

Vaccines and Global Health: The Week in Review 23 March 2024 :: Issue 743 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 <u>https://centerforvaccineethicsandpolicy.net</u>. 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 <u>david.r.curry@centerforvaccineethicsandpolicy.org</u>

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>.

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Milestones, Perspectives

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Cholera - OCV

Millions at risk from cholera due to lack of clean water, soap and toilets, and shortage of cholera vaccine

The International Coordinating Group (ICG) on Vaccine Provision calls for urgent fast-tracking of lifesaving measures

GENEVA/NEW YORK, 20 March 2024 – **Immediate action is needed to stem an unprecedented multi-year upsurge in cholera cases worldwide, according to the International Coordinating Group (ICG) on Vaccine Provision**. Actions include investing in access to safe water, sanitation and hygiene, testing and detecting outbreaks quickly, improving quality of and access to healthcare, and fast-tracking additional production of affordable oral cholera vaccine (OCV) doses to better prevent cases.

The ICG manages the global cholera vaccine stockpile. The group includes the International Federation of Red Cross and Red Crescent Societies, Médecins Sans Frontières, UNICEF and WHO. Gavi, the Vaccine Alliance, finances the vaccine stockpile and the delivery of OCV. ICG members are calling for governments, donors, vaccine manufacturers, partners and communities to join in an urgent effort to halt and reverse the rise in cholera.

Cholera has been surging globally since 2021, with the **473 000 cases reported to WHO in 2022, more than double those reported in 2021.** Preliminary data for 2023 reveal further increases, with over 700 000 cases reported. Several of the outbreaks have high case fatality rates, exceeding the 1% threshold used as an indicator for early and adequate treatment of cholera patients. These trends are tragic given that cholera is a preventable and treatable disease and that cases had been declining in previous years...

Currently, the most severely impacted countries include the Democratic Republic of the Congo, Ethiopia, Haiti, Somalia, Sudan, Syria, Zambia, and Zimbabwe.

Now more than ever, countries must adopt a multisectoral response to fight cholera. Members of the ICG call on currently and potentially affected countries to take urgent steps to ensure their populations have access to clean water, hygiene and sanitation services, and the information critical to prevent cholera's spread. The establishment of these services requires political will and investment at the country level. This includes creating capacity for early detection and response, enhanced disease detection, rapid access to treatment and care, and working closely with communities, including on risk communication and community engagement.

The severe gap in the number of available vaccine doses, compared with the level of current need, puts unprecedented pressure on the global stockpile of vaccines. Between 2021 and 2023, more doses were requested for outbreak response than the entire previous decade.

In October 2022, the ongoing vaccine shortage necessitated the ICG to **recommend a single vaccine dose, down from a previous, long-standing two-dose regimen.** Approximately 36

million doses were produced last year, while 14 affected countries registered a need for 72 million doses for a one-dose reactive strategy. **These requests understate the true need. Preventive vaccination campaigns have had to be delayed to preserve doses for emergency outbreak control efforts, creating a vicious cycle**. The change in strategy enabled available vaccines to protect more people and respond to more cholera outbreaks amid the ongoing supply shortfall, but a return to a two-dose regimen and a resumption of preventive vaccination would provide longer protection.

Global production capacity in 2024 is forecast to be 37-50 million doses but will likely continue to be inadequate to serve the needs of millions of people directly affected by cholera. Only one manufacturer, EuBiologics, currently produces the vaccine; while the company is doing its utmost to maximize output, more doses are needed. **Currently, new manufacturers are not expected to join the market before 2025; they must be fast-tracked. The same urgency and innovation that we saw for COVID-19 must be applied to cholera.**

Additional manufacturers planning to enter the market need to accelerate their efforts and make doses available at affordable prices.

We appeal to vaccine manufacturers, governments, donors and partners to prioritize an urgent scale-up of vaccine production, and to invest in all the efforts needed to prevent and control cholera.

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<u>IVI Starts Technology Transfer to Biological E. Limited to Manufacture Oral Cholera</u> <u>Vaccine for India and Global Markets</u>

- IVI will complete the technology transfer by 2025
- Oral Cholera Vaccine to be manufactured by Biological E. Limited for India and international markets

March 20, 2024

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Multi-country outbreak of cholera, External situation report #12 - 14 March 2024 Edition 12

14 March 2024 | Emergency Situational Updates *Overview*

Since the beginning of 2023, a cumulative total 787 813 cholera cases and 5586 deaths have been reported from 31 countries across five WHO regions, with the Eastern Mediterranean region recording the highest numbers, followed by the African, South-East Asia, Americas, and Western Pacific regions. No outbreaks have been reported in the European Region during this period.

The global cholera response continues to be affected by a critical shortage of Oral Cholera Vaccines (OCV). From January 2023 to February 2024, requests for OCV have surged, with 79 million doses requested by 14 countries, double the 40 million doses available during that period. The global stockpile of vaccines is awaiting replenishment and all production up to 4 March has been allocated to requests already approved.

WHO classified the global resurgence of cholera as a grade 3 emergency in January 2023, its highest internal level for emergencies. Based on the number of outbreaks and their geographic expansion, alongside the shortage of vaccines and other resources, WHO continues to assess the risk at the global level as very high and the event remains classified as a grade 3 emergency.

For the latest data, please refer to the new <u>WHO Global Cholera and AWD Dashboard</u>. Cholera upsurge (2021-present): <u>https://www.who.int/emergencies/situations/cholera-upsurge/</u>

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TB Vaccine

Bill & Melinda Gates Medical Research Institute Initiates Phase 3 Clinical Trial of <u>Tuberculosis Vaccine Candidate</u>

- A large Phase 3 trial will evaluate whether the **M72/AS01E vaccine candidate** can protect adolescents and adults from pulmonary tuberculosis
- Clinical trial site at University of the **Witwatersrand**, **Johannesburg**, **South Africa**, **is first of up to 60 sites in seven countries**
- The M72/AS01E vaccine candidate could be the first new TB vaccine in 100 years if proven effective

Cambridge, Mass., USA (19 March 2024) – The Bill & Melinda Gates Medical Research Institute (Gates MRI) today announced that a Phase 3 clinical trial to assess the efficacy of the M72/AS01E tuberculosis (TB) vaccine candidate is now underway, with first doses given in South Africa, where TB takes a heavy toll. If shown to be well-tolerated and effective, M72/AS01E could potentially become the first vaccine to help prevent pulmonary TB in adolescents and adults, the most common form of the disease, and the first new TB vaccine in over a century.

Globally, according to the World Health Organization, an estimated <u>10.6 million people</u> fell ill with TB in 2022 and <u>1.3 million</u> died — over 3,500 people per day. The disease primarily affects people in low- and middle-income countries, and those at highest risk are often living in poverty, with poor living and working conditions and undernutrition. In South Africa alone, around <u>280,000 people</u> are diagnosed with TB each year.

"The launch of this pivotal Phase 3 trial demonstrates our commitment to harnessing the power of medical innovation to fight diseases like TB that are particularly devastating for low- and middleincome countries," said Emilio A. Emini, Ph.D., CEO of the Gates MRI. "**Clinical study of the vaccine will still require years, but our incredible partners in South Africa and elsewhere who have come together for the Phase 3 study share our hope in the vaccine's potential."...**

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SAGE

Highlights from the Meeting of the Strategic Advisory Group of Experts (SAGE) on Immunization - 11-13 March 2024

(The full report will be published in the Weekly Epidemiological Record on 31 May 2024, and only the wording of the full report should be considered final) Session 1

Report from the Department of Immunization, Vaccines, and Biologicals.

• On the 50th anniversary of the establishment of the Expanded Programme on Immunization (EPI) in 1974, the report reflected on the massive achievements of the programme over the past 50 years and aspirations for the next decades.

• Over these 5 decades, immunization has contributed to driving up child survival, controlling, eliminating or eradicating vaccine-preventable diseases, and has served as the backbone of primary healthcare (PHC) and a foundation for improving equity in access.

• The past 50 years have seen innovations in vaccines through platform development like viral vector, bacterial polysaccharide conjugate, and mRNA vaccines; adjuvants; and immunization technologies for facilitating cold chain, improving injection safety, leveraging GIS systems, and temperature monitoring. These innovations have led to a large number of new and improved vaccines and facilitated their distribution and delivery.

• The capacity for manufacturing vaccines of assured quality in emerging economies has substantially increased and African regional vaccine manufacturing will be a crucial additional step to vaccine equity and resilience.

• Despite these achievements, EPI faced a recent setback, and progress towards the Immunization Agenda 2030 (IA2030) goals is off-course for all but one of the 7 impact goals. Preliminary data from the first half of 2023 are a cause for cautious optimism on coverage gains toward prepandemic levels.

• Going forward, the four core principles of IA2030, country-owned, people-centred, partnershipbased and data-guided will guide actions while accounting for the contextual changes.

• Notwithstanding preventive vaccination programmes, vaccine-preventable disease (VPD) outbreaks will continue to occur, and vaccines will be a key countermeasure for global health security. Preparedness to address future epidemics and pandemics, building on the lessons from the COVID-19 vaccine response will be key.

Update from Gavi, the Vaccine Alliance.

