

Vaccines and Global Health: The Week in Review 25 May 2024 :: Issue 752 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

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Milestones, Perspectives

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WHA77

"All for Health, Health for All" sets the stage for the Seventy-seventh World Health Assembly

23 May 2024 News release

As the world continues to grapple with the aftermath of the most severe pandemic in a century, the <u>Seventy-seventh session of the World Health Assembly</u> will convene under the banner of "All for Health, Health for All." Scheduled to run from 27 May to 1 June, with the participation of ministers of health and other high-level country representatives, the Health Assembly serves as a critical platform for addressing existing global health challenges such as HIV, measles and polio, amidst the climate emergency and the rise of conditions like hypertension and obesity.

One of the pivotal moments anticipated during the Health Assembly is the <u>Pandemic prevention</u>, <u>preparedness and response accord</u> and the <u>amendments to the International Health Regulations</u>, signaling a concerted effort by Member States to bolster global preparedness and response mechanisms.

A pre-Health Assembly opening event on Sunday 26 May will kickstart the <u>WHO Investment Round</u> efforts, an engagement with current and potential donors aimed at ensuring sustainable funding for WHO. Additionally, the launch on Tuesday 28 May of WHO's third Investment case will explain the value proposition, in terms of additional lives saved, if the <u>Fourteenth General Programme of Work (GPW 14)</u>, WHO's strategy for 2025–2028, is carried out in its entirety.

"The cumulative effects of climate change, disease outbreaks and conflict mean ever more pressure on WHO to respond to the world's health needs," said Dr Tedros Adhanom Ghebreyesus, WHO Director-General. "This Health Assembly presents our Member States with key opportunities to promote, provide and protect health and well-being for everyone, by adopting the Fourteenth General Programme of Work, the global health strategy for the next four years; by supporting WHO's continued transformation through the WHO Investment Round; and by making the world safer through the Pandemic Agreement and the amendments to the International Health Regulations."

Key highlights and decisions

Key moments and outcomes expected during the Health Assembly include the approval on 28 May of WHO's 2025–2028 strategy, GPW 14, to address health-related implications of such megatrends as climate change, ageing, migration, and advances in science and technology. The four-year period represents a window to get the health-related Sustainable Development Goals (SDGs) back on track.

Crucial decisions are expected on a range of health priorities such as climate and health, WHO's work in health emergencies, access to transformative tools, communicable diseases, noncommunicable diseases, mental health, women's health and the reform of WHO itself.

The Health Assembly will feature high-level participation from political leaders and ambassadors, and representatives from civil society and non-State actors, underscoring the global commitment to advancing the public health agenda.

On Friday 31 May, the Health Assembly President will present six 2024 public health awards to eight laureates for outstanding contributions to public health...

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Seventy-seventh World Health Assembly #WHA77

The Seventy-seventh World Health Assembly is being held in Geneva, Switzerland, on 27 May -1 June 2024. The theme of this year's Health Assembly is: All for Health, Health for All. Proceedings will be webcast live from this web page.

WHA77 Documents [selected documents at 25 May 2024]

A77/1

Provisional agenda

A77/4

Consolidated report by the Director-General

<u>A77/5</u>

Antimicrobial resistance: accelerating national and global responses WHO strategic and operational priorities to address drug-resistant bacterial infections in the human health sector, 2025–2035

A77/6

Global technical strategy and targets for malaria 2016–2030

A77/7

Public health emergencies: preparedness and response

The Independent Oversight and Advisory Committee for the WHO Health Emergencies Programme

A77/8

A77/8 Add.1

A77/8 Add.2

A77/8 Add.3

A77/8 Add.4

Implementation of the International Health Regulations (2005)

A77/11

WHO's work in health emergencies

Public health emergencies: preparedness and response

A77/12

WHO's work in health emergencies

Health conditions in the occupied Palestinian territory, including east Jerusalem

A77/13

Implementation of resolution WHA75.11 (2022)

A77/18

Health conditions in the occupied Palestinian territory, including east Jerusalem, and in the occupied Syrian Golan

Summary of support and health-related technical assistance to the Palestinian people in the occupied Palestinian territory, including east Jerusalem, in the period from 1 January to 7 October 2023

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Pandemic Accord - IHR Revisions

WHO Member States agree to share outcomes of historic IHR, pandemic agreement processes to World Health Assembly

24 May 2024 News release

WHO Member States have ended intensive negotiations aimed at strengthening global capacities to respond to future pandemics and outbreaks in the wake of the COVID-19 pandemic, and agreed to submit outcomes of their work for consideration by the upcoming World Health Assembly, starting Monday.

Two parallel negotiation processes were undertaken to make a series of amendments to the International Health Regulations (2005) and to develop a first-ever pandemic agreement, convention or other legal instrument.

Delegations to the Seventy-seventh World Health Assembly, running from 27 May-1 June, will consider the outcomes of both processes, and the next steps for the two.

"Over the past two years, WHO Member States have dedicated enormous effort to rise to this challenge posted by COVID-19 and respond to the losses it caused, including at least 7 million lives lost," said Dr Tedros Adhanom Ghebreyesus, WHO Director-General. "COVID-19 affected everybody, in many ways, and that is why Member States started a process to develop a pandemic agreement to make the world better prepared for the next pandemic. While great progress was made during these negotiations, there are challenges still to overcome. We need to use the World Health Assembly to re-energize us and finish the job at hand, which is to present the world with a generational pandemic agreement."

Countries today ended their resumed 9th meeting of the <u>Intergovernmental Negotiating Body (INB)</u> comprising WHO's 194 Member States. Initial agreement was reached by the INB on multiple elements of the draft agreement, and convergence on others. There were also areas of non-convergence and divergent views.

The INB Bureau, which has been guiding the process, will present a report outlining the two-plus years of work of the process, and the outcome of that work, which is the draft text that has been negotiated to date. Options for next steps to conclude the agreement process will also be put to the WHA for consideration. ..

<u>The Working Group on the IHR (WGIHR) amendments</u> will also be presenting its outcome to the WHA for consideration, including some provisions for which agreement in principle was reached and others that the WGIHR Bureau updated its proposed text for consideration by Member States...

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Malaria

<u>Serum Institute of India ships its first set of R21/Matrix-M™ Malaria Vaccine doses to</u> Africa

- Distribution of R21/Matrix-MTM Malaria Vaccine across the African region marks a significant step in the global fight against malaria. The initial shipment will be sent to the Central African Republic (CAR), followed by other African countries such as South Sudan and Democratic Republic of Congo in the next coming days.
- Out of the total 1,63[0],800 doses specifically allocated for the CAR region, only 43,200 doses will be dispatched today from Serum Institute of India's facility.
- Serum Institute of India (SII), Novavax, and the University of Oxford celebrate this milestone during an event attended by Hon. Eric Garcetti, US Ambassador to India, in Pune, India, highlighting the successful global partnership between the three countries.
- Till now, Serum Institute of India has manufactured 25 million doses with a capacity to scale up to 100 million doses annually.

PUNE, India May 20, 2024 - Serum Institute of India, the world's largest manufacturer of vaccines by number of doses, marks a significant milestone with the shipment of its first set of R21/Matrix-M™ malaria vaccine to Africa. The initial shipment will be sent to the Central African Republic (CAR), followed by other African countries such as South Sudan and Democratic Republic of Congo in the next coming days. In total, 1,63,800 doses of the R21/Matrix-M™ malaria vaccine have been specifically allocated for CAR region, out of which only 43,200 doses will be dispatched today from Serum Institute of India's facility.

Developed in collaboration with the University of Oxford and Novavax's Matrix-M[™] adjuvant, the R21//Matrix-M[™] vaccine is the second malaria vaccine to be authorized for use in children in malaria-endemic regions...

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Shipment of newest malaria vaccine, R21, to Central African Republic marks latest milestone for child survival

With two recommended vaccines and expanded supply, **Gavi, UNICEF, WHO are working closely with governments and partners** to increase malaria prevention and protection for children.

Geneva/Copenhagen/New York, 24 May 2024 – **UNICEF delivered over 43,000 doses of the R21/Matrix-M malaria vaccine by air to Bangui, Central African Republic, today, with more than 120,000 doses to follow in the next days.** It is the first country to receive the R21 malaria vaccine for use in routine childhood immunization, marking another step forward in preventing the disease and saving children's lives.

R21 is the second malaria vaccine to be recommended by WHO for children living in endemic areas. Along with the earlier WHO recommendation of the RTS,S vaccine, there is now sufficient vaccine supply to scale up malaria vaccination in Africa. The rollout of both vaccines is funded by Gavi, the Vaccine Alliance.

