Vaccines and Global Health: The Week in Review
21 November 2020 :: Number 581
Center for Vaccine Ethics & Policy (CVEP)

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

Vaccines and Global Health: The Week in Review is published as a PDF and scheduled for release each Saturday [U.S.] at midnight [0000 GMT-5]. The PDF is posted and the elements of each edition are presented as a set of blog posts at https://centerforvaccineethicsandpolicy.net. This blog allows full-text searching of over 9,000 entries.

Comments and suggestions should be directed to
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Center for Vaccine Ethics & Policy
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Request email delivery of the pdf: *If you would like to receive the PDF of each edition via email [Constant Contact], please send your request to david.r.curry@centerforvaccineethicsandpolicy.org.*

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Contents *[click on link below to move to associated content]*

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Milestones :: Perspectives :: Research

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COVID-19 Vaccines: Regulatory Processes/Milestones

Advisory Committee on Immunization Practices (ACIP) - CDC
Webcast: November 23, 2020 meeting is a virtual meeting. No registration is required.
Meeting time, 12:00 – 5:00pm EDT (times subject to change).
Webcast Link
Meeting Agenda – Final pdf icon

MEETING OF THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (ACIP)
Centers for Disease Control and Prevention
Atlanta, Georgia 30329
November 23, 2020

	AGENDA ITEM	PRESIDER/PRESENTER(s)
Monday, November 23, 2020		
12:00	Welcome & Introductions	Dr. José Romero (ACIP Chair) Dr. Amanda Cohn (ACIP Executive Secretary, CDC)
	Coronavirus Disease 2019 (COVID-19) Vaccines	
	Introduction	Dr. Beth Bell (ACIP, WG Chair)
	EtR Framework: Public Health Problem, Resource Use and Equity Domains Discussion	Dr. Sara Oliver (CDC/NCIRD)
1:15	*Break*	
1:30	EtR Framework: Values, Acceptability and Feasibility Domains Discussion	Dr. Sara Oliver (CDC/NCIRD)
2:30	*Break*	
3:00	Phased Allocation of COVID-19 Vaccines Discussion	Dr. Kathleen Dooling (CDC/NCIRD)
4:30	*Break*	
4:40	Public comment	
5:00	Adjourn	

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How CDC Is Making COVID-19 Vaccine Recommendations
Updated Nov. 20, 2020
CDC is making coronavirus disease 2019 (COVID-19) vaccination recommendations for the United States based on input from the Advisory Committee on Immunization Practices (ACIP). ACIP is a federal advisory committee made of up of medical and public health experts who develop recommendations on the use of vaccines in the U.S. public. ACIP holds regular meetings, which are open to the public and provide opportunity for public comment.

Since the pandemic began, ACIP has been holding special meetings to review U.S. data on COVID-19 and the vaccines in development to help prevent it. Before making recommendations, ACIP plans to review all available clinical trial information, including descriptions of
:: Who is receiving each candidate vaccine (age, race, ethnicity, underlying medical conditions)

:: How different groups respond to the vaccine
:: Side effects experienced

If the Food and Drug Administration (FDA) authorizes or approves a COVID-19 vaccine, ACIP will quickly hold a public meeting to review all available data about that vaccine (sign up to receive email updates whenever ACIP's Meeting Information is updated). From these data, ACIP will then vote on whether to recommend the vaccine and, if so, who should receive it. Included in ACIP's recommendations will be guidance on who should receive COVID-19 vaccines if supply is limited. Recommendations must go to the director of CDC for approval before becoming official CDC policy.

Goals for vaccination if supply is limited

ACIP has set the following goals for recommending which groups should receive COVID-19 vaccines if supply is limited:
:: Decrease death and serious disease as much as possible
:: Preserve functioning of society
:: Reduce the extra burden the disease is having on people already facing disparities
:: Increase the chance for everyone to enjoy health and well-being

Ethical principles

ACIP has identified four ethical principles to guide their decision-making process if supply is limited:
:: Maximize benefits and minimize harms — Respect and care for people using the best available data to promote public health and minimize death and severe illness.
:: Mitigate health inequities — Reduce health disparities in the burden of COVID-19 disease and death, and make sure everyone has the opportunity to be as healthy as possible.
:: Promote justice — Treat affected groups, populations, and communities fairly. Remove unfair, unjust, and avoidable barriers to COVID-19 vaccination.
:: Promote transparency — Make a decision that is clear, understandable, and open for review. Allow and seek public participation in the creation and review of the decision processes.

Groups considered for early vaccination if supply is limited

ACIP is considering four groups to possibly recommend for early COVID-19 vaccination if supply is limited:
:: Healthcare personnel
:: Workers in essential and critical industries
:: People at high risk for severe COVID-19 illness due to underlying medical conditions
:: People 65 years and older

Healthcare personnel continue to be on the front line of the nation's fight against this deadly pandemic. By providing critical care to those infected with the virus that causes COVID-19, many healthcare personnel have a high risk of being exposed to and getting sick with COVID-19. Healthcare personnel who get COVID-19 can also spread the virus to their patients seeking care for medical conditions that, in turn, increase their patients' risk for severe COVID-19 illness. Early vaccine access is critical to ensuring the health and safety of this essential workforce of approximately 21 million people, protecting not only them but also their patients, communities, and the broader health of our country. Learn who is included under the broad term "healthcare personnel."

Workers in essential and critical industries are considered part of America's critical infrastructure, as defined by the Cybersecurity & Infrastructure Security Agencyexternal icon. Current data show that

many of these workers are at increased risk for getting COVID-19. Early vaccine access is critical not only to protect them but also to maintain the essential services they provide U.S. communities.

People with certain underlying medical conditions are at increased risk for severe COVID-19 illness, regardless of their age. Severe illness means that the person with COVID-19 may require hospitalization, intensive care, or a ventilator to help them breathe, or that they may even die. Early vaccine access is critical to ensuring the health and safety of this population that is disproportionately affected by COVID-19.

Among adults, the risk for severe illness and death from COVID-19 increases with age, with older adults at highest risk. Early vaccine access is critical to help protect this population that is disproportionately affected by COVID-19.

Other frameworks

Input from the public and the following professional groups is informing ACIP's discussions on who should receive COVID-19 vaccines if supply is limited:

:: Johns Hopkins Bloomberg School of Public Health: Interim Framework for COVID-19 Vaccine Allocation and Distribution in the United Statesexternal icon

:: The National Academies of Sciences, Engineering, and Medicine: Framework for Equitable Allocation of COVID-19 Vaccineexternal icon

:: World Health Organization (WHO) Strategic Advisory Group of Experts (SAGE): WHO SAGE Values Framework for the Allocation and Prioritization of COVID-19 Vaccinationpdf

:: WHO SAGE: WHO SAGE Roadmap for Prioritizing Uses of COVID-19 Vaccines in the Context of Limited Supplypdf

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November 20, 2020 - Coronavirus (COVID-19) Update: FDA Announces Advisory Committee Meeting to Discuss COVID-19 Vaccine Candidates

The U.S. Food and Drug Administration has scheduled a meeting of its Vaccines and Related Biological Products Advisory Committee (VRBPAC) on Dec. 10 to discuss the request for emergency use authorization (EUA) of a COVID-19 vaccine from Pfizer, Inc. in partnership with BioNTech Manufacturing GmbH.

"The FDA recognizes that transparency and dialogue are critical for the public to have confidence in COVID-19 vaccines. I want to assure the American people that the FDA's process and evaluation of the data for a potential COVID-19 vaccine will be as open and transparent as possible," said FDA Commissioner Stephen M. Hahn, M.D. "The FDA has been preparing for the review of EUAs for COVID-19 vaccines for several months and stands ready to do so as soon as an EUA request is submitted. While we cannot predict how long the FDA's review will take, the FDA will review the request as expeditiously as possible, while still doing so in a thorough and science-based manner, so that we can help make available a vaccine that the American people deserve as soon as possible. A discussion about the safety and effectiveness of Pfizer and BioNTech's vaccine with this committee, made up of outside scientific and public health experts from around the country, will help ensure clear public understanding of the scientific data and information that the FDA will evaluate in order to make a decision about whether to authorize a vaccine for emergency use for the prevention of COVID-19."…

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News: EMA organises public meeting on COVID-19 vaccines

Last updated: 19/11/2020

EMA will organise a public meeting on 11 December 2020 to inform European citizens about the EU regulatory processes for the approval of COVID-19 vaccines and the Agency's role in their development, evaluation, approval and safety monitoring…

The public meeting will inform citizens about EMA's role in the pandemic and of EU regulatory procedures. It will also give the opportunity to the public and stakeholder groups to speak and share their needs, expectations and any concerns, that will be considered by EMA and the European medicines regulatory network in the decision-making process.

The agenda of the event is available on the EMA website.

News: EMA starts rolling review of mRNA COVID-19 vaccine by Moderna Biotech Spain, S.L.

Last updated: 16/11/2020

MA's human medicines committee (CHMP) has started a 'rolling review' of data on a vaccine for COVID-19 known as mRNA-1273, which is being developed by Moderna Biotech Spain, S.L. (a subsidiary of Moderna, Inc.).

The CHMP's decision to start the rolling review of mRNA-1273 is based on preliminary results from non-clinical studies and early clinical studies in adults which suggest that the vaccine triggers the production of antibodies and T cells (cells of the immune system, the body's natural defences) that target the virus.

The Committee has started evaluating the first batch of data on the vaccine, which come from laboratory studies (non-clinical data). Large-scale clinical trials involving several thousands of people are ongoing, and results are expected shortly. These results will provide information on how effective the vaccine is in protecting people against COVID-19 and will be assessed once submitted to the agency. All the available data on the safety of the vaccine as well as its pharmaceutical quality (such as its ingredients, the way it is produced, stability and storage conditions) will also be reviewed as they become available.

The rolling review will continue until enough evidence is available to support a formal marketing authorisation application…

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CHINA - Vaccine to undergo 3rd phase of trials

Updated: 2020-11-20 *China Daily*

China began its first Phase 3 clinical trials of a recombinant subunit vaccine against COVID-19 on Nov 18, making it the fifth Chinese vaccine candidate to enter late-stage human testing.

The recombinant subunit vaccine is being jointly developed by Anhui Zhifei Longcom Biologic Pharmacy and the Institute of Microbiology, part of the Chinese Academy of Sciences.

This vaccine falls under the category of an adjuvanted recombinant protein subunit (RBD-Dimer) vaccine.

The Phase 3 trials of the vaccine candidate began in Xiangtan county, Hunan province, on Wednesday.

Uzbekistan will also host a trial later this month, followed by Indonesia, Pakistan and Ecuador in the coming months, the vaccine developer said during the launch ceremony.

The trials will enlist 29,000 volunteers age 18 and older for the randomized, double-blind placebo experiment.

On Oct 22, Anhui Zhifei said the vaccine is generally safe and effective based on data from the first two clinical trial phases.

A protein subunit vaccine uses pieces of the protein components of a pathogen to trigger a protective immune response.

It has distinct advantages over live attenuated and inactivated vaccines since it can induce humoral and cell-mediated immune responses, and the risks associated with processing live pathogens for vaccine production are eliminated, according to the Vaccine Book, a medical textbook published by Academic Press.

However, subunit vaccines may be more expensive and may require specific adjuvants to enhance immune response.