• Gavi is supporting countries in strengthening immunization programmes and reducing the number of zero-dose children. It has also allocated US \$290 million to fully fund the procurement of vaccine doses for catch-up vaccination for those who missed doses during the COVID-19 pandemic.

• There has been significant progress with the introduction of malaria and HPV vaccines in eligible countries through Gavi support.

• The Gavi 6.0 (2025-30) strategy that will be presented to the Gavi Board in June 2024 will remain ambitious despite concerns about financing. An investment strategy will be developed to support replenishment.

• The Gavi Board has approved investments for global health security to use the lessons from the COVID-19 response to address public health emergencies.

• Gavi will sustain support for polio eradication and cholera outbreak prevention and response. In addition, Gavi has simplified its processes to support VPD outbreak prevention.

• Investment cases for new vaccines shortlisted for Gavi support under the Gavi 2024 vaccine investment strategy are under development; among these, the introduction of a new tuberculosis vaccine is expected to be a game-changer.

Regional reports

• All regions experienced setbacks in vaccination during the COVID-19 pandemic though a recovery in vaccination coverage was observed in 2022 in all regions, except for the African region. Despite the progress, there is an accumulation of susceptible individuals that contributed to VPD outbreaks.

• Many, though not all, countries across all regions have revised policies and established catch-up vaccination schedules, developed catch-up vaccination plans to fill immunity gaps using a variety of approaches, and many have started implementing their plans.

• Regions reported major challenges in identifying children who missed vaccination doses and in delivering and monitoring vaccination to children older than 2 years.

• Exemplary initiatives in some countries have resulted in rapid progress. SAGE noted that close monitoring and robust accountability processes were key to success.

• SAGE took note of the challenges with monitoring progress with catch-up vaccination related to weaknesses in health information systems, which will need to be addressed to mainstream catch-up vaccination as part of routine immunization delivery.

• SAGE noted the need for program flexibility especially in fragile, conflict-affected, and vulnerable settings, and to establish linkages with other essential services and engage with local non-state actors to accelerate recovery.

Session 2

Immunization Agenda 2030 (IA2030) deep dive

• SAGE was presented with an overview of the Big Catch-up and progress in its implementation, including the successes and challenges. A country presentation from Cameroon exemplified the efforts taken and challenges faced.

• SAGE underscored the need for political will, community engagement, and health worker capacity strengthening and encouraged National Immunization Technical Advisory Groups (NITAGs) to guide the efforts.

• Monitoring the Big Catch-Up is vital to document progress, learn lessons, inform future actions, and ensure accountability. The IA2030 Data Strengthening and Use Working group has developed a guidance document laying out indicators and suggested processes and tools to monitor and evaluate catch-up vaccination.

• SAGE acknowledges that generating granular data to fully monitor catch-up efforts will not be feasible in the short term. During this period triangulated data from a combination of data sources using innovative analytic methods should be used to understand the impact of the BCU.

• Long-term investments will be required to strengthen immunization data and VPD surveillance systems and scale up the use of digital and other innovative solutions grounded on the five building blocks stated in the IA2030 Data Action Framework.1

1 https://www.immunizationagenda2030.org/resources/34-ia2030-data-action-framework

Session 3

Poliomyelitis

• SAGE was pleased to note that WPV1 circulation is confined to a small geographic area at the border between Afghanistan and Pakistan and that the genetic diversity of detected WPV1s is very low; however, SAGE expressed concern about the continued circulation of cVDPV2 in Africa and detections of cVDPV1 in several countries.

• SAGE stressed the need for increased efforts to improve routine coverage of all polio vaccinations, especially for IPV1.

• SAGE extended its support to the bOPV Cessation Team in planning for the eventual cessation of the use of Sabin bOPV in routine immunization programmes; SAGE will review the triggers and prerequisites developed by the bOPV cessation team to ensure a successful cessation, also taking into account the learnings from the tOPV-bOPV vaccine switch.

• SAGE reiterated that only low-polio-risk countries with high coverage with at least two IPV doses in the routine immunization schedule should consider transitioning to IPV-only vaccination schedules ahead of planned synchronised bOPV cessation.

• SAGE recommended that to stop persistent poliovirus circulation, countries opting for off-label fractional dose vaccination of IPV may choose either an intradermal or intramuscular route of administration in outbreak response campaigns.

Session 4

Hepatitis E

• SAGE recommended that in fragile, conflict-affected and vulnerable (FCV) settings with documented hepatitis E virus circulation, the benefits of vaccinating women of childbearing age (≥16 years and over) outweigh the potential harms, including during pregnancy where the risk of severe disease in particularly high during the second and third trimester.

• When implementing vaccination campaigns, SAGE stressed the importance of accompanying hepatitis E vaccine (HEV) use with public health research, whenever possible.

• SAGE recommended the use of an off-label 2-dose schedule (0 and 1 month) instead of the 3dose schedule during campaigns in FCV settings.

• SAGE encouraged additional research on hepatitis E vaccination during pregnancy, in people living with HIV and in individuals under 16 years of age. In addition, SAGE asked to be informed of the outcomes of further analysis of the Bangladesh trial.

Session 5

COVID-19

• The number of cases, hospitalizations and deaths from COVID-19 continues to show a declining trend.

• While inequity in access to COVID-19 vaccines, in particular updated vaccine formulations, persists, demand has also declined, especially in low- and middle-income countries (LMICs).

• Booster doses of the Omicron-adapted bivalent vaccines (BA.1/2 and BA.4/5) continue to protect against symptomatic disease and severe disease during the XBB dominant period; there is a moderate benefit of the monovalent XBB vaccines over the bivalent or index virus vaccines.

• SAGE reiterated that monovalent XBB vaccines should be used when available. However, countries should not delay the administration of ancestral or bivalent vaccines to high-priority-use groups if monovalent XBB vaccines are not available.

• SAGE reaffirmed the priority-use groups and frequency of re-vaccination as outlined in the WHO SAGE Roadmap for prioritizing the use of COVID-19 vaccines.

Session 6

Мрох

• SAGE reviewed the most recent data on the epidemiology of mpox and noted that while reported cases and deaths had declined in all other WHO regions, reported cases and deaths persisted in the African region which has a distinct epidemiology and case distribution, including a reported high morbidity and mortality in children under 15 years old.

• SAGE was presented with data from systematic reviews of available smallpox/ mpox vaccines that demonstrated MVA-BN vaccine effectiveness in pre-exposure vaccination but more limited effectiveness in post-exposure vaccination, noting that all data were generated during the multi-country outbreak.

• Based on the data presented, SAGE updated its recommendations on the use of vaccines to prevent mpox in outbreak settings and preventive vaccination for high-risk groups in non-outbreak settings.

• In the context of an outbreak, to allow the greatest flexibility for local risk assessment, varied modes of transmission and response options, populations to consider for vaccination may include: (i) adults and children in a geographically defined area or community (e.g. villages) with a documented risk of exposure; (ii) persons with multiple sexual contacts; (iii) health workers at risk of repeated exposure; and (iv) known contacts of persons with mpox.

• Noting the endemicity of disease in the African continent, the distinct epidemiology of mpox in this region and the inequitable access to vaccination, SAGE issued a strong call to action to promote epidemiological and vaccine research on mpox in the region and urgent steps to facilitate equitable access to vaccination. Research should also be embedded in the outbreak response.

Session 7

Immune correlates

• For some vaccines, the Phase 3 trials with clinical outcomes are challenging either because they require very large sample sizes (e.g., group B streptococcus [GBS]) or because of the unpredictability of outbreaks (e.g., chikungunya). In such instances, regulatory approval may be

issued based on immunological correlates of protection against disease, followed by postauthorization requirements to demonstrate effectiveness.

• SAGE was briefed on the proposed regulatory pathways using this approach for GBS and chikungunya vaccines and the evidence in support of the proposed immunological correlates of protection.

• Since a chikungunya vaccine had received regulatory approval and there was interest in introducing this vaccine in several countries, SAGE requested WHO to initiate a process to conduct a detailed review of the evidence and assess use case scenarios for the optimal use of this vaccine.

• SAGE also noted that requiring evidence of clinical efficacy for GBS vaccines before issuing policy recommendations could delay the use of the vaccine in LMICs.

Session 8

Respiratory syncytial virus (RSV)

• SAGE was provided with data on products that recently received regulatory approval for the prevention of RSV disease in infants and adults. These included RSV pre-F protein vaccines for use in pregnant women to provide protection to young infants and to protect older adults, and long-acting monoclonal antibodies to protect young infants.

All products demonstrated high efficacy in protecting the target groups against medically attended and severe RSV lower respiratory tract illness. The products have been rolled out in a few countries.
A SAGE Working Group has been established to review the evidence on the use of these products and the findings of their review will be presented to SAGE in September 2024.

• SAGE recommended that products for the prevention of RSV disease in infants be prioritised for presentation in September 2024, followed by vaccines for the protection of older adults and articulated several issues that should be considered by the Working Group in their review of the evidence.

• Since a numerical imbalance was seen towards preterm births in the RSV vaccinated pregnant women compared to the control vaccine pregnant women, particular attention will be given to that signal.

