

Vaccines and Global Health: The Week in Review 18 January 2020 :: Number 537 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 also **posted in pdf form** and as a set of blog posts at https://centerforvaccineethicsandpolicy.net. This blog allows full-text searching of over 8,000 entries. Comments and suggestions should be directed to

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Request an email version: Vaccines and Global Health: The Week in Review is published as a single email summary, scheduled for release each Saturday evening at midnight (EST/U.S.). If you would like to receive the email version, please send your request to david.r.curry@centerforvaccineethicsandpolicy.org.

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Milestones :: Perspectives :: Research

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WHO :: Urgent health challenges for the next decade

13 January 2020

As a new year and a new decade kick off, WHO is releasing a list of urgent, global health challenges. This list, developed with input from our experts around the world, reflects a deep concern that leaders are failing to invest enough resources in core health priorities and systems. This puts lives, livelihoods and economies in jeopardy. None of these issues are simple to address, but they are within reach. Public health is ultimately a political choice.

We need to realize that health is an investment in the future. Countries invest heavily in protecting their people from terrorist attacks, but not against the attack of a virus, which could be far more deadly, and far more damaging economically and socially. A pandemic could bring economies and nations to their knees. Which is why health security cannot be a matter for ministries of health alone.

All the challenges in this list demand a response from more than just the health sector. We face shared threats and we have a shared responsibility to act. With the deadline for the 2030 Sustainable Development Goals quickly approaching, the United Nations General Assembly has underscored that the next 10 years must be the "decade of action".

This means advocating for national funding to address gaps in health systems and health infrastructure, as well as providing support to the most vulnerable countries. Investing now will save lives – and money – later. The cost of doing nothing is one we cannot afford.

Governments, communities, and international agencies must work together to achieve these critical goals. There are no shortcuts to a healthier world. 2030 is fast approaching, and we must hold our leaders accountable for their commitments.

Dr Tedros Adhanom Ghebreyesus, WHO Director-General

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Wuhan - Coronavirus

CEPI Blog

Newly discovered coronavirus in Wuhan China

CEO, Richard Hatchett discusses how the rapid publication of the genetic sequence of the newly discovered beta coronavirus could help speed up the development of diagnostic tests, case...
17 Jan 2020

The world faces a new disease threat from a previously unknown pneumonia-causing virus in China – but the good news is scientists already have vital genetic data that will help speed the development of diagnostic tests, case detection and, potentially, a vaccine.

The decision by Chinese authorities to release the genetic sequence of the newly discovered beta coronavirus (labelled 2019-nCoV by the World Health Organization) for researchers worldwide exemplifies the transparency needed to tackle unfolding public health emergencies.

The rapid publication of genetic sequences, less than a month after the 'mystery' disease caused the first of a cluster of pneumonia cases in the Chinese city of Wuhan, demonstrates the speed we can now achieve in identifying and characterizing new threats (by comparison, the sequencing and sharing of Severe Acute Respiratory Syndrome (SARS) coronavirus took 6 months from initial case identification in November 2002).

Understanding the genetic make-up of 2019-nCoV is vital for learning how closely related it is to SARS and Middle East Respiratory Syndrome (MERS), the other beta coronaviruses that have presented significant epidemic threats in recent years. Sequencing facilitates the development of PCR-based diagnostics, which in turn will help hospitals and public health authorities test for new cases and track the global spread of the disease. The genome data is also essential as researchers seek to fast-track work on a vaccine using cutting-edge technology platforms. Such platforms use standard components as a backbone but can be adapted to fight specific diseases by plugging in their genetic sequences as this information becomes available.

Disease outbreaks present a unique opportunity for research, but this can only happen if experts in different countries share information promptly. China's openness in this case is therefore hugely welcome.

So far, two people have died and dozens of others have been hospitalised with pneumonia in China. Over the past week, two confirmed cases have also been reported in Thailand, with an additional case in Japan. While there was no relation between cases, all three had recently visited Wuhan. With possible limited human-to-human transmission, the World Health Organization is braced for the possibility of 2019-nCoV spreading further, especially ahead of the Lunar New Year holiday, beginning on January 25, when many millions of Chinese citizens are expected to travel.

CEPI has been monitoring the situation since the outbreak was first reported and we are working closely with WHO, who is leading the development of a coordinated international response. Within CEPI, we have convened our response steering committee to explore how we can contribute to the global effort to better understand and fight this disease. Our Scientific Advisory Committee has met twice and advised that we take early steps in vaccine development in case the situation worsens, and we have kept the Executive and Investment Committee of CEPI's Board apprised of both these recommendations and developments more generally.

While additional investigation into 2019-nCoV is now needed to ascertain transmission routes and the source of exposure, the decision by the Chinese Center for Disease Control and Prevention, the Chinese Academy of Science and the Chinese Academy of Medical Science to share the genome sequence of the new virus with the world is a model for how scientists and government agencies must collaborate to tackle future disease threats.

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CDC [U.S.] <u>Public Health Screening to Begin at 3 U.S. Airports for 2019 Novel Coronavirus ("2019-nCoV")</u>

Friday, January 17, 2020

The Centers for Disease Control and Prevention (CDC) and the Department of Homeland Security's Customs and Border Protection (CBP) will implement enhanced health screenings to detect ill travelers traveling to the United States on direct or connecting flights from Wuhan, China. This activity is in response to an outbreak in China caused by a novel (new) coronavirus (2019 nCoV), with exported cases to Thailand and Japan.

Starting January 17, 2020, travelers from Wuhan to the United States will undergo entry screening for symptoms associated with 2019-nCoV at three U.S. airports that receive most of the travelers from Wuhan, China: San Francisco (SFO), New York (JFK), and Los Angeles (LAX) airports.

"To further protect the health of the American public during the emergence of this novel coronavirus, CDC is beginning entry screening at three ports of entry. Investigations into this novel coronavirus are ongoing and we are monitoring and responding to this evolving situation," said Martin Cetron, M.D., Director of CDC's Division of Global Migration and Quarantine.

Based on current information, the risk from 2019-nCoV to the American public is currently deemed to be low. Nevertheless, CDC is taking proactive preparedness precautions. Entry screening is part of a layered approach used with other public health measures already in place to detect arriving travelers who are sick (such as detection and reporting of ill travelers by airlines during travel and referral of ill travelers arriving at a US port of entry by CBP) to slow and reduce the spread of any disease into the United States.

CDC is deploying about 100 additional staff to the three airports (SFO, JFK, and LAX) to supplement existing staff at CDC quarantine stations located at those airports...

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13 January 2020 News release

WHO statement on novel coronavirus in Thailand

The World Health Organization (WHO) is working with officials in Thailand and China following reports of confirmation of the novel coronavirus in a person in Thailand.

The person was a traveler from Wuhan, China, and was identified by Thai officials on 8 January, and hospitalized that day. The person is recovering from the illness according to Thai officials.

The possibility of cases being identified in other countries was not unexpected, and reinforces why WHO calls for on-going active monitoring and preparedness in other countries. WHO has issued guidance on how to detect and treat persons ill with the new virus.

The genetic sequencing shared by China enables more countries to rapidly diagnose patients. WHO reiterates that it is essential that investigations continue in China to identify the source of this outbreak and any animal reservoirs or intermediate hosts.

Given developments, WHO Director-General Dr Tedros Adhanom Ghebreyesus will consult with Emergency Committee members and could call for a meeting of the committee on short notice.

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Lack of new antibiotics threatens global efforts to contain drug-resistant infections

17 January 2020 WHO News release

Declining private investment and lack of innovation in the development of new antibiotics are undermining efforts to combat drug-resistant infections, says the World Health Organization (WHO).

Two new reports reveal a weak pipeline for antibiotic agents. The 60 products in development (50 antibiotics and 10 biologics) bring little benefit over existing treatments and very few target the most critical resistant bacteria (Gram-negative bacteria).

While pre-clinical candidates (those in early-stage testing) are more innovative, it will take years before they reach patients.

"Never has the threat of antimicrobial resistance been more immediate and the need for solutions more urgent," says Dr Tedros Adhanom Ghebreyesus, Director-General of WHO. "Numerous initiatives are underway to reduce resistance, but we also need countries and the pharmaceutical industry to step up and contribute with sustainable funding and innovative new medicines."

The reports (<u>Antibacterial agents in clinical development – an analysis of the antibacterial clinical development pipeline</u> and its companion publication, <u>Antibacterial agents in preclinical development</u>) also found that research and development for antibiotics is primarily driven by small- or medium-sized enterprises with large pharmaceutical companies continuing to exit the field...

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IAVI Makes Available Unique Dataset and Samples from Pioneering HIV/AIDS Study in Africa to Researchers

NEW YORK — 14 JANUARY 2020 — Today IAVI, a nonprofit scientific research organization dedicated to addressing urgent, unmet global health challenges, announces the launch of IAVI <u>DataSpace</u>, an open-access, online portal to a one-of-a-kind dataset from a study of early HIV infection in a unique sub-Saharan African cohort. Researchers from across the world are invited to interact with the data through powerful visualization tools that help them understand the interplay between HIV and the human immune system and the complex dynamics of HIV transmission. IAVI DataSpace, funded by the U.S. Agency for International Development (USAID), is backed by an extensive sample library also available to researchers.

The data and samples were collected in IAVI's landmark USAID-funded Protocol C epidemiological study between 2006 and 2017. The study followed 613 participants newly infected with HIV in Eastern and Southern Africa, including heterosexual men and women with a regular HIV-positive sex partner; at-risk young women, including sex workers; and men who have sex with men. The data convey years of immunological events from the earliest stages of

HIV infection. Aggregate data from the Protocol C cohort are freely available on the portal; researchers who wish to analyze anonymized participant-level data and samples may request access.

Professor Jill Gilmour, Ph.D., Executive Director, Human Immunology, and Principal Investigator, IAVI Human Immunology Laboratory (HIL) at Imperial College London, said, "We are gratified that USAID support is allowing us to make this truly unique dataset widely available to the HIV research community, and especially to researchers in Africa. These data represent diverse African populations, risk groups, and viral genetics of HIV acquired through various modes of transmission, giving researchers insights into the complexity of HIV transmission and infection. The fact that Protocol C researchers collected samples from a complete spectrum of viral control — from participants who had poor viral control to those called elite controllers — makes us hopeful that these data could drive discoveries eventually leading to new HIV prevention tools and even novel treatment approaches."...