The other four Chinese vaccines in Phase 3 clinical trials are: two inactivated vaccines developed by the China National Pharmaceutical Group (Sinopharm); one inactivated vaccine developed by Sinovac Biotech Co; and the adenoviral vector vaccine jointly developed by the Academy of Military Science and Chinese biotech company CanSino

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China Sinopharm's coronavirus vaccine taken by about a million people in emergency use

November 19, 2020

By Reuters Staff

BEIJING (Reuters) - Nearly one million people have taken an experimental coronavirus vaccine developed by China National Pharmaceutical Group (Sinopharm) through the country's emergency use programme, the firm said late on Wednesday.

China launched the emergency use programme in July, which so far includes three vaccine candidates for essential workers and other limited groups of people even as clinical studies have yet to be completed to prove their safety and efficacy.

No serious adverse reaction has been reported from those who received the vaccine in emergency use, Sinopharm said in an article on social media WeChat, citing Chairman Liu Jingzhen from a recent media interview.

Two vaccine candidates developed by Sinopharm's subsidiary China National Biotec Group (CNBG) and third one developed by Sinovac Biotech SVA.O have been used for the emergency programme.

It's unclear which vaccine Liu referred to, and Sinopharm was not immediately available to comment.

Sinopharm's vaccines, which use inactivated virus unable to replicate in human cells to trigger immune responses, require two doses, clinical trial registration data showed.

The experimental vaccines are undergoing Phase 3 clinical trials overseas that have recruited nearly 60,000 people, and blood samples of more than 40,000 participants have been taken 14 days after they took the second dose, the article said citing Liu, without breaking down the numbers for each vaccine.

Among construction project employees, diplomats and students who went abroad after taking Sinopharm's vaccine, no one has been infected, it added.

But experts have cautioned against using data solely from emergency use programme, without comparable results from a clinical trial-standard control group, to determine a vaccine's effectiveness.

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COVID-19 Vaccines – Development/Procurement

Pfizer and BioNTech to Submit Emergency Use Authorization Request Today to the U.S. FDA for COVID-19 Vaccine
November 20, 2020

Pfizer and BioNTech Conclude Phase 3 Study of COVID-19 Vaccine Candidate, Meeting All Primary Efficacy Endpoints
November 18, 2020

Moderna Announces Supply Agreement with United Kingdom Government to Supply mRNA Vaccine Against COVID-19 (mRNA-1273) if Approved for Use
November 17, 2020

Moderna's COVID-19 Vaccine Candidate Meets its Primary Efficacy Endpoint in the First Interim Analysis of the Phase 3 COVE Study
November 16, 2020

Moderna's COVID-19 Vaccine Candidate Meets its Primary Efficacy Endpoint in the First Interim Analysis of the Phase 3 COVE Study
November 16, 2020

Biological E. Limited Starts Phase I/II Clinical Trial of its COVID-19 Vaccine Candidate
Nov 16, 2020, 06:00 ET

Johnson & Johnson and U.S. Department of Health & Human Services Expand Agreement to Support Next Phase of COVID-19 Vaccine Candidate Research and Development
Nov 14, 2020, 09:34 ET

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EMERGENCIES

Coronavirus [COVID-19]
Public Health Emergency of International Concern (PHEIC)

Weekly Epidemiological and Operational updates
last update: 14 November 2020, 10:30 GMT-4

Confirmed cases :: 57 274 018 [week ago: 53 164 803] [two weeks ago: 49 106 931]
Confirmed deaths :: 1 368 000 [week ago: 1 300 576] [two weeks ago: 1 239 157]
Countries, areas or territories with cases :: 220

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WHO Director-General's opening remarks at the media briefing on COVID-19 - 20 November 2020
20 November 2020

Weekly epidemiological update - 17 November 2020
Overview
Globally in the past week, rates of new COVID-19 cases and deaths continued to increase, with almost 4 million new cases and 60 000 new deaths recorded. Cumulatively as of 15 November 2020, 53.7 million confirmed cases and 1.3 million deaths have been reported to WHO.

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Emergencies

POLIO
Public Health Emergency of International Concern (PHEIC)

Polio this week as of 18 November 2020
:: On 13 November, the World Health Organization's (WHO) Prequalification (PQ) program issued an Emergency Use Listing (EUL) recommendation for the type 2 novel oral polio vaccine (nOPV2). This will allow rollout of the vaccine for limited initial use in countries affected by circulating vaccine-derived poliovirus type 2 (cVDPV2) outbreaks…Read more

Summary of new WPV and cVDPV viruses this week *(AFP cases and environmental samples):*
:: Afghanistan: one WPV1 case, one WPV1 positive environmental sample and one cVDPV2 positive environmental sample
:: Pakistan: one WPV1 case, three WPV1 positive environmental samples, three cVDPV2 cases and two cVDPV2 positive environmental samples
:: Burkina Faso: five cVDPV2 cases
:: Democratic Republic of the Congo: three cVDPV2 cases
:: Ghana: one cVDPV2 positive environmental sample
:: Nigeria: one cVDPV2 case
:: Sudan: five cVDPV2 cases and three positive environmental samples

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WHO Grade 3 Emergencies [to 21 Nov 2020]
Democratic Republic of the Congo - *No new digest announcements identified*
Mozambique floods - *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 21 Nov 2020]
Iraq
:: Prioritizing a transition from psychiatric hospital-based to community-based mental health services in Iraq 16 November 2020

Afghanistan - *No new digest announcements identified*
Angola - *No new digest announcements identified*
Burkina Faso - *No new digest announcements identified*
Burundi - *No new digest announcements identified*
Cameroon - *No new digest announcements identified*
Central African Republic - *No new digest announcements identified*
Ethiopia - *No new digest announcements identified*
Iran floods 2019 - *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*
Mozambique - *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*
HIV in Pakistan - *No new digest announcements identified*
Sao Tome and Principe Necrotizing Cellulitis (2017) - *No new digest announcements identified*
Sudan - *No new digest announcements identified*
Ukraine - *No new digest announcements identified*
Zimbabwe - *No new digest announcements identified*

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WHO Grade 1 Emergencies [to 21 Nov 2020]
Chad - *No new digest announcements identified*
Djibouti – *Page not responding at inquiry*
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

:: Recent Developments in Northwest Syria - Situation Report No. 22 - As of 18 November 2020

…Some 80 percent of all confirmed COVID-19 cases in northwest Syria were identified in the past month. Seven new treatment centres have been added, for a total of 26 with a capacity of 1,110 beds, and precautionary measures are being reintroduced especially in the Idleb area.

…Ongoing hostilities encroach on population areas, leading to higher civilian casualties…

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.

East Africa Locust Infestation

:: Desert Locust situation update - 20 November 2020

COVID-19

:: Coronavirus Disease (COVID-19): Weekly Epidemiological Update (17 November 2020)

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WHO & Regional Offices [to 21 Nov 2020]

20 November 2020 News release
World leaders join forces to fight the accelerating crisis of antimicrobial resistance

20 November 2020 Departmental news
WHO and other stakeholders join forces to accelerate access to effective paediatric HIV and tuberculosis diagnostics and medicines

19 November 2020 Statement
Joint Statement on Data Protection and Privacy in the COVID-19 Response

19 November 2020 Departmental news
Learning from history: Sanitation for prosperity

19 November 2020 Departmental news
Regulating sanitation services as a public good

18 November 2020 Departmental news
Your Right To A Better World

17 November 2020 News release
A cervical cancer-free future: First-ever global commitment to eliminate a cancer

17 November 2020 Departmental news
WHO-commissioned global systematic review finds high HCV prevalence and incidence among men who have sex with men

17 November 2020 Departmental news
WHO announces certification programme for trans fat elimination

17 November 2020 Departmental news
WHO launches new roadmap on human resource strategies to ensure that all newborns survive and thrive

Today, on World Prematurity Day, WHO launched a new *Roadmap on human resource strategies to improve newborn care in health facilities in low- and middle-income countries*, aimed at improving quality of care for newborns, including small and sick babies, and supporting countries to achieve the SDG target to reduce neonatal mortality to less than 12 per 1000 live births by 2030…

17 November 2020 Departmental news
HIV drug resistance: World Antimicrobial Awareness Week 2020

16 November 2020 Departmental news
WHO releases new estimates of the global burden of cervical cancer associated with HIV

16 November 2020 Departmental news
WHO launches assistive technology capacity assessment (ATA-C)

15 November 2020 Departmental news
MVIP update – 1 million doses administered, Kenya 1st anniversary, cooperation for vaccine access

More than one year on across the pilot countries of Ghana, Kenya and Malawi, more than 1 million doses of the RTS,S/AS01 malaria vaccine have been administered, and an estimated 480,000 children have received their first dose of vaccine in childhood vaccination and should benefit from this additional malaria prevention.

Kenya marked its 1st anniversary of the launch of the pilot in September, with more than 128,000 children reached with vaccine, and one country health official expressing "a great sense of pride" in being part of the effort to protect children from malaria.

Malaria vaccination is continuing in all participating countries without major disruptions and there is good uptake of the vaccine, despite the challenges posed by the COVID-19 pandemic..

15 November 2020 Departmental news
Henrietta Lacks: A centennial celebration

15 November 2020 Departmental news
Towards Cervical Cancer elimination in the Americas

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Immunization as an essential health service: guiding principles for immunization activities during the COVID-19 pandemic and other times of severe disruption

10 November 2020
Download (333.7 kB)
Overview
This document, endorsed by the WHO Strategic Advisory Group of Experts on Immunization, provides guiding principles to support countries in their decision-making regarding provision or resumption of immunization services during severe disruptive events such as COVID-19, natural disasters or humanitarian emergencies. It incorporates the Immunization Agenda 2030 principles of being people-centred, country-owned, partnership-based and data-guided.

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Weekly Epidemiological Record, 20 November 2020, vol. 95, 47 (pp. 573–584)
:: Progress towards poliomyelitis eradication – Pakistan, January 2019–September 2020
:: Performance of acute flaccid paralysis (AFP) surveillance and incidence of poliomyelitis, 2020

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WHO Regional Offices
Selected Press Releases, Announcements
WHO African Region AFRO
:: What's the cause? Certifying deaths in sub-Saharan Africa
19 November 2020 Brazzaville – About two thirds of countries in the African region do not have reliable data on births, deaths, and causes of death, a recent World Health Organization (WHO) assessment found. The absence of this crucial information complicates effective health responses and policy-making in region.
:: Defeating Ebola in the Democratic Republic of the Congo 18 November 2020
:: How chats on private parts and cervical cancer are helping to defeat the disease in ...
17 November 2020 Playing on radios across Zambia this month is an upbeat piano snippet with a female radio personality speaking words of warning for women that have always been considered taboo.

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
:: Regional Director's visit cements stronger cooperation on health in Albania 20-11-2020
:: Next steps to deliver "United Action for Better Health" in Europe 20-11-2020
:: Doing our share, a new horizon with technological and pharmaceutical development, and preserving the rights of children 19-11-2020
:: WHO/Europe highlights how alcohol undermines sustainable development across the WHO European Region 18-11-2020
::Coming together to identify health-workforce needs in small countries 18-11-2020

WHO Eastern Mediterranean Region EMRO
:: WHO Regional Director's statement for virtual press briefing, 19 November

WHO Western Pacific Region
No new digest content identified

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CDC/ACIP [to 21 Nov 2020]
http://www.cdc.gov/media/index.html
https://www.cdc.gov/vaccines/acip/index.html
Latest News Releases, Announcements
Transcript for CDC Telebriefing on the COVID-19 Outbreak
Thursday, November 19, 2020
…THANK YOU FOR JOINING US TODAY FOR THIS BRIEFING TO DISCUSS SAFE WAYS TO ENJOY THE UPCOMING HOLIDAYS AMID THE COVID-19 PANDEMIC

Ebola Outbreak in the Democratic Republic of the Congo Ends
Wednesday, November 18, 2020

CDC Foundation Launches Crush COVID-19 Campaign to Meet Urgent Needs Caused by Pandemic
ATLANTA, Nov. 16, 2020 /PRNewswire/ -- As the coronavirus pandemic accelerates, the CDC Foundation today announced it is redoubling its response efforts through the official launch of the "Crush COVID" campaign. This campaign aims to raise support and advance work targeted to end the COVID-19 pandemic, which has taken hundreds of thousands of lives in America alone and shaken the global economy.