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Ninth meeting of the Intergovernmental Negotiating Body (INB) for a WHO instrument on pandemic prevention, preparedness and response

18 – 28 March 2024

09:00-12:00, 13:00-16:00 and 16:30-18:30 CET, Geneva, Switzerland

In December 2021, the World Health Assembly established an <u>Intergovernmental Negotiating</u> <u>Body</u> (INB) to draft and negotiate a convention, agreement or other international instrument under the Constitution of the World Health Organization to strengthen pandemic prevention, preparedness and response.

The ninth meeting of the INB is to be held in hybrid format from 18 to 28 March 2024. At INB8, Member States requested the INB Bureau, formed by six officers, one from each of the six WHO regions, to develop a revised draft of the negotiating text of the WHO Pandemic Agreement. This draft will be the basis of textual negotiations at INB9.

The opening and closing plenary sessions of the INB are open to WHO Member States, Associate Members, Observers and regional economic integration organizations, as well all relevant stakeholders. These sessions will be publicly webcast and archived for later viewing. Substantive negotiating sessions will be held in closed format.

A/INB/9/1 - Provisional agenda

A/INB/9/2 - Draft programme of work

A/INB/9/3 - Revised draft of the negotiating text of the WHO Pandemic Agreement

Polio – PHEIC

Polio this week as of 20 Mar 2024 - GPEI

:: Two Wild Poliovirus type 1 (WPV1) cases were reported from <u>Dera Bugti</u> and <u>Chaman</u> districts of Balochistan, Pakistan. The cases had onset of paralysis on 22 February 2024 and 29 February 2024. The virus isolated from the cases are linked to the YB3A cluster that was detected in environmental samples in Quetta and Chaman in 2023. Outbreak response to the detected cases in Balochistan and recent environmental detections from other districts are ongoing with a polio vaccination campaign taking place from 25-28 March in polio-affected districts in Balochistan, Sindh and Punjab. Eradication efforts, particularly surveillance in the endemic areas where no cases linked to YB3C cluster have been reported since September 2023, continue to be intensified, particularly as the country is currently in the 'low transmission season' for poliovirus.

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

- Pakistan: two WPV1 cases and 21 positive environmental samples
- Burkina Faso: one cVDPV2-positive environmental sample
- DR Congo: one cVDPV2-positive environmental sample
- Guinea: one cVDPV2 case and 11 cVDPV2-positive environmental samples
- Mali: one cVDPV2 case
- Mauritania: one cVDPV2-positive environmental sample
- Nigeria: three cVDPV2-positive environmental samples
- Somalia: one cVDPV2 case
- Yemen: two cVDPV2 cases
- Zimbabwe: four cVDPV2-positive environmental samples

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WHO & Regional Offices [to 23 Mar 2024]

https://www.who.int/news Selected News/Announcements/Statements 22 March 2024 Departmental news World Water Day 2024: bridging divides through water cooperation

22 March 2024 Departmental news Unpacking artificial intelligence in sexual and reproductive health and rights 22 March 2024 Departmental news

Global Research Agenda on Knowledge Translation and Evidence-informed Policymaking

22 March 2024 Departmental news WHO launches new toolkit empowering health professionals to tackle climate change

22 March 2024 Departmental news WHO World TB Day Message

21 March 2024 Departmental news <u>Charting an evidence-based roadmap for WHO Global Traditional Medicine Centre</u> <u>collaborations</u>

20 March 2024 News release Call for urgent agreement on international deal to prepare for and prevent future pandemics

20 March 2024 Statement <u>Millions at risk from cholera due to lack of clean water, soap and toilets, and shortage of</u> <u>cholera vaccine</u>

20 March 2024 Departmental news <u>WHO to begin development of parallel recommendation and regulatory pathways;</u> <u>shortening the time taken for people to access health products</u>

20 March 2024 Departmental news <u>WHO launches new guidance on the use of targeted next-generation sequencing tests</u> <u>for the diagnosis of drug-resistant TB and a new sequencing portal</u>

18 March 2024 Statement Famine in Gaza is imminent, with immediate and long-term health consequences

18 March 2024 WHO urges investments for the scale up of tuberculosis screening and preventive treatment

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WHO Regional Offices
Selected Press Releases, Announcements
WHO African Region
24 March 2024
Combined HIV-TB testing, care curbing infection and mortality in Niger
23 March 2024
Intensifying new initiatives for TB case-finding in Nigeria
23 March 2024
Rate of TB diagnosis, treatment in Africa increasing
20 March 2024
Tanzania prioritizes delivery of oral health services at primary care level

WHO Region of the Americas PAHO

:: 22 Mar 2024

PAHO urges adoption of innovative technologies and treatments to eliminate tuberculosis

Washington, D.C., March 22, 2024 (PAHO)- On the eve of World Tuberculosis Day (24 March), the Pan American Health Organization (PAHO) is calling countries to intensify the fight against this preventable and curable disease. Tuberculosis, or TB, is the leading cause of death from a single infectious agent worldwide, surpassed only by COVID-19....

:: 21 Mar 2024

PAHO briefs health professionals on measles as cases increase in the Americas

Washington, DC, March 21, 2024 (PAHO) – A webinar organized by the Pan American Health Organization (PAHO) this week updated medical, nursing, laboratory, and epidemiology personnel on the clinical, surveillance, and vaccination aspects of measles. The webinar was organized following a recent uptick in cases in the Americas.As of March 16, 2024, a... :: 20 Mar 2024

PAHO and the Korea International Cooperation Agency join forces to improve access to health for migrants in Peru

Lima, Peru, 20 March 2024 (PAHO) – The Pan American Health Organization (PAHO) and the Korea International Cooperation Agency (KOICA) have launched a joint project to strengthen social inclusion and access to health for migrant and refugee populations in Peru. The project aims to address some of the primary barriers to health for migrants, which...

WHO South-East Asia Region SEARO

No new digest content identified.

WHO European Region EURO

No new digest content identified.

WHO Eastern Mediterranean Region EMRO

No new digest content identified.

WHO Western Pacific Region

No new digest content identified.

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WHO - Emergency situation reports

Latest WHO official reports for emergency situations. No new digest content identified.

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Disease Outbreak News (DONs)

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

20 March 2024 | Yellow fever – African Region (AFRO)

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Weekly Epidemiological Record https://www.who.int/publications/journals/weekly-epidemiological-record Vol. 99, No. 12, pp. 135–146 22 March 2024 <u>https://iris.who.int/bitstream/handle/10665/376320/WER9912-eng-fre.pdf</u> :: Recommended composition of influenza virus vaccines for use in the 2024–2025 northern hemisphere influenza season

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New WHO Publications https://www.who.int/publications/i Selected 22 March 2024 Guidance on conducting reviews of tuberculosis programmes

21 March 2024 The role of artificial intelligence in sexual and reproductive health and rights

21 March 2024 <u>Preparedness and Resilience for Emerging Threats Module 1: Planning for respiratory</u> <u>pathogen pandemics</u>

21 March 2024 Malaria Elimination Programme Review India 2022

20 March 2024

Surveillance, case investigation and contact tracing for mpox (monkeypox): Interim guidance, 20 March...

20 March 2024 <u>Public health resource pack for countries experiencing outbreaks of influenza in</u> <u>animals: revised guidance</u>

20 March 2024

WHO operational handbook on tuberculosis: module 3: diagnosis: rapid diagnostics for tuberculosis detection,...

20 March 2024

WHO consolidated guidelines on tuberculosis: module 3: diagnosis: rapid diagnostics for tuberculosis...

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USA – HHS, FDA, CDC

HHS <u>News</u> No new digest content identified.

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

FDA VRBPAC

<u>Advisory Committee Calendar</u> <u>Vaccines and Related Biological Products Advisory Committee May 16, 2024 Meeting</u> <u>Announcement - 05/16/2024</u>

CDC/ACIP [U.S.] [to 23 Mar 2024]

http://www.cdc.gov/media/index.html Latest News Releases No new digest content identified.

ACIP Meetings

Next ACIP Meeting June 26-28

MMWR Weekly

https://www.cdc.gov/mmwr/index2023.html March 21, 2024 / No. 11

PDF of this issue

- <u>Tuberculosis Preventive Treatment Update U.S. President's Emergency Plan for AIDS Relief,</u> <u>36 Countries, 2016–2023</u>
- <u>Surveillance for Coccidioidomycosis, Histoplasmosis, and Blastomycosis During the COVID-19</u> <u>Pandemic — United States, 2019–2021</u>
- Notes from the Field: Expanded Laboratory Testing for Varicella Minnesota, 2016–2023

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Europe

European Medicines Agency [EMA]

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

News & Press Releases

<u>Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP)</u> <u>18-21 March 2024</u>

EMA's human medicines committee (CHMP) recommended 12 medicines for approval at its March 2024 meeting.

22 March 2024

Accelerating stakeholder collaboration to enhance the clinical trials environment in the EU

The Accelerating Clinical Trials in the EU (ACT EU) initiative has established a multi-stakeholder platform (MSP) aimed at improving the environment for clinical trials across the European Union (EU).