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Stronger Food and Drug Regulatory Systems Abroad

National Academies 15 Jan 2020

Overview

By recent estimates, unsafe food kills over 400,000 people a year—a third of them children under 5, mostly in low- and middle-income countries. In sub-Saharan Africa alone, poor quality medicines cause about 70,000 excess deaths from childhood pneumonia and roughly 8,500 to 20,000 deaths from malaria every year. Ensuring the safety and quality of food and medicines in a country is an important role of government and essential for public health.

The capacity of regulatory systems abroad is of special interest to the U.S. Food and Drug Administration (FDA) Office of Global Policy and Strategy, the office that commissioned this study and a similar one released in 2012. This report discusses changes in the field since the 2012 study and outlines a strategy to strengthen food and medical products regulatory systems in low- and middle-income countries, recommending actions at the global, national and agency levels (see condensed recommendations table).

PDF: http://www.nationalacademies.org/hmd/Reports/2020/stronger-food-and-drug-regulatory-systems-abroad.aspx?utm_source=HMD+Email+List&utm_campaign=6f808a19d4-ncpf-pw-Dec1 COPY 01&utm_medium=email&utm_term=0_211686812e-6f808a19d4-180590365&mc_cid=6f808a19d4&mc_eid=f3b6c2ba44

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Emergencies

Ebola - DRC+

Public Health Emergency of International Concern (PHEIC)

Ebola Outbreak in DRC 75: 14 January 2020

Situation Update

From 6 to 12 January 2020, eight new confirmed cases of Ebola virus disease (EVD) were reported from Mabalako, Beni, and Musienene Health Zones in North Kivu Province in the Democratic Republic of the Congo. Of these cases, three were reported in Beni Health Zone, where no cases had been reported for 29 days, and one was reported in Musienene Health Zone, where no cases had been reported for 132 days. These four cases are linked to the transmission chain that originated in Aloya Health Area, Mabalako Health Zone, and were not unexpected given known links between Mabalako and Beni...

... Vaccines

- :: From 8 August 2018 to 12 January 2020, 265 309 people were vaccinated with the rVSV-ZEBOV-GP Ebola vaccine.
- :: Vaccination with the Ad26.ZEBOV/MVA-BN-Filo vaccine continued in Karisimbi Health Zone, with 5684 people vaccinated since its introduction on 14 November 2019.
- ...Risk communication, social mobilization and community engagement
- :: Traditional healers and managers of private structures which had contact with suspected EVD cases participated in response activities after community dialogue in Aloya, Mabalako Health Zone.
- :: A forum for popular expression was also organized with village chiefs and civil society leaders to address questions related to vaccination activities in Métal and Aloya Health Zones.
- :: Teams continue to involve local actors in communication and vaccination activities in Lwemba and Biakato.

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DR Congo: Red Cross volunteers attacked during Ebola burial

Goma/Nairobi/Geneva, 15 January 2020 – Two volunteers from the Democratic Republic of Congo (DR Congo) Red Cross were seriously injured following an attack during a safe and dignified burial of a suspected Ebola case near Mambasa, in eastern DR Congo on Monday, 13 January. The volunteers are now in hospital, receiving medical care and psychosocial support.

DR Congo Red Cross teams have faced incidents of violence and aggression from communities resisting safe and dignified burial protocols since the start of the Ebola outbreak in North Kivu and Ituri. In this most recent attack, the family had consented to the burial but rumours and panic quickly spread among the community resulting in a violent assault against the Red Cross team.

Grégoire Mateso Mbuta, President of the DR Congo Red Cross Society said: "This incident is a stark reminder of the serious risks our volunteers face when they carry out the dangerous task of safe and dignified burials. While we deplore any violence towards our volunteers or staff, we understand first hand, the fear and frustration that communities harbour and shall continue to render the needed services to the affected populations."

The current Ebola outbreak, which began on 1 August 2018, is unfolding in an area affected by a two decades-long conflict that has claimed countless lives and raised fear and hostility towards responders.

Building community trust and acceptance has been at the core of the Red Cross' Ebola response operations. This investment has paid off. Since the beginning of the outbreak nearly 20,000 successful safe and dignified burials have been conducted with a consistently high success rate. Red Cross volunteers continue to work within affected communities, listening to concerns and gathering feedback that is then analysed and used to provide improved support to people in need. As a result, community resistance for safe and dignified burials has drastically declined over the course of the operation.

Nicole Fassina, Ebola Operations Manager for the International Federation of Red Cross and Red Crescent Societies (IFRC) said: "While we experienced an overall improvement in community's acceptance of burials, this attack underscores why we cannot become complacent. The Red Cross will continue to engage and involve communities in the Ebola response if we want to bring this outbreak to end."

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POLIO

Public Health Emergency of International Concern (PHEIC) http://polioeradication.org/polio-today/polio-now/this-week/

Polio this week as of 14 January 2020

:: Pakistan intensifies cVDPV2 response efforts, focusing on comprehensive outbreak response, strengthened routine immunization, communication and enhanced surveillance.

Summary of new viruses this week (AFP cases and ES positives):

- :: Pakistan: seven WPV1 cases; and, five WPV1-positive environmental samples
- :: Angola: two cVDPV2 cases
- :: Benin: one cVDPV2 case
- :: Central African Republic (CAR): two cVDPV2 cases
- :: Ghana: one cVDPV2 case; and, six cVDPV2-positive environmental samples
- :: Malaysia: one cVDPV1-positive environmental sample; and, one cVDPV2-positive

environmental sample

- :: Philippines: two cVDPV2 cases
- :: Togo: two cVDPV2 cases

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Editor's Note:

WHO has posted a <u>refreshed emergencies page</u> which presents an updated listing of Grade 3,2,1 emergencies as below.

WHO Grade 3 Emergencies [to 18 Jan 2020]

Democratic Republic of the Congo

:: <u>Ebola Outbreak in DRC 75: 14 January 2020</u> [See Ebola above for detail]

<u>Mozambique floods</u> - No new digest announcements identified

Nigeria - No new digest announcements identified
Somalia - No new digest announcements identified
South Sudan - No new digest announcements identified
Syrian Arab Republic - No new digest announcements identified
Yemen - No new digest announcements identified

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WHO Grade 2 Emergencies [to 18 Jan 2020]

Iraq

:: WHO assesses capacity and preparedness of Al Jumhury Teaching Hospital for influenza Erbil, Iraq, 14 January 2020

Afghanistan - No new digest announcements identified

Angola - No new digest announcements identified

Burkina Faso [in French] - No new digest announcements identified

Burundi - No new digest announcements identified

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

Central African Republic - No new digest announcements identified

Ethiopia - No new digest announcements identified

HIV in Pakistan - No new digest announcements identified

<u>Iran floods 2019</u> - No new digest announcements identified

Libya - No new digest announcements identified

Malawi floods - No new digest announcements identified

Measles in Europe - No new digest announcements identified

MERS-CoV - No new digest announcements identified

Myanmar - No new digest announcements identified

Niger - No new digest announcements identified

occupied Palestinian territory - No new digest announcements identified

Sudan - No new digest announcements identified

Ukraine - No new digest announcements identified

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

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WHO Grade 1 Emergencies [to 18 Jan 2020]

Chad - No new digest announcements identified

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

Kenya - No new digest announcements identified

Mali - No new digest announcements identified

Namibia - viral hepatitis - No new digest announcements identified

Tanzania - No new digest announcements identified

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UN OCHA – L3 Emergencies

The UN and its humanitarian partners are currently responding to three 'L3' emergencies. This is the global humanitarian system's classification for the response to the most severe, large-scale humanitarian crises.

Syrian Arab Republic

:: <u>Syrian Arab Republic: Recent Developments in Northwestern Syria Situation Report No. 6 - As of 15 January 2020</u>

Yemen - No new digest announcements identified

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UN OCHA – Corporate Emergencies

When the USG/ERC declares a Corporate Emergency Response, all OCHA offices, branches and sections provide their full support to response activities both at HQ and in the field.

CYCLONE IDAI and Kenneth - No new digest announcements identified

EBOLA OUTBREAK IN THE DRC - No new digest announcements identified

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WHO & Regional Offices [to 18 Jan 2020]

17 January 2020 News release

From political commitment to concrete reality: moving ahead on UHC in 2020

17 January 2020 News release

Lack of new antibiotics threatens global efforts to contain drug-resistant infections

13 January 2020 News release

WHO statement on novel coronavirus in Thailand

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Weekly Epidemiological Record, 17 January 2020, vol. 95, 03 (pp. 13-24)

Report of the third Global Forum of Malaria-eliminating Countries, 18–20 June 2019, Wuxi, China

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WHO African Regions Immunization Technical Advisory Group (RITAG)

- :: Call for nominations pdf, 147kb Deadline for applications: 28 February 2020
- :: RITAG Terms of Reference pdf, 211kb
- :: RITAG application annexes pdf, 91kb

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GIN November and December 2019 pdf, 2.83Mb

13 January 2020

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WHO Regional Offices

Selected Press Releases, Announcements

WHO African Region AFRO

:: Three African countries halt polio outbreaks 20 December 2019

Kenya, Mozambique and Niger have curbed polio outbreaks that erupted in different episodes over the past 24 months, allowing them to regain their polio-free status, World Health Organization (WHO) announced today.

:: WHO unveils plan to tackle rising HIV drug resistance in Africa 06 December 2019 WHO and partners unveil a five-year plan to monitor, prevent and respond to growing HIV drug resistance in Africa. HIV drug resistance is threatening the significant progress made in the global fight against the virus.

WHO Region of the Americas PAHO

No new digest content identified.

WHO South-East Asia Region SEARO

No new digest content identified.

WHO European Region EURO

- :: WHO/Europe and Norway discuss improving affordable access to innovative medicines 16-01-2020
- :: Violence against children: tackling hidden abuse 13-01-2020

WHO Eastern Mediterranean Region EMRO

- :: WHO responds to urgent health needs in El Geneina, West Darfur 14 January 2020
- :: WHO assesses hospital's influenza preparedness in Erbil 14 January 2020

WHO Western Pacific Region

:: <u>China virus outbreak shows Asia needs to step up infection preparation</u>
Region is safer after epidemic lessons but new diseases always arising 15 January 2020

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CDC/ACIP [to 18 Jan 2020]

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

https://www.cdc.gov/vaccines/acip/index.html

Friday, January 17, 2020

<u>Public Health Screening to Begin at 3 U.S. Airports for 2019 Novel Coronavirus</u> ("2019-nCoV")

[See Milestones above for detail]

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Africa CDC [to 18 Jan 2020] http://www.africacdc.org/

News

No new digest content identified.