"With two products now available to countries, expanded supply of malaria vaccines is a game changer for child survival and health," said Director of UNICEF Supply Division Leila Pakkala. "Previous concerns about supply meeting demand are firmly behind us. Now our priority is for the vaccines to reach every child at risk."

The R21 and RTS,S vaccines are proven safe and effective in preventing malaria in children. The RTS,S vaccine was delivered to more than 2 million children in Ghana, Kenya, and Malawi in a four-year pilot programme that demonstrated a 13 per cent reduction in all-cause mortality...

The Central African Republic has one of the highest rates of malaria incidence globally. In 2022, an estimated 1,733,000 malaria cases were reported in the country, averaging about 4,747 cases a day. The disease also claimed around 5,180 lives over the year, or 14 deaths each day...

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Featured Journal Content: Cholera

The Lancet Infectious Diseases

Volume 24, ISSUE 6, P557, June 2024 *Editorial*

A simplified vaccine for cholera outbreak control

Published: June, 2024

DOI: https://doi.org/10.1016/S1473-3099(24)00301-3

Cholera is a disease linked to poverty and poor access to clean water and sanitation. Caused by Vibrio cholerae, the disease is often asymptomatic but in its severe form, if left untreated, it can rapidly lead to death because of loss of liquids with diarrhoea. While water, sanitation and hygiene (WASH) interventions are at the core of cholera risk mitigation, cases are rising because of conflict, climate change, and lack of sanitation infrastructure. During 2022, 472697 cholera cases and 2349 deaths were reported to WHO from 44 countries, but the real burden of the disease is expected to be much higher because of underreporting. From the dramatic 2010 outbreak in Haiti which was caused by reintroduction of the disease by UN officers coming from Nepal, to the large outbreak in 2016 in wartorn Yemen, cholera has returned to be a serious threat to the most vulnerable communities. Just in 2024, outbreaks have been reported from several countries, including Zimbabwe, the Democratic Republic of the Congo, Afghanistan, and Ethiopia.

Besides sanitation interventions and rapid diagnosis, cholera outbreak control hinges on the availability and use of specific vaccines. WHO has prequalified three oral cholera vaccines: Dukoral (Valneva), Shanchol (Sanofi), and Euvichol-Plus (EuBiologicals Co, Ltd). However, only Shanchol and Euvichol-Plus are currently available for mass vaccination campaigns through the global oral cholera vaccine stockpile with the support of Gavi, the Vaccine Alliance. Such a stockpile has been insufficient to meet the needs of the increasingly recurrent outbreaks of cholera; in an Article published in our May issue, Malenbaka et al described the use of a single Euvichol-Plus dose, instead of the required two, to alleviate the lack of enough vaccine doses in an outbreak in DR Congo in 2020. In 2023, the production of Shanchol stopped permanently, further challenging the provision of enough vaccine doses to control cholera outbreaks. Thus, it was welcome news when on April 12, 2024, WHO prequalified a new vaccine, the killed whole-cell monovalent vaccine Euvichol-S.

Euvichol-S, produced by EuBiologicals Co, Ltd, is a simplified version of Euvichol-Plus, because it is based on a reduction of its components from five to two and has undergone a single inactivation process instead of two. This simplification can reduce production costs and increase production capacity; in fact, it is expected that the production of Euvichol vaccines will ramp up to 50 millions in 2024 from 38 million doses produced in 2023. The prequalification of Euvichol-S was based on the data obtained in a phase 3 clinical trial comparing administration of two doses of Euvichol-S to two doses of Shancho in Nepal in October 2022 and published in The Lancet Global Health. The trial demonstrated the non-inferiority of Euvichol-S compared to Shanchol in terms of seroconversion rates laying the foundation for regulatory approvals. Safety was also demonstrated. The prequalification has the benefit of making Euvichol-S available for Gavi and UNICEF for inclusion in their vaccination programs and the replenishment of the oral cholera vaccine stockpile. In a recent statement, Leila Pakkala, Director of UNICEF Supply Division, said "The approval means that UNICEF can increase the procurement and delivery of cholera vaccines by more than 25%, pushing back harder on deadly cholera outbreaks".

The addition of Euvichol-S will contribute to WHO's ambitious plan to reduce cholera deaths by 90% and eliminate the disease in 20 countries by 2030. The Ending cholera: a global roadmap to 2030 was launched in 2017, but with cholera outbreaks on the rise, any tool will be crucial to get closer to meeting the targets set by the organisation. As part of this effort, Gavi, UNICEF, and partners announced the largest ever global deployment of cholera diagnostics to support surveillance and response. More than 1·2 million cholera rapid diagnostic tests will be shipped to 14 countries, with the first shipment having already arrived in Malawi on April 4.

Euvichol-S will certainly help to reduce the current gap between available vaccines and vaccine needs on the ground. Looking at the future, having only one manufacturer responsible for the production of the entire stockpile of oral cholera vaccines is problematic, and there is the hope that additional manufacturers will contribute to vaccine production in the coming years. But, while cholera vaccines have an important role in curbing the rise of the disease seen in recent years, we should not forget that at the root of the global cholera crisis there is inadequate access to safe water and basic sanitation and governments must work to address this persisting issue.

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<u>Largest number of regulatory agencies for medical products approved as WHO Listed</u> <u>Authorities</u>

20 May 2024 News release

WHO has approved designation of 33 national and regional regulatory authorities as WHO Listed Authorities (WLAs) that can be relied on for fulfilling the highest level of regulatory standards and practices for quality, safety and efficacy of medicines and vaccines. This listing makes a total of 36 regulatory authorities from 34 Member States now designated as WLAs since the launch of the initiative in March 2022.

The newly approved WLAs include the U.S. Food and Drug Administration (US FDA) and the European Medicines Regulatory Network (EMRN), which is composed of the European Commission, the European Medicines Agency (EMA) and the medicines regulatory authorities of the following 30 countries: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany (Federal Institute for Drugs and Medical Devices & Paul-Ehrlich-Institut), Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain and Sweden.

Furthermore, the Health Sciences Authority (HSA) of Singapore, which was previously designated as a WLA in October 2023, was approved for an expanded scope of functions.

"Today marks a significant progress in our collective efforts to improve access to safe, quality and effective medicines and vaccines. With leading regulatory authorities joining our list, we are stronger and more united to improve access to quality, safe and effective medicines and vaccines for millions more people," said Dr Tedros Adhanom Ghebreyesus, WHO Director-General. "I would like to congratulate all agencies designated as WLAs for their investment and commitment to the quality and safety of medicines and vaccines. My thanks also to our experts for their diligent work to implement a transparent and evidence-based assessment throughout the evaluation process".

The decision is based on the recommendation by the WHO technical advisory group on WHO Listed Authorities (TAG-WLA) following WHO performance evaluations confirming consistency of advanced performance by these authorities in line with international standards and best regulatory practices for ensuring the quality, safety and efficacy of medicines and vaccines...

WHO approval for U.S. FDA and EMRN includes all regulatory functions for the product streams of medicines – including multisource (generics) and new medicines (new chemical entities), biotherapeutics and similar biotherapeutic products – and vaccines.

WHO approval for HSA includes an additional regulatory function of market surveillance and control. With this inclusion, HSA's WLA status now covers all regulatory functions, for the product stream of medicines – including multisource (generics) and new medicines (new chemical entities) and biotherapeutics and similar biotherapeutic products.

Attaining WLA status signifies not only compliance with these standards but also a commitment to continuous improvement and excellence in regulatory oversight – a commitment consistently demonstrated by the EMRN, HSA and U.S. FDA. There are a few stringent regulatory authorities pending evaluations following their expressions of interest in being assessed for WHO Listed Authorities designation.

Polio - PHEIC

Polio this week as of 22 May 2024 - GPEI

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

- Angola: one cVDPV2-positive environmental sample
- Côte d'Ivoire: two cVDPV2-positive environmental samples
- Ethiopia: six cVDPV2 casesGuinea: one cVDPV2 case
- Liberia: four cVDPV2-positive environmental samples
- Nigeria: six cVDPV2 cases and one cVDPV2-positive environmental sample
- Somalia: one cVDPV2-positive environmental sample

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WHO & Regional Offices [to 25 May 2024]

https://www.who.int/news

Selected News/Announcements/Statements

24 May 2024 News release

WHO Member States agree to share outcomes of historic IHR, pandemic agreement processes to World Health Assembly

24 May 2024 Joint News Release

<u>Shipment of newest malaria vaccine, R21, to Central African Republic marks latest</u> milestone for child survival

24 May 2024 News release

WHO releases a strategic framework for enhancing prevention and control of mpox

24 May 2024 News release

COVID-19 eliminated a decade of progress in global level of life expectancy

23 May 2024 News release

"All for Health, Health for All" sets the stage for the Seventy-seventh World Health Assembly

22 May 2024 News release

New research flags the urgent need for research and evidence on the impact of climate change on neglected tropical diseases and malaria

21 May 2024 News release

New report flags major increase in sexually transmitted infections, amidst challenges in HIV and hepatitis

20 May 2024 News release

<u>Largest number of regulatory agencies for medical products approved as WHO Listed</u>

Authorities

19 May 2024 Public notice and comment on new members of the Global Validation Advisory Committee (GVAC)

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WHO Regional Offices

Selected Press Releases, Announcements

WHO African Region

No new digest content identified.