20 March 2024

European Centre for Disease Prevention and Control

<u>https://www.ecdc.europa.eu/en</u> *News/Updates/Reports/Publications* [Selected] *Scientific and technical publications* <u>The cascade-of-care for tuberculosis infection in low-incidence countries – a scoping</u> <u>review protocol</u>

21 Mar 2024

The purpose of this scoping review is to describe and summarise the rationale behind and methodological approaches used to conduct cascade-of-care analyses for TB infection in low-TB incidence countries.

The untold story: new report reveals 7000 additional TB deaths during COVID-19 pandemic

21 Mar 2024

ECDC issues recommendations for strengthening emergency and pandemic preparedness planning

20 Mar 2024

In a report released today, ECDC outlines key strategic and operational considerations to inform preparedness planning around the design and implementation of Public Health and Social Measures (PHSMs) in the EU/EEA for health emergencies and pandemics.

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Africa CDC [to 23 Mar 2024] https://africacdc.org/ Press Releases, Statements [Selected] High-level event kicks off expansion of strategic EU-AU partnership, pledging joint commitments to strengthen Global Health and African Health Sovereignty 20 March 2024

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China CDC

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

National Health Commission of the People's Republic of China [to 23 Mar 2024]

<u>http://en.nhc.gov.cn/</u> *News No new digest content identified.*

National Medical Products Administration – PRC [to 23 Mar 2024]

<u>http://english.nmpa.gov.cn/</u> *News No new digest content identified.*

China CDC Weekly Reports: Current Volume (6)

2024-03-22 / No. 12 <u>View PDF of this issue</u> <u>Preplanned Studies: Tuberculosis Prevalence Trends from a Predictive Modelling Study — 10 High-Burden Countries, 1980–2035</u> <u>Preplanned Studies: Molecular Epidemiological Study of a Human Brucellosis Outbreak — Weihai</u> <u>City, Shandong Province, China, 2022</u> <u>Vital Surveillances: Epidemiological Characteristics of Human Parainfluenza Viruses Infections —</u> <u>China, 2019–2023</u> Outbreak Reports: An Outbreak of Serogroup Y Meningococcal Meningitis in a Private Secondary Vocational School — Guangzhou City, Guangdong Province, China, 2023 Notifiable Infectious Diseases Reports: Reported Cases and Deaths of National Notifiable Infectious Diseases — China, January 2024*

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Contents [click to move among sections]

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

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Organization Announcements

Paul G. Allen Frontiers Group[to 23 Mar 2024]https://alleninstitute.org/news-p ress/NewsNo new digest content identified.

BMGF - Gates Foundation [to 23 Mar 2024]

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

Bill & Melinda Gates Medical Research Institute [to 23 Mar 2024]

https://www.gatesmri.org/news

The Bill & Melinda Gates Medical Research Institute is a non-profit biotech organization. Our mission is to develop products to fight malaria, tuberculosis, and diarrheal diseases—three major causes of mortality, poverty, and inequality in developing countries. The world has unprecedented scientific tools at its disposal; now is the time to use them to save the lives of the world's poorest people News: Articles and Publications

Bill & Melinda Gates Medical Research Institute Initiates Phase 3 Clinical Trial of Tuberculosis Vaccine Candidate

March 19, 2024 Press Release

A large Phase 3 trial will evaluate whether the M72/AS01E vaccine candidate can protect adolescents and adults from pulmonary tuberculosis. Clinical trial site at University of the Witwatersrand, Johannesburg, South Africa, is first of up to 60 sites in seven countries. The M72/AS01E vaccine candidate could be the first new TB vaccine in 100 years if proven effective.

CARB-X [to 23 Mar 2024] https://carb-x.org/ News No new digest content identified. CEPI – Coalition for Epidemic Preparedness Innovations [to 23 Mar 2024] <u>http://cepi.net/</u> *Latest News* CEPI calls for experts to join its Scientific Advisory Committee CEPI 19th March 2024

CIOMS - COUNCIL FOR INTERNATIONAL ORGANIZATIONS OF MEDICAL SCIENCES [to

23 Mar 2024] https://cioms.ch/ News; Publications; Events No new digest content identified.

DARPA – Defense Advanced Research Projects Agency [U.S.] [to 23 Mar 2024 https://www.darpa.mil/news News No new digest content identified.

Duke Global Health Innovation Center [to 23 Mar 2024]

<u>https://dukeghic.org/</u> *News No new digest content identified.*

EDCTP [to 23 Mar 2024]

<u>http://www.edctp.org/</u> 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 [to 23 Mar 2024]

http://www.vaccines.emory.edu/ Vaccine Center News No new digest content identified.

European Vaccine Initiative [to 23 Mar 2024]

http://www.euvaccine.eu/ Latest News, Events No new digest content identified.

Evidence Aid [to 23 Mar 2024]

Evidence Aid aims to save lives and livelihoods in disasters by providing decision-makers with the best available evidence and by championing its use. <u>http://www.evidenceaid.org/</u> *Resources [Selected] No new digest content identified.*

Fondation Merieux [to 23 Mar 2024]

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

News, Events Announcement

Yes! We can end TB: in 2024, the Mérieux Foundation is more committed than ever to the fight against tuberculosis

March 22, 2024 - Global

World Tuberculosis Day is marked worldwide every year on March 24. The Mérieux Foundation is taking this opportunity to reiterate its commitment to eradicating the disease by 2030

Gavi [to 23 Mar 2024] https://www.gavi.org/ News Releases 22 March 2024 France to co-host with African Union and Gavi the launch of the African Vaccine Manufacturing Accelerator (AVMA) and Gavi's Investment Opportunity for 2026–2030

19 March 2024 Gavi and Seedstars launch INFUSE 2024: a global open call for innovations to foster climate-resilient health systems

GE2P2 Global Foundation [to 23 Mar 2024]

www.ge2p2.org

News/Analysis/Publications-Digests/Statements

:: Vaccines and Global Health: The Week in Review - Current edition

:: Informed Consent: A Monthly Review - March 2024

:: <u>Genomic Medicine – Governance, Ethics, Policy, Practice: A Monthly Digest</u> – Oct 2023

:: Public Consultations Watch :: Global Calls for Input/Public Comment – 07 March 2024 – Issue 14

GHIT Fund [to 23 Mar 2024] https://www.ghitfund.org/newsroom/press Press Releases No new digest content identified.

Global Fund [to 23 Mar 2024]. https://www.theglobalfund.org/en/news/ News & Stories No new digest content identified.

Global Research Collaboration for Infectious Disease Preparedness [GloPID-R] [to 23 Mar

2024]

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

News

news

Wellcome Open Research publishes Pandemic PACT research funding protocol March 21, 2024

news

GloPID-R announces the launch of Pandemic PACT

March 20, 2024

GloPID-R is proud to announce the official launch of Pandemic PACT, the Pandemic Preparedness Analytical Capacity and Funding Tracking Programme. This cutting-edge programme to track and analyse global research funding and evidence is being showcased at a special event on 20 March 2024 co-organised with the Pandemic Sciences Institute (PSI) at the University of Oxford, who lead the programme.

Hilleman Laboratories [to 23 Mar 2024]

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

HHMI - Howard Hughes Medical Institute [to 23 Mar 2024]

<u>https://www.hhmi.org/news</u> *Press Room No new digest content identified.*

Human Immunome Project [nee Human Vaccines Project] [to 23 Mar 2024]

http://www.humanvaccinesproject.org/ News No new digest content identified.

IAVI [to 23 Mar 2024] https://www.iavi.org/ News, Features No new digest content identified.

INSERM [to 23 Mar 2024] 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 [to 23 Mar 2024]

https://www.ich.org/page/press-releases News/Pubs/Press Releases [Selective] No new digest content identified.

ICRC [to 23 Mar 2024] https://www.icrc.org/en/whats-new What's New [Selected] No new digest content identified.

IFFIm

http://www.iffim.org/ Press Releases/Announcements Vaccination and supportive care stave off deaths in Ugandan measles outbreak

15 Mar 2024

With a sizeable cohort of unimmunised children built up over years, the measles epidemic is expected to grow among communities lining the lakeshore in Hoima district.

IFRC [to 23 Mar 2024] http://media.ifrc.org/ifrc/news/press-releases/ *Press Releases [Selected] No new digest content identified.*

Institut Pasteur [to 23 Mar 2024]

https://www.pasteur.fr/en/press-area Press Documents No new digest content identified.

ISC / International Science Council [to 23 Mar 2024]

<u>https://council.science/current/</u> 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 Blogs No new digest content identified.

International Union of Immunological Societies (IUIS)

<u>https://iuis.org/</u> *News/Events [Selected] No new digest content identified.* IVAC [to 23 Mar 2024] https://www.jhsph.edu/research/centers-and-institutes/ivac/index.html Updates; Events March 22, 2024 Low Immunization Coverage Leads to Global Increase in Measles Cases

IVI [to 23 Mar 2024] http://www.ivi.int/ IVI News & Announcements IVI starts technology transfer to Biological E. Limited to manufacture oral cholera vaccine for India and global markets Mar 20, 2024

Johns Hopkins Center for Health Security [to 23 Mar 2024] https://centerforhealthsecurity.org/newsroom Center News [Selected] March 19: New policy analysis offers pathways for collaboration across primary care, public health, and community-based organizations

MSF/Médecins Sans Frontières_ [to 23 Mar 2024] http://www.msf.org/ Latest [Selected Announcements] Ukraine Against stigma and drug-resistance: five years of treating tuberculosis in Ukraine Project Update 22 Mar 2024

Haemorrhagic fevers Five things to remember a decade after the Ebola outbreak in West Africa Project Update 20 Mar 2024

Tuberculosis MSF launches unprecedented project to tackle under-diagnosed tuberculosis among children Project Update 18 Mar 2024

National Academy of Medicine - USA [to 23 Mar 2024]

https://nam.edu/programs/ News [Selected] No new digest content identified.