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China CDC

http://www.chinacdc.cn/en/
No new digest content identified.

National Health Commission of the People's Republic of China

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

2020-01-12

China to share with WHO new-type coronavirus' genome sequence: official

[See Milestones above for detail]

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Announcements

Paul G. Allen Frontiers Group [to 18 Jan 2020]

https://alleninstitute.org/what-we-do/frontiers-group/news-press/

News

Hodgkin lymphoma recruits and trains immune cells to help it thrive

January 14, 2020

Study also highlights possible new targets for treatment, how to better tailor cancer therapies for individual patients

BMGF - Gates Foundation [to 18 Jan 2020]

http://www.gatesfoundation.org/Media-Center/Press-Releases

No new digest content identified.

Bill & Melinda Gates Medical Research Institute [to 18 Jan 2020]

https://www.gatesmri.org/

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

No new digest content identified.

CARB-X [to 18 Jan 2020]

https://carb-x.org/

CARB-X is a non-profit public-private partnership dedicated to accelerating antibacterial research to tackle the global rising threat of drug-resistant bacteria.

01.13.2020

<u>CARB-X funds Trellis Bioscience to support the development of a monoclonal</u> <u>antibody designed to disrupt superbugs' protective coating so that antibiotics can</u> <u>kill them</u>

CARB-X is awarding Trellis Bioscience, of Redwood City, California, USA, up to \$3.2 million in non-dilutive funding, with the possibility of \$3.8 million more if certain project milestones are met, to develop an innovative monoclonal antibody designed to disrupt the protective biofilm that makes bacteria resistant to antibiotics.

CEPI – Coalition for Epidemic Preparedness Innovations [to 18 Jan 2020]

http://cepi.net/

Latest news

Newly discovered coronavirus in Wuhan China

Our CEO, Richard Hatchett, discusses how the rapid publication of the genetic sequence of the newly discovered beta coronavirus could help speed up the development of diagnostic tests, case...

Blog 17 Jan 2020

[See Milestones above for detail]

Clinton Health Access Initiative, Inc. (CHAI) [to 18 Jan 2020]

https://clintonhealthaccess.org/ News & Press Releases No new digest content identified.

EDCTP [to 18 Jan 2020]

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 Latest news

No new digest content identified.

Emory Vaccine Center [to 18 Jan 2020]

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

European Medicines Agency [to 18 Jan 2020]

http://www.ema.europa.eu/ema/

News & Press Releases

News: Mandatory use of international standard for the reporting of side effects to

improve safety of medicines Last updated: 15/01/2020 At its December 2019 meeting, EMA's <u>Management Board</u> agreed to the mandatory use of a consistent international format, the ISO ICSR format, for reporting individual cases of suspected side effects in patients across the world. This follows a recommendation from EMA's safety committee (<u>PRAC</u>) in October 2019. The use of the new international standard will become mandatory as of 30 June 2022 for all reporting to <u>EudraVigilance</u>, the European database of suspected side effects with medicines authorised in the European Economic Area (EEA).

The ISO ICSR standard is based on the <u>ICH</u> E2B(R3) modalities for the reporting of suspected side effects of medicines in <u>individual case safety reports</u> (ICSRs). Compared to the older reporting formats it improves the quality of data collected and increases the ability to search and analyse these data. This will better support regulatory authorities and companies to detect and address safety issues with medicines and therefore protect patients. In addition, the ISO standard strengthens personal data protection in the records of ICSRs collected by regulatory authorities and companies.

A <u>guide</u>, jointly developed by EMA and the <u>Heads of Medicines Agencies</u> (HMA), was published in 2015 to help pharmaceutical companies, sponsors of <u>clinical trials</u> and medicines regulatory authorities in EU Member States prepare for the use of the new standard. The guide specifically defines the electronic transmission process of ICSRs, the format and content of the ICSR, the business rules for report validation, as well as classification and data quality principles. It also assists software providers and IT developers in the development of pharmacovigilance and safety databases...

European Vaccine Initiative [to 18 Jan 2020]

http://www.euvaccine.eu/news-events No new digest content identified.

FDA [to 18 Jan 2020]

https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/default.htm Press Announcements No new digest content identified.

Fondation Merieux [to 18 Jan 2020]

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

News, Events

The Malagasy Ministry of Education and Technical and Vocational training and the Mérieux Foundation sign an agreement to promote good health practices in schools January 9, 2020 - Anosy, Antananarivo (Madagascar)

Her Excellency, Marie Thérèse Volahaingo, Minister of the Malagasy Ministry of Education and Technical and Vocational Training, and Luciana Rakotoarisoa, Manager of the Mérieux Foundation in Madagascar, have signed a partnership agreement for the distribution of health education kits throughout the country's schools...

https://www.gavi.org/

No new digest content identified.

GHIT Fund [to 18 Jan 2020]

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

GHIT was set up in 2012 with the aim of developing new tools to tackle infectious diseases that No new digest content identified.

Global Fund [to 18 Jan 2020]

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

News & Stories

Updates

Data Service: Country Coordinating Mechanism Contacts

17 January 2020

Updates

Data Explorer: Location Detail Pages

14 January 2020

Hilleman Laboratories [to 18 Jan 2020]

http://www.hillemanlabs.org/

News

<u>Hilleman Laboratories Expands into Maternal and Child Health; Plans to Develop a</u> Novel Vaccine Against Group B Streptococcus

16th January 2020, New Delhi: In a bid to strengthen its vaccine portfolio and expand into areas of unmet need, Hilleman Laboratories, a global research and development organization focused on delivering high-impact and affordable vaccines, announced today about plans to venture into the area of maternal and child health.

In this regard, Hilleman Labs is undertaking research and development of an effective and affordable vaccine against Group B Streptococcus to add a positive impact to women and children living in low middle-income countries.

Streptococcus agalactiae or group B streptococcus (GBS) is a leading cause of serious neonatal infections including septicaemia, pneumonia and less frequently meningitis, and urinary tract infections, chorioamnionitis, endometritis and bacteremia in women. GBS is an opportunistic commensal constituting a part of the intestinal and vaginal physiologic flora in almost 25% of healthy adult women. Maternal colonization is the principal route of GBS transmission. GBS converts from the asymptomatic mucosal carriage state to a major bacterial pathogen causing severe invasive infections...

Dr Davinder Gill, CEO, Hilleman Laboratories, said, "Hilleman Labs has embarked on a project to develop a safe, effective and affordable vaccine against Group B Streptococcus. In this project, we will use our expertise in the conjugate vaccine technology in which we have substantial experience. We will design, assemble and test the vaccine within our R&D centre in

India." We will pay close attention to Group B Streptococcus strains that are prevalent in India and South East Asia. Thereafter, we will partner with a vaccine manufacturing company for further development, manufacture and sale of the vaccine. Since there is currently no approved vaccine for Group B Streptococcus, our initiative is an important one for women and children living in low middle-income countries," he added...

Human Vaccines Project [to 18 Jan 2020]

http://www.humanvaccinesproject.org/media/press-releases/

Press Releases

No new digest content identified.

IAVI [to 18 Jan 2020]

https://www.iavi.org/newsroom

January 14, 2020

IAVI Makes Available Unique Dataset and Samples from Pioneering HIV/AIDS Study in Africa to Researchers

[See Milestones above for detail]

International Coalition of Medicines Regulatory Authorities [ICMRA]

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

International Generic and Biosimilar Medicines Association [IGBA]

https://www.igbamedicines.org/

News

No new digest content identified.

IFFIm

http://www.iffim.org/

No new digest content identified.

IFRC [to 18 Jan 2020]

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

Selected Press Releases, Announcements

Africa, Democratic Republic of the Congo

DR Congo: Red Cross volunteers attacked during Ebola burial

15 January 2020

[See Ebola above for detail]

IVAC [to 18 Jan 2020]

https://www.jhsph.edu/research/centers-and-institutes/ivac/index.html Updates No new digest content identified.

IVI [to 18 Jan 2020] http://www.ivi.int/ Selected IVI News & Announcements

IVI and Sweden renew partnership to accelerate vaccines for global public health

January 13, 2020 – SEOUL, South Korea – The International Vaccine Institute (IVI), a Seoul, Korea-based international organization, announced today that the Swedish International Cooperation Agency (Sida) will continue to support IVI's mission to accelerate vaccine research and development for global health with a total contribution of SEK 50 million (approximately 5.24 million USD) over the next five years as part of a longstanding partnership between the Swedish government and IVI...

Sweden was one of the first countries to sign the IVI Establishment Agreement in 1997 and started funding IVI in 2002 through Sida. Since IVI's first research collaboration with the University of Gothenburg and Swedish Biological Laboratories in 2000, Sweden has played an invaluable role in developing IVI's landmark oral cholera vaccine (OCV), Shanchol, and later, Euvichol and Euvichol Plus, vaccines developed through technology transfer from IVI and prequalified by the WHO. To date, over 42 million doses of these low-cost OCVs have been deployed worldwide...

JEE Alliance [to 18 Jan 2020] https://www.jeealliance.org/ Selected News and Events No new digest content identified.

MSF/Médecins Sans Frontières [to 18 Jan 2020]

http://www.msf.org/ Latest [Selected Announcements] No new digest content identified.

National Vaccine Program Office - U.S. HHS [to 18 Jan 2020]

https://www.hhs.gov/vaccines/about/index.html
NVAC 2020 Meetings
February 13-14, 2020 NVAC Meeting
June 9-10, 2020 NVAC Meeting
September 23-24, 2020 Meeting (Virtual)

NIH [to 18 Jan 2020] http://www.nih.gov/news-events/news-releases Selected News Releases

<u>Panel identifies need for improved implementation of preventive services and reduced health disparities</u>

January 15, 2020 — Scientists urged to engage stakeholders inside and outside the health care system.

PATH [to 18 Jan 2020] https://www.path.org/media-center/ Selected Announcements No new digest content identified.

Sabin Vaccine Institute [to 18 Jan 2020]

http://www.sabin.org/updates/pressreleases
Statements and Press Releases
No new digest content identified.

UNAIDS [to 18 Jan 2020]
http://www.unaids.org/en
Selected Press Releases/Reports/Statements
No new digest content identified.

UNICEF [to 18 Jan 2020]

https://www.unicef.org/media/press-releases Selected Statements, Press Releases, Reports Statement

<u>Libya: Tens of thousands of children at risk amidst violence and chaos of unrelenting conflict</u>

Statement by UNICEF Executive Director Henrietta Fore 17/01/2020

Press release

<u>First drone and data academy opens in Africa to improve service delivery for children</u>

NEW YORK/ LILONGWE, 13 January 2020 – The first African Drone and Data Academy (ADDA) opened today in Lilongwe, Malawi, UNICEF announced.