WHO Region of the Americas PAHO

:: 24 May 2024

<u>PAHO urges countries to strengthen dengue prevention in Central America, Mexico and the Caribbean</u>

Washington, DC, 24 May 2024 (PAHO)- As a result of the increase in cases of dengue fever in the southern hemisphere and the beginning of the season of increased transmission in the northern hemisphere, the Pan American Health Organization (PAHO) urges countries of Central America, Mexico and the Caribbean to strengthen preventive measures against...

:: 24 May 2024

COVID-19 eliminated a decade of progress in global level of life expectancy

World Health Statistics 2024 report urges countries to redouble efforts towards health-related SDGs by 2030Geneva, May 24, 2024 — The latest edition of the World Health Statistics released today by the World Health Organization (WHO) reveals that the COVID-19 pandemic reversed the trend of steady gain in life expectancy at birth and healthy life...

:: 22 May 2024

Syphilis cases increase in the Americas

Washington, DC, May 22, 2024 (PAHO)- New syphilis cases among adults aged 15-49 years increased by 30% between 2020 and 2022 in the Americas, according to a new World Health Organization (WHO) report, Implementing the global health sector strategies on HIV, viral hepatitis and sexually transmitted infections, 2022–2030. Syphilis, a...

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.

No new digest content identified.

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Weekly Epidemiological Record

https://www.who.int/publications/journals/weekly-epidemiological-record

Vol. 99, No. 21, pp. 271-284 24 May 2024

PDF: https://iris.who.int/bitstream/handle/10665/376866/WER9921-eng-fre.pdf

:: WHO's Health Emergencies Programme: acute emergencies monthly summary – April 2024

:: Progress towards polio eradication – worldwide, January 2022–December 2023

:::::

New WHO Publications

https://www.who.int/publications/i Selected 24 May 2024

Strategic Framework for Enhancing Prevention and Control of mpox- 2024-2027.

23 May 2024

Research prioritization for pandemic and epidemic intelligence: technical brief Overview

Robust evidence from high-quality research is vital for pandemic and epidemic intelligence, forming the basis for effective collaborative surveillance and informed public health decisions. The COVID-19 pandemic has spurred innovation in data and laboratory science and improved our ability to detect, assess and respond to health threats. However, research on surveillance methods and tools requires greater coherence and more efficient ways to translate research for evidence-based policy-making.

The WHO Pandemic Hub has coordinated a process to set research priorities that should be particularly relevant for routine public health surveillance practices in collaboration with the Global Research Collaboration for Infectious Disease Preparedness (GloPID-R), Charité University Hospital Berlin and the WHO Science Division and with a financial contribution and observer role of Wellcome Trust. The goal was to identify the key research areas that would generate high-quality evidence and methods to better inform decision-making in global health emergencies. This technical brief outlines the priorities for research in pandemic and epidemic intelligence identified through the prioritization process.

23 May 2024

2024 progress report on the Global Action Plan for Healthy Lives and Well-being for All

23 May 2024

Global meeting on sustaining gains in genomics for managing pandemic and epidemic threats: Istanbul, , Türkiye, 14–15 December 2023: report

Overview

WHO held the Global meeting on sustaining gains in genomics for managing pandemic and epidemic threats on 14–15 December 2023 in Istanbul, Türkiye. This meeting was organised to support countries into stabilizing genomic surveillance systems and formulate future action plans based on the global strategy, regional initiatives and latest tools and guidance including the Step-by-Step Guide to establish strategies at the country level and using the Genomics Costing Tool to inform investments. Countries and other stakeholders shared experiences, discussed key use cases and shared good practices that ensure readiness for future pandemics and epidemics.

WHO procurement report 2023

22 May 2024

The Third Global Consultation on the Health of Refugees and Migrants

Summary of key messages, Rabat, Morocco, 13-15 June 2023 Overview

With a goal of establishing enduring leadership and commitment for the health of refugees and migrants, WHO, the International Organization for Migration (IOM), the United Nations High Commissioner for Refugees (UNHCR) and Morocco co-organized the Third Global Consultation on the Health of Refugees and Migrants in Rabat, Morocco, on 13–15 June 2023, and led to the adoption of the Rabat Declaration.

The Third Global Consultation aimed to strengthen high-level political commitment with an aim to improve, protect and preserve the health and well-being of refugees, migrants and host communities. This document is a summary of key messages from report of the consultation, which includes the centrality of country-led action; understanding population needs; and importance of inclusion of refugees and migrants in universal health coverage, tackling the social determinants of health and in data- and research-driven approaches.

22 May 2024

Report on the third global consultation on the health of refugees and migrants, Rabat, Morocco, 13-15...

22 May 2024

<u>Implementing the global health sector strategies on HIV, viral hepatitis and sexually transmitted infections,...</u>

21 May 2024

Pandemic influenza severity assessment (PISA)

Overview

The updated WHO pandemic influenza severity assessment (PISA) framework set out in this document provides a systematic approach for interpreting data collected through existing surveillance systems and improving their usefulness for risk communication and decision-making. The approach enables the severity of current influenza and syndromic respiratory illness activity to be assessed relative to previous years by using historical data to set thresholds that then allow for the qualitative categorization of such activity. PISA is designed to be implemented continuously based on stable/routine reporting systems, enabling activity during epidemic and pandemic periods to be compared. Information to assess severity especially early and throughout the course of a pandemic will also be provided through investigations, studies and modelling.

21 May 2024

World health statistics 2024

20 May 2024

Behavioral science around the world: volume III: public health

20 May 2024

Global report on neglected tropical diseases 2024: executive summary

20 May 2024

Guidance on social protection for people affected by tuberculosis

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USA – HHS, FDA, CDC

HHS

News

HHS Secretary Xavier Becerra Issues Statement on the National Institutes of Health Request for Information

Seeking Input on Draft Policy Involving NIH-Owned Inventions: Promoting Equity Through Access Planning

May 21, 2024

FDA

Press Announcements

No new digest content identified.

FDA VRBPAC

Advisory Committee Calendar

<u>Vaccines and Related Biological Products Advisory Committee June 5, 2024 Meeting</u> <u>Announcement - 06/05/2024</u>

CDC/ACIP [U.S.] [to 25 May 2024]

http://www.cdc.gov/media/index.html

Latest News Releases

CDC Reports Second Human Case of H5 Bird Flu Tied to Dairy Cow Outbreak
May 22, 2024

Readout of CDC Call with State Public Health Partners on H5N1 Influenza Monitoring May 21, 2024

ACIP Meetings

Next ACIP Meeting
June 26-28

MMWR Weekly

https://www.cdc.gov/mmwr/index2023.html

May 23, 2024 / No. 20

PDF of this issue

- <u>Monkeypox Virus Infections After 2 Preexposure Doses of JYNNEOS Vaccine United States, May 2022–May 2024</u>
- Notes from the Field: Clade II Mpox Surveillance Update United States, October 2023–April 2024

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Europe

European Medicines Agency [EMA]

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

News & Press Releases

Medical devices: new guidance for industry and notified bodies

Question-and-answer document clarifies regulatory requirements for devices used in combination with medicines 21 May 2024

European medicines network designated as WHO listed authority

The European Medicines Regulatory Network (EMRN) has been designated as WHO Listed Authority (WLA) by the World Health Organization (WHO). 20 May 2024

European Centre for Disease Prevention and Control

https://www.ecdc.europa.eu/en

News/Updates/Reports/Publications [Selected]

News

<u>Challenges and approaches for effective communication around the benefit and risk balance of vaccination</u>

22 May 2024

Guidance

Effective communication around the benefit and risk balance of vaccination in the EU/EEA 22 May 2024

This report presents the results of a study that dealt specifically with effective communication around the benefit and risk balance of vaccination people's risk perceptions around vaccines and diseases, and approaches to enhancing communication about the safety and effectiveness of vaccines.

Effective communication around balance of vaccination EN - [PDF-7.21 MB]

Executive summary

Vaccination protects people against serious and potentially life-threatening infectious diseases: the World Health Organization (WHO) estimates that vaccination prevents 3.5 to 5 million deaths every year globally [1]. However, despite the importance of vaccines, numerous surveys done in European Union/European Economic Area (EU/EEA) countries show that the concerns of some people regarding the safety of vaccines as well as the perception that they are not effective pose a major challenge to the efforts of public health authorities to promote vaccine acceptance and uptake.