National Academy of Sciences - USA [to 23 Mar 2024] https://www.nationalacademies.org/newsroom? News Report Lays Out Road Map to Transform Understanding of RNA and Invest in RNA Science and Biotechnology News Release | March 21, 2024 WASHINGTON — A <u>new report</u> from the National Academies of Sciences, Engineering, and Medicine provides a road map to develop the capacity to sequence any RNA molecule from any biological system with all its modifications. The report provides priorities and milestones for a 15year initiative to advance technology, centralize data resources, expand research and develop standards, and cultivate a skilled workforce in the field.

The core of the proposed initiative is an overarching, strategic U.S. government effort and coordinated investment in the study and mapping of RNA modifications, led by an established oversight body, such as the White House Office of Science and Technology Policy. The impacts could span far beyond biomedical sciences and health, so the report calls on key federal entities such as the National Institutes of Health, National Science Foundation, National Institute of Standards and Technology, and the U.S. departments of Defense and Energy to collaborate with academia, industry, philanthropic organizations, and international partners to drive innovation...

National Vaccine Program Office - U.S. HHS [to 23 Mar 2024]

https://www.hhs.gov/vaccines/about/index.html Upcoming Meetings/Latest Updates June 13-14, 2024

NIH [to 23 Mar 2024] <u>http://www.nih.gov/</u> *No new digest content identified.*

PATH [to 23 Mar 2024] https://www.path.org/media-center/ Newsroom New partnership aims to improve immunization efforts in conflict-afflicted and under immunized settings

PATH, the George Washington University, Kinshasa School of Public Health, and Conception, Etude, Sécurité Alimentaire & Formation announce a partnership to improve routine immunization efforts.

WASHINGTON (March 25, 2024)—PATH and the George Washington University, in partnership with several universities and research organizations in the Democratic Republic of Congo, Niger, Pakistan, and Somalia, were awarded a \$5 million, five-year award by the Bill & Melinda Gates Foundation to establish a Learning Consortium focused on routine immunization in conflict-afflicted and under immunized settings. The learning agenda will be focused on identifying routine immunization results, exploring how routine immunization programs operate, what challenges and opportunities for improvement they face, and explaining why they work or not. Such learnings will be iteratively shared with domestic decision-makers, global stakeholders, and partners who are working in routine immunization programs in other conflict-afflicted and under immunized settings...

Sabin Vaccine Institute [to 23 Mar 2024] https://www.sabin.org/press/ Latest News & Press Releases No new digest content identified.

UNAIDS [to 23 Mar 2024] http://www.unaids.org/en

Selected Press Releases/Reports/Statements Press statement

UNAIDS welcomes the adoption of a crucial resolution recognizing harm reduction measures at the UN Commission on Narcotic Drugs

22 March 2024— UNAIDS welcomes the adoption of a key resolution today at the 67th session of the United Nations Commission on Narcotic Drugs (CND), recognizing harm reduction for the first time as an important part of an effective public health response. The resolution encourages member states to develop and implement harm reduction measures to minimize the adverse public health and social consequences of the non-medical use of illicit drugs. UNAIDS congratulates the CND and the CND Chair for this historic milestone.

The <u>resolution</u> represents a landmark in political commitment to a rebalancing of drug policy towards a public health approach. Such a shift is critical to meeting the targets in the 2021-2026 Global AIDS Strategy...

UNICEF [to 23 Mar 2024]

https://www.unicef.org/media/press-releases Latest press releases, news notes and statements

Statement 20 March 2024

Millions at risk from cholera due to lack of clean water, soap and toilets, and shortage of cholera vaccine

GENEVA/NEW YORK, 20 March 2024 – Immediate action is needed to stem an unprecedented multi-year upsurge in cholera cases worldwide, according to the International Coordinating Group (ICG) on Vaccine Provision. Actions include investing in access to safe water, sanitation and hygiene, testing and detecting outbreaks quickly, improving quality of...

Unitaid [to 23 Mar 2024] https://unitaid.org/ Featured News 22 March 2024 Act now for tomorrow: equitable access to pandemic life-saving health tools is needed

21 March 2024

Ahead of World TB Day, Unitaid and FIND welcome WHO resources to accelerate access to faster, more accurate tests for drug-resistant tuberculosis

20 March 2024

Joint UNFPA-Unitaid venture backed by major EU funding aims to eliminate the leading cause of mothers dying in childbirth in Africa

19 March 2024 Overlooked No More: Access to TB Innovations for Children and Pregnant Women is a Must

Vaccine Equity Cooperative [nee Initiative] [to 23 Mar 2024] https://vaccineequitycooperative.org/news/ News No new digest content identified.

Vaccination Acceptance & Demand Initiative [Sabin) [to 23 Mar 2024]

https://www.vaccineacceptance.org/ Announcements, Blog No new digest content identified.

Vaccine Confidence Project [to 23 Mar 2024] http://www.vaccineconfidence.org/ News, Research and Reports No new digest content identified.

Vaccine Education Center – Children's Hospital of Philadelphia [to 23 Mar 2024] http://www.chop.edu/centers-programs/vaccine-education-center News March 2024: Vaccines and Infectious Diseases in the News Published on Mar 19, 2024

Wellcome Trust [to 23 Mar 2024]

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

The Wistar Institute [to 23 Mar 2024]

https://www.wistar.org/news/press-releases Press Releases No new digest content identified.

World Bank [to 23 Mar 2024] http://www.worldbank.org/en/news/all All News [Selected]

World Bank Group Statement on Gaza

WASHINGTON, March 19, 2024—The World Bank Group today issued the following statement on Gaza:

"With more than half the population of Gaza on the brink of famine—including children and the elderly—the World Bank Group calls for urgent action to save lives. We join the international community in calling for immediate, free, and unimpeded access of medical supplies, food and life-essential services through all available means at speed and scale to the people of Gaza." *About the World Bank Group's Response in Gaza*

In <u>December 2023</u>, the World Bank Group Board of Directors approved the commitment of \$35 million funds to development partners which are active in Gaza, including UNICEF, the World Food Programme (WFP), and the World Health Organization (WHO). This includes a \$10 million package to the WFP to purchase food parcels and vouchers to reach an estimated 377,000 people.

WFPHA: World Federation of Public Health Associations [to 23 Mar 2024] https://www.wfpha.org/ Blog WFPHA Intervention at INB9 Mar 22, 2024

WFPHA Intervention at The Intergovernmental Negotiating Body (INB9) The ninth meeting of the Intergovernmental Negotiating Body (INB) for a WHO instrument on pandemic prevention, preparedness, and response is currently being held in a hybrid format...

World Medical Association [WMA] [to 23 Mar 2024]

https://www.wma.net/news-press/press-releases/ Press Releases No new digest content identified.

World Organisation for Animal Health [to 23 Mar 2024]

https://www.oie.int/en/ Press Releases, Statements Statements Wildlife under threat as avian influenza reaches Antarctica

Published on 13 March 2024

The ongoing spread of high pathogenicity avian influenza (HPAI) has now reached an unprecedented milestone with reports of its recent detection on Antarctica's mainland. Originally surfacing in Europe in 2021, the virus has traversed continents, reaching North America in the same year and South America by 2022. Most recently, it has extended its reach to Antarctic islands in 2023. However, the gravity of the situation intensifies as it infiltrates the northern tip of Antarctica's mainland, as <u>reported</u> through the <u>World Animal Health Information System (WAHIS).</u>...

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ARM [Alliance for Regenerative Medicine] [to 23 Mar 2024]

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

BIO [to 23 Mar 2024] https://www.bio.org/press-releases Press Releases No new digest content identified.

DCVMN – Developing Country Vaccine Manufacturers Network [to 23 Mar 2024]

<u>http://www.dcvmn.org/</u> *News; Upcoming events No new digest content identified.*

ICBA – International Council of Biotechnology Associations [to 23 Mar 2024] https://internationalbiotech.org/news/ News No new digest content identified. IFPMA [to 23 Mar 2024] https://ifpma.org/ News Statement 21 Mar 2024 9th Meeting of the Interge

<u>9th Meeting of the Intergovernmental Negotiating Body (INB): Open session with</u> relevant stakeholders focusing on critical elements for a pandemic agreement

On 21 March 2024, Thomas Cueni, Director General, IFPMA delivered a statement at the 9th Meeting of the INB in an open session with relevant stakeholders focusing on critical elements for a pandemic agreement. IFPMA strongly supports the efforts to find agreement on a Pandemic Accord and we reaffirm our full commitment to constructively contribute...