The move is part of efforts to promote the use of drones in programmes and services that will impact the lives of children and young people.

"Humanitarian and development programme delivery in Africa and beyond can benefit significantly from the application of drone technology," said UNICEF Executive Director Henrietta Fore. "The African Drone and Data Academy will be instrumental in equipping young people with the skills they need to use the technology to benefit children and their communities."

Building on the work of Africa's first humanitarian corridor launched in Malawi in 2017, the academy will develop expertise in the use of drones for humanitarian, development and commercial purposes across the continent through a 12-week course. It plans to train

approximately 150 students to build and pilot drones by 2021. Funding from UNICEF's partners will provide free tuition to the first cohort of 26 students from across Africa...

Media Advisory

Countries gather for the Global Forum on Childhood Pneumonia

World's first conference on childhood pneumonia to take place in Barcelona from Jan 29-31 13/01/2020

Vaccination Acceptance Research Network (VARN) [to 18 Jan 2020]

https://vaccineacceptance.org/news.html#header1-2r No new digest content identified.

Vaccine Confidence Project [to 18 Jan 2020]

http://www.vaccineconfidence.org/ No new digest content identified.

Vaccine Education Center – Children's Hospital of Philadelphia [to 18 Jan 2020]

http://www.chop.edu/centers-programs/vaccine-education-center No new digest content identified.

Wellcome Trust [to 18 Jan 2020]

https://wellcome.ac.uk/news Opinion | 15 January 2020

It's now beyond doubt: we need to reimagine the way research works

by Beth Thompson

The findings of our survey of more than 4,000 researchers expose the stark pressures that many face. But together, we can learn from one another's good practice and come up with new ways to improve research culture.

The Wistar Institute [to 18 Jan 2020]

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

No new digest content identified.

World Organisation for Animal Health (OIE) [to 18 Jan 2020]

https://www.oie.int/en/for-the-media/press-releases/2020/ No new digest content identified.

::::::

ARM [Alliance for Regenerative Medicine] [to 18 Jan 2020]

https://alliancerm.org/press-releases/ No new digest content identified. **BIO** [to 18 Jan 2020]

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

Press Releases

<u>China Phase I Agreement Represents Important Step Towards Addressing Biotech</u> <u>Issues</u>

Washington, D.C. (January 15, 2020) – BIO President and CEO Jim Greenwood released the following statement today regarding the signing of Phase One of the trade agreement with China: "..."We are currently reviewing the details, but we are pleased to see important commitments for agricultural biotechnology, biopharmaceuticals, and GM microorganisms, in addition to commitments related to forced technology transfer and intellectual property. We look forward to working closely with the Administration to monitor the implementation and enforcement of these provisions..."

DCVMN – Developing Country Vaccine Manufacturers Network [to 18 Jan 2020]

http://www.dcvmn.org/

News

No new digest content identified.

IFPMA [to 18 Jan 2020]

http://www.ifpma.org/resources/news-releases/ Selected Press Releases, Statements, Publications No new digest content identified.

PhRMA [to 18 Jan 2020]

http://www.phrma.org/

Selected Press Releases, Statements

Press Release

ICYMI: 2019 brings innovative medicines to patients

Andrew Powaleny January 17, 2020

New reports from the U.S. Food and Drug Administration (FDA) show a total of 56 novel new medicines were approved in 2019. Among these, 48 were approved by the Center for Drug Evaluation and Research (CDER) and 8 were approved by the Center for Biologics Evaluation and Research (CBER). While medicine approval numbers vary each year, 2019 saw exciting advancements in drug development. These strong approval figures demonstrate biopharmaceutical companies' unwavering commitment to developing innovative treatments for patients, offering hope for improved health outcomes...

* * * *

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 focu-s 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

American Journal of Infection Control

January 2020 Volume 48, Issue 1, p1-122 http://www.ajicjournal.org/current [Reviewed earlier]

American Journal of Preventive Medicine

January 2020 Volume 58, Issue 1, p1-164 http://www.ajpmonline.org/current [Reviewed earlier]

American Journal of Public Health

January 2020 110(1) http://ajph.aphapublications.org/toc/ajph/current [Reviewed earlier]

American Journal of Tropical Medicine and Hygiene

Volume 101, Issue 6, 2019 http://www.ajtmh.org/content/journals/14761645/101/6 [Reviewed earlier]

Annals of Internal Medicine

7 January 2020 Vol: 172, Issue 1 http://annals.org/aim/issue Editorials [Reviewed earlier]

BMC Cost Effectiveness and Resource Allocation

http://resource-allocation.biomedcentral.com/ (Accessed 18 Jan 2020) [No new digest content identified]

BMJ Global Health

January 2020 - Volume 5 - 1

https://gh.bmj.com/content/5/1

[Reviewed earlier]

BMC Health Services Research

http://www.biomedcentral.com/bmchealthservres/content (Accessed 18 Jan 2020) [No new digest content identified]

BMC Infectious Diseases

http://www.biomedcentral.com/bmcinfectdis/content (Accessed 18 Jan 2020)

Editorial

Filling the gaps in global antimicrobial resistance research/surveillance

Authors: Luis Furuya-Kanamori and Laith Yakob Citation: BMC Infectious Diseases 2020 20:39

Published on: 14 January 2020

BMC Medical Ethics

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

(Accessed 18 Jan 2020)

<u>Do patients and research subjects have a right to receive their genomic raw data?</u> <u>An ethical and legal analysis</u>

As Next Generation Sequencing technologies are increasingly implemented in biomedical research and (translational) care, the number of study participants and patients who ask for release of their genomic raw data is set to increase. This raises the question whether research participants and patients have a legal and moral right to receive their genomic raw data and, if so, how this right should be implemented into practice.

Authors: Christoph Schickhardt, Henrike Fleischer and Eva C. Winkler

Citation: BMC Medical Ethics 2020 21:7

Content type: Research article Published on: 16 January 2020

BMC Medicine

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

(Accessed 18 Jan 2020)

<u>Vaccinating children against influenza: overall cost-effective with potential for undesirable outcomes</u>

The present study aims to assess the cost-effectiveness of an influenza vaccination program for children in the Netherlands. This requires an evaluation of the long-term impact of such a program on the burden ...

Authors: Pieter T. de Boer, Jantien A. Backer, Albert Jan van Hoek and Jacco Wallinga

Citation: BMC Medicine 2020 18:11 Content type: Research article Published on: 14 January 2020

BMC Pregnancy and Childbirth

http://www.biomedcentral.com/bmcpregnancychildbirth/content (Accessed 18 Jan 2020) [No new digest content identified]

BMC Public Health

http://bmcpublichealth.biomedcentral.com/articles

(Accessed 18 Jan 2020)

<u>Using mobile phones to improve community health workers performance in low-and-middle-income countries</u>

In low-and-middle-income countries community health workers are the core component of the PHC system as they act as a liaison between the communities and the healthcare facilities. Evidence suggests that the s...

Authors: Anam Feroz, Rawshan Jabeen and Sarah Saleem

Citation: BMC Public Health 2020 20:49

Content type: Debate

Published on: 13 January 2020

<u>Factors affecting HBV vaccination in a Medical training College in Kenya: A mixed</u> methods Study

Hepatitis B Virus (HBV) is highly endemic in Sub-Saharan Africa with 70 to 90% of the population becoming infected before the age of 40 years. Healthcare workers (HCWs) including healthcare students (HCSs) are...

Authors: Anne Njeri Maina and Leah Chebet Bii

Citation: BMC Public Health 2020 20:48

Content type: Research article Published on: 13 January 2020

BMC Research Notes

http://www.biomedcentral.com/bmcresnotes/content (Accessed 18 Jan 2020)
[No new digest content identified]

BMJ Open

January 2020 - Volume 10 - 1 http://bmjopen.bmj.com/content/current [Reviewed earlier]

Bulletin of the World Health Organization

Volume 98, Number 1, January 2020, 1-76 https://www.who.int/bulletin/volumes/98/1/en/ [Reviewed earlier]

Child Care, Health and Development

Volume 46, Issue 1 Pages: 1-153 January 2020 https://onlinelibrary.wiley.com/toc/13652214/current [Reviewed earlier]

Clinical Therapeutics

December 2019 Volume 41, Issue 12, p2461-2680 http://www.clinicaltherapeutics.com/current [Reviewed earlier]

Clinical Trials

Volume 16 Issue 6, December 2019 https://journals.sagepub.com/toc/ctja/16/6 [Reviewed earlier]

Conflict and Health

http://www.conflictandhealth.com/ [Accessed 18 Jan 2020] [No new digest content identified]

Contemporary Clinical Trials

Volume 88 January 2020 https://www.sciencedirect.com/journal/contemporary-clinical-trials/vol/88/suppl/C [Reviewed earlier]

The CRISPR Journal

Volume 2, Issue 6 / December 2019 https://www.liebertpub.com/toc/crispr/2/6 [Reviewed earlier]

Current Genetic Medicine Reports

Volume 7, Issue 4, December 2019 https://link.springer.com/journal/40142/7/4 [Reviewed earlier]

Current Opinion in Infectious Diseases

February 2020 - Volume 33 - Issue 1 https://journals.lww.com/co-infectiousdiseases/pages/currenttoc.aspx [Reviewed earlier]

Developing World Bioethics

Volume 19, Issue 4 Pages: 187-247 December 2019 https://onlinelibrary.wiley.com/toc/14718847/current [Reviewed earlier]

Development in Practice

Volume 29, Issue 8, 2019 http://www.tandfonline.com/toc/cdip20/current [Reviewed earlier]

Disaster Medicine and Public Health Preparedness

Volume 13 - Issue 5-6 - December 2019 https://www.cambridge.org/core/journals/disaster-medicine-and-public-health-preparedness/ [Reviewed earlier]

Disasters

Volume 44, Issue 1 Pages: 1-232 January 2020 https://onlinelibrary.wiley.com/toc/14677717/current [Reviewed earlier]

EMBO Reports

Volume 21 Issue 1 7 January 2020 https://www.embopress.org/toc/14693178/current Editorial 23 December 2019 Free Access Registered animal studies and null data

Bernd Pulverer

EMBO Press encourages to document or pre-register animal experiments on the new Animal Study Registry to increase reproducibility and efficacy of animal research.