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Webcast Linkexternal icon
Meeting Agenda – Finalpdf icon

Coronavirus Disease 2019 (COVID-19)
Selected Resources
:: Scientific Brief: Community Use of Cloth Masks to Control the Spread of SARS-CoV-2 Friday, November 20, 2020
:: 10 Things Healthcare Professionals Need to Know about U.S. COVID-19 Vaccination Plans Friday, November 20, 2020
:: How CDC Is Making COVID-19 Vaccine Recommendations Friday, November 20, 2020
:: Celebrating Thanksgiving Thursday, November 19, 2020

MMWR News Synopsis Friday, November 20, 2020
:: Vital Signs: Deaths Among Persons with Diagnosed HIV Infection, United States, 2010-2018
:: COVID-19 Outbreak — New York City, February 29–June 1, 2020

:: Characterization of COVID-19 in Assisted Living Facilities — 39 States, October 2020
:: Implementation of a Pooled Surveillance Testing Program for Asymptomatic SARS-CoV-2 Infections on a College Campus — Duke University, Durham, North Carolina, August–October, 2020 (Early Release November 17, 2020)
:: Progress Toward Poliomyelitis Eradication — Pakistan, January 2019–September 2020
:: COVID-19 Stats: COVID-19 Incidence, by Urban-Rural Classification — United States, January 22–October 31, 2020

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Africa CDC [to 21 Nov 2020]
http://www.africacdc.org/
Press Releases
Announcements
Kofi Annan Global Health Leadership Programme
19 November 2020

Press Releases
African Development Bank supports continental strategy on COVID-19 with US$27.33 million
19 November 2020
… Awarded under three key components – technical assistance and capacity building (US$19.33 million), institutional support (US$7 million) and contribution to the African Union COVID-19 Response Fund (US$ 1 million) – the grant is to support implementation of the Africa Joint Continental Strategy for COVID-19 Outbreak. It will enable Africa CDC to provide technical assistance and capacity building support in combating the COVID-19 pandemic and mitigating its impact in 37 African Development Fund eligible African Union Member States…

Press Releases
International and African organizations partner to fight antimicrobial resistance in Africa
18 November 2020

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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/
News
Nov 21: Daily briefing on novel coronavirus cases in China
On Nov 20, 31 provincial-level regions and the Xinjiang Production and Construction Corps on the Chinese mainland reported 16 new cases of confirmed infections.

Vaccine to undergo 3rd phase of trials
Updated: 2020-11-20 *China Daily*

China began its first Phase 3 clinical trials of a recombinant subunit vaccine against COVID-19 on Nov 18, making it the fifth Chinese vaccine candidate to enter late-stage human testing.

The recombinant subunit vaccine is being jointly developed by Anhui Zhifei Longcom Biologic Pharmacy and the Institute of Microbiology, part of the Chinese Academy of Sciences.

This vaccine falls under the category of an adjuvanted recombinant protein subunit (RBD-Dimer) vaccine.

The Phase 3 trials of the vaccine candidate began in Xiangtan county, Hunan province, on Wednesday.

Uzbekistan will also host a trial later this month, followed by Indonesia, Pakistan and Ecuador in the coming months, the vaccine developer said during the launch ceremony.

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It has distinct advantages over live attenuated and inactivated vaccines since it can induce humoral and cell-mediated immune responses, and the risks associated with processing live pathogens for vaccine production are eliminated, according to the Vaccine Book, a medical textbook published by Academic Press.

However, subunit vaccines may be more expensive and may require specific adjuvants to enhance immune response.

The other four Chinese vaccines in Phase 3 clinical trials are: two inactivated vaccines developed by the China National Pharmaceutical Group (Sinopharm); one inactivated vaccine developed by Sinovac Biotech Co; and the adenoviral vector vaccine jointly developed by the Academy of Military Science and Chinese biotech company CanSino.

China, BRICS partners work on COVID-19 vaccines: Xi

Updated: 2020-11-19 | *Xinhua*

BEIJING -- Chinese companies are carrying out phase-III clinical trials of COVID-19 vaccines with Russian and Brazilian partners, said Chinese President Xi Jinping on Nov 17.

China is also willing to have relevant cooperation with South Africa and India, Xi said when addressing the 12th BRICS summit in Beijing via video link.

Xi said to support the development of the BRICS Vaccine R&D Center, China has designated its own national center.

China will work with other BRICS countries both online and offline to advance collective vaccine research and trials, set up plants, authorize production and recognize each other's standards, Xi said.

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Announcements

Paul G. Allen Frontiers Group [to 21 Nov 2020]
https://alleninstitute.org/what-we-do/frontiers-group/news-press/
News
No new digest content identified.

BARDA – U.S. Department of HHS [to 21 Nov 2020]
https://www.phe.gov/about/barda/Pages/default.aspx
BARDA News
No new digest content identified.

BMGF - Gates Foundation [to 21 Nov 2020]
http://www.gatesfoundation.org/Media-Center/Press-Releases
Press Releases and Statements
No new digest content identified.

Bill & Melinda Gates Medical Research Institute [to 21 Nov 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 21 Nov 2020]
https://carb-x.org/
News
11.18.2020 |
CARB-X is funding Clarametyx Biosciences to develop an innovative immune-enabling antibody therapy targeting serious biofilm-associated infections
CARB-X is awarding up to US$2.42 million to Clarametyx Biosciences to develop a new treatment for serious bacterial biofilm infections, including those such as pneumonia caused by antibiotic-resistant ESKAPE pathogens and polymicrobial biofilms.

CEPI – Coalition for Epidemic Preparedness Innovations [to 21 Nov 2020]
http://cepi.net/
Latest News
CEPI creates new collaborative taskforce to assess impact of emerging viral strains on effectiveness of COVID-19 vaccines
8 November 2020, Oslo, Norway – To rapidly monitor the emergence of new COVID-19 viral strains and evaluate their impact on vaccine candidates in development, CEPI, the Coalition for Epidemic Preparedness Innovations, has today announced the launch of a first-of-its-kind collaboration with the GISAID Initiative, Public Health England (PHE) and the National Institute for Biological Standards and Control (NIBSC) to further strengthen real-time global tracking and testing of SARS-CoV-2 sequences– the virus behind COVID-19. The announcement follows recent attention to a mutant strain of the virus detected in mink and human populations in Denmark…
Dr. Richard Hatchett, Chief Executive Officer, CEPI: "This joint collaboration between CEPI, GISAID, Public Health England, and the National Institute for Biological Standards and Control, fills a key gap in the global outbreak response through acting as a mechanism to both monitor and test emerging viral

strains and evaluate whether these circulating strains may impact COVID-19 vaccine development. Through this effort we can provide information to support continuing global efforts to develop effective COVID-19 vaccines and bring an end to this pandemic as quickly as possible."

CEPI welcomes Moderna announcement of positive interim data from Phase III trial of COVID-19 vaccine candidate
16 Nov 2020

EDCTP [to 21 Nov 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 21 Nov 2020]
http://www.vaccines.emory.edu/
Vaccine Center News
No new digest content identified.

European Medicines Agency [to 21 Nov 2020]
http://www.ema.europa.eu/ema/
News & Press Releases
News: Update on remdesivir - EMA will evaluate new data from Solidarity trial
Last updated: 20/11/2020
EMA is aware that the World Health Organization (WHO) has updated its guidelines advising against the use of remdesivir in hospitalised patients with COVID-19, regardless of disease severity based on a recent meta-analysis…
EMA has requested the full Solidarity data from WHO and the marketing authorisation holder. Once the data are available, EMA will assess the evidence, together with other relevant data, to see if any changes are needed to the marketing authorisation of Veklury (remdesivir) in the EU…

News: HMA/EMA statement on approval of vaccines
Last updated: 20/11/2020
Development and deployment of safe and effective vaccines is seen as an essential element in the management and solution of the COVID-19 pandemic. There are no COVID-19 vaccines approved yet in the European Union, but due to the urgency posed by this health crisis, different mechanisms are in place to expedite the development of such vaccines in order to make them available as soon as possible while safeguarding the mandatory requirements of quality, safety and efficacy.
According to EU legislation (Regulation 726/2004) most COVID-19 vaccines fall under the scope of the centralised procedure since they are produced by biotechnological processes for which the centralised procedure is mandatory (as listed in Annex 1 to the Regulation). For other types of vaccines currently under development, such as those composed of whole-inactivated virus or live attenuated

virus, the European Medicines Agency (EMA) and the Heads of Medicines Agencies (HMA) network encourage marketing authorisation holders to submit their applications through the centralised procedure in order to ensure that those vaccines reach all Member States at the same time, with no unfair access in the Union. This is possible according to Article 3.2 of the above-mentioned Regulation:

"Any medicinal product not appearing in the Annex may be granted a marketing authorisation by the Union in accordance with the provisions of this Regulation, if:

(a) the medicinal product contains a new active substance which, on the date of entry into force of this Regulation, was not authorised in the Union; or

(b) the applicant shows that the medicinal product constitutes a significant therapeutic, scientific or technical innovation or that the granting of authorisation in accordance with this Regulation is in the interests of patients or animal health at Union level."

In such a procedure, EMA's Committee for Medicinal Products for Human Use (CHMP), which is composed of national experts, carries out a scientific assessment of the application and gives a recommendation on whether the medicine should be authorised or not. This procedure, subsequently finalised by the European Commission's decision, gives all EU Member States, as well as those in the European Economic Area, the possibility of access to thoroughly and effectively evaluated medicines at the same time and ensures centralised safety monitoring across their life cycle.

In accordance with predefined standards for quality, safety and effectiveness that adequately protect EU patients and all people who receive medicines or vaccines, EMA in close cooperation with NCA experts in scientific committees, uses accelerated procedures to speed up the process. The goal is to deliver assessments of high-quality applications in the shortest possible timeframes while ensuring robust scientific opinions. Therefore, COVID-19 vaccine applications should be assessed via the centralised procedure and, in addition to the centralised procedure itself, EMA's scientific advice mechanism should be used whenever necessary, to advise developers on the quality, safety and efficacy requirements that must be met to enter the European market.

News: EMA organises public meeting on COVID-19 vaccines

Last updated: 19/11/2020

EMA will organise a public meeting on 11 December 2020 to inform European citizens about the EU regulatory processes for the approval of COVID-19 vaccines and the Agency's role in their development, evaluation, approval and safety monitoring…

The public meeting will inform citizens about EMA's role in the pandemic and of EU regulatory procedures. It will also give the opportunity to the public and stakeholder groups to speak and share their needs, expectations and any concerns, that will be considered by EMA and the European medicines regulatory network in the decision-making process.

The agenda of the event is available on the EMA website.

News: EMA starts rolling review of mRNA COVID-19 vaccine by Moderna Biotech Spain, S.L.