Statement 18 Mar 2024

9th Meeting of the Intergovernmental Negotiating Body (INB)

On 18 March 2024, IFPMA submitted and delivered statements at the 9th Meeting of the Intergovernmental Negotiating Body (INB). The full submitted statement is below.

International Alliance of Patients' Organizations – IAPO [to 23 Mar 2024]

<u>https://www.iapo.org.uk/news</u> *Press and media [Selected] No new digest announcements identified.*

International Generic and Biosimilar Medicines Association [IGBA]

<u>https://www.igbamedicines.org/</u> *News No new digest announcements identified.*

PhRMA [to 23 Mar 2024] http://www.phrma.org/ Press Releases No new digest announcements identified.

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Vaccines/Therapeutics/Medicines – Selected Developer/Manufacturer Announcements

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

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

BioCubaFarma – Cuba <u>Últimas Noticias</u> - No new digest announcements identified

Biological E

<u>News</u>

IVI Starts Technology Transfer to Biological E. Limited to Manufacture Oral Cholera Vaccine for India and Global Markets

- IVI will complete the technology transfer by 2025
- Oral Cholera Vaccine to be manufactured by Biological E. Limited for India and international markets

March 20, 2024

BioNTech

Press Releases 20 March 2024

BioNTech Announces Appointment of Annemarie Hanekamp to Management Board as Chief Commercial Officer

Boehringer

Press Releases - No new digest announcements identified.

CanSinoBIO

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

CIGB

Latest News - No new digest announcements identified.

Cinnagen

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

Clover Biopharmaceuticals – China

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

Curevac [Bayer Ag – Germany]

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

Gamaleya National Center/Sputnik

<u>Latest News and Events</u> - No new digest announcements identified <u>https://sputnikvaccine.com/</u> - No new digest announcements identified

GSK <u>Press releases for media</u> - No new digest announcements identified

IMBCAMS, China <u>Home</u> - Website not responding at inquiry.

Janssen/JNJ <u>Press Releases</u> Mar 19, 2024 United States U.S. FDA Approves EDURANT® PED (rilpivirine) for Certain Pediatric Patients Living with <u>HIV-1</u>

Merck

<u>News releases</u> <u>March 19, 2024</u> <u>Merck Announces Positive Data on V116, an Investigational, 21-Valent Pneumococcal</u> <u>Conjugate Vaccine Specifically Designed for Adults, Demonstrated Immune Responses</u> <u>in Adults</u>

Moderna

Press Releases - No new digest announcements identified.

Nanogen

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

Novartis

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

Novavax

Press Releases - No new digest announcements identified.

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

R-Pharm <u>https://rpharm-us.com/index.php</u> [No news or media page identified]

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

Serum Institute of India <u>NEWS & ANNOUNCEMENTS</u> - No new digest announcements identified

Sinopharm/WIBPBIBP <u>News</u> - No new digest announcements identified [English translation function not operating]

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

SK Biosciences

Press Releases

SK bioscience Exports Influenza Vaccine to Thailand, Entering Southern Hemisphere Vaccine Market

- Company exported 440,000 doses to Thailand, marking its entry into the Southeast Asian market 2024.03.21

Takeda

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

Valneva

<u>Press Releases</u> March 21, 2024 Valneva to Present on its Chikungunya Vaccine IXCHIQ®, Participate in Multiple Events at the 24th World Vaccine Congress in Washington D.C.

Vector State Research Centre of Viralogy and Biotechnology

<u>Home</u> - Website not responding [404 error]

WestVac Biopharma

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

Zhifei Longcom, China

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

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Journal Watch

Vaccines and Global Health: The Week in Review continues its weekly scanning of key peerreviewed 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: <u>david.r.curry@centerforvaccineethicsandpolicy.org</u>

AJOB Empirical Bioethics

Volume 15, 2023 Issue 1 <u>https://www.tandfonline.com/toc/uabr21/current</u> [Reviewed earlier]

AMA Journal of Ethics

Volume 26, Number 3: E195-273 Mar 2024 https://journalofethics.ama-assn.org/issue/critical-pedagogies-health-professions-education

Psychiatric Inpatient Environmental Architecture

Inpatient psychiatric units designed to reduce patients' risk of harm to self or others can compromise patients' comfort. Some environmental modifications prioritize safety by limiting patients' access to personal items. This set of clinical phenomena is not ethically neutral and should prompt us to carefully consider when and how patients' experiences of their care environments undermine therapeutic goals of their hospitalizations. This theme issue investigates which criteria we should use to assess and evaluate patients' risk of harm to self or others and which values we should rely upon to guide which iatrogenic harm risks we accept as products or byproducts of clinical and organizational environmental designs. [Reviewed earlier]

American Journal of Human Genetics

Mar 07, 2024 Volume 111 Issue 3 p403-620 https://www.cell.com/ajhg/current This Month in The Journal

Alyson B. Barnes, Kylee L. Spencer, Sara B. Cullinan

In Our DNA SC, a program developed to ensure that all individuals in South Carolina have access to genomic screening, recently reached an interim milestone of 20,000 participants. Over 14 months, 20,478 participants enrolled, and 13,643 samples were collected through clinical appointments, 108 community events, or at-home sample collection. A total of 1.3% of participants were found to have a pathogenic or likely pathogenic variant for a CDC Tier 1 condition; 77.4% of those agreed to genetic counseling and 80.2% completed counseling.

American Journal of Infection Control

March 2024 Volume 52 Issue 3 p261-380 <u>http://www.ajicjournal.org/current</u> [Reviewed earlier]

American Journal of Preventive Medicine

March 2024 Volume 66 Issue 3 p389-572 <u>https://www.ajpmonline.org/current</u> [Reviewed earlier]

American Journal of Public Health

March 2024 114(3) <u>http://ajph.aphapublications.org/toc/ajph/current</u> [Reviewed earlier]

American Journal of Tropical Medicine and Hygiene

Volume 110 (2024): Issue 2 (Feb 2024) https://www.ajtmh.org/view/journals/tpmd/110/2/tpmd.110.issue-2.xml [Reviewed earlier]

Annals of Internal Medicine

February 2024 Volume 177, Issue 2 <u>https://www.acpjournals.org/toc/aim/current</u> [Reviewed earlier]

Artificial Intelligence – An International Journal

Volume 328 March 2024 <u>https://www.sciencedirect.com/journal/artificial-intelligence/vol/328/suppl/C</u> [New issue; No digest content identified]

BMC Cost Effectiveness and Resource Allocation

http://resource-allocation.biomedcentral.com/ (Accessed 23 Mar 2024) [No new digest content identified]

BMC Health Services Research

http://www.biomedcentral.com/bmchealthservres/content (Accessed 23 Mar 2024) [No new digest content identified]

BMC Infectious Diseases

http://www.biomedcentral.com/bmcinfectdis/content (Accessed 23 Mar 2024)

Immune response to the recombinant herpes zoster vaccine in people living with HIV over 50 years of age compared to non-HIV age-/gender-matched controls (SHINGR'HIV): a multicenter, international, non-randomized clinical trial study protocol

The burden of herpes zoster (shingles) virus and associated complications, such as post-herpetic neuralgia, is higher in older adults and has a significant impact on quality of life. The incidence of herpes zo...

Authors: Maxime Hentzien, Fabrice Bonnet, Enos Bernasconi, Emmanuel Biver, Dominique L. Braun, Aline Munting, Karoline Leuzinger, Olivier Leleux, Stefano Musardo, Virginie Prendki, Patrick Schmid, Cornelia Staehelin, Marcel Stoeckle, Carla S. Walti, Linda Wittkop, Victor Appay...

Citation: BMC Infectious Diseases 2024 24:329

Content type: Study Protocol Published on: 19 March 2024

BMC Medical Ethics

http://www.biomedcentral.com/bmcmedethics/content (Accessed 23 Mar 2024) [No new digest content identified]

BMC Medicine

http://www.biomedcentral.com/bmcmed/content (Accessed 23 Mar 2024) [No new digest content identified]

BMC Pregnancy and Childbirth

http://www.biomedcentral.com/bmcpregnancychildbirth/content (Accessed 23 Mar 2024) [No new digest content identified]

BMC Public Health

http://bmcpublichealth.biomedcentral.com/articles (Accessed 23 Mar 2024) The role of collectivism, liberty, COVID fatigue, and fatalism in public support for the zero-COVID policy and relaxing restrictions in China

China was the last country in the world to relax COVID-19 restrictions. A successful public health policy requires public support. This analysis examined the factors associated with Chinese support for zero-CO... Authors: Xiao Wang Citation: BMC Public Health 2024 24:873 Content type: Research Published on: 21 March 2024

Prevalence and factors associated with hepatitis b vaccination uptake and completion among communities targeted for mass vaccination in gulu: a cross-sectional study

Hepatitis B virus (HBV) is associated with several acute and long-term complications and vaccination is the cornerstone of prevention. A recent outbreak in Gulu, Uganda, one of the districts covered by a mass ...