Science & Society 23 December 2019 Open Access

Rethinking the incentive system in science: animal study registries: Preregistering experiments using animals could greatly improve transparency and reliability of biomedical studies and improve animal welfare

<u>Céline Heinl</u>, <u>Justyna Chmielewska</u>, <u>Anastasia Olevska</u>, <u>Barbara Grune</u>, <u>Gilbert Schönfelder</u>, Bettina Bert

The Animal Study Registry offers scientists a range of benefits by preregistering their studies. Wider adoption could address the reproducibility problem in biomedical research and enhance animal welfare.

Emerging Infectious Diseases

Volume 26, Number 1—January 2020

http://wwwnc.cdc.gov/eid/ [Reviewed earlier]

Epidemics

Volume 29 December 2019 https://www.sciencedirect.com/journal/epidemics/vol/29/suppl/C [Reviewed earlier]

Epidemiology and Infection

Volume 148 - 2020

https://www.cambridge.org/core/journals/epidemiology-and-infection/latest-issue [New issue; No digest content identified]

Ethics & Human Research

Volume 41, Issue 6 November–December 2019
https://onlinelibrary.wiley.com/toc/25782363/current **Trial Design, Stakeholder Perspectives, Pregnancy and Research**[Reviewed earlier]

The European Journal of Public Health

Volume 29, Issue 6, December 2019 https://academic.oup.com/eurpub/issue/29/6 [Reviewed earlier]

Gates Open Research

https://gatesopenresearch.org/browse/articles [Accessed 18 Jan 2020] [No new digest content identified]

Genome Medicine

https://genomemedicine.biomedcentral.com/articles [Accessed 18 Jan 2020] [No new digest content identified]

Global Health Action

Volume 12, 2019 Issue 1 https://www.tandfonline.com/toc/zgha20/12/sup1?nav=tocList [No new digest content identified]

Global Health: Science and Practice (GHSP)

Vol. 7, No. 4 December 23, 2019 http://www.ghspjournal.org/content/current [Reviewed earlier]

Global Public Health

Volume 15, 2020 Issue 1 http://www.tandfonline.com/toc/rgph20/current [Reviewed earlier]

Globalization and Health

http://www.globalizationandhealth.com/

[Accessed 18 Jan 2020]

<u>Spatial and temporal distribution of infectious disease epidemics, disasters and other potential public health emergencies in the World Health Organisation Africa region, 2016–2018</u>

Emerging and re-emerging diseases with pandemic potential continue to challenge fragile health systems in Africa, creating enormous human and economic toll. To provide evidence for the investment case for publ...

Authors: Ambrose Otau TALISUNA, Emelda Aluoch OKIRO, Ali Ahmed YAHAYA, Mary STEPHEN, Boukare BONKOUNGOU, Emmanuel Onuche MUSA, Etienne Magloire MINKOULOU, Joseph OKEIBUNOR, Benido IMPOUMA, Haruna Mamoudou DJINGAREY, N'da Konan Michel YAO, Sakuya OKA, Zabulon YOTI and Ibrahima Socé FALL

Content type: Research

15 January 2020

Methods to promote equity in health resource allocation in low- and middle-income countries: an overview

Unfair differences in healthcare access, utilisation, quality or health outcomes exist between and within countries around the world. Improving health equity is a stated objective for many governments and inte...

Authors: James Love-Koh, Susan Griffin, Edward Kataika, Paul Revill, Sibusiso Sibandze and

Simon Walker

Content type: Review 13 January 2020

Health Affairs

Vol. 39, No. 1 January 2020 https://www.healthaffairs.org/toc/hlthaff/current **Patient Costs, Bundled Payment & More** [New issue; No digest content identified]

Health and Human Rights

Volume 21, Issue 2, December 2019 https://www.hhrjournal.org/volume-21-issue-2-december-2019/ Special Section: Abortion in the Middle East and North Africa

Special Section: Abortion Law Reform

Special Section: Human Rights for Health across the United Nations

[Reviewed earlier]

Health Economics, Policy and Law

Volume 15 - Issue 1 - January 2020 https://www.cambridge.org/core/journals/health-economics-policy-and-law/latest-issue [Reviewed earlier]

Health Policy and Planning

Volume 34, Issue Supplement_3, December 2019 https://academic.oup.com/heapol/issue/34/Supplement_3

Access to Medicines through Health Systems in Low- and Middle-Income Countries
[Reviewed earlier]

Health Research Policy and Systems

http://www.health-policy-systems.com/content [Accessed 18 Jan 2020] [No new digest content identified]

Human Gene Therapy

Volume 30, Issue 12 / December 2019 https://www.liebertpub.com/toc/hum/30/12 [Reviewed earlier]

Humanitarian Exchange Magazine

Number 75, May 2019

https://odihpn.org/magazine/making-humanitarian-action-work-for-women-and-girls/

Special Feature: Making humanitarian action work for women and girls by HPN May 2019

The theme of this edition of Humanitarian Exchange, co-edited with Women Deliver, is making humanitarian action work for women and girls. Despite gains, including commitments made at the World Humanitarian Summit, there is still much to be done to address the gendered impacts of humanitarian crises and improve gender-sensitive humanitarian action.

In the lead article, <u>Jacqueline Paul</u> advocates for feminist humanitarian action based on evidence that improvements in women's socio-economic status can reduce excess mortality among women after shocks. <u>Jean Kemitare, Juliet Were and Jennate Eoomkham</u> look at the role of local women's rights organisations in preventing and responding to violence against women and girls, and <u>Marcy Hersh and Diana Abou Abbas</u> highlight opportunities for more concrete action on sexual and reproductive health in emergencies.

Citing experience from Vanuatu, <u>Jane Newnham</u> explains how women will choose to use contraceptives even during a humanitarian response, when services and counselling are delivered in an appropriate and responsive way. Drawing on experience in Bangladesh, <u>Tamara Fetters and colleagues</u> challenge the belief that abortion is a non-essential service, or too complicated for humanitarian actors to provide. <u>Darcy Ataman, Shannon Johnson, Justin Cikuru and Jaime Cundy</u> reflect on an innovative programme using music therapy to help survivors of trauma.

Emilie Rees Smith, Emma Symonds and Lauryn Oates highlight lessons from the STAGE education programme in Afghanistan, and <u>Degan Ali and Dega Saleh</u> outline how African Development Solutions is helping women and girls take on leadership and decision-making roles in Somalia. <u>Fiona Samuels and Taveeshi Gupta</u> explore patterns of suicide among young people in Vietnam, with a particular focus on girls, and <u>Subhashni Raj</u>, <u>Brigitte Laboukly and Shantony Moli</u> illustrate the importance of a gendered approach to community-based disaster risk reduction in the South-West Pacific. <u>Nicola Jones</u>, <u>Workneh Yadete and Kate Pincock</u> draw on research in Ethiopia to explore the gender- and age-specific vulnerabilities of adolescents. The edition ends with an article by <u>Julie Rialet-Cislaghi</u> on how humanitarian responses can better address child marriage.

[Reviewed earlier]

Human Vaccines & Immunotherapeutics (formerly Human Vaccines)

Volume 15, Issue 12, 2019 http://www.tandfonline.com/toc/khvi20/current [Reviewed earlier]

Infectious Agents and Cancer

http://www.infectagentscancer.com/content [Accessed 18 Jan 2020] [No new digest content identified]

Infectious Diseases of Poverty

http://www.idpjournal.com/content [Accessed 18 Jan 2020] [No new digest content identified]

International Health

Volume 11, Issue Supplement_1, November 2019 https://academic.oup.com/inthealth/issue/11/6 [Reviewed earlier]

International Journal of Community Medicine and Public Health

Vol 7, No 1 (2020) January 2020 https://www.ijcmph.com/index.php/ijcmph/issue/view/58

[Reviewed earlier]

International Journal of Epidemiology

Volume 48, Issue 6, December 2019 https://academic.oup.com/ije/issue/48/6 [Reviewed earlier]

International Journal of Human Rights in Healthcare

Volume 12 Issue 5 https://www.emerald.com/insight/publication/issn/2056-4902/vol/12/iss/5 [Reviewed earlier]

International Journal of Infectious Diseases

January 2020 Volume 90, p1-242 https://www.ijidonline.com/issue/S1201-9712(19)X0019-3 [Reviewed earlier]

JAMA

January 14, 2020, Vol 323, No. 2, Pages 105-196 http://jama.jamanetwork.com/issue.aspx Special Communication

FDA Approval and Regulation of Pharmaceuticals, 1983-2018

Jonathan J. Darrow, SJD, JD, MBA; Jerry Avorn, MD; Aaron S. Kesselheim, MD, JD, MPH JAMA. 2020;323(2):164-176. doi:10.1001/jama.2019.20288 Key Points

Question How has the regulation of prescription drugs evolved from the 1980s to 2018, and what trends have occurred in drug approvals?

Findings Approvals of new generic drugs have increased over time, leading to greater competition. Technological advances have been reflected in increased approvals of biologics over time. The number of expedited development and approval programs has expanded greatly since 1983, reducing the amount of evidence available at the time of approval and increasing uncertainty about the existence or amount of clinical benefit. These regulatory innovations have not clearly led to an increase in new drug approvals or to reduced total development times.

Meaning While retaining policies that encourage efficient review, Congress and other government officials should also consider the implications of less rigorous clinical outcome requirements and whether the current complex array of regulatory programs should be simplified.

Abstract

Importance US law requires testing of new drugs before approval to ensure that they provide a well-defined benefit that is commensurate with their risks. A major challenge for the US Food and Drug Administration (FDA) is to achieve an appropriate balance between rigorous testing and the need for timely approval of drugs that have benefits that outweigh their risks.

Objective To describe the evolution of laws and standards affecting drug testing, the use of new approval programs and standards, expansions of the role and authority of the FDA, and changes in the number of drugs approved from the 1980s to 2018.

Evidence Sources of evidence included principal federal laws and FDA regulations (1962-2018) and FDA databases of approved new drugs (1984-2018), generic drugs (1970-2018), biologics (1984-2018), and vaccines (1998-2018); special development and approval programs (Orphan drug [1984-2018], Fast-Track [1988-2018], Priority Review and its predecessors [1984-2018], Accelerated Approval [1992-2018], and Breakthrough Therapy [2012-2018]); expanded access (2010-2017) and Risk Evaluation and Mitigation Strategies (2008-2018); and user fees paid to the FDA by industry (1993-2018).