Last updated: 16/11/2020

MA's human medicines committee (CHMP) has started a 'rolling review' of data on a vaccine for COVID-19 known as mRNA-1273, which is being developed by Moderna Biotech Spain, S.L. (a subsidiary of Moderna, Inc.).

The CHMP's decision to start the rolling review of mRNA-1273 is based on preliminary results from non-clinical studies and early clinical studies in adults which suggest that the vaccine triggers the production of antibodies and T cells (cells of the immune system, the body's natural defences) that target the virus.

The Committee has started evaluating the first batch of data on the vaccine, which come from laboratory studies (non-clinical data). Large-scale clinical trials involving several thousands of people are ongoing, and results are expected shortly. These results will provide information on how effective the vaccine is in protecting people against COVID-19 and will be assessed once submitted to the agency. All the available data on the safety of the vaccine as well as its pharmaceutical quality (such as its ingredients, the way it is produced, stability and storage conditions) will also be reviewed as they become available.

The rolling review will continue until enough evidence is available to support a formal marketing authorisation application…

European Vaccine Initiative [to 21 Nov 2020]
http://www.euvaccine.eu/
Latest News
No new digest content identified.

FDA [to 21 Nov 2020]
https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/default.htm
Press Announcements / *Selected Details*
November 20, 2020 - Coronavirus (COVID-19) Update: November 20, 2020
:: The FDA, yesterday, issued an EUA for the drug baricitinib (Olumiant), in combination with remdesivir (Veklury) for the treatment of suspected or laboratory confirmed COVID-19 in hospitalized adults and pediatric patients two years of age or older requiring supplemental oxygen, invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).
:: The FDA has updated a webpage, Vaccine Development – 101, to provide an overview of the vaccine development process.
:: In a new webpage, Emergency Use Authorization for Vaccines Explained, the FDA offers answers to questions about EUAs, in general, and more specifically, about EUA requests for a vaccine intended to prevent COVID-19.

November 20, 2020 - Coronavirus (COVID-19) Update: FDA Announces Advisory Committee Meeting to Discuss COVID-19 Vaccine Candidate

The U.S. Food and Drug Administration has scheduled a meeting of its Vaccines and Related Biological Products Advisory Committee (VRBPAC) on Dec. 10 to discuss the request for emergency use authorization (EUA) of a COVID-19 vaccine from Pfizer, Inc. in partnership with BioNTech Manufacturing GmbH.

"The FDA recognizes that transparency and dialogue are critical for the public to have confidence in COVID-19 vaccines. I want to assure the American people that the FDA's process and evaluation of the data for a potential COVID-19 vaccine will be as open and transparent as possible," said FDA Commissioner Stephen M. Hahn, M.D. "The FDA has been preparing for the review of EUAs for COVID-19 vaccines for several months and stands ready to do so as soon as an EUA request is submitted. While we cannot predict how long the FDA's review will take, the FDA will review the request as expeditiously as possible, while still doing so in a thorough and science-based manner, so that we can help make available a vaccine that the American people deserve as soon as possible. A discussion about the safety and effectiveness of Pfizer and BioNTech's vaccine with this committee, made up of outside scientific and public health experts from around the country, will help ensure clear

public understanding of the scientific data and information that the FDA will evaluate in order to make a decision about whether to authorize a vaccine for emergency use for the prevention of COVID-19."…

November 19, 2020 - Coronavirus (COVID-19) Update: FDA Authorizes Drug Combination for Treatment of COVID-19

November 17, 2020 - Coronavirus (COVID-19) Update: FDA Authorizes First COVID-19 Test for Self-Testing at Home

November 17, 2020 - Coronavirus (COVID-19) Update: November 17, 2020
:: Today, the FDA reaffirmed its commitment to transparency around the EUA process and shared updates on its plan to provide more information about the agency's decisions to issue, revise or revoke EUAs for drugs and biological products, including vaccines, as part of our COVID-19 response

November 17, 2020 - COVID-19 Update: FDA's Ongoing Commitment to Transparency for COVID-19 EUAs
…I am announcing today that our drug and biological product centers intend, to the extent appropriate and permitted by law, to publicly post their reviews of the scientific data and information supporting the issuance, revision or revocation of EUAs for all drug and biological products, including vaccines, as part of our COVID-19 response. We have already posted some scientific review documents, for instance for an EUA revocation as well as an EUA authorization, and we are committing to continuing to post these documents moving forward…

November 16, 2020 - Coronavirus (COVID-19) Update: November 16, 2020
:: Today, FDA updated its guidance on investigational COVID-19 convalescent plasma. The updated guidance extends the period of enforcement discretion through the end of February 2021. This extension will allow continued access to convalescent plasma for the treatment of hospitalized COVID-19 patients while blood establishments develop the necessary operating procedures to manufacture the plasma consistent with the EUA.
:: The agency also today published a new webpage, *A Closer Look at COVID-19 Diagnostic Testing*, to provide health care providers and other public health professionals, including those who might purchase COVID-19 tests, more technical information and resources.

FDA - COVID-19 Vaccines [to 21 Nov 2020]
www.fda.gov/covid19vaccines
Upcoming Events
11/20/2020
Coronavirus (COVID-19) Update: FDA Announces Advisory Committee Meeting to Discuss COVID-19 Vaccine Candidate
The FDA has scheduled a meeting of its Vaccines and Related Biological Products Advisory Committee (VRBPAC) on Dec. 10 to discuss the request for emergency use authorization (EUA) of a COVID-19 vaccine from Pfizer, Inc. in partnership with BioNTech Manufacturing GmbH.

11/20/2020
The FDA published new information about the vaccine development and review process:
:: **Vaccine Development 101**
:: **Emergency Use Authorization for Vaccines Explained**

:: **The Path for a COVID-19 Vaccine from Research to Emergency Use Authorization (PDF-723KB)**

11/19/2020
FDA and Vaccinate Your Family Talk COVID With Minority Community LeadersExternal Link Disclaimer
FDA leaders participate in a virtual meeting with racial and ethnic minority community members about FDA's COVID-19 vaccine work.

11/17/2020
COVID-19 Update: FDA's Ongoing Commitment to Transparency for COVID-19 EUAs
Statement reaffirming FDA's commitment to transparency around the EUA process and updates on FDA's plan to provide more information about decisions to issue, revise or revoke EUAs for drugs and biological products, including vaccines.

Fondation Merieux [to 21 Nov 2020]
http://www.fondation-merieux.org/
News, Events
Mérieux Foundation co-organized event
7th Meeting of the GTFCC Working Group on Oral Cholera Vaccine Webinars
November 19 - December 10, 2020 - Webinars

Gavi [to 21 Nov 2020]
https://www.gavi.org/
News releases
No new digest content identified.

GHIT Fund [to 21 Nov 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 21 Nov 2020]
https://www.theglobalfund.org/en/news/
News
Opportunity for Evaluation of Selected Medicines
20 November 2020
The Global Fund, Stop TB Partnership Global Drug Facility and Unitaid are inviting manufacturers of antiretroviral (HIV/AIDS), antihepatitis B and C, antituberculosis and antimalarial medicines to submit an expression of interest to have their products evaluated by the Expert Review Panel for Pharmaceutical Products.

COVID-19 must transform the definition of global health security
19 November 2020

By Peter Sands, Executive Director

The recent announcements that multiple new coronavirus vaccines are showing strong results provide hope that life will eventually return to normal and the catastrophic death toll will end – good news we all desperately need right now.

But despite this truly astonishing scientific achievement, the stark reality is that the COVID-19 pandemic is getting worse, with accelerating infections, and a weekly death toll of around 50,000. Even if vaccines are approved quickly, they will not be available in large volumes in countries where the Global Fund invests until late 2021 at best. It is therefore vital that the progress on vaccines is not used to justify backing off from current efforts to contain the pandemic and mitigate its devastating consequences on health systems and economies worldwide. On the contrary, we need to step up the global response. We can now see the light at the end of the tunnel; let's get there as fast as we can and minimize the damage on the way…

Lao PDR aims to achieve universal health coverage with new Global Fund, Government of Australia and World Bank investment

18 November 2020

The first co-financing investment under a new agreement between the Global Fund to Fight AIDS, Tuberculosis (TB) and Malaria, and the World Bank, will support the Government of the Lao People's Democratic Republic's goal of achieving universal health coverage by 2025.

Global Research Collaboration for Infectious Disease Preparedness [GloPID-R] [to 21 Nov 2020]

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

News

No new digest content identified.

Hilleman Laboratories [to 21 Nov 2020]

http://www.hillemanlabs.org/

No new digest content identified.

Human Vaccines Project [to 21 Nov 2020]

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

Press Releases

No new digest content identified.

COVID-19 Vaccines: What's Next?

Interview with Margaret Hamburg, M.D.

Former Commissioner, U.S. Food and Drug Administration

Margaret Hamburg is a former Commissioner of the U.S. Food and Drug Administration (FDA), having served in this post from 2009-2015. A physician-scientist and public health expert, she recently completed a term as Chair of the Board/President of the American Association for the Advancement of Science (AAAS). HVP Editor Kristen Jill Abboud recently spoke with Hamburg about the regulatory issues concerning the eventual licensure of COVID-19 vaccines. These issues are particularly relevant given recent reports that indicate vaccine candidates being developed by Pfizer/BioNTech and Moderna are highly effective.

An edited version of the conversation appears below.

What do you think about the potential risk of politics influencing the licensure of COVID-19 vaccines?

Developing a vaccine is a very big scientific challenge that requires enormous focus and attention on conducting the right studies, ensuring that they are sufficiently rigorous to determine safety and efficacy, and making sure that they are designed and structured ethically. Those issues are generally taken for granted, but in this highly charged political environment there have been concerns raised about the chance that either there will be corners cut in the effort to accelerate vaccine development, or that political pressure will lead regulators to make decisions without adequate and complete information. In my view, it is essential that all of the stakeholders come together to support a robust vaccine research and development process, and I think that has been happening. I have enormous confidence and faith in the FDA and in the teams of scientists and experts that are reviewing these candidate vaccines. We need to have COVID-19 vaccines, preferably more than one, and we need them to be safe and effective. But we also need people to have trust and confidence in those vaccines. If they don't trust these new vaccines, they won't take them and then they will not serve their intended purpose to help manage, control, and ultimately end this devastating pandemic.

Pfizer/BioNTech and Moderna have both reported that their vaccine candidates are 95% effective against COVID-19. Was this surprising? Do you anticipate that COVID-19 vaccines will far exceed the U.S. FDA's minimum efficacy level of 50%?

This was very encouraging news. We are all eager to see more data, but these announcements suggest that these vaccines will meet criteria for authorization and their administration in priority, high-risk populations may begin soon. The data also suggest that the SARS-CoV-2 Spike protein is an appropriate vaccine target, and this bodes well for many of the other vaccine candidates in development that are using different approaches, but are using the Spike protein as the antigen.

Many vaccines are not as effective as we would ideally want them to be. The FDA was thinking about COVID-19 vaccines with regard to the experience with influenza vaccines, which range from 40-70% efficacy. The FDA guidance indicated a 50% efficacy as the minimum threshold for authorization/approval, so these results are coming in dramatically higher than initially expected for this respiratory virus.

Do you suspect these trials will be sufficient to determine the efficacy of COVID-19 vaccines in specific subpopulations such as the elderly?