This report presents the results of a study that dealt specifically with effective communication around the benefit and risk balance of vaccination, people's risk perceptions around vaccines and diseases, and approaches to enhancing communication about the safety and effectiveness of vaccines. The study was performed between June and November 2023, with an aim to increase knowledge about:

- How to communicate effectively about vaccination with a focus on its individual and community benefits outweighed against risks. The risks include the individual risk of contracting the disease and its outcomes, and potential risks associated with being vaccinated (i.e. side-effects).
- How people and communities perceive risks related to vaccines and infectious diseases.
- How the safety and effectiveness of vaccines can be better communicated to different audiences based on innovative and effective approaches.

This study used a literature review, an online survey, interviews and an online workshop to contribute to the knowledge base on these topics. The literature review consisted of a structured review of both grey and published literature to get an overview of existing, peer-reviewed and other academic

literature, and other documentary evidence, and covered the period 2018 to 2023 (2015 to 2023 for review articles).

The work took into account lessons learned by public health organisations during the COVID-19 pandemic. In addition to COVID-19 vaccination, it also focused on recent influenza, MMR, and HPV vaccination campaigns conducted by public health organisations in the EU/EEA.

The findings of this study can support public health professionals in the EU/EEA involved in vaccination programmes, in particular in communication on vaccines, and other organisations in their work to promote vaccine acceptance and uptake in the EU/EEA.

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Africa CDC [to 25 May 2024]

https://africacdc.org/ Press Releases, Statements [Selected] No new digest content identified.

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China CDC

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

National Health Commission of the People's Republic of China [to 25 May 2024]

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

News

No new digest content identified.

National Medical Products Administration – PRC [to 25 May 2024]

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

News

No new digest content identified.

China CDC

Weekly Reports: Current Volume (6)

2024-05-24 / No. 21 THEORETICAL EPIDEMIOLOGY ISSUE

View PDF of this issue

- <u>Methods and Applications: The Impact of Medical Resources and Oral Antiviral Drugs on SARS-CoV-</u> 2 Mortality Hong Kong SAR, China, 2022
- HTML(169) PDF 682KB(2) Methods and Applications: Adaptive Fourier Decomposition of the First Three SARS-CoV-2 Infection Waves with Epidemic Intervention London, UK, 2020–2022
- <u>Methods and Applications: Advancing Underlying Cause of Death Inference Through Wide and Deep</u> Model
- <u>Vital Surveillances: Prevalence and Influencing Factor Analysis of Typhoid/Paratyphoid Fever China, 2011–2020</u>
- Review: Theoretical Epidemiology Needs Urgent Attention in China

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Contents [click to move among sections]

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- :: WHO
- :: Organization Announcements
- :: Journal Watch
- :: Pre-Print Servers

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Organization Announcements

Paul G. Allen Frontiers Group [to 25 May 2024]

https://alleninstitute.org/news-press/

News

No new digest content identified.

BMGF - Gates Foundation [to 25 May 2024]

https://www.gatesfoundation.org/ideas/media-center

Press Releases & Statements Press Release May 21, 2024

Bill & Melinda Gates Foundation Welcomes New Chief DEI Officer

Bill & Melinda Gates Medical Research Institute [to 25 May 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 No new digest content identified.

CARB-X [to 25 May 2024]

https://carb-x.org/

News

05.21.2024 |

CARB-X FUNDS UNIVERSITY OF MARYLAND TO DEVELOP A VACCINE TO PREVENT NEONATAL SEPSIS

Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator (CARB-X) will award US\$3.96 million to the Center for Vaccine Development and Global Health (CVD) at the University of Maryland School of Medicine to develop a maternal vaccine that prevents sepsis caused by Klebsiella pneumoniae in newborns and infants.

CEPI – Coalition for Epidemic Preparedness Innovations [to 25 May 2024]

http://cepi.net/ Latest News News

<u>University of Oxford pandemic computer simulations to guide future vaccine trials</u> CEPI 22nd May 2024

OXFORD, UK/OSLO, May 23 – University of Oxford scientists are launching new computer simulations that will model how we can strengthen the world's response to some of the viruses most likely to cause the next pandemic.

Their work, known as the 'PREpare using Simulated Trial Optimisation (PRESTO)' research project, will generate important insights for vaccine developers and public health officials on what vaccine clinical trial designs could help stop the spread of an emerging outbreak.

With up to US \$2.4 million funding from CEPI, researchers at the University of Oxford's Pandemic Sciences Institute will simulate real-life scenarios of deadly disease outbreaks in order to model how possible vaccine clinical trials could run and what outcomes they could produce. The infectious threats that will be tested are Nipah, Chikungunya, Lassa, Rift Valley fever, Ebola and related viruses, Coronaviruses and a new or as-yet-identified 'Disease X'. These diseases are prioritised by CEPI and recognised on the WHO R&D Blueprint.

"When a new outbreak strikes, we won't have time to get all the information we need to tell us how best to conduct pivotal clinical trials that test the efficacy or effectiveness of promising epidemic or pandemic vaccines" said Dr Richard Hatchett, CEO of the Coalition for Epidemic Preparedness Innovations (CEPI). "But mathematical modelling can give us a headstart by forecasting how a worrisome virus might spread and what we need to do to respond. Having PRESTO's optimal study designs readily available in an outbreak will allow health officials to make quick, informed decisions on the best steps to take for more efficient vaccine testing and rapid evidence generation, thereby creating a faster outbreak response."

Data from existing CEPI-funded research will be fed into the computer model alongside evidence from previous outbreaks to create hypothetical scenarios looking at how a selected virus could spread, who it could impact and its potential severity.

Findings from these scenarios will be used to produce analysis sheets that rank the suitability of different clinical trial options measuring the efficacy or real-world effectiveness of vaccines against each selected infectious disease. For example, the modelling data could recommend that health officials conduct either a randomised controlled trial or a ring vaccination trial in response to an escalating outbreak. The analysis sheets will also suggest the optimal number of participants to enroll in the preferred trial design and the likely time needed to run the study to obtain the necessary data...

CIOMS - COUNCIL FOR INTERNATIONAL ORGANIZATIONS OF MEDICAL SCIENCES [to 25]

May 2024]

https://cioms.ch/

News; Publications; Events

<u>PUBLIC CONSULTATION OF THE DRAFT SCAR [Severe Cutaneous Adverse Reactions]</u>
REPORT IS NOW OPEN!

Deadline: Friday 7 June 2024

Working Group objectives

To establish a balanced, efficient, global perspective on SCAR detection, susceptibility factors, severity, outcome and probability through causality assessment tools, monitoring and management during the drug development and post-marketing phases.

- :: Draft report
- :: Comment form

DARPA - Defense Advanced Research Projects Agency [U.S.] [to 25 May 2024

https://www.darpa.mil/news

News

No new digest content identified.

Duke Global Health Innovation Center [to 25 May 2024]

https://dukeghic.org/

News

No new digest content identified.

EDCTP [to 25 May 2024]

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 [to 25 May 2024]

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

European Vaccine Initiative [to 25 May 2024]

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

Evidence Aid [to 25 May 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.

http://www.evidenceaid.org/

Resources [Selected]

<u>Screening for tuberculosis and latent tuberculous infection among migrant populations in Europe</u>

Added May 24, 2024

Fondation Merieux [to 25 May 2024]

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

News, Events

No new digest content identified.

Gavi [to 25 May 2024]

https://www.gavi.org/

Press Releases 24 May 2024

<u>Shipment of newest malaria vaccine, R21, to Central African Republic marks latest</u> milestone for child survival

GE2P2 Global Foundation [to 25 May 2024]

www.ge2p2.org

News/Analysis/Publications-Digests/Statements

- :: Vaccines and Global Health: The Week in Review Current edition
- :: Informed Consent: A Monthly Review May 2024
- :: Public Consultations Watch :: Global Calls for Input/Public Comment 08 May 2024 Issue 17

GHIT Fund [to 25 May 2024]

https://www.ghitfund.org/newsroom/press

Press Releases

No new digest content identified.

Global Fund [to 25 May 2024]

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

News & Stories

21 May 2024

The Global Fund Commits Nearly US\$800,000 in Emergency Funding for Mass Drug Administration to Internally Displaced People in Mozambique

The Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund) has committed nearly US\$800,000 to Mozambique to cover the operational costs for a mass drug administration campaign for formerly internally displaced people that have returned...

Global Research Collaboration for Infectious Disease Preparedness [GloPID-R] [to 25 May

2024]

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

News

No new digest content identified.