Findings From 1983 to 2018, legislation and regulatory initiatives have substantially changed drug approval at the FDA. The mean annual number of new drug approvals, including biologics, was 34 from 1990-1999, 25 from 2000-2009, and 41 from 2010-2018. New biologic product approvals increased from a median of 2.5 from 1990-1999, to 5 from 2000-2013, to 12 from 2014-2018. The median annual number of generic drugs approved was 136 from 1970 to the enactment of the Hatch-Waxman Act in 1984; 284 from 1985 to the enactment of the Generic Drug User Fee Act in 2012; and 588 from 2013-2018. Prescription drug user fee funding expanded from new drugs and biologics in 1992 to generic and biosimilar drugs in 2012. The amount of Prescription Drug User Fee Act fees collected from industry increased from an annual mean of \$66 million in 1993-1997 to \$820 million in 2013-2017, and in 2018, user fees accounted for approximately 80% of the salaries of review personnel responsible for the approval of new drugs. The proportion of drugs approved with an Orphan Drug Act designation increased from 18% (55/304) in 1984-1995, to 22% (82/379) in 1996-2007, to 41% (154/380) in 2008-2018. Use of Accelerated Approval, Fast-Track, and Priority Review for new drugs has increased over time, with 81% (48/59) of new drugs benefiting from at least 1 such expedited program in 2018. The proportion of new approvals supported by at least 2 pivotal trials decreased from 80.6% in 1995-1997 to 52.8% in 2015-2017, based on 124 and 106 approvals, respectively, while the median number of patients studied did not change significantly (774 vs 816). FDA drug review times declined from more than 3 years in 1983 to less than 1 year in 2017, but total time from the authorization of clinical testing to approval has remained at approximately 8 years over that period.

Conclusions and Relevance Over the last 4 decades, the approval and regulation processes for pharmaceutical agents have evolved and increased in complexity as special programs have been added and as the use of surrogate measures has been encouraged. The FDA funding needed to implement and manage these programs has been addressed by expanding industry-paid user fees. The FDA has increasingly accepted less data and more surrogate measures, and has shortened its review times.

Viewpoint

<u>Treatment Decisions for a Future SelfEthical Obligations to Guide Truly Informed</u> Choices

Claire J. Creutzfeldt, MD; Robert G. Holloway, MD, MPH JAMA. 2020;323(2):115-116. doi:10.1001/jama.2019.19652

This Viewpoint discusses the reality that most decisions about treatment for incapacitated patients involve surrogate assessments of patients' past values at their baseline health, and it proposes that more ethical and informed decision-making would help surrogates consider the degree to which their loved one might be able to adapt to and value a future health state at what is a higher level of disability.

JAMA Pediatrics

January 2020, Vol 174, No. 1, Pages 1-108 http://archpedi.jamanetwork.com/issue.aspx [Reviewed earlier]

JBI Database of Systematic Review and Implementation Reports

December 2019 - Volume 17 - Issue 12 https://journals.lww.com/jbisrir/Pages/currenttoc.aspx [Reviewed earlier]

Journal of Adolescent Health

December 2019 Volume 65, Issue 6, Supplement, S1-S62 https://www.jahonline.org/issue/S1054-139X(19)X0005-1

Adolescent Sexual and Reproductive Health and Rights: Progress in the 25 Years Since the International Conference on Population and Development and Prospects for the Next 25 years

[Reviewed earlier]

Journal of Community Health

Volume 45, Issue 1, February 2020 https://link.springer.com/journal/10900/45/1 [Reviewed earlier]

Journal of Development Economics

Volume 142, January 2020
https://www.sciencedirect.com/journal/journal-of-development-economics/vol/142/suppl/C
Special Issue on papers from "10th AFD-World Bank Development Conference held at CERDI, Clermont-Ferrand, on June 30 - July 1, 2017"

Edited by Caglar Ozden, David McKenzie, Hillel Rapoport [Reviewed earlier]

Journal of Empirical Research on Human Research Ethics

Volume 14 Issue 5, December 2019
http://journals.sagepub.com/toc/jre/current

**Special Issue: Empirical Studies in Empirical Ethics

[Reviewed earlier]

Journal of Epidemiology & Community Health

January 2020 - Volume 74 - 1 https://jech.bmj.com/content/74/1

[Reviewed earlier]

Journal of Evidence-Based Medicine

Volume 14 Issue 5, December 2019

https://onlinelibrary.wiley.com/toc/17565391/current

Special Issue: Why Ethically Reflect on Empirical Studies in Empirical Ethics? Case

Studies and Commentaries

[Reviewed earlier]

Journal of Global Ethics

Volume 15, Issue 3, 2019 http://www.tandfonline.com/toc/rjge20/current **Special Issue: Global Justice and Childhood** [Reviewed earlier]

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

Volume 30, Number 4, November 2019, Supplement https://muse.jhu.edu/issue/41320 [Reviewed earlier]

Journal of Immigrant and Minority Health

Volume 22, Issue 1, February 2020 https://link.springer.com/journal/10903/22/1 [Reviewed earlier]

Journal of Immigrant & Refugee Studies

Volume 18, 2020_ Issue 1 https://www.tandfonline.com/toc/wimm20/current [Reviewed earlier]

Journal of Infectious Diseases

Volume 220, Issue 6, 15 September 2019 https://academic.oup.com/jid/issue/220/6 [Reviewed earlier]

Journal of Medical Ethics

January 2020 - Volume 46 - 1
http://jme.bmj.com/content/current
[New issue; No digest content identified]

Journal of Patient-Centered Research and Reviews

Volume 6, Issue 4 (2019) https://digitalrepository.aurorahealthcare.org/jpcrr/ [Reviewed earlier]

Journal of Pediatrics

January 2020 Volume 216, p1-258 http://www.jpeds.com/current Editorials

<u>The Road to Precision Medicine for Children: Resilience, Vulnerability, and Gene Polymorphism</u>

Benard P. Dreyer

p11–12 Published online: September 18, 2019

Journal of Pharmaceutical Policy and Practice

https://joppp.biomedcentral.com/ [Accessed 18 Jan 2020] [No new digest content identified]

Journal of Public Health Management & Practice

January/February 2020 - Volume 26 - Issue 1 https://journals.lww.com/jphmp/pages/currenttoc.aspx [Reviewed earlier]

Journal of Public Health Policy

Volume 40, Issue 4, December 2019 https://link.springer.com/journal/41271/40/4 [Reviewed earlier]

Journal of Refugee & Global Health

Volume 2, Issue 2 (2019) https://ir.library.louisville.edu/rgh/ [Reviewed earlier]

Journal of the Royal Society – Interface

01 January 2020 Volume 17Issue 162 https://royalsocietypublishing.org/toc/rsif/current [Reviewed earlier]

Journal of Travel Medicine

Volume 26, Issue 8, 2019

https://academic.oup.com/jtm/issue/26/8 [Reviewed earlier]

Journal of Virology

February 2020; Volume 94, Issue 3 http://jvi.asm.org/content/current [New issue; No digest content identified]

The Lancet

Jan 18, 2020 Volume 395Number 10219p165-246, e6-e13 https://www.thelancet.com/journals/lancet/issue/current *Viewpoint*

<u>Monitoring the health-related Sustainable Development Goals: lessons learned and recommendations for improved measurement</u>

Samira Asma, Rafael Lozano, Somnath Chatterji, Soumya Swaminathan, Maria de Fátima Marinho, Naoko Yamamoto, Elena Varavikova, Awoke Misganaw, Michael Ryan, Lalit Dandona, Ren Minghui, Christopher J L Murray

The UN General Assembly launched the Sustainable Development Goals (SDGs) in September, 2015.1 The original global SDG framework included 17 goals, 169 targets, and 232 unique indicators.2 Of these, 12 goals, 33 targets, and 57 indicators have been identified as health-related SDGs (HRSDGs),3,4,5,6 that is, pertaining to health outcomes, health services, and well-established environmental, occupational, behavioural, and metabolic risks. The scope of health in the SDGs is much broader than in the Millennium Development Goals, spanning from maternal and child health and infectious diseases to non-communicable diseases, injuries, risk factors, and health-system functions. Regular monitoring of the HRSDGs is important for fostering a shared notion of accountability for results, identifying important gaps in resources and rates of progress, and taking into account emerging challenges that can influence the trajectory of progress. Regular monitoring and accountability will be essential to sustain policy focus and funding for the broad and complex HRSDG agenda.

The Lancet Child & Adolescent Health

<u>Volume 4, ISSUE 1</u>, P1, January 01, 2020 <u>https://www.thelancet.com/journals/lanchi/issue/current</u> [Reviewed earlier]

Lancet Digital Health

Volume 2, ISSUE 1, Pe1, January 01, 2020 https://www.thelancet.com/journals/landig/issue/current [Reviewed earlier]

Lancet Global Health

Volume 8, ISSUE 1, Pe1, January 01, 2020 http://www.thelancet.com/journals/langlo/issue/current

[Reviewed earlier]

Lancet Infectious Diseases

<u>Volume 20, ISSUE 1</u>, P1, January 01, 2020 <u>http://www.thelancet.com/journals/laninf/issue/current</u> [Reviewed earlier]

Lancet Respiratory Medicine

Volume 8, ISSUE 1, P1, January 01, 2020 http://www.thelancet.com/journals/lanres/issue/current [Reviewed earlier]

Maternal and Child Health Journal

Volume 24, Issue 1, January 2020 https://link.springer.com/journal/10995/24/1 [New issue; No digest content identified]

Medical Decision Making (MDM)

Volume 39 Issue 8, November 2019 http://mdm.sagepub.com/content/current [Reviewed earlier]

The Milbank Quarterly

A Multidisciplinary Journal of Population Health and Health Policy Volume 97, Issue 4 Pages: 881-1242 December 2019 https://onlinelibrary.wiley.com/toc/14680009/current [Reviewed earlier]

Nature

Volume 577 Issue 7790, 16 January 2020 http://www.nature.com/nature/current_issue.html Review Article | 15 January 2020

The arms race between bacteria and their phage foes

Understanding the dynamics between bacteria and bacteriophages could enable the development of phage-based therapies and biotechnological tools and provide insights into the ecology and evolution of these microorganisms.

Hannah G. Hampton, Bridget N. J. Watson & Peter C. Fineran

Nature Biotechnology

Volume 38 Issue 1, January 2020 https://www.nature.com/nbt/volumes/38/issues/1

[Reviewed earlier]

Nature Genetics

Volume 52 Issue 1, January 2020 https://www.nature.com/ng/volumes/52/issues/1 Editorial | 07 January 2020

Navigating 2020 and beyond

As we usher in a new year of a new decade and ponder what the future will bring for the genetics field, we wish to reflect on some specific areas related to diversity, privacy and genome editing that require attention and vigilance from the community.