Determining efficacy across all relevant populations is a problem for vaccine studies, but we are noticing it more acutely now because there is a very wide range of individuals that will ultimately need to be vaccinated against COVID-19. There has been an effort from the beginning to include elderly individuals in the vaccine studies because we know they are a very important target group because of their elevated risk. Other high-risk groups have been included in the vaccine studies as well, including those with comorbidities, but there will probably need to be expanded studies in some key subpopulations as well. One critical group will be pregnant women, who have not been recruited in a targeted way in the ongoing studies. Another important group is children and youth. A couple of the studies, most notably Pfizer/BioNTech's, have lowered the age cutoff down to include age 12 and up, but we are going to have to do additional work to understand safety and efficacy, as well as appropriate dosing and immunization schedules in younger children, who may not be at the greatest risk of life-threatening disease, but are certainly important in the dynamics of disease transmission. We will want to have COVID vaccines for all of these population groups, and this will require bridging

studies to further flesh-out appropriate use of these vaccines in populations that either weren't included or a large part of the initial studies.

It will be important to have ongoing oversight of vaccines, even as they move out of the research context and into broader use, because we always want to monitor for emerging safety concerns and deepen our understanding of efficacy. It will be particularly important that we learn more about the duration of protection and determine if certain vaccines work better in specific subpopulations. We will learn much more about that over time and with expanded use as we go from controlled studies of tens of thousands of people, to millions, or even billions of people receiving vaccines worldwide.

If the first candidate vaccines are found to be effective, will all future vaccine candidates need to be compared to those in head-to-head trials for them to receive licensure?
That is a hugely important question and one that is being debated as we speak. It is unusual to be developing and testing so many different vaccines for the same disease at one time. The good news is that there are lot of potential COVID-19 vaccines, but this does make the testing scenarios much more complicated, both scientifically and ethically. Some of the best scientific minds and most qualified vaccine researchers are discussing these issues and it will be critically important that a clear strategy is developed. For now, it is still very much under discussion.

As data from efficacy trials continues to emerge, what are some of the most pressing issues facing regulators?
One of the critical regulatory issues is whether COVID-19 vaccines will receive an Emergency Use Authorization (EUA) or a full approval. I think it's pretty safe to say that the first candidate vaccines will most likely be authorized using an EUA and that their use will be targeted to a well-defined set of priority groups for vaccination. The EUA allows more flexibility to move a vaccine out in the context of a massive public health crisis. The process of getting a full licensure is a longer one with more specific data and administrative aspects. My guess is that companies that seek an initial EUA will move quickly to a full licensure application, but that the FDA might ask them to collect additional information before full licensure is granted.

One of the regulatory issues related to actually moving vaccines out into larger and larger populations involves the continued need for "pharmacovigilance" as touched on earlier, which is the ongoing monitoring/oversight to detect any emerging safety concerns and to learn more about levels of efficacy and duration across various subpopulations. Another key regulatory focus will concern vaccine scale up and manufacturing. There has been a great deal of attention paid to this early in the development process of COVID-19 vaccines, which is atypical. Because of the urgency of this situation, decisions were made to "manufacture at risk" before the candidate vaccines are authorized or approved. That will significantly speed the ability to get the vaccine out to people who need it, but there will still be a need for robust regulatory oversight of the scale up and manufacturing process to compare different lots of vaccine as it gets manufactured in larger and larger volumes.

From the beginning of this crisis, regulators around the world have tried very hard to work together and I think have done so in important ways, including collaborative activities to look at the science of developing COVID vaccines and accelerating both the research and development efforts and the regulatory process for reviewing these candidates globally.

What other issues do you think we will face as vaccines become available?
One of the important issues is understanding what having a vaccine will mean. Early on, vaccines will

be a huge step forward, but we will still need to follow many of the non-pharmaceutical public health interventions we have come to know so well—wearing masks, social distancing, washing hands, and avoiding large groups. We have to realize that even though there has been a huge push to scale up the manufacturing of vaccines even before authorization or approval, there are still going to be limited quantities in the beginning, and so it could be a while until everyone who wants the vaccines are going to be able to get them. Many of the vaccines that may be available early on are going to require two doses so that limits the supply, and also means it will take longer until you reach your desired level of protection.

Vaccines differ, and some may reduce the seriousness of the symptoms of disease or the length of the course of disease, but they may not always prevent infection per se, so people can still get sick. And if you can get sick, most likely you can still transmit the virus, so we're going to have to be mindful of all of that as we move into a world where vaccines are available.

We need to be careful not to convey the message that vaccines are going to be the magic bullet that will turn the COVID crisis around overnight and we can go right back to our normal lives. On the other hand, we need to work much more aggressively to help the public understand why vaccines matter and to encourage use of the vaccines once they are available. It's been distressing to see the decreasing number of people who are expressing the conviction that they will take the vaccine. We have to ensure that the right message about the safety and efficacy of the vaccines is getting out so that people trust the vaccines. That message shouldn't just come from the government or companies. We also need to engage a network of communities—and trusted community leaders—to do outreach to help people understand the use of these vaccines and their potential benefits in a way that is meaningful to them. The great tragedy will be if we have vaccines that work and are safe and nobody wants to take them.

Interview by Kristen Jill Abboud

IAVI [to 21 Nov 2020]
https://www.iavi.org/newsroom
PRESS RELEASES/FEATURES
No new digest content identified.

International Coalition of Medicines Regulatory Authorities [ICMRA]
http://www.icmra.info/drupal/en/news
Selected Statements, Press Releases, Research
No new digest content identified.

International Generic and Biosimilar Medicines Association [IGBA]
https://www.igbamedicines.org/
News
IGBA Launches First Global Biosimilars Week (November 2020)
Geneva, November 16, 2020 – Today the International Generic and Biosimilar Medicines Association (IGBA) launched the first ever Global Biosimilars Week, which is aimed at raising the awareness of biosimilar medicines worldwide through a globally aligned educational initiative.

IFFIm
http://www.iffim.org/
Press Releases/Announcements
The Innovative Humanitarian Financing Forum to develop collaboration with WEF
19 Nov 2020
The Innovative Humanitarian Financing Forum (IHFF), founded by leaders from IFFIm's Board and the British Red Cross, convened online on 4 November 2020, bringing to the table 33 people from 17 organisations, both returning and new participants, to explore ways to catalyse humanitarian investing initiatives.

IFRC [to 21 Nov 2020]
http://media.ifrc.org/ifrc/news/press-releases/
Selected Press Releases, Announcements
Austria, Europe, Germany, Greece, Italy, Malta, Portugal, Spain
Red Cross expands COVID-19 testing in seven countries with €35.5 million EU support
Budapest/Geneva, 19 November 2020 – As Europe continues to experience a surge in coronavirus cases and deaths, the Red Cross will scale up COVID-19 testing with the announcement of a €35.5 million European Commission partnership. The International Fede …
19 November 2020

Democratic Republic of the Congo
DR Congo: The latest Ebola outbreak is over, but major challenges remain
Goma/Kinshasa/Nairobi/Geneva, 18 November 2020 – The International Federation of Red Cross and Red Crescent Societies (IFRC) joins the people of the Democratic Republic of the Congo (DRC) in celebrating the end of the country's 11th Ebola outbreak. Thi …
18 November 2020

Global
Climate change: New report shows global response is failing people in greatest need
IFRC's World Disasters Report 2020: Come Heat or High Water shows that the countries most affected by climate-related disasters receive only a fraction of the funding that is available for climate change adaptation and thus struggle to protect people from the aggravating effects of climate change.
17 November 2020

Asia Pacific, Philippines
Catastrophic floods submerge whole towns in Philippines
Kuala Lumpur/Manila/Geneva, 15 November 2020 – Catastrophic floods have completely submerged entire towns and villages in the northern region of the Philippines, forcing tens of thousands of people from their homes just days after Typhoon Vamco tore th …
15 November 2020

Asia Pacific, Vietnam
Millions brace for dangerous floods as severe storm hits Viet Nam
Kuala Lumpur/Hanoi/Geneva, 14 November 2020 – Millions of people in Viet Nam are bracing themselves for further floods and landslides, as the thirteenth big storm of the year threatens the country's hard-hit central provinces. Typhoon Vamco has caused …

14 November 2020

Institut Pasteur [to 21 Nov 2020]
https://www.pasteur.fr/en/press-area
Press documents
Press Info
16.11.2020
Operation and reliability of RT-PCR tests in the detection of SARS-CoV-2
The National Reference Center (CNR) for Respiratory Viruses at the Institut Pasteur specializes in viruses such as influenza and bronchiolitis in infants. As an expert center in France, the CNR is responsible for monitoring cases of respiratory infections and for epidemic surveillance. When a new virus emerges, like the novel coronavirus in China, the CNR's task is to do everything it can to detect the novel pathogen.
In response to the crisis caused by COVID-19, as soon as the first cases began emerging at international level, and especially in Europe (in late January 2020), the CNR at the Institut Pasteur developed a diagnostic test to detect the SARS-CoV-2 virus (known at the time as 2019-nCoV) in suspected cases of infection…

IRC International Rescue Committee [to 21 Nov 2020]
http://www.rescue.org/press-release-index
Media highlights [Selected]
Press Release
As Yemen teeters on the brink of famine, IRC urges G20 leaders to fulfil humanitarian commitments at Saudi Arabia summit
November 20, 2020

Press Release
As COVID-19 second waves threaten conflict-affected countries, IRC urges incoming Biden Administration to prioritize pandemic response in humanitarian contexts
November 16, 2020
New IRC report "Catalyzing the U.S. Response to COVID-19 in Humanitarian Settings" outlines failures in U.S. response and calls on Biden administration to commit at least $20 billion to address virus response abroad in first 100 days.

IVAC [to 21 Nov 2020]
https://www.jhsph.edu/research/centers-and-institutes/ivac/index.html
Updates; Events
No new digest content identified.

IVI [to 21 Nov 2020]
http://www.ivi.int/
Selected IVI News, Announcements, Events
IVI, Vaccine Innovative Technology ALliance Korea (VITAL-Korea) to partner up for innovative vaccine research and development

11/17/2020
Aim to accelerate R&D and globalization of Korean vaccines to increase contributions to global health The International Vaccine Institute (IVI) and the Vaccine Innovative Technology ALliance Korea (VITAL-Korea) agreed to join forces to promote vaccine research and development for global health.

JEE Alliance [to 21 Nov 2020]
https://www.jeealliance.org/
Selected News and Events
No new digest content identified.

MSF/Médecins Sans Frontières [to 21 Nov 2020]
http://www.msf.org/
Latest [Selected Announcements]
Mediterranean migration
"What Europe is experiencing today, is not a humanitarian crisis, b…
Speech 19 Nov 2020

Democratic Republic of Congo
MSF denounces ongoing violence in Salamabila
Statement 19 Nov 2020

DRC Ebola outbreaks
Improved medical response sees the end of DRC's eleventh Ebola outbreak
Project Update 19 Nov 2020

Coronavirus COVID-19 pandemic
Governments must support landmark proposal to waive COV…
Press Release 19 Nov 2020
:: In October, India and South Africa proposed to waiver some intellectual property rights on coronavirus tools during the COVID-19 pandemic.
:: The landmark request would allow countries to choose not to grant nor enforce patents on COVID-19 drugs and vaccines.
:: MSF urges all countries to back the proposal, which is already supported by 99 countries, to allow COVID-19 tools to be more affordable and accessible.

Tuberculosis
Step up for TB report 2020
Report 16 Nov 2020

Tuberculosis
MSF calls on governments and donors to speed up TB testing …
Press Release 16 Nov 2020

National Vaccine Program Office - U.S. HHS [to 21 Nov 2020]

https://www.hhs.gov/vaccines/about/index.html
No new digest content identified.