Authors: Andrew Kimera, Lynn Atuyambe, Huzaifa Mutyaba, Claire Nantongo, Agnes Namagembe, Anna Maria Nalumansi, Andrew Basenero, Prisca Auma, Nelson Mukiza and Joan Mutyoba Citation: BMC Public Health 2024 24:866

Content type: Research Published on: 20 March 2024

Uptake of human papilloma virus vaccine and its determinants among females in East Africa: a systematic review and meta-analysis

Cervical cancer is the most common malignant tumor among women. It is the main cause of death among women in sub-Saharan African countries. Particularly, the incidence and mortality rates are highest in East A...

Authors: Muluken Chanie Agimas, Dagnew Getnet Adugna, Nebiyu Mekonnen Derseh, Amare Kassaw, Yohannes Tesfahun Kassie, Hailemichael Kindie Abate and Chilot Kassa Mekonnen Citation: BMC Public Health 2024 24:842

Content type: Research Published on: 18 March 2024

BMC Research Notes

http://www.biomedcentral.com/bmcresnotes/content (Accessed 23 Mar 2024) Factors associated with vaccine hesitancy against COVID-19 among adults in Europe: a descriptive study analysis applying socio-ecological framework Authors: Megumi Nagase

Content type: Research Note 19 March 2024

BMJ Evidence-Based Medicine

February 2024 - Volume 29 - 1 <u>https://ebm.bmj.com/content/29/1</u> [Reviewed earlier]

BMJ Global Health

March 2024 - Volume 9 - 3 <u>https://gh.bmj.com/content/9/3</u> [Reviewed earlier]

Bulletin of the Atomic Scientists

March 2024 <u>https://thebulletin.org/magazine/2024-03/</u> [Reviewed earlier]

Bulletin of the World Health Organization

Volume 102(3); 2024 Mar 1

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March 19, 2024, Vol 331, No. 11, Pages 899-988 <u>https://jamanetwork.com/journals/jama/currentissue</u> *Original Investigation* <u>Stroke Risk After COVID-19 Bivalent Vaccination Among US Older Adults</u> Yun Lu, PhD; Kathryn Matuska, BA; Gita Nadimpalli, PhD; et al. JAMA. 2024;331(11):938-950. doi:10.1001/jama.2024.1059

This self-controlled case series evaluates stroke risk after administration of either brand of the COVID-19 bivalent vaccine, either brand of the COVID-19 bivalent plus a high-dose or adjuvanted influenza vaccine on the same day, and a high-dose or adjuvanted influenza vaccine in Medicare beneficiaries aged 65 years or older.

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Mar 23, 2024 Volume 403 Number 10432 p1109-1204 <u>https://www.thelancet.com/journals/lancet/issue/current</u> *Comment* **First Africa-based clinical trial for novel type 2 oral poliovirus vaccine** Laura V Cooper, Isobel M Blake

Articles

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Therapeutics **mRNA-based therapeutics: looking beyond COVID-19 vaccines** Hamideh Parhiz, Elena N Atochina-Vasserman, Drew Weissman

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A cluster randomized controlled trial in Sierra Leone shows that targeting access to vaccines in remote areas increases uptake, an approach that can be used to improve vaccine equity in developing countries.

Niccolò F. Meriggi, Maarten Voors, Ahmed Mushfiq Mobarak

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Nature Medicine

Volume 30 Issue 3, March 2024 <u>https://www.nature.com/nm/volumes/30/issues/3</u> *Editorial* 19 Mar 2024 **How to support the transition to AI-powered healthcare**

To make health systems more sustainable in the long-term, incentivize artificial intelligence (AI) and digital technologies that are grounded on careful testing and real-world validation.

Consensus Statement 29 Feb 2024 <u>Recommendations to address respondent burden associated with patient-reported</u> <u>outcome assessment</u>

Patient-reported outcomes are invaluable tools, but may impose a burden on patients; this consensus statement provides a set of 19 recommendations to reduce respondent burden. Olalekan Lee Aiyegbusi, Samantha Cruz Rivera, Melanie J. Calvert

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Exploring trends and determinants of basic childhood vaccination coverage: Empirical evidence over 41 years

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13 March 2024 Volume 291 Issue 2018 <u>https://royalsocietypublishing.org/toc/rspb/current</u> [Reviewed earlier]

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 <u>COVID-19 vaccination plans in Latin America and the Caribbean: a multi-country</u> <u>comparative analysis of prioritization strategies</u>
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Special Section on Disease Surveillance & Response Research article Open access The state of integrated disease surveillance globally: synthesis report of a mixed methods study Andrew C.K. Lee, Bjorn G. Iversen, Sadaf Lynes, Jean-Claude Desenclos, ... Thidar Pyone

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Volume 383| Issue 6689| 22 Mar 2024

https://www.science.org/toc/science/current In Depth Rifts over equity imperil WHO's pandemic treaty BY Jon Cohen 21 Mar 2024: 1276-1277 As deadline nears, negotiations continue over sharing pathogen sequences and vaccine doses

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Volume 30, Issue 2 April 2024 <u>https://link.springer.com/journal/11948/volumes-and-issues/30-2</u> <u>Mapping Ethical Artificial Intelligence Policy Landscape: A Mixed Method Analysis</u> Tahereh Saheb Original Research/Scholarship Open access 07 March 2024 Article: 9

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Volume 16| Issue 739| 20 Mar 2024 <u>https://link.springer.com/journal/11017/volumes-and-issues/45-2</u> [New issue; No digest content identified]

Travel Medicine and Infectious Diseases

Volume 58 March–April 2024 <u>https://www.sciencedirect.com/journal/travel-medicine-and-infectious-disease/vol/58/suppl/C</u> *Editorial* Open access **Zoonotic diseases in a changing climate scenario: Revisiting the interplay between** <u>environmental variables and infectious disease dynamics</u> Priyanka Choudhary, Maryam Shafaati, Mai Abdel Haleem Abu Salah, Hitesh Chopra, ... Alfonso J. Rodriguez-Morales Article 102694

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Volume 29, Issue 3 Pages: i-iv, 161-255 March 2024 <u>https://onlinelibrary.wiley.com/toc/13653156/current</u> [Reviewed earlier]

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Volume 42, Issue 8 Pages 1855-2114 (19 March 2024) <u>https://www.sciencedirect.com/journal/vaccine/vol/42/issue/8</u> *Short communication Abstract only* <u>Cryptic vaccine-associated adverse events: The critical need for a new vaccine safety</u> <u>surveillance paradigm to improve public trust in vaccines</u> Gregory A. Poland, Steven Black

Pages 1860-1862

Abstract

Vaccination is one of the most important public health tools in the prevention of infectious diseases, and in preserving life and health. While vaccines are generally safe and usually produce only transient side effects, other types of vaccine-associated adverse events do occur. Some of these reactions are immediate and easily observable or measurable, such as swelling at the injection site or a transient fever. Others however are not immediately obvious, or are even clinically "silent" or cryptic, making them challenging to identify and link directly to a vaccine. It is critical to be vigilant about rare, silent, or subtle reactions. Public health agencies and healthcare providers can play a much more favorable and vital role in establishing vaccine trust by enlarging the current vaccine safety paradigm, and in publishing and communicating, in full, these risks and benefits transparently to the public. While there are challenges in collecting and studying cryptic adverse events characterized by subjective symptoms without biomarkers, rigorous pharmacovigilance, continued research, and high-quality study designs can assist in better understanding and addressing these concerns – and in building public trust about vaccines and vaccine safety surveillance completeness.

Short communication Open access

Lassa fever vaccine use cases and demand: Perspectives from select West African experts Lassané Kaboré, Clint Pecenka, William P. Hausdorff

Lassane Kabore, Clint Pecenka, William P. Hausdorff Pages 1873-1877

Research article Open access

Immunogenicity and lot-to-lot consistency of booster shot with Sabin inactivated poliomyelitis vaccine in Chinese children aged 18–24 Months: A phase IV clinical trial Qiongzhou Yin, Yan Zheng, Zhifang Ying, Jingyu Li, ... Li Shi Pages 1973-1979

Research article Open access

Intensification of integrated immunization services to recover routine vaccination coverage and bring COVID-19 vaccine to the population of Iraq in 2022 Firas Jabbar, Kamal A Kadhim, Riyadh A Alhilfi, Abdulaal Chitheer, ... David B Hipgrave

Pages 2036-2043

Research article Open access

Impact evaluation of a youth led intervention to increase COVID-19 vaccine uptake in Kwazulu-Natal, South Africa

Edmore Marinda, Qaqambile Mathentamo, Nancy Coulson, Saahier Parker, ... Heidi van Rooyen Pages 2089-2098

Vaccines

https://www.mdpi.com/journal/vaccines [Accessed 23 Mar 2024] Latest Articles [Selected] Open Access Review Global Disparities in Access to Vaccine Clinical Trials: A Review of the Literature

by Ali Mardini, Norhan Shaykhon, Asher Khan, Ahmad Mardini and Hajirah N. Saeed Vaccines 2024, 12(4), 348; https://doi.org/10.3390/vaccines12040348 (registering DOI) - 23 Mar 2024

Abstract

Vaccines are an effective tool to reduce the disease burden from infectious diseases on a population, infrastructural, and individual level. Before vaccines can be administered to populations at large, they must go through rigorous testing in the form of clinical trials...