Comment | 25 November 2019

Returning incidental findings in African genomics research

Ancestral and geographical issues underlie the need to develop Africa-specific guidelines for the return of genomics research results in Africa. In this Commentary, we outline the challenges that will inform policies and practices in the future.

Ambroise Wonkam & Jantina de Vries

Comment | 23 December 2019

A call for global action for rare diseases in Africa

The 11th International Conference on Rare Diseases and Orphan Drugs (ICORD), South Africa, included the Africa-Rare initiative launch and facilitated multi-stakeholder engagement in the challenges facing, and opportunities for, Africans living with rare diseases. The following ICORD Global Call to Action, developed in collaboration with the International Rare Diseases Research Consortium, synthesizes the outcomes of the deliberations and emphasizes the international collaborative efforts required to address the global effects of rare diseases on public health. Gareth S. Baynam, Stephen Groft[...] & Manuel Posada

Nature Medicine

Volume 26 Issue 1, January 2020 https://www.nature.com/nm/volumes/26/issues/1 *Editorial* | 13 January 2020

Big hopes for big data

Large-scale multi-modal information on patients' health is ever increasing, providing an opportunity to use big data for taking individualized medicine to a global scale.

Review Article | 13 January 2020

Axes of a revolution: challenges and promises of big data in healthcare

Health data are being generated and collected at an unprecedented scale, but whether big data will truly revolutionize healthcare is still a matter of much debate.

Smadar Shilo, Hagai Rossman & Eran Segal

Nature Reviews Genetics

Volume 21 Issue 1, January 2020 https://www.nature.com/nrg/volumes/21/issues/1

[Reviewed earlier]

Nature Reviews Immunology

Volume 20 Issue 1, January 2020 https://www.nature.com/nri/volumes/20/issues/1 [Reviewed earlier]

New England Journal of Medicine

January 16, 2020 Vol. 382 No. 3
http://www.nejm.org/toc/nejm/medical-journal
[New issue, No digest content identified]

Pediatrics

January 01, 2020; Volume 145,Issue 1 https://pediatrics.aappublications.org/content/145/1 [Reviewed earlier]

Pharmaceutics

Volume 11, Issue 12 (December 2019) https://www.mdpi.com/1999-4923/11/12 [Reviewed earlier]

PharmacoEconomics

Volume 38, Issue 1, January 2020 https://link.springer.com/journal/40273/38/1 [New issue, No digest content identified]

PLoS Genetics

https://journals.plos.org/plosgenetics/ (Accessed 18 Jan 2020) [No new digest content identified]

PLoS Medicine

http://www.plosmedicine.org/ (Accessed 18 Jan 2020) [No new digest content identified]

PLoS Neglected Tropical Diseases

http://www.plosntds.org/ (Accessed 18 Jan 2020)

<u>Characterization and analytical validation of a new antigenic rapid diagnostic test</u> <u>for Ebola virus disease detection</u>

Céline Couturier, Atsuhiko Wada, Karen Louis, Maxime Mistretta, Benoit Beitz, Moriba Povogui, Maryline Ripaux, Charlotte Mignon, Bettina Werle, Adrien Lugari, Delphine Pannetier, Sabine Godard, Anne Bocquin, Stéphane Mely, Ismaël Béavogui, Jean Hébélamou, David Leuenberger, Philippe Leissner, Takeshi Yamamoto, Patrick Lécine, Christophe Védrine, Julie Chaix Research Article | published 17 Jan 2020 PLOS Neglected Tropical Diseases https://doi.org/10.1371/journal.pntd.0007965

PLoS One

http://www.plosone.org/ (Accessed 18 Jan 2020)

<u>Family Health Days program contributions in vaccination of unreached and underimmunized children during routine vaccinations in Uganda</u>

Ezekiel Mupere, Harriet M. Babikako, Violet Okaba-Kayom, Robert B. Mutyaba, Milton Nasiero Mwisaka, Emmanuel Tenywa, Albert Lule, Jane Ruth Aceng, Flavia Mpanga-Kaggwa, David Matseketse, Eresso Aga

Research Article | published 17 Jan 2020 PLOS ONE https://doi.org/10.1371/journal.pone.0218239

<u>Correction: Limited indirect effects of an infant pneumococcal vaccination program in an aging population</u>

Mark van der Linden, Matthias Imöhl, Stephanie Perniciaro Correction | published 16 Jan 2020 PLOS ONE https://doi.org/10.1371/journal.pone.0228126

<u>Constructing and influencing perceived authenticity in science communication:</u> <u>Experimenting with narrative</u>

Lise Saffran, Sisi Hu, Amanda Hinnant, Laura D. Scherer, Susan C. Nagel Research Article | published 15 Jan 2020 PLOS ONE https://doi.org/10.1371/journal.pone.0226711

PLoS Pathogens

http://journals.plos.org/plospathogens/ [Accessed 18 Jan 2020] [No new digest content identified]

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

http://www.pnas.org/content/early/ [Accessed 18 Jan 2020] [No new digest content identified]

Prehospital & Disaster Medicine

Volume 34 - Issue 6 - December 2019 https://www.cambridge.org/core/journals/prehospital-and-disaster-medicine/latest-issue [Reviewed earlier]

Preventive Medicine

Volume 130 January 2020 https://www.sciencedirect.com/journal/preventive-medicine/vol/130/suppl/C [Reviewed earlier]

Proceedings of the Royal Society B

15 January 2020 Volume 287Issue 1918 https://royalsocietypublishing.org/toc/rspb/current Review articles

The ecology of human-nature interactions

Masashi Soga and Kevin J. Gaston

Published:15 January 2020Article ID:20191882

The direct interactions between people and nature are critically important in many ways, with growing attention particularly on their impacts on human health and wellbeing (both positive and negative), on people's attitudes and behaviour towards nature, ...

Public Health

Volume 177 Pages A1-A4, 1-144 (December 2019) https://www.sciencedirect.com/journal/public-health/vol/177/suppl/C [Reviewed earlier]

Public Health Ethics

Volume 12, Issue 3, November 2019 http://phe.oxfordjournals.org/content/current [Reviewed earlier]

Public Health Reports

Volume 135 Issue 1, January 2020 https://journals.sagepub.com/toc/phrg/135/1 [New issue, No digest content identified]

Qualitative Health Research

Volume 30 Issue 2, January 2020 http://qhr.sagepub.com/content/current [Reviewed earlier]

Research Ethics

Volume 15 Issue 3-4, July-October 2019 http://journals.sagepub.com/toc/reab/current [Reviewed earlier]

Reproductive Health

http://www.reproductive-health-journal.com/content [Accessed 18 Jan 2020] [No new digest content identified]

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

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

Risk Analysis

Volume 40, Issue 1 Pages: 1-214 January 2020 https://onlinelibrary.wiley.com/toc/15396924/current

Special Issue: Engineering Systems and Risk Analytics

[Reviewed earlier]

Risk Management and Healthcare Policy

https://www.dovepress.com/risk-management-and-healthcare-policy-archive56 [Accessed 18 Jan 2020] [No new digest content identified]

Science

17 January 2020 Vol 367, Issue 6475 http://www.sciencemag.org/current.dtl Feature

Transparency on trial

Bv Charles Piller

Science17 Jan 2020 : 240-243 Full Access

Many clinical trial results aren't posted publicly, as U.S. law requires—and a promised crackdown has fizzled.

Summary

Companies, universities, and other institutions that conduct clinical trials are required to record the results of most of them in a federal database, so that doctors and patients can see whether new treatments are safe and effective. But a Science investigation has found that many persist in not reporting those results, and the U.S. Food and Drug Administration (FDA) and National Institutes of Health (NIH) are doing little to nothing to enforce the reporting requirement—despite recent promises to the contrary. While many pharma companies have improved their reporting of trial results over the past few years, a large number of universities and academic

medical centers continue to have bad records. Ironically, NIH itself is part of the problem—its top institutes for clinical trials have a poor record of reporting results of those trials for which they are responsible. Science checked all 4768 trials whose results have come due under legal requirements finalized by NIH and FDA 3 years ago. Overall, sponsors violated the reporting law more than 55% of the time. Yet FDA has never fined a trial sponsor for noncompliance and NIH has never publicly named or withdrawn a grant from violators, although such actions were vowed in 2016 when ClinicalTrials.gov's requirements were clarified.

Science Translational Medicine

15 January 2020 Vol 12, Issue 526 https://stm.sciencemag.org/
[New issue; No digest content identified]

Social Science & Medicine

Volume 245 January 2020 https://www.sciencedirect.com/journal/social-science-and-medicine/vol/245/suppl/C [Reviewed earlier]

Systematic Reviews

https://systematicreviewsjournal.biomedcentral.com/articles [Accessed 18 Jan 2020] [No new digest content identified]

Travel Medicine and Infectious Diseases

Volume 32 November–December 2019 https://www.sciencedirect.com/journal/travel-medicine-and-infectious-disease/vol/32/suppl/C [Reviewed earlier]

Tropical Medicine & International Health

Volume 24, Issue 12 Pages: i-iv, 1341-1475 December 2019 https://onlinelibrary.wiley.com/toc/13653156/current [Reviewed earlier]

Vaccine

Volume 38, Issue 4 Pages 709-950 (22 January 2020) https://www.sciencedirect.com/journal/vaccine/vol/38/issue/4 Discussion No access

<u>Words matter: Vaccine hesitancy, vaccine demand, vaccine confidence, herd immunity and mandatory vaccination</u>

Matthew Z. Dudley, Lois Privor-Dumm, Ève Dubé, Noni E. MacDonald Pages 709-711

Short communication Abstract only

An intervention for increasing HPV vaccination on a university campus

Mary A. Gerend, Caitlyn Murdock, Kelly Grove Pages 725-729

Research article Abstract only

<u>Genotype distribution of Group A rotavirus in children before and after massive vaccination in Latin America and the Caribbean: Systematic review</u>

Juan Ignacio Degiuseppe, Juan Andrés Stupka

Pages 733-740

Research article Abstract only

<u>Perception of mandatory infant vaccines and trust in vaccination among first-year healthcare students: An opportunity window for the training of future healthcare workers</u>

Lola Daudel, Jessica Mary, Olivier Epaulard Pages 794-799

Research article Abstract only

<u>First year allopathic medical student attitudes about vaccination and vaccine hesitancy</u>

Emily Onello, Samantha Friedrichsen, Kristine Krafts, Glenn Simmons, Kevin Diebel Pages 808-814