NIH [to 21 Nov 2020]
http://www.nih.gov/news-events/news-releases
News Releases
NIH expands research to improve COVID-19 testing among underserved and vulnerable populations
November 20, 2020 — Research designed to rapidly implement testing strategies in populations disproportionately affected by COVID-19.

Promising Interim Results from Clinical Trial of NIH-Moderna COVID-19 Vaccine
November 16, 2020 — An interim review of trial data suggests that the vaccine is safe and effective at preventing symptomatic COVID-19 in adults.

PATH [to 21 Nov 2020]
https://www.path.org/media-center/
Press Release
No new digest content identified.

Sabin Vaccine Institute [to 21 Nov 2020]
http://www.sabin.org/updates/pressreleases
Statements and Press Releases
No new digest content identified.

UNAIDS [to 21 Nov 2020]
http://www.unaids.org/en
Selected Press Releases/Reports/Statements
20 November 2020
UNAIDS joins partners to call for better testing, treatment and prevention of HIV and TB among children
On World Children's Day, UNAIDS is joining with partners to call for accelerated access to better tools to prevent, diagnose and treat HIV in children and tuberculosis (TB) in children living with HIV with a joint statement announcing the launch of the Rome Action Plan 2020…
On 5 and 6 November, the Vatican's Cardinal Turkson convened the virtual Rome Five meeting. This innovative dialogue brought together leaders from the private and public sectors, governments, regulatory authorities, faith-based and community-based organizations and other implementing partners to find solutions to reduce the burden of HIV and TB among children
The meeting resulted in a new Rome Action Plan 2020, a series of ambitious commitments made by participating organizations aimed at overcoming the bottlenecks to HIV and TB services for children. Among the many commitments made by the partner organizations, UNAIDS has committed to supporting governments to collect and report on the burden of HIV and TB among children so that national responses can be targeted to where they are most needed. UNAIDS will set and report on ambitious age-specific global targets for the prevention, testing and successful treatment of HIV in

children and TB in children living with HIV. UNAIDS will continue to advocate at the highest political level for increased investment and committed actions at the country level so that the world can get on track to ending AIDS and TB among children living with HIV.

16 November 2020
New faith-based initiative launched in Côte d'Ivoire

16 November 2020
HIV financing gap widening
The funding gap for HIV responses is widening. Momentum established following global agreement on the Millennium Development Goals in 2000 has been lost in the Sustainable Development Goal era. Increases in resources for HIV responses in low- and middle-income countries halted in 2017, with funding decreasing by 7% between 2017 and 2019 (to US$ 18.6 billion in constant 2016 United States dollars).
The total funding available in 2019 for HIV in these countries amounted to about 70% of the 2020 target set by the United Nations General Assembly…

UNICEF [to 21 Nov 2020]
https://www.unicef.org/media/press-releases
Selected Press releases, Statements
Press release
11/20/2020
Presidents, Prime Ministers, UNICEF Goodwill Ambassadors and global businesses unite with children and young people on World Children's Day

News note
11/20/2020
Geneva Palais briefing note on the situation of Ethiopian children fleeing into Sudan and UNICEF's response

Statement
11/19/2020
2.3 million children in Tigray region of Ethiopia need humanitarian assistance, as thousands flee across border into Sudan
Statement by UNICEF Executive Director Henrietta Fore

Press release
11/19/2020
UNICEF appeals for US$42.6 million to deliver humanitarian assistance in hurricane-struck Central America

Press release
11/18/2020
UNICEF calls for averting a lost generation as COVID-19 threatens to cause irreversible harm to children's education, nutrition and well-being
Children and adolescents account for 1 in 9 of reported COVID-19 infections, according to new analysis released ahead of World Children's Day

Press release
11/18/2020
UNICEF welcomes end of Ebola outbreak in the Equateur Province of the DRC

Unitaid [to 21 Nov 2020]
https://unitaid.org/
Featured News
19 November 2020
Unitaid reaffirms its support to the Medicines Patent Pool, a key player for equitable access to life-saving medicines
Geneva – Through the approval of a new $34.3 million grant for the next five years to the Medicines Patent Pool (MPP), Unitaid has reinforced its historic commitment to equitable access to affordable, quality medicines for all.

Founded by Unitaid 10 years ago, MPP has established itself as a key player in global health through facilitating rapid access to medicines for people affected by HIV/AIDS, tuberculosis and hepatitis C in low- and middle-income countries (LMICs).

Since its inception, MPP's work with pharmaceutical manufacturers and partners has contributed to supplying over 15 billion doses of quality generic treatments for HIV and hepatitis C in LMICs.

Over the past six years, as part of a coalition of partners including the World Health Organization (WHO), the Global Fund to Fight AIDS, Tuberculosis and Malaria, PEPFAR, Unitaid, and countries such as South Africa and civil society, MPP has facilitated the development, scale-up, and roll-out of dolutegravir (DTG) and the DTG combination regimen TLD (tenofovir/lamivudine/dolutegravir). TLD is a more efficient fixed-dose combination that contributes to decreasing the pill burden and increasing adherence to treatment for people living with HIV.

Joint efforts have contributed to making these life-saving drugs available at historically low prices. Countries are now procuring DTG for less than US$ 70 per person, per year — bringing substantial savings that can be reinvested in other areas. Current annual savings are enough to procure treatment for an additional 5 million people every year.

The WHO recommends DTG-based treatment as the preferred first- and second-line regimen for people living with HIV. MPP has also contributed to the development and distribution of different pediatric formulations that are better suited to children, and has played a critical role in enabling affordable access to hepatitis C treatments in many LMICs.

This new grant, that covers the period 2021-2025, will enable MPP to further its work centered around negotiating voluntary licenses and expanding production capacities for HIV, tuberculosis and hepatitis C medicines in order to make them more widely available and affordable for those who need it. The project also includes extending MPP's scope to long-acting therapeutics, working alongside all Unitaid-funded long-acting projects with the objective to bring simplified treatments to patients and increase adherence. A further area of work targets voluntary licensing of patented medicines on the WHO Model List of Essential Medicines…

17 November 2020
Unitaid supports the WHO's cervical cancer elimination strategy launch
Geneva – Unitaid is delighted to give its support to today's launch of the WHO's Global Strategy to Accelerate the Elimination of Cervical Cancer – the first time the world has ever committed to eliminating a cancer…

Unitaid is now the largest funder of innovative tools to find and treat precancerous lesions in women living in low-resource settings. These investments have laid a firm foundation for the elimination strategy, and Unitaid remains on-target to reach one million women within three years, with an estimated 100,000 additional lives saved over eight years.

Our partnerships with CHAI, Expertise France, Jhpiego and UICC focus on introducing innovation and making it accessible and affordable. Many of the successful techniques for reducing cervical cancer in high-income countries are difficult to transfer over to low-and-middle income countries, so Unitaid's fresh and targeted approach has transformational potential.
We have already made significant progress towards our ambitious goal of delivering screening and treatment for less than US$1 per woman. Thermal Ablation devices are now available for less than US$900, representing an average price reduction of 50%...

Vaccination Acceptance Research Network (VARN) [to 21 Nov 2020]
https://vaccineacceptance.org/news.html#header1-2r
Announcements
No new digest content identified.

Vaccine Confidence Project [to 21 Nov 2020]
http://www.vaccineconfidence.org/
Research and Reports
No new digest content identified.

Vaccine Education Center – Children's Hospital of Philadelphia [to 21 Nov 2020]
http://www.chop.edu/centers-programs/vaccine-education-center
News
Experts Issue Recommendations for Equitable Distribution of COVID-19 Vaccine
--CHOP-led paper outlines five principles that would allow for equity, transparency, accountability, availability and access--
PHILADELPHIA, Nov. 19, 2020 /PRNewswire/ -- A group of vaccine experts led by Children's Hospital of Philadelphia (CHOP) has published recommendations to ensure equitable distribution of a COVID-19 vaccine when it becomes available. The framework, published today in Heath Affairs, focuses on five principles the authors believe would strengthen the current immunization delivery system to ensure equitable access to everyone for whom vaccination is recommended.

"It is critical for the federal government to set policy and provide coordinated guidance and resources to states and localities for meaningful, rapid implementation of a vaccine strategy, so that areas may begin immunizing prioritized populations as soon as they receive vaccine doses," said lead author Angela K. Shen, ScD, MPH, a visiting research scientist at CHOP's Vaccine Education Center.

The paper outlines five main principles by which policymakers can implement an equitable COVID-19 vaccine distribution strategy:
[1] Recruit diverse populations to participate in clinical trials for a COVID-19 vaccine to ensure the data reflect the racial, ethnic, age and gender diversity of the US.
[2] Require transparency when it comes to reviewing safety and efficacy data, with approval discussions taking place in the public eye, particularly in the event of an Emergency Use Authorization.
[3] Follow guidance from the Advisory Committee on Immunization Practices (ACIP) and the National Academy of Sciences, Engineering, and Medicine (NASEM) working groups as they identify priority groups and develop recommendations for vaccinating the civilian population.
[4] Ensure access to vaccinations for all individuals, regardless of their ability to pay.
[5] Engage state-level task forces and working groups in discussions about how to distribute vaccines effectively to recommended populations, with a focus on communication strategies and ensuring proper representation of minority voices.

Health Affairs *Ahead of Print*
Analysis
Ensuring Equitable Access To COVID-19 Vaccines In The US: Current System Challenges And Opportunities
Angela K. Shen, Richard Hughes IV, Erica DeWald, Sara Rosenbaum, Amy Pisani, and Walt Orenstein
PUBLISHED:November 19, 2020 Free Accesshttps://doi.org/10.1377/hlthaff.2020.01554
Abstract
There has been a worldwide effort to accelerate the development of safe and effective severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) vaccines. When vaccines become licensed and available broadly to the public, the final hurdle is equitable distribution and access for all who are recommended for vaccination. Frameworks and existing systems for allocation, distribution, vaccination, and monitoring for safety and effectiveness are assets of the current immunization delivery system that should be leveraged to ensure equitable distribution and broad uptake of licensed vaccines. The system should be strengthened where possible to address gaps in access to immunization services and to modernize the public health infrastructure. We offer five recommendations as guideposts to ensure that policies and practices at the federal, state, local and tribal levels support equity, transparency, accountability, availability and access to coronavirus disease 2019 (COVID-19) vaccines. [Editor's Note: This Fast Track Ahead Of Print article is the accepted version of the peer-reviewed manuscript. The final edited version will appear in an upcoming issue of Health Affairs.]

Wellcome Trust [to 21 Nov 2020]
https://wellcome.ac.uk/news
Opinion | 20 November 2020
Four reasons why we need multiple vaccines for Covid-19
Charlie Weller, Head of Vaccines Programme, Wellcome
Having a range of Covid-19 vaccines available for people to use around the world will be essential to bringing the pandemic under control. Here's why.

Explainer | 19 November 2020
Seven vital questions about the RNA Covid-19 vaccines emerging from clinical trials

Preliminary data from phase III clinical trials has shown the Pfizer-BioNTech and Moderna Covid-19 vaccines to be more than 90% effective. They are the first vaccine candidates to produce such positive results, and this is great news.

These vaccines, unlike the vaccines we already use for other diseases, have been developed using ribonucleic acid (RNA) technology. So, how do they work, are they safe, and when will they be available?

Opinion | 16 November 2020
Drug-resistant infections: what we're doing now to tackle this slow-moving pandemic
Tim Jinks, Head of Drug-resistant Infections Programme, Wellcome

To stop life-threatening infections from escalating, the world must control the spread of drug-resistant infections. Tim Jinks explains Wellcome's role in the global response to antimicrobial resistance.