Hilleman Laboratories [to 25 May 2024]

http://www.hilleman-labs.org/

News & Insights

No new digest content identified.

HHMI - Howard Hughes Medical Institute [to 25 May 2024]

https://www.hhmi.org/news

Press Room

No new digest content identified.

Human Immunome Project [nee Human Vaccines Project] [to 25 May 2024]

https://www.humanimmunomeproject.org/

News

No new digest content identified.

IAVI [to 25 May 2024] https://www.iavi.org/ *News, Features No new digest content identified.*

INSERM [to 25 May 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 25 May 2024]

https://www.ich.org/

News/Pubs/Press Releases [Selective]

24 May 2024

The ICH M12 Guideline reaches Step 4 of the ICH Process

The ICH M12 Guideline "Drug Interaction Studies" and "Drug Interaction Studies Questions and Answers" reached Step 4 of the ICH Process on 21 May 2024.

24 May 2024

ICH M14 draft Guideline reaches Step 2 of the ICH process

The ICH M14 draft Guideline on "General Principles on Plan, Design and Analysis of Pharmacoepidemiological Studies That Utilize Real-World Data for Safety Assessment of Medicines" has reached Step 2 of the ICH process on 21 May 2024.

ICRC [to 25 May 2024]

https://www.icrc.org/en/whats-new

What's New [Selected]

<u>UNSCR 2730 is an urgent and timely reminder of parties' obligations to respect and protect humanitarian personnel</u>

This obligation is a duty for parties to a conflict and a collective responsibility of all states to uphold that rule; states must also ensure respect for international humanitarian law as a whole. Just as the civilian population is paying an increasi

IFFIm

http://www.iffim.org/ Press Releases/Announcements No new digest content identified.

IFRC [to 25 May 2024] http://media.ifrc.org/ifrc/news/press-releases/ Press Releases [Selected] No new digest content identified.

Institut Pasteur [to 25 May 2024] https://www.pasteur.fr/en/press-area Press Documents
No new digest content identified.

ISC / International Science Council [to 25 May 2024]

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

News

Global Call for Science Missions for Sustainability | deadline: 31 May

The International Science Council and its Global Commission on Science Missions for Sustainability proudly announce the launch of the Science Missions for Sustainability Global Call. Consortia are invited to submit pilot proposals to become part of the transformative collective action to shape the future of science and humanity.

21.03.2024

Blogs

Official Launch of the IDRC and ISC Project to Explore AI's Impact on Science Systems in the Global South

Canada's International Development Research Centre visited the ISC to launch innovative new partnership 22.05.2024

International Union of Immunological Societies (IUIS)

https://iuis.org/ News/Events [Selected] No new digest content identified.

IVAC [to 25 May 2024]

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

Updates; Events

No new digest content identified.

IVI [to 25 May 2024]

http://www.ivi.int/

IVI News & Announcements

No new digest content identified.

Johns Hopkins Center for Health Security [to 25 May 2024]

https://centerforhealthsecurity.org/newsroom

Center News [Selected]

No new digest content identified.

MSF/Médecins Sans Frontières_ [to 25 May 2024]

http://www.msf.org/

Latest [Selected Announcements]

Democratic Republic of Congo

Civilians caught in crossfire in North and South Kivu

Interview 24 May 2024

Syria

Syrians suffer from more funding cuts despite severe medical needs

Press Release 24 May 2024

Haiti

Urgent need of medical supplies in Haiti as extreme violence isolates people in need

Press Release 21 May 2024

Brazil

<u>Unprecedented flooding in Brazil leaves millions affected and hundreds of thousands</u> displaced

Project Update 20 May 2024

National Academy of Medicine - USA [to 25 May 2024]

https://nam.edu/programs/

News [Selected]

No new digest content identified.

National Academies-Sciences-Engineering-Medicine [NASEM] - USA [to 25 May 2024]

https://www.nationalacademies.org/newsroom?

News

<u>Human Accountability and Responsibility Needed to Protect Scientific Integrity in an Age</u> of AI, Says New Editorial

News Release | May 21, 2024

WASHINGTON — In an editorial published today in the Proceedings of the National Academy of Sciences, an interdisciplinary group of experts urges the scientific community to follow five principles of human accountability and responsibility when using artificial intelligence in research. The authors also call for the establishment of a Strategic Council on the Responsible Use of AI in Science to provide ongoing guidance and oversight on responsibilities and best practices as the technology evolves.

The <u>editorial</u> emphasizes that advances in generative AI represent a transformative moment for science — one that will accelerate scientific discovery but also challenge core norms and values of science, such as accountability, transparency, replicability, and human responsibility.

"We welcome the advances that AI is driving across scientific disciplines, but we also need to be vigilant about upholding long-held scientific norms and values," said National Academy of Sciences President Marcia McNutt, one of the co-authors of the editorial. "We hope our paper will prompt reflection among researchers and set the stage for concerted efforts to protect the integrity of science as generative AI increasingly is used in the course of research."...

Register for June 26 State of the Science Address

Issues to be discussed include:

- U.S. global competitiveness in science and technology
- Alignment of U.S. research efforts with critical national priorities as public and private R&D funding shifts
- STEMM education to adequately prepare the next generation of leaders
- Public trust in science in an era of misinformation and disinformation

National Vaccine Program Office - U.S. HHS [to 25 May 2024]

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

NIH [to 25 May 2024] http://www.nih.gov/ New Releases No new digest content identified.

PATH [to 25 May 2024]

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

Newsroom

Join PATH at the Africa Health ExCon 2024

PATH is excited to participate in the Africa Health ExCon from June 3 to June 6, 2024 at the Egypt International Exhibition Center in Cairo, Egypt.

Sabin Vaccine Institute [to 25 May 2024]

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

UNAIDS [to 25 May 2024]

http://www.unaids.org/en

News, Stories, Updates

UNAIDS launches inequalities visualization tool

20 May 2024

Tackling inequalities is how the world will end AIDS, so it is vital to know what type of inequalities exist in each country and how are they affecting the national AIDS responses. That is what a <u>new UNAIDS inequalities visualization tool</u> is set out to measure.

The new tool will allow countries, development partners, civil society, academia, and advocates to see and measure the effects that different dimensions of inequalities have on the HIV response...

UNICEF [to 25 May 2024]

https://www.unicef.org/media/press-releases Latest press releases, news notes and statements No new digest content identified.

Unitaid [to 25 May 2024]

https://unitaid.org/ Featured News 23 May 2024

Countdown to 2030: Stronger alignment for country impact

Ahead of the 77th World Health Assembly, the 13 signatory agencies of the Global Action Plan for Healthy Lives and Well-being for All (SDG3 GAP) have released their fifth progress report, Aligning for Country Impact. Past the crucial SDG midpoint, with only 15% of the 50+ health-related SDGs on track to reach their 2030 targets, the SDG3 GAP's goal remains the same: multilateral collaboration evolves in response to a rapidly changing world and, crucially, in alignment with country priorities and needs.

Vaccine Equity Cooperative [nee Initiative] [to 25 May 2024]

https://vaccineequitycooperative.org/news/

News

No new digest content identified.

Vaccination Acceptance & Demand Initiative [Sabin) [to 25 May 2024]

https://www.vaccineacceptance.org/ Announcements, Blog

No new digest content identified.

Vaccine Confidence Project [to 25 May 2024]

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

Vaccine Education Center – Children's Hospital of Philadelphia [to 25 May 2024]

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

News

May 2024: Vaccines and Infectious Diseases in the News

Published on May 14, 2024

Find information about the latest vaccines and infectious diseases that have been in the news. *Measles*

- Cases of measles diagnosed in the U.S. as of early May are <u>higher than the total cases for any year</u> since 2019.
- To find out more about measles and the vaccine, check these VEC resources:
- Why are we seeing measles outbreaks? Video featuring Dr. Paul Offit, VEC Director
- Do People Need a Measles Vaccine Booster During an Outbreak? Video featuring Dr. Lori Handy, VEC Associate Director
- <u>Doctors Talk: Measles</u> Video featuring Drs. Paul Offit, VEC Director, and Katie Lockwood, CHOP Primary Care Physician and host of "Primary Care Perspectives" podcast
- Measles: What You Should Know (Q&A) in English | Spanish | Japanese
- Rash information (webpage) Go to "Measles viral" section of page
- A Look at Each Vaccine: Measles, Mumps and Rubella (MMR) Vaccine (webpage)
- MMR (infographic)
- Parents PACK Personal stories: Measles

<u>Announcements: New resources address measles boosters and misinformation related to vaccines and chronic diseases; essay contest winners</u>

New resources address measles boosters and misinformation related to vaccines and chronic diseases

The May 2024 issue of Parents PACK, the Vaccine Education Center's newsletter for the public, offered resources that may be helpful in your interactions with patients and families.