Research article Abstract only

<u>Strengthening vaccination frameworks: Findings of a study on the legal foundations of National Immunization Technical Advisory Groups (NITAGs)</u>

Shawn H.E. Harmon, David Faour, Noni E. MacDonald, Janice Graham, ... Stephanie Shendale Pages 840-846

Vaccines — Open Access Journal

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

(Accessed 18 Jan 2020)

Open Access Article

Human Papillomavirus (HPV) Vaccine Uptake and the Willingness to Receive the HPV Vaccination among Female College Students in China: A Multicenter Study

by <u>Dingyun You</u>, <u>Liyuan Han</u>, <u>Lian Li</u>, <u>Jingcen Hu</u>, <u>Gregory D. Zimet</u>, <u>Haridah Alias</u>, Mahmoud Danaee, Le Cai, Fangfang Zeng and Li Ping Wong

Vaccines 2020, 8(1), 31; https://doi.org/10.3390/vaccines8010031 - 16 Jan 2020 Abstract

Background: This study aimed to determine human papillomavirus (HPV) vaccine uptake and willingness to receive HPV vaccination among female college students, in China, and its associated factors. Methods: An online cross-sectional survey of female college students across the eastern, central, and western regions of China was undertaken between April and September 2019. Partial least squares structural equation modeling (PLS-SEM) was used to examine factors associated with the HPV vaccine uptake and willingness to receive the HPV vaccine. Results: Among the total 4220 students who participated in this study, 11.0% reported

having been vaccinated against HPV. There are direct effects of indicators of higher socioeconomic status, older age ($\beta = 0.084$ and p = 0.006), and geographical region (residing in Eastern China, $\beta = 0.033$, and p = 0.024) on HPV vaccine uptake. Higher knowledge ($\beta =$ 0.062 and p < 0.000) and perceived susceptibility (β = 0.043 and p = 0.002) were also predictors of HPV vaccine uptake. Of those who had not received the HPV vaccine, 53.5% expressed a willingness to do so. Likewise, social economic status indicators were associated with the willingness to receive the HPV vaccine. Total knowledge score (β = 0.138 and p < 0.001), both perceived susceptibility ($\beta = 0.092$ and p < 0.001) and perceived benefit ($\beta =$ 0.088 and p < 0.001), and sexual experience (β = 0.041 and p = 0.007) had a positive and significant direct effect on the willingness to receive the HPV vaccine, while perceived barriers $(\beta = -0.071 \text{ and p} < 0.001)$ had a negative effect on the willingness to receive the HPV vaccine. Conclusions: Geographical region and socioeconomic disparities in the HPV vaccination uptake rate and willingness to receive the HPV vaccine provide valuable information for public health planning that aims to improve vaccination rates in underserved areas in China. The influence of knowledge and perceptions of HPV vaccination suggests the importance of communication for HPV immunization.

Value in Health

January 2020 Volume 23, Issue 1, p1-138 https://www.valueinhealthjournal.com/issue/S1098-3015(20)X0002-7 [New issue; No digest content identified]

Viruses

Volume 11, Issue 12 (December 2019) https://www.mdpi.com/1999-4915/11/12 [Reviewed earlier]

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<u>From Google Scholar & other sources: Selected Journal Articles, Newsletters, Dissertations, Theses, Commentary</u>

International Journal for Equity in Health

19, Article number: 10 (2020

The impact of vaccination on gender equity: conceptual framework and human papillomavirus (HPV) vaccine case study

A Portnoy, S Clark, S Ozawa, M Jit -

Although the beneficial effects of vaccines on equity by socioeconomic status and geography are increasingly well-documented, little has been done to extend these analyses to examine the linkage between vaccination and gender equity. In this paper, evidence from the published literature is used to develop a conceptual framework demonstrating the potential impact of vaccination on measures of gender equity. This framework is then applied to human

papillomavirus (HPV) vaccination in three countries with different economic and disease burden profiles to establish a proof of concept in a variety of contexts.

International Journal of Nursing Science Practice and Research

Vol 5, No 2 (2019)

Exploring Vaccine Hesitancy

CE Fisher

Abstract

According to the World Health Organization, the coverage of vaccine-preventable diseases rests at 86% with nearly 20 million children worldwide who have not received basic vaccines. Vaccine-hesitant individuals are a heterogeneous group who hold varying degrees of indecision about specific vaccines or vaccination in general. Vaccine hesitancy is a behavior influenced by several factors including issues of confidence, complacency, and convenience. In countries where access is not the main issue for lack of vaccination, there are many cultural influences that affect the decision for parents to seek vaccination for their children or themselves. Media and social media can create a negative or positive vaccine sentiment and can provide a platform for lobbies and key opinion leaders to influence others. Community leaders and influencers, including religious leaders in some settings, celebrities in others, can all have a significant influence on vaccine acceptance or hesitancy. Vaccine mandates can provoke vaccine hesitancy not necessarily because of safety or other concerns, but due to resistance to the notion of forced vaccination. Lastly, the pharmaceutical industry may be distrusted and influence vaccine hesitancy when perceived as driven only by financial motives and not by public health interest. This can extend to distrust in government when perceived that it also is being pushed by industry and is not transparent. When working with patients faced with the decision of whether vaccination will be undertaken, it is imperative to understand the cultural, ethical, and legal implications that may affect their decision. Working from a place of understanding and acceptance of various views and beliefs about vaccination, nurses can be better advocates for the wishes of their patients.

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<u> Media/Policy Watch</u>

This watch section is intended to alert readers to substantive news, analysis and opinion from the general media and selected think tanks and similar organizations on vaccines, immunization, global public health and related themes. *Media Watch* is not intended to be exhaustive, but indicative of themes and issues CVEP is actively tracking. This section will grow from an initial base of newspapers, magazines and blog sources, and is segregated from *Journal Watch* above which scans the peer-reviewed journal ecology.

We acknowledge the Western/Northern bias in this initial selection of titles and invite suggestions for expanded coverage. We are conservative in our outlook in adding news sources which largely report on primary content we are already covering above. Many electronic media sources have tiered, fee-based subscription models for access. We will provide full-text where content is published without restriction, but most publications require registration and some subscription level.

The Atlantic

http://www.theatlantic.com/magazine/ Accessed 18 Jan 2020 [No new, unique, relevant content]

BBC

http://www.bbc.co.uk/ Accessed 18 Jan 2020 [No new, unique, relevant content]

The Economist

http://www.economist.com/ Accessed 18 Jan 2020 [No new, unique, relevant content]

Financial Times

http://www.ft.com/home/uk [No new, unique, relevant content]

Forbes

http://www.forbes.com/ Accessed 18 Jan 2020 Editors' Pick Jan 12, 2020

Fighting Polio: What Happened In 2019 And What Is Next

Bruce Y. Lee Senior Contributor

Foreign Affairs

http://www.foreignaffairs.com/ Accessed 18 Jan 2020 [No new, unique, relevant content]

Foreign Policy

http://foreignpolicy.com/ Accessed 18 Jan 2020

China Deserves Some Credit for Its Handling of the Wuhan Pneumonia

The country's response to this outbreak has been far better than to SARS, although even more information-sharing is important.

Argument |

Daniel Lucey, Annie Sparrow

The Guardian

http://www.guardiannews.com/ Accessed 18 Jan 2020 [No new, unique, relevant content]

New Yorker

http://www.newyorker.com/ Accessed 18 Jan 2020 [No new, unique, relevant content]

New York Times

http://www.nytimes.com/ Accessed 18 Jan 2020 New York

How Anti-Vaccine Activists Doomed a Bill in New Jersey

Angry parents, an ultra-Orthodox Jewish group and anti-vaccine celebrities rallied to outmatch one of the state's most powerful elected leaders.

By Tracey Tully, Sharon Otterman and Jan Hoffman
Jan. 16

Washington Post

https://www.washingtonpost.com/ Accessed 18 Jan 2020

Vaccine foes raise more money than supporters ahead of vote

Jan 16, 2020

AUGUSTA, Maine — A group that wants to overturn Maine's law eliminating religious and philosophical exemptions for vaccinations raised more than three times more money than supporters of the law, according to campaign finance reports.

Mainers for Health and Parental Rights reported \$203,988 in contributions and loans to press for rejection of the law in a statewide referendum on the March 3 ballot. Top donors included a University of Maine professor who gave \$13,500, according to the Maine Ethics Commission Campaign Finance website.

A group that wants to keep the law, Maine Families for Vaccines PAC, reported raising \$58,098. The top donors were the Maine Hospital Association, which gave \$25,000, and the Maine Academy of Family Physicians, which gave nearly \$5,000...

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Think Tanks et al

Brookings

http://www.brookings.edu/ Accessed 18 Jan 2020 [No new relevant content]

Center for Global Development

http://www.cgdev.org/page/press-center Accessed 18 Jan 2020 [No new relevant content]

CSIS

https://www.csis.org/ Accessed 18 Jan 2020 [No new relevant content]

Council on Foreign Relations

http://www.cfr.org/ Accessed 18 Jan 2020 January 15, 2020 Health

Why Experts Are Worried About a New Virus in China

The virus appears to be less dangerous than SARS, but there are still concerns of a wider outbreak in Asia.

In Brief by Yanzhong Huang

Kaiser Family Foundation

https://www.kff.org/search/?post_type=press-release Accessed 18 Jan 2020 [No new relevant content]

Vaccines and Global Health: The Week in Review is a service of the Center for Vaccine Ethics and Policy (<u>CVEP</u>)/GE2P2 Global, which is solely responsible for its content, and is an open access publication, subject to the terms of the Creative Commons Attribution License (<u>http://creativecommons.org/licenses/by-nc/3.0/</u>). Copyright is retained by CVEP.

CVEP is a program of the <u>GE2P2 Global Foundation</u> – whose purpose and mission is to advance ethical and scientific rigor in research and evidence generation for governance, policy and practice in health, human rights action, humanitarian response, heritage stewardship, education and sustainable development. The Foundation serves governments, international agencies, INGOs, civil society organizations (CSOs), commercial entities, consortia and alliances. CVEP maintains an academic affiliation with the Division of Medical Ethics, NYU School of Medicine, and an operating affiliation with the Vaccine Education Center of Children's Hospital of Philadelphia [CHOP].

Support for this service is provided by the <u>Bill & Melinda Gates Foundation</u>; <u>PATH</u>, and industry resource members Janssen/J&J, Pfizer, Sanofi Pasteur U.S., Takeda, Moderna Therapeutics (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.