The Wistar Institute [to 21 Nov 2020]
https://www.wistar.org/news/press-releases
Press Releases
No new digest content identified.

WFPHA: World Federation of Public Health Associations [to 21 Nov 2020]
https://www.wfpha.org/
Latest News
No new digest content identified.

World Organisation for Animal Health (OIE) [to 21 Nov 2020]
https://www.oie.int/en/for-the-media/press-releases/2020/
Press Releases
20/11/20
World leaders join forces to fight the accelerating crisis of antimicrobial resistance

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ARM [Alliance for Regenerative Medicine] [to 21 Nov 2020]
https://alliancerm.org/press-releases/
Press Releases
ARM Statement on the Trump Administration's Interim Final Rule on Drug Pricing
November 20, 2020 Washington, DC

Cell, gene, and tissue-based therapies are the future of medicine, with the potential to durably treat or even cure the most challenging diseases. The administration's 'Most Favored Nation' Interim Final Rule could threaten innovation in regenerative medicine. If the administration is concerned about clinical outcomes and high expenditures, policymakers should embrace innovative payment models, including outcomes-based agreements that reward scientific investment when therapies work and patients' conditions improve.

BIO [to 21 Nov 2020]
https://www.bio.org/press-releases
Press Releases
BIO's Dr. McMurry-Heath Calls Foreign Price Controls a "Fatally Flawed Regulation" That Will "Endanger Our Most Vulnerable Americans"
Washington, DC (November 20, 2020) – Dr. Michelle McMurry-Heath, president and CEO of the Biotechnology Innovation Organization (BIO), issued the following statement after the Trump administration moved forward with its threat to impose…

DCVMN – Developing Country Vaccine Manufacturers Network [to 21 Nov 2020]
http://www.dcvmn.org/
News; Upcoming events
No new digest content identified.

ICBA – International Council of Biotechnology Associations [to 21 Nov 2020]
https://internationalbiotech.org/news/
News
No new digest content identified.

IFPMA [to 21 Nov 2020]
http://www.ifpma.org/resources/news-releases/
Selected Press Releases, Statements, Publications
Biopharmaceutical representative joins new antibiotic resistance fighting United Nations group to avert looming superbugs public
20 November 2020

Joint Statement On World Antimicrobial Awareness Week
18 November 2020

PhRMA [to 21 Nov 2020]
http://www.phrma.org/
Selected Press Releases, Statements
Press Release
PhRMA Announces First-Ever, Industry-Wide Principles on Clinical Trial Diversity
WASHINGTON, D.C. (November 17, 2020) – Today, the Pharmaceutical Research and Manufacturers of America (PhRMA) announced first-ever, industry-wide principles on clinical trial diversity. The principles focus on four main areas: building trust and acknowledging the historic mistrust of clinical trials within Black and Brown communities, reducing barriers to clinical trial access, using real-world data to enhance information on diverse populations beyond product approval and enhancing information about diversity and inclusion in clinical trial participation. These principles were approved by the PhRMA Board of Directors and will take effect in April of 2021.

"The industry's new clinical trial diversity principles are an important step toward greater health equity," said Stephen J. Ubl, president and chief executive officer of PhRMA. "We are addressing issues

of mistrust and working to reduce systemic issues that deter communities of color from participating in clinical trials, so that those patients who want to participate, can."
America's biopharmaceutical companies are committed to learning and leading forward to address systematic racism and stand up to injustice. At the core of this effort is the need for our industry to better serve historically underserved communities, including Black and Brown communities.

Critical to health equity for these communities is clinical trial diversity that better reflects intended treatment populations for different medicines and therapeutics. With the voluntary adoption of these industry-wide principles by PhRMA member companies, we are pledging to work on addressing the systemic issues that deter people from participating in clinical trials.

To view the principles, please visit: https://www.phrma.org/en/Codes-and-guidelines/PhRMA-Principles-on-Conduct-of-Clinical-Trials

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Journal Watch

Vaccines and Global Health: The Week in Review continues its weekly scanning of key peer-reviewed journals to identify and cite articles, commentary and editorials, books reviews and other content supporting our 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

AJOB Empirical Bioethics
Volume 11, 2020 Issue 4
https://www.tandfonline.com/toc/uabr21/current
[Reviewed earlier]

AMA Journal of Ethics
Volume 22, Number 11: E907-980 November 2020
https://journalofethics.ama-assn.org/issue/caring-native-americans

Risk Management Ethics

Patients' rights to self-determination or clinicians' professional judgments in some cases deviate from standard of care and challenge risk managers' tendencies to implement routine legal risk-mitigation strategies. Risk managers' roles on care teams are particularly key when patients don't progress clinically, when patients do not feel safe or satisfied with their services, when interventions are not well coordinated, or when care is not safely, efficiently, or equitably executed. Risk managers' collaborations with ethics consultants and clinicians in these cases help individuals and organizations respond well to complex questions at the intersections of professional caregiving, ethics, and law. Issue PDF
[Reviewed earlier]

American Journal of Infection Control
November 2020 Volume 48 Issue 11 p1287-1414
http://www.ajicjournal.org/current
[Reviewed earlier]

American Journal of Preventive Medicine
November 2020 Volume 5 9Issue 5 p621-772
http://www.ajpmonline.org/current
[Reviewed earlier]

American Journal of Public Health
November 2020 110(11)
http://ajph.aphapublications.org/toc/ajph/current
[Reviewed earlier]

American Journal of Tropical Medicine and Hygiene
Volume 103, Issue 5, November 2020
http://www.ajtmh.org/content/journals/14761645/103/5
[Reviewed earlier]

Annals of Internal Medicine
17 November 2020 Volume 173, Issue 10
http://annals.org/aim/issue
Original Research
National Trends in Drug Payments for HIV Preexposure Prophylaxis in the United States, 2014 to 2018
A Retrospective Cohort Study
Nathan W. Furukawa, MD, MPH, Weiming Zhu, MD, PhD, Ya-Lin A. Huang, PhD, ... et al.
Improving uptake of preexposure prophylaxis (PrEP) for people at risk for HIV is a priority of the National HIV/AIDS Federal Action Plan. This analysis estimates the distribution of PrEP costs in the United States between 2014 and 2018.

Ideas and Opinions
The Moral Imperative to Include Pregnant Women in Clinical Trials of Interventions for COVID-19
FREE
Isabelle Malhamé, MD, MSc, Rohan D'Souza, MD, PhD, and Matthew P. Cheng, MDCM
Although the number of clinical trials of interventions for COVID-19 is increasing, many exclude pregnant women or do not address pregnancy. This commentary discusses why pregnant women should be included in these trials.

Editorials
Payments for Preexposure Prophylaxis in the United States: Too Much for Too Few

Kevin L. Ard, MD, MPH and
Rochelle P. Walensky, MD, MPH
Furukawa and colleagues provided a detailed analysis suggesting that costs are a fundamental reason why PrEP uptake is low. The editorialists discuss strategies to increase use of PrEP to prevent HIV infection.

Artificial Intelligence – An International Journal
Volume 289, December 2020
https://www.sciencedirect.com/journal/artificial-intelligence/vol/289/suppl/C
Research article Abstract only
Explanation in AI and law: Past, present and future
Katie Atkinson, Trevor Bench-Capon, Danushka Bollegala
Article 103387
Abstract
Explanation has been a central feature of AI systems for legal reasoning since their inception. Recently, the topic of explanation of decisions has taken on a new urgency, throughout AI in general, with the increasing deployment of AI tools and the need for lay users to be able to place trust in the decisions that the support tools are recommending. This paper provides a comprehensive review of the variety of techniques for explanation that have been developed in AI and Law. We summarise the early contributions and how these have since developed. We describe a number of notable current methods for automated explanation of legal reasoning and we also highlight gaps that must be addressed by future systems to ensure that accurate, trustworthy, unbiased decision support can be provided to legal professionals. We believe that insights from AI and Law, where explanation has long been a concern, may provide useful pointers for future development of explainable AI.

BMC Cost Effectiveness and Resource Allocation
http://resource-allocation.biomedcentral.com/
(Accessed 21 Nov 2020)
[No new digest content identified]

BMJ Global Health
November 2020 - Volume 5 - 11
https://gh.bmj.com/content/5/11
[Reviewed earlier]

BMC Health Services Research
http://www.biomedcentral.com/bmchealthservres/content
(Accessed 21 Nov 2020)
[No new digest content identified]

BMC Infectious Diseases
http://www.biomedcentral.com/bmcinfectdis/content
(Accessed 21 Nov 2020)

Acceptability of on-site rapid HIV/HBV/HCV testing and HBV vaccination among three at-risk populations in distinct community-healthcare outreach centres: the ANRS-SHS 154 CUBE study

HIV, HBV and HCV infections continue to represent major health concerns, especially among key at-risk populations such as men who have sex with men (MSM), people who inject drugs (PWIDs), transgender women (TG...

Authors: Ruxandra Calin, Véronique Massari, Gilles Pialoux, Nelly Reydellet, Eve Plenel, Carole Chauvin, Marie Jauffret-Roustide, Nesrine Day, Georges Kreplak, Anaenza Freire Maresca, Nicolas Derche, Sandra Louis, Stanislas Pol, Véronique Doré, Christine Rouzioux and Pierre Chauvin
Citation: BMC Infectious Diseases 2020 20:851
Content type: Research article
Published on: 16 November 2020

Impact of HPV-16/18 AS04-adjuvanted vaccine on preventing subsequent infection and disease after excision treatment: post-hoc analysis from a randomized controlled trial

It is widely acknowledged that HPV prophylactic vaccine could prevent new infections and their associated lesions among women who are predominantly HPV-naive at vaccination. Yet there still remains uncertainty...

Authors: Shuang Zhao, Shangying Hu, Xiaoqian Xu, Xun Zhang, Qinjing Pan, Feng Chen and Fanghui Zhao
Citation: BMC Infectious Diseases 2020 20:846
Content type: Research article
Published on: 16 November 2020

BMC Medical Ethics

http://www.biomedcentral.com/bmcmedethics/content
(Accessed 21 Nov 2020)

Sharing genomic data from clinical testing with researchers: public survey of expectations of clinical genomic data management in Queensland, Australia

Authors: Miranda E. Vidgen, Sid Kaladharan, Eva Malacova, Cameron Hurst and Nicola Waddell
Content type: Research article
19 November 2020

Ethics framework for treatment use of investigational drugs

Authors: Jan Borysowski and Andrzej Górski
Content type: Debate
18 November 2020

Abstract

Background

Expanded access is the use of investigational drugs (IDs) outside of clinical trials. Generally it is performed in patients with serious and life-threatening diseases who cannot be treated satisfactorily with authorized drugs. Legal regulations of expanded access to IDs have been introduced among others in the USA, the European Union (EU), Canada and Australia. In addition, in the USA an alternative to expanded access is treatment under the Right-to-Try law. However, the treatment use of IDs is inherently associated with a number of ethically relevant problems.

Main text

The objective of this article is to present a coherent framework made up of eight requirements which have to be met for any treatment use of an ID to be ethical. These include a justified need for the use of an ID, no threat to clinical development of the ID, adequate scientific evidence to support the treatment, patient's benefit as the primary goal of the use of an ID, informed decision of a patient, fair access of patients to IDs, independent review, as well as the dissemination of treatment results.
Conclusions
While this framework is essentially consistent with the legal regulations of expanded access of the USA, the EU, Canada and Australia, it is substantially wider in scope because it addresses some important issues that are not covered by the regulations. Overall, the framework that we developed minimizes the risks and threats, and maximizes potential benefits to each of the four key stakeholders involved in the treatment use of IDs including patients, doctors, drug manufacturers, and society at large.