Wellcome Trust [to 25 May 2024]

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

The Wistar Institute [to 25 May 2024]

https://www.wistar.org/news/press-releases Press Releases

No new digest content identified.

World Bank [to 25 May 2024]

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

All News [Selected]

Water security is critical for poverty reduction, but billions will remain without water access unless urgent action is taken

WASHINGTON, May 20, 2024 — Access to safe drinking water and sanitation, reliable water-supply for agriculture and industry, and protection against droughts and floods are essential for human and economic...

Date: May 20, 2024 Type: Press Release

WFPHA: World Federation of Public Health Associations [to 25 May 2024]

https://www.wfpha.org/

Blog, Event

No new digest content identified.

World Medical Association [WMA] [to 25 May 2024]

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

Press Releases

No new digest content identified.

World Organisation for Animal Health [OIE] [to 25 May 2024]

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

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ARM [Alliance for Regenerative Medicine] [to 25 May 2024]

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

BIO [to 25 May 2024]

https://www.bio.org/press-releases

Press Releases

No new digest content identified.

DCVMN – Developing Country Vaccine Manufacturers Network [to 25 May 2024]

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

ICBA – International Council of Biotechnology Associations [to 25 May 2024]

https://internationalbiotech.org/news/

News

Website not responding at inquiry.

IFPMA [to 25 May 2024]

https://ifpma.org/

News, Statements [Selected] Statement 21 May 2024

<u>Pharmaceutical trade associations welcome latest announcement of largest number of regulatory agencies recognized under the WHO Listed Authorities Framework</u>

On 21 May, pharmaceutical trade associations at international, European and US-level have welcomed the recognition of the European Medicines Regulatory Network (EMRN) and the United States Food and Drug Administration (FDA) as WHO Listed Authorities, as well as the expanded scope of functions of the Health Sciences Authority (HSA) of Singapore.

International Alliance of Patients' Organizations – IAPO [to 25 May 2024]

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

International Generic and Biosimilar Medicines Association [IGBA]

https://www.igbamedicines.org/

News

No new digest announcements identified.

PhRMA [to 25 May 2024]

http://www.phrma.org/

Press Releases

No new digest announcements identified.

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Vaccines/Therapeutics/Medicines - Selected Developer/Manufacturer Announcements

AstraZeneca

Press Releases

<u>AstraZeneca plans \$1.5 billion manufacturing facility for antibody drug conjugates (ADCs) in Singapore</u>

20 May 2024

Operationally ready by 2029, it will be the Company's first-ever facility to cover the full manufacturing process for ADCs

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> - No new digest announcements identified

BioNTech

Press Releases

21 May 2024

<u>BioNTech to Present Clinical Data Updates for Next-Generation Immunotherapy</u>
<u>Candidates at the ASCO Annual Meeting 2024</u>

Boehringer

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

CanSinoBIO

News - 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

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

Curevac [Bayer Ag – Germany]

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

News - No new digest announcements identified.

IMBCAMS, China

Home - Website not responding at inquiry.

Janssen/JNJ

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

Merck

News releases - No new digest announcements identified

Moderna

Press Releases

May 22, 2024

Moderna Announces Data to be Presented at 2024 ASCO Annual Meeting

Nanogen

News - No new digest announcements identified

Novartis

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

Novavax

Press Releases

May 20, 2024

Press release Malaria

First Doses of R21/Matrix-M™ Malaria Vaccine Shipped to Africa

- Distribution of R21/Matrix-MTM across the African region is expected to begin in coming weeks
- Serum Institute of India, Novavax and University of Oxford mark achievement during event with Hon. Eric Garcetti, U.S. Ambassador to India, in Pune, India

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 May 21, 2024

Press Release: Sanofi, Formation Bio and OpenAI announce first-in-class AI collaboration

Paris, New York, N.Y., and San Francisco, CA, May 21, 2024. Sanofi, Formation Bio and OpenAI are collaborating to build AI-powered software to accelerate drug development and bring new medicines to patients more efficiently. The three teams will bring together data, software and tuned models to develop custom, purpose-built solutions across the drug development lifecycle. This represents a first collaboration of its kind within the pharma and life sciences industries.

Sanofi will leverage this partnership to provide access to proprietary data to develop AI models as it continues on its path to becoming the first biopharma company powered by AI at scale...

Serum Institute of India

NEWS & ANNOUNCEMENTS Monday, May 20, 2024

Serum Institute of India ships its first set of R21/Matrix-M™ Malaria Vaccine doses to Africa

Sinopharm/WIBPBIBP

News

Sinopharm general manager delivers opening speech at CBioPC2024 2024-05-22

Sinovac

Press Releases - No new digest announcements identified

SK Biosciences

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

Takeda

Newsroom - No new digest announcements identified.

Valneva

Press Releases May 21, 2024

Valneva Appoints Dr. Hanneke Schuitemaker, Ph.D. as Chief Scientific Officer

Vector State Research Centre of Viralogy and Biotechnology

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

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]

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

AMA Journal of Ethics

Volume 26, Number 5: E361-433 May 2024

https://journalofethics.ama-assn.org/issue/antimicrobial-resistance

Antimicrobial Resistance

Microbes include bacteria, parasites, viruses, and fungi that constantly evolve. Antimicrobial resistance (AMR) happens when microbes change, becoming harder to treat in individual human and nonhuman animals and plants with antibiotic, antiparasitic, antiviral, and antifungal agents. Resistant pathogens are easily transmissible across human and nonhuman ecology, and this theme issue attends to ethical, clinical, and policy dimensions of this set of problems. National and international burden of AMR has

been assessed in terms of infection incidence, deaths, hospital length of stay, and location-specific costs of developing and applying specific pathogen-drug combinations to try to save lives and preserve food supplies. Routine and focused surveillance is key to understanding microbiological, individual, social, and ecological root causes, downstream effects, and sources of domestic and global inequity in AMR.

American Journal of Human Genetics

May 02, 2024 Volume 111 Issue 5 p807-996 https://www.cell.com/ajhg/current [Reviewed earlier]

American Journal of Infection Control

May 2024 Volume 52 Issue 5 p501-624 http://www.ajicjournal.org/current [Reviewed earlier]

American Journal of Preventive Medicine

May 2024 Volume 66 Issue 5 p751-926 https://www.ajpmonline.org/current [Reviewed earlier]

American Journal of Public Health

May 2024 114(5) http://ajph.aphapublications.org/toc/ajph/current [Reviewed earlier]

American Journal of Tropical Medicine and Hygiene

Volume 110 (2024): Issue 5 (May 2024) https://www.ajtmh.org/view/journals/tpmd/110/4/tpmd.110.issue-5.xml [Reviewed earlier]

Annals of Internal Medicine

May 2024 Volume 177, Issue 5 https://www.acpjournals.org/toc/aim/current Original Research

<u>Evaluation of Strategies for Transitioning to Annual SARS-CoV-2 Vaccination Campaigns in the United States</u>

Chad R. Wells, PhD, Abhishek Pandey, PhD, Seyed M. Moghadas, PhD, Meagan C. Fitzpatrick, PhD, <u>...</u> et al. Pages:609–617

Artificial Intelligence - An International Journal

Volume 330 May 2024

https://www.sciencedirect.com/journal/artificial-intelligence/vol/330/suppl/C

BMC Cost Effectiveness and Resource Allocation

http://resource-allocation.biomedcentral.com/ (Accessed 25 May 2024) [No new digest content identified]

BMC Health Services Research

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

(Accessed 25 May 2024)

Non-uptake of COVID-19 vaccines and reasons for non-uptake among healthcare workers in Uganda: a cross-sectional study

Vaccines play a crucial role in eradicating and containing disease outbreaks. Therefore, understanding the reasons behind vaccine refusal and associated factors is essential for improving vaccine acceptance ra...

Authors: Nasimu Kyakuwa, Andrew Abaasa, Simon Mpooya, Hamza Kalutte, Christine Atuhairwe,

Laurent Perez and Bernard Kikaire

Citation: BMC Health Services Research 2024 24:663 Content type: Research Published on: 25 May 2024

BMC Infectious Diseases

http://www.biomedcentral.com/bmcinfectdis/content (Accessed 25 May 2024) [No new digest content identified]

BMC Medical Ethics

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

(Accessed 25 May 2024)

A scoping review of ethics review processes during public health emergencies in Africa

The COVID-19 pandemic forced governments, multilateral public health organisations and research institutions to undertake research quickly to inform their responses to the pandemic. Most COVID-19-related studi...

