations.

Since 2018, there have been advances in technology and additional interventions have arisen, prompted by the global pandemic. These, together with calls from expert communities and other stakeholders, have prompted the need to update the CDHI v1.0.

To ensure a broad consultation process, WHO will work with an expert panel and expert groups to review relevant evidence on the application of the CDHI by stakeholders and provide recommendations for update. To enable the process of the update and to ensure the input and consideration of a global group of stakeholders, WHO is issuing this public call, appealing to researchers, government and public health stakeholders, technologists, healthcare providers, donors, implementers and other agencies that utilize (or aim to utilize) the CDHI to provide comments.

Solicitation of Nominations for Appointment to the Advisory Council for the Elimination of Tuberculosis

A Notice by the Centers for Disease Control and Prevention on 07/11/2025. **Nominations must be received no later than September 30, 2025**SUMMARY:

In accordance with the Federal Advisory Committee Act, the Centers for Disease Control and Prevention (CDC), within the Department of Health and Human Services (HHS), is seeking nominations

for membership on the Advisory Council for the Elimination of Tuberculosis (ACET). ACET consists of 10 experts including the Chair in fields associated with public health, epidemiology, immunology, infectious disease, pulmonary disease, pediatrics, tuberculosis, microbiology, and preventive health care delivery. SUPPLEMENTARY INFORMATION:

The Advisory Council for the Elimination of Tuberculosis (ACET) provides advice and recommendations regarding the elimination of tuberculosis (TB) to the Secretary, Department of Health and Human Services (HHS); the Assistant Secretary for Health, HHS; and the Director, Centers for Disease Control and Prevention (CDC). ACET (a) makes recommendations on policies, strategies, objectives, and priorities; (b) addresses development and application of new technologies; (c) provides guidance and review of CDC's TB prevention research portfolio and program priorities; and (d) reviews the extent to which progress has been made toward eliminating TB.

Draft guideline on the quality aspects of mRNA vaccines

EMA Draft: consultation open Consultation dates: 31/03/2025 to 30/09/2025

Reference Number: EMA/CHMP/BWP/82416/2025

Summary:

This guideline addresses the quality aspects of mRNA vaccines. It addresses specific aspects regarding the manufacturing process, characterisation, specifications and analytical control of mRNA vaccines, as well as the definition of starting materials, active substance and finished product for mRNA vaccines. Additional regulatory considerations are provided for changes in existing mRNA vaccine strains, bivalent and multivalent vaccines, self-amplifying mRNA vaccines, other delivery systems and use of platform technology/prior knowledge. The scope of this guideline is applicable to mRNA vaccines against infectious diseases. Other mRNA-based medicinal products are out of scope of this guideline, although relevant parts of this guideline may be applicable to those. It is not intended to address specific requirements for mRNA vaccines to be used in clinical trials, however the scientific principles described may also be applicable during pharmaceutical development.

* * * *

Contents [click to move among sections]

:: Milestones, Perspectives

:: <u>WHO</u>

:: Organization Announcements

:: <u>Journal Watch</u>

:: Pre-Print Servers

Vaccines and Global Health: The Week in Review is a service of the Center for Vaccine Ethics and Policy (<u>CVEP</u>) / GE2P2 Global Foundation, which is solely responsible for its content.

:::::::

Copyright GE2P2 Global Foundation 2025. Some Rights Reserved.

This work is licensed under the Creative Commons Attribution 4.0 International License. To view a copy of this license, visit http://creativecommons.org/licenses/by/4.0/ or send a letter to Creative Commons, PO Box 1866, Mountain View, CA 94042, USA.

Under the terms of this license, you may copy, redistribute, and adapt the work for non-commercial purposes, provided the work is appropriately cited, as indicated below. In any use of this work, there should be no suggestion that the GE2P2 Global Foundation endorses any specific organization, products, or services. The use of the GE2P2 Global Foundation logo is not permitted. If you adapt the work, then you must license your work under the same or equivalent Creative Commons license.

:::::::

CVEP is a program of the <u>GE2P2 Global Foundation</u> whose purpose and mission is to advance ethical and scientific rigor in research and evidence generation for governance, policy and practice in health, human rights action, humanitarian response, heritage stewardship, education and sustainable development. The Foundation serves governments, international agencies, INGOs, civil society organizations (CSOs), commercial entities, consortia and alliances.

Support for this service is provided by the <u>Bill & Melinda Gates Foundation</u> and industry resource members Janssen/J&J, Pfizer, Sanofi US, and GSK. (list in formation).

Support is also provided by a growing list of individuals who use this membership service to support their roles in public health, clinical practice, government, NGOs and other international institutions, academia and research organizations, and industry.