Open Access Article

Malaria Vaccine Introduction in Cameroon: Early Results 30 Days into Rollout

by Shalom Tchokfe Ndoula, Frank Mboussou, Andreas Ateke Njoh, Raoul Nembot, Simon Franky Baonga, Arnaud Njinkeu, Joseph Biey, Mohamed Kaba II, Adidja Amani, Bridget Farham, Jean-Christian Kouontchou Mimbe, Christian Armel Kouakam, Konstantin Volkmann, Crépin Hilaire Dadjo, Phanuel Habimana and Benido Impouma

Vaccines 2024, 12(4), 346; https://doi.org/10.3390/vaccines12040346 (registering DOI) - 22 Mar 2024

Abstract

Cameroon introduced the malaria vaccine in its routine immunization program on 22 January 2024 in the 42 districts out of 200 that are among the most at risk of malaria.

Value in Health

March 2024 Volume 27 Issue 3 p271-382 <u>https://www.valueinhealthjournal.com/current</u> [Reviewed earlier]

World Development

Volume 175 March 2024 https://www.sciencedirect.com/journal/world-development/vol/175/suppl/C [Reviewed earlier]

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:: <u>Milestones, Perspectives</u>

:: <u>WHO</u>

:: Organization Announcements

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Pre-Print Servers

Gates Open Research https://gatesopenresearch.org/browse/articles [Accessed 23 Mar 2024] Selected Research Open Letter metrics AWAITING PEER REVIEW Better methods, better data: landscaping the priorities for improving methodologies in vector control [version 1; peer review: awaiting peer review] Katherine Gleave, Rosemary Susan Lees Peer Reviewers Invited Funder Bill and Melinda Gates Foundation PUBLISHED 21 Mar 2024

medRxiv

https://www.medrxiv.org/content/about-medrxiv [Accessed 23 Mar 2024] [Filter: All articles] Exposure patterns and the risk factors of zoonotic Crimean Congo hemorrhagic fever virus amongst pastoralists, livestock and selected wild animals species at the human/livestock/wildlife interface in Isiolo County, upper eastern Kenya Eugine Mukhaye, James Akoko, Richard Nyamota, Athman Mwatondo, Mathew Muturi, Daniel Nthiwa, Lynn J. Kirwa, Joel L. Bargul, Hussein M. Abkallo, Bernard Bett medRxiv 2024.03.20.24304573; doi: https://doi.org/10.1101/2024.03.20.24304573

Development of Prediction Models of COVID-19 Vaccine Uptake among Lebanese and Syrians in a district of Beirut, Lebanon: a population-based study

Marie Elizabeth Ragi, Hala Ghattas, Hazar Shamas, Jocelyn DeJong, Nada M Melhem, Stephen J McCall, CAEP Study Group medRxiv 2024.03.21.24304659; doi: https://doi.org/10.1101/2024.03.21.24304659

Factors associated with correct vaccination among children aged 24 to 48 months hospitalized in the national hospitals of Bujumbura

Felix Niyongabo, Jean M. Butoyi, Niyoyunguruza Laetitia, Kabusoni Esperance, Yves Coppieters medRxiv 2024.03.18.24304508; doi: https://doi.org/10.1101/2024.03.18.24304508

Publication status of 95 clinical trials of 3 COVID-19 vaccines developed by Chinese companies: An observational cohort study

Till Bruckner, Yixuan Chen, Carolina Cruz, Christie Ebube Dike, Belen Chavarria, Shiyu Chen, Ernest Dela Dzidzornu

medRxiv 2024.03.17.24304386; doi: https://doi.org/10.1101/2024.03.17.24304386

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: Preprints] [No new digest content identified]

Wellcome Open Research

https://wellcomeopenresearch.org/browse/articles [Accessed 23 Mar 2024] Selected Research Study Protocol Open Access A protocol for a living mapping review of global research funding for infectious diseases with a pandemic potential – PANDEMIC PACT [version 1; peer review: awaiting peer review] Olena Seminog, et al. Abstract

The COVID CIRCLE initiative Research Project Tracker by UKCDR and GloPID-R and associated living mapping review (LMR) showed the importance of sharing and analysing data on research at the point of funding to improve coordination during a pandemic. This approach can also help with research preparedness for outbreaks and hence our new programme the Pandemic Preparedness: Analytical Capacity and Funding Tracking Programme (Pandemic PACT) has been established...

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<u>Think Tanks</u>

Brookings [to 23 Mar 2024] http://www.brookings.edu/ Research No new digest content identified.

Center for Global Development [to 23 Mar 2024]

<u>https://www.cgd ev.org/</u> *All Research [Selected] No new digest content identified.*

Chatham House [to 23 Mar 2024] https://www.chathamhouse.org/ Selected Analysis, Comment, Events No new digest content identified.

Council on Foreign Relations [to 23 Mar 2024]

https://www.cfr.org/media/news-releases New Releases [Selected] No new digest content identified. **CSIS** [to 23 Mar 2024] https://www.csis.org/ Reports [Selected] No new digest content identified.

Kaiser Family Foundation [to23 Mar 2024]

https://www.kff.org/search/?post_type=press-release Newsroom No new digest content identified.

McKinsey Global Institute [to 23 Mar 2024]

https://www.mckinsey.com/mgi/overview Latest Research No new digest content identified.

ODI [Overseas Development Institute] [to 23 Mar 2024]

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

Pew Research Center [to 23 Mar 2024]

https://www.pewresearch.org/ Latest Publications [Selected] No new digest content identified.

Rand [to 23 Mar 2024]

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Urban Institute [to 23 Mar 2024] https://www.urban.org/publications New Research Publications - Selected

World Economic Forum [to 23 Mar 2024]

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

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Public Consultations/Call for Inputs/Call for Papers

Public consultation of the Global Ethics Charter for the Protection of Healthy Volunteers in Clinical Trials

Inserm Issued 26 Feb 2024 Comments due by March 30, 2024.

The « Global Ethics Charter for the Protection of Healthy Volunteers in Clinical Trials » is a key deliverable of the VolREthics initiative that was set up to promote ethical guidelines to protect healthy volunteers in biomedical research. The draft Charter, available in English, French and Spanish is open for public comments up to March 30, 2024.

Download the draft Charter (pdf, 201 Ko)

To submit your or your organization's feedback, <u>download the public comment document (docx, 27 Ko)</u>. Please email the completed document to <u>hvworkshop.disc@inserm.fr</u>

Online public consultation on the draft Key criteria for the ethical acceptability of controlled human infection studies during public health emergencies

WHO 7 March 2024 Call for consultation

Deadline for submission: 7th April 2024 [11:59 on Sunday, Central European Time (GMT/UHC +1)

Objective of the consultation

The goal of this online, open public consultation is to gather feedback from stakeholders on the draft/

Background

This consultation is part of the WHO Health Ethics and Governance Unit's commitment to promoting ethical research. The Unit produced Key Criteria for the Ethical Acceptability of COVID-19 Human Challenge Studies (2020) and broader WHO Guidance on the Ethical Conduct of Controlled Human Infection Studies (2021). Controlled human infection studies (CHIS) were conducted with COVID19 in the United Kingdom during the COVID-19 pandemic public health emergency.

It is likely that CHIS may be considered in future infectious disease public health emergencies. The draft document circulated in this consultation aims to provide general ethics guidance for CHIS during emergencies. Such guidance is intended to supplement existing mechanisms for ethical consideration and research ethics review of CHIS by highlighting issues that would be likely to be highly salient to CHIS during an emergency.

Future emergencies may be caused by different types of pathogens and the features of future emergencies may be difficult to predict. However, recent experience has demonstrated that certain ethical issues may be particularly relevant to CHIS in such settings and that prospective ethical guidance may be useful to inform the evaluation of such studies. While the current draft document focuses on CHIS during emergencies, the Health Ethics and Governance Unit also aims to produce complimentary guidance on CHIS with pathogens of pandemic potential as part of emergency preparedness.

Key Information and Facilitating Understanding in Informed Consent; Draft Guidance for Sponsors, Investigators, and Institutional Review Boards

21 CFR Part 50 [Docket No. FDA-2022-D-2997] **Comments due: 04/30/2024** *SUMMARY:*

This draft guidance provides recommendations related to two provisions of the revised Federal Policy for the Protection of Human Subjects (the revised Common Rule) by the U.S. Department of Health and Human Services (HHS) and identical provisions in FDA's proposed rule "Protection of Human Subjects and Institutional Review Boards." FDA's proposed rule, if finalized, would harmonize certain sections of FDA's regulations on human subject protections and institutional review boards (IRBs), to the extent practicable and consistent with other statutory provisions, with the revised Common Rule, in accordance with the 21st Century Cures Act (Cures Act). The guidance addresses the provisions of the revised Common Rule that require informed consent to begin with key information about the research and to present information in a way that facilitates understanding and identical provisions in FDA's proposed rule.

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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.

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Support for this service is provided by the <u>Bill & Melinda Gates Foundation</u>; the <u>Bill & Melinda Gates</u> <u>Medical Research Institute</u>, and industry resource members Janssen/J&J, Pfizer, Sanofi US, and Takeda, (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.

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