Authors: Kingsley Orievulu, Alex Hinga, Busisiwe Nkosi, Nothando Ngwenya, Janet Seeley, Anthony

Akanlu, Paulina Tindana, Sassy Molyneux, Samson Kinyanjui and Dorcas Kamuya

Citation: BMC Medical Ethics 2024 25:63

Content type: Research Published on: 22 May 2024

BMC Medicine

http://www.biomedcentral.com/bmcmed/content (Accessed 25 May 2024) [No new digest content identified]

BMC Pregnancy and Childbirth

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

(Accessed 25 May 2024)
[No new digest content identified]

BMC Public Health

http://bmcpublichealth.biomedcentral.com/articles (Accessed 25 May 2024) [No new digest content identified]

BMC Research Notes

http://www.biomedcentral.com/bmcresnotes/content (Accessed 25 May 2024) [No new digest content identified]

BMJ Evidence-Based Medicine

June 2024 - Volume 29 - 3 https://ebm.bmj.com/content/29/3 [New issue; No digest content identified]

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Volume 115, Issue 5 Pages: 907-1175 May 2024

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Paul Beninger

Published online: April 25, 2024 p305-306

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<u>Characteristics of X (Formerly Twitter) Community Notes Addressing COVID-19 Vaccine</u> Misinformation

Matthew R. Allen, BS; Nimit Desai, BS; Aiden Namazi; et al. JAMA. 2024;331(19):1670-1672. doi:10.1001/jama.2024.4800

This study evaluated the topics, accuracy, and credibility of X (formerly Twitter) Community Notes addressing COVID-19 vaccination.

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May 25, 2024 Volume 403 Number 10441 p2263-2348, e32 https://www.thelancet.com/journals/lancet/issue/current Comment

Expanded Programme on Immunization at 50 years: its legacy and future

Brian Wahl, Virginia E Pitzer

The successful eradication of smallpox, certified in 1980, <u>1</u> showcased the immense potential of vaccines to control diseases. The momentum of the Smallpox Eradication Program in its final years and the vision of providing life-saving vaccines to children everywhere led WHO to establish the Expanded Programme on Immunization (EPI) in 1974, with support from all member states. <u>2</u> This year, the global health community commemorates 50 years of this momentous effort and looks ahead to maximising the potential impact of one of the most potent interventions in public health.

Articles

<u>Contribution of vaccination to improved survival and health: modelling 50 years of the Expanded Programme on Immunization</u>

Andrew J Shattock, et al.

Open Access

Summary

Background

WHO, as requested by its member states, launched the Expanded Programme on Immunization (EPI) in 1974 to make life-saving vaccines available to all globally. To mark the 50-year anniversary of EPI, we sought to quantify the public health impact of vaccination globally since the programme's inception. Methods

In this modelling study, we used a suite of mathematical and statistical models to estimate the global and regional public health impact of 50 years of vaccination against 14 pathogens in EPI. For the modelled pathogens, we considered coverage of all routine and supplementary vaccines delivered since 1974 and estimated the mortality and morbidity averted for each age cohort relative to a hypothetical scenario of no historical vaccination. We then used these modelled outcomes to estimate the contribution of vaccination to globally declining infant and child mortality rates over this period. Findings

Since 1974, vaccination has averted 154 million deaths, including 146 million among children younger than 5 years of whom 101 million were infants younger than 1 year. For every death averted, 66 years of full health were gained on average, translating to $10 \cdot 2$ billion years of full health gained. We estimate that vaccination has accounted for 40% of the observed decline in global infant mortality, 52% in the African region. In 2024, a child younger than 10 years is 40% more likely to survive to their next birthday relative to a hypothetical scenario of no historical vaccination. Increased survival probability is observed even well into late adulthood.

Interpretation

Since 1974 substantial gains in childhood survival have occurred in every global region. We estimate that EPI has provided the single greatest contribution to improved infant survival over the past 50 years. In the context of strengthening primary health care, our results show that equitable universal access to immunisation remains crucial to sustain health gains and continue to save future lives from preventable infectious mortality.

Funding WHO.

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May 2024 Volume 8 Number 5 p311-384 https://www.thelancet.com/journals/lanchi/issue/current [Reviewed earlier]

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May 01, 2024 Volume 32 Issue 5 p1179-1596 https://www.cell.com/molecular-therapy/current [Reviewed earlier]

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Volume 629 Issue 8013, 23 May 2024 https://www.nature.com/nature/volumes/627/issues/8013 EDITORIAL 21 May 2024

A global pandemic treaty is in sight: don't scupper it

Millions of people died of COVID-19 because the fundamental principle of equity between nations was ignored during the outbreak. That must not be allowed to happen again.

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Nature Reviews Immunology

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Volume 390 No. 19 May 16/23, 2024 https://www.nejm.org/toc/nejm/medical-journal [New issue; No digest content identified]

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Volume 3 No. 4 April 2024

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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 25 May 2024] Meeting Report Open access

Published: 24 May 2024

Continuing development of vaccines and monoclonal antibodies against Zika virus

Sara E. Woodson & Kaitlyn M. Morabito

npj Vaccines volume 9, Article number: 91 (2024)

The 2016 Zika virus (ZIKV) epidemic catalyzed a global effort to develop diagnostic tests, vaccines, and therapeutic treatments. However, the rapid waning epidemiology of ZIKV stalled many countermeasure development efforts. On January 31 and February 1, 2023, the National Institute of Allergy and Infectious Diseases (NIAID) hosted "Continuing Development of Vaccines and Monoclonal Antibodies Against Zika Virus," a workshop of assembled experts from multiple fields and sectors to review the latest ZIKV research findings and develop recommendations for advancing vaccines and monoclonal antibodies. This report describes the workshop proceedings and summarizes the key challenges and major recommendations identified at the workshop. While the current incidence and testing for ZIKV are low globally, ZIKV has not disappeared, and future large-scale outbreaks are possible. Developing an effective vaccine and monoclonal antibody treatment is still a public health priority, especially for persons who can become pregnant and who live or travel in ZIKV-endemic regions.

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Low COVID-19 vaccine uptake in people living with HIV and those with hypertension and diabetes without HIV at Mbarara and Masaka regional referral hospitals: A cross-sectional survey

Asiphas Owaraganise, Brian Beesiga, Jaffer Okiring, Michelle E. Roh, Elijah Kakande, Joan Nangendo, Cecilia Akatukwasa, Jordan John Lee, Florence Mwangwa, Jane Kabami, Fred C. Semitala, Moses R. Kamya

Research Article | published 23 May 2024 PLOS Global Public Health https://doi.org/10.1371/journal.pgph.0003270

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May 21, 2024 vol. 121 no. 21 https://www.pnas.org/toc/pnas/121/21 Opinion May 15, 2024 Front Matter

<u>Making evidence go further: Advancing synergy between agent-based modeling and randomized control trials</u>

Ross A. Hammond and Shari Barkin

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Volume 3, Issue 4, April 2024 https://academic.oup.com/pnasnexus/issue/3/4 [Reviewed earlier]

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Volume 20 Issue 2, April 2024

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24 May 2024

G20's commitment to telehealth for reducing global health disparities: from a global commitment to regional actions

Editorial | English

Risk Analysis

Volume 44, Issue 5 Pages: 1007-1267 May 2024 https://onlinelibrary.wiley.com/toc/15396924/current

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Volume 384| Issue 6698| 24 May 2024

https://www.science.org/toc/science/current

Special issue: Decoding the brain

Introduction to Special Issue

Decoding the brain

BY Yevgeniya Nusinovich

23 May 2024: 858-859

A cell-by-cell look at neuropsychiatric diseases

Policy Forum

Managing extreme AI risks amid rapid progress

BY Yoshua Bengio, et al. 20 May 2024: 842-845

Preparation requires technical research and development, as well as adaptive, proactive governance

Science and Engineering Ethics

Volume 30, Issue 3 June 2024 https://link.springer.com/journal/11948/volumes-and-issues/30-3 [Reviewed earlier]

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Volume 16| Issue 748| 22 May 2024 https://www.science.org/toc/stm/current [New issue; No digest content identified]

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Volume 29, Issue 5 Pages: i-iv, 343-445 May 2024

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Volume 42, Issue 15 Pages 3375-3528 (31 May 2024)

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Short communication Open access

Report from the World Health Organization's immunization and vaccines-related implementation research advisory committee (IVIR-AC) meeting, virtual gathering, 26 February-1 March 2024

Philipp Lambach, Sheetal Silal, Alyssa N. Sbarra, Mitsuki Koh, ... Xuan-Yi Wang Pages 3379-3383

Research article Abstract only

<u>COVID-19 vaccine uptake among children and adolescents in Norway: A comprehensive registry-based cohort study of over 800,000 individuals</u>

Saima Orangzeb, Anteneh Desalegn, Nhung T.H. Trinh, Jing Zhao, ... Angela Lupattelli Pages 3420-3428

Research article Abstract only

<u>Collective good and individual choice: Perceptions on COVID-19 vaccine mandate among COVID-19 vaccinated individuals</u>

Kaivalya Gudooru, Kimberly Nguyen, Kathy Le, Vyas Sarabu, ... Luz M. Garcini Pages 3493-3498

Vaccines

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

[Accessed 25 May 2024]

Open Access Review

Vaccines for the Elderly and Vaccination Programs in Europe and the United States

by Cleo Anastassopoulou, Stefanos Ferous, Snežana Medić, Nikolaos Siafakas, Fotini Boufidou, Georgia Gioula and Athanasios Tsakris

Vaccines 2024, 12(6), 566;

https://doi.org/10.3390/vaccines12060566 - 22 May 2024

Abstract

The share of the elderly population is growing worldwide as life expectancy increases.

Immunosenescence and comorbidities increase infectious diseases' morbidity and mortality in older adults. Here, we aimed to summarize the latest findings on vaccines for the elderly against herpes zoster, influenza, respiratory...

Value in Health

May 2024 Volume 27 Issue 5 p543-686 https://www.valueinhealthjournal.com/current [Reviewed earlier]

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Volume 177 May 2024

https://www.sciencedirect.com/journal/world-development/vol/177/suppl/C

[Reviewed earlier]

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:: WHO

:: Organization Announcements

:: Journal Watch

:: Pre-Print Servers

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Pre-Print Servers

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medRxiv

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

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Child Mortality in England after the Pandemic. Increasing Mortality and Inequalities

David Odd, Sylvia Stoianova, Tom Williams, Peter Fleming, Karen Luyt

medRxiv 2024.05.24.24307855; doi: https://doi.org/10.1101/2024.05.24.24307855

<u>Multiplexed detection, partitioning, and persistence of wild type and vaccine strains of measles, mumps, and rubella viruses in wastewater</u>

Jingjing Wu, Michael X Wang, Prashant Kalvapalle, Michael Nute, Todd J Treangen, Katherine Ensor, Loren Hopkins, Rachel Poretsky, Lauren B Stadler

medRxiv 2024.05.23.24307763; doi: https://doi.org/10.1101/2024.05.23.24307763

Role of human challenge trials (HCTs) in drug development for respiratory syncytial virus (RSV)

Prosenjit Kundu, Mark Quinn, Jared C. Christensen, Elaine Thomas, Sima S. Toussi, Negar Niki Alami, Anindita Banerjee

medRxiv 2024.05.24.24307680; doi: https://doi.org/10.1101/2024.05.24.24307680

Human challenge trials (HCTs) are powerful in establishing early proof-of-concept for experimental drugs and understanding disease pathogenesis. In this study, we conducted a comprehensive assessment of HCTs to understand the viral load dynamics and symptom score kinetics of respiratory syncytial virus (RSV) to facilitate drug development for RSV. We estimated viral load (VL) and symptom related measures in placebo and relative reduction (RR) of the measures in the experimental drug using a systematic search on double-blind, placebo-controlled RSV HCTs from clinical databases...

COVID-19 vaccination atlas: an integrative systems vaccinology approach

Wasim Aluísio Prates-Syed, Dennyson Leandro M Fonseca, Shahab Zaki Pour, Igor Salerno Filgueiras, Lena F Schimke, Aline Aparecida Lira, Nelson Cortes de Oliveira, Jaqueline Dinis Queiroz Silva, Evelyn Carvalho, Tania Geraldine Churasacari-Vinces, Lorena C S Chaves, Gerhard Wunderlich, Ricardo Durães-Carvalho, Niels O S Câmara, Haroldo Dutra Dias, Hans D Ochs, Ester C Sabino, Jose E Krieger, Helder I Nakaya, Otavio Cabral-Marques, Gustavo Cabral-Miranda medRxiv 2024.05.22.24307755; doi: https://doi.org/10.1101/2024.05.22.24307755 Revision

COVID-19 vaccinations have significantly controlled the pandemic. To elucidate their impact on the immune system, we developed a COVID-19 vaccination atlas through an integrative systems vaccinology approach. Our atlas includes both healthy individuals and those infected with or without prior vaccination, and covers the administration of five vaccines in different regimens: Covilo®, Zifivax®, Vaxzebria® or Covishield®, Spikevax®, and Comirnaty®. We identified critical markers to discriminate the various types of vaccines and infection, in which infection was associated with GATA3, ZNF3, KMT2A, ASXL1, SP100, and GZMM, and vaccine types were marked by ITGAM, ACTG1, LGALS3, and STAT5B. Additionally, we described the immunological signatures resulting from heterologous vaccination and infection, and also showed how a full vaccination regimen markedly limited the shift of immune responses during natural infection, thereby constraining disease progression. Finally, we described the common transcripts shared across COVID-19 vaccines and vaccines against other pathogens.

The selective pressure induced by malaria vaccines on Plasmodium falciparum

Thiery Masserey, Tamsin Lee, Aurélien Cavelan, Daniel E. Neafsey, Josephine Malinga, Melissa A Penny medRxiv 2024.05.22.24307679; doi: https://doi.org/10.1101/2024.05.22.24307679

OSF Pre-prints

Abstract

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-No new digest content identified.

Wellcome Open Research

https://wellcomeopenresearch.org/browse/articles
[Accessed 25 May 2024]
Selected Research
No new digest content identified.

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Think Tanks

Brookings [to 25 May 2024] http://www.brookings.edu/Research

How foes can defeat a common enemy: US-China collaboration to combat Ebola

Health Care
Gayle E. Smith

Center for Global Development [to 25 May 2024]

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

Chatham House [to 25 May 2024]

https://www.chathamhouse.org/ Selected Analysis, Comment, Events No new digest content identified.

Council on Foreign Relations [to 25 May 2024]

https://www.cfr.org/media/news-releases
New Releases [Selected]
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CSIS [to 25 May 2024]

https://www.csis.org/ Reports [Selected]

How Foes Can Defeat a Common Enemy: U.S.-China Collaboration to Combat Ebola

Gayle Smith, CEO of the ONE Campaign and former administrator of the U.S. Agency for International Development (USAID), details the spread of Ebola in the mid-2010s and how the United States and China came together to address the crisis.

Brief by Gayle Smith — May 21, 2024

Kaiser Family Foundation [to 25 May 2024]

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

No new digest content identified.

McKinsey Global Institute [to 25 May 2024]

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

ODI [Overseas Development Institute] [to 25 May 2024]

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

Pew Research Center [to 25 May 2024]

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

Rand [to 25 May 2024] https://www.rand.org/pubs.html Published Research [Selected] No new digest content identified.

Urban Institute [to 25 May 2024] https://www.urban.org/publications New Research Publications - Selected

Guide

Guide to Equity in Pharmacy Services May 24, 2024

Guide

Guide to Equity in Behavioral Health Care May 24, 2024

World Economic Forum [to 25 May 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

National Institutes of Health (NIH) Office of Science Policy (OSP): Request for Information on Draft NIH Intramural Research Program Policy: Promoting Equity Through Access Planning

A Notice by the National Institutes of Health on 05/22/2024 **Comments Close: 07/22/2024** *SUMMARY:*

The National Institutes of Health (NIH) is proposing to develop and implement a new policy within its Intramural Research Program (IRP) to promote access to products stemming from taxpayer-funded inventions. NIH seeks input on this draft policy and accompanying draft license agreement language that incorporates patient access in the commercialization process for NIH-owned inventions. *Supplemental Information*

...NIH is proposing a new policy within the NIH IRP (see Appendix), to require that licensees that succeed in bringing certain products toward market submit a plan outlining steps they intend to take to promote patient access to those products. This new IRP policy makes it clear that access, defined broadly to include product affordability, availability, acceptability, and sustainability, is of paramount importance in providing a return on taxpayers' investment in biomedical research. This new policy would apply to patent licenses for the commercialization of drugs, biologics, vaccines, or devices. NIH

would also employ a tiered approach, where licenses granted for late-stage inventions that are closer to market launch would include more specific, tailored access-oriented provisions, while licenses granted for early-stage inventions would be more flexible to reflect the higher uncertainty associated with technologies that lead to drugs, biologics, vaccines, or devices. Importantly, a final policy approach should be reasonable and not seek to force licensees into access obligations that obstruct commercial development or damage the viability and sustainability of a product in the market, while also balancing the need to promote access through reforms to various policies. The agency is proposing a flexible approach that allows appropriately tailored, commercially reasonable strategies to promote patient access across a range of technologies. This RFI is in relation to the licensing of government-owned inventions in accordance with 35 U.S.C. 207 and 37 CFR part 404....

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 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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