Clinical Ethics Committees in Africa: lost in the shadow of RECs/IRBs?

Clinical Ethics Committees (CECs) are well established at healthcare institutions in resource-rich countries. However, there is limited information on established CECs in resource poor countries, especially in Africa. This study aimed to establish baseline data regarding existing formal CECs in Africa to raise awareness of and to encourage the establishment of CECs or Clinical Ethics Consultation Services (CESs) on the continent.

Authors: Keymanthri Moodley, Siti Mukaumbya Kabanda, Leza Soldaat, Anita Kleinsmidt, Adetayo Emmanuel Obasa and Sharon Kling
Citation: BMC Medical Ethics 2020 21:115
Content type: Research article
Published on: 18 November 2020

BMC Medicine
http://www.biomedcentral.com/bmcmed/content
(Accessed 21 Nov 2020)
[No new digest content identified]

BMC Pregnancy and Childbirth
http://www.biomedcentral.com/bmcpregnancychildbirth/content
(Accessed 21 Nov 2020)
[No new digest content identified]

BMC Public Health
http://bmcpublichealth.biomedcentral.com/articles
(Accessed 21 Nov 2020)
[No new digest content identified]

BMC Research Notes
http://www.biomedcentral.com/bmcresnotes/content
(Accessed 21 Nov 2020)
[No new digest content identified]

BMJ Open
November 2020 - Volume 10 - 11
https://bmjopen.bmj.com/content/10/11
[Reviewed earlier]

Bulletin of the World Health Organization
Volume 98, Number 11, November 2020, 725-820
https://www.who.int/bulletin/volumes/98/11/en/
[Reviewed earlier]

Child Care, Health and Development
Volume 46, Issue 6 Pages: 651-750 November 2020
https://onlinelibrary.wiley.com/toc/13652214/current
[Reviewed earlier]

Clinical Pharmacology & Therapeutics
Volume 108, Issue 5 Pages: 897-1106 November 2020
https://ascpt.onlinelibrary.wiley.com/toc/15326535/current
[Reviewed earlier]

Clinical Therapeutics
October 2020 Volume 42 Issue 10 p1847-2118
http://www.clinicaltherapeutics.com/current
[New issue; No digest content identified]

Clinical Trials
Volume 17 Issue 6, December 2020
https://journals.sagepub.com/toc/ctja/17/5
[Reviewed earlier]

Conflict and Health
http://www.conflictandhealth.com/
[Accessed 21 Nov 2020]
[No new digest content identified]

Contemporary Clinical Trials
Volume 97 October 2020
https://www.sciencedirect.com/journal/contemporary-clinical-trials/vol/97/suppl/C
Research article Full text access

Selecting appropriate endpoints for assessing treatment effects in comparative clinical studies for COVID-19
Zachary R. McCaw, Lu Tian, Kevin N. Sheth, Wan-Ting Hsu, ... Lee-Jen Wei
Article 106145
Abstract
To evaluate the efficacy and safety of a new treatment for COVID-19 vs. standard care, certain key endpoints are related to the duration of a specific event, such as hospitalization, ICU stay, or receipt of supplemental oxygen. However, since patients may die in the hospital during study follow-up, using, for example, the duration of hospitalization to assess treatment efficacy can be misleading. If the treatment tends to prolong patients' survival compared with standard care, patients in the new treatment group may spend more time in hospital. This can lead to a "survival bias" issue, where a treatment that is effective for preventing death appears to prolong an undesirable outcome. On the other hand, by using hospital-free survival time as the endpoint, we can circumvent the survival bias issue. In this article, we use reconstructed data from a recent, large clinical trial for COVID-19 to illustrate the advantages of this approach. For the analysis of ICU stay or oxygen usage, where the initiating event is potentially an outcome of treatment, standard survival analysis techniques may not be appropriate. We also discuss issues with analyzing the durations of such events.

The CRISPR Journal
Volume 3, Issue 5 / October 2020
https://www.liebertpub.com/toc/crispr/3/5
[Reviewed earlier]

Current Genetic Medicine Reports
Volume 8, issue 3, September 2020
https://link.springer.com/journal/40142/volumes-and-issues/8-3
[Reviewed earlier]

Current Opinion in Infectious Diseases
December 2020 - Volume 33 - Issue 6
https://journals.lww.com/co-infectiousdiseases/pages/currenttoc.aspx
[Reviewed earlier]

Developing World Bioethics
Volume 20, Issue 3 Pages: 115-171 September 2020
https://onlinelibrary.wiley.com/toc/14718847/current
[Reviewed earlier]

Development in Practice
Volume 30, Issue 7, 2020
http://www.tandfonline.com/toc/cdip20/current
[Reviewed earlier]

Disaster Medicine and Public Health Preparedness
Volume 14 - Issue 3 - June 2020
https://www.cambridge.org/core/journals/disaster-medicine-and-public-health-preparedness/latest-issue
[Reviewed earlier]

Disasters
Volume 44, Issue 4 Pages: 619-752 October 2020
https://onlinelibrary.wiley.com/toc/14677717/current
[Reviewed earlier]

EMBO Reports
Volume 21 Issue 11 5 November 2020
https://www.embopress.org/toc/14693178/current
[Reviewed earlier]

Emerging Infectious Diseases
Volume 26, Number 11—November 2020
http://wwwnc.cdc.gov/eid/
[Reviewed earlier]

Epidemics
Volume 32 September 2020
https://www.sciencedirect.com/journal/epidemics/vol/32/suppl/C
[Reviewed earlier]

Epidemiology and Infection
Volume 148 - 2020
https://www.cambridge.org/core/journals/epidemiology-and-infection/latest-issue
[Reviewed earlier]

Ethics & Human Research
Volume 42, Issue 6 Pages: 1-40 November–December 2020
https://onlinelibrary.wiley.com/toc/25782363/current
Video-capture studies • Benefit sharing and genomics research
[Reviewed earlier]

The European Journal of Public Health
Volume 30, Issue 5, October 2020
https://academic.oup.com/eurpub/issue/30/5

[Reviewed earlier]

Expert Review of Vaccines
Vol 19 (9) 2020
https://www.tandfonline.com/toc/ierv20/current
Case Report
Long-term durability of immunogenicity induced by standard and triple-dose hepatitis B vaccine in patients receiving methadone maintenance treatment
Tian Yao , Yuanting Wu , Shuang Dong , Linying Gao , Shan Shi , Zhihong Shao , Lina Wu , Dan Feng , Jing Shi , Yawei Zhang , Yongliang Feng , Xiaofeng Liang & Suping Wang
Pages: 785-794
Published online: 14 Sep 2020

An overview of Middle East respiratory syndrome coronavirus vaccines in preclinical studies
Naru Zhang , Jian Shang , Chaoqun Li , Kehui Zhou & Lanying Du
Pages: 817-829
Published online: 08 Sep 2020

Gates Open Research
https://gatesopenresearch.org/browse/articles
[Accessed 21 Nov 2020]
Open Letter
Integration of health solutions into government systems: a tool for assessing readiness
[version 1; peer review: awaiting peer review]
Emily Lawrence
https://orcid.org/0000-0002-4572-1800
1, Amanda Pain1, Jessica Crawford1, Kim Baker1, Ruth Bechtel2, Aida Coelho2, Alvo Ofumane2, Joseph Roussel1, Bvudzai Magadzire
https://orcid.org/0000-0002-4164-6233
Abstract
Government partnerships are essential for many health solutions to sustain impact at scale, particularly in low-resource settings where strengthening health systems is critical for Universal Health Coverage. Many non-governmental organizations (NGOs) and funders ultimately want solutions to be integrated into public health systems by transitioning solution ownership, management and/or operation to government. However, NGOs and their government partners have limited guidance on how to effectively determine when a solution is ready to transition in a way that will maintain impact long term. To address this need, VillageReach developed the Transition Readiness Assessment (TRA) based on our transition to government theoretical framework. The framework was developed to define both factors related to a solution, as well as external influences that affect a solution's success. The framework identifies seven dimensions of solution readiness: the political, economic, and social context; solution design; resource availability; financial management; government strategy; government policy and regulations; and organizational management. The TRA measures those dimensions and assigns each one a readiness score. We developed the framework and TRA for VillageReach solutions, as well as to share with government partners and stakeholders.
This Open Letter outlines the TRA development, details empirical examples from applying the tool on

two VillageReach solutions, and presents recommendations based on our lessons learned. Stakeholders working to transition solutions to government can utilize both the TRA and our lessons.

Genome Medicine
https://genomemedicine.biomedcentral.com/articles
[Accessed 21 Nov 2020]
Comment
Transparency, trust, and community welfare: towards a precision public health ethics framework for the genomics era
Authors: Eric T. Juengst and Annelies Van Rie
Citation: Genome Medicine 2020 12:98
Published on: 20 November 2020
Abstract
Infectious disease control is experiencing a paradigm shift, as pathogen sequencing technologies and digital applications are increasingly implemented for control of diseases such as tuberculosis, Ebola, and COVID-19. A new ethical framework should be a critical part of this emerging paradigm to ensure that the benefit of precision public health interventions based on advances in genomics research is not outweighed by the risks they pose to individuals, families, and vulnerable segments of the population. We suggest that the ethical framework guiding practice in this domain combines standard precepts from public health ethics with emerging ethics principles from precision medicine.

Global Health Action
Volume 13, Issue 1 (2020)
https://www.tandfonline.com/toc/zgha20/current?nav=tocList
Article
Establishment of COVID-19 testing laboratory in resource-limited settings: challenges and prospects reported from Ethiopia
Adugna Abera , Habtamu Belay , Aboma Zewude , Bokretsion Gidey , Desalegn Nega , Boja Dufera , Abnet Abebe , Tujuba Endriyas , Birhanu Getachew , Henok Birhanu , Hailemariam Difabachew , Bacha Mekonnen , Helina Legesse , Firdawek Bekele , Kalkidan Mekete , Seble Seifu , Heven Sime , Nebiyou Yemanebrhan , Mesfin Tefera , Hiwot Amare , Berhane Beyene , Estifanos Tsige , Adisu Kebede , Geremew Tasew , Getachew Tollera , Ebba Abate , Adugna Woyessa & Ashenafi Assefa
Article: 1841963
Published online: 17 Nov 2020

Article
Universal access to essential medicines as part of the right to health: a cross-national comparison of national laws, medicines policies, and health system indicators
Katrina Perehudoff
Article: 1699342
Published online: 02 Nov 2020
ABSTRACT
Background
Access to essential medicines for the world's poor and vulnerable has made little progress since 2000, except for a few specific medicines such as antiretrovirals for HIV/AIDS. Human rights principles

written into national law can create a supportive environment for universal access to medicines; however, systematic research and policy guidance on this topic is lacking.
Objective
To examine how international human rights law and WHO's essential medicines policies are embedded in national law for medicines affordability and financing, and interpreted and implemented in practice to promote universal access to essential medicines.
Methods
This thesis consists of (1) a cross-national content analysis of 192 national constitutions, 71 national medicines policies, and legislation for universal health coverage (UHC) from 16 mostly low- and middle-income countries; (2) a case study of medicines litigation in Uruguay, and (3) a follow-up report of eight right to health indicators for access to medicines from 195 countries.
Results
Some, but not all, of the 12 principles from human rights law and WHO's policy are embedded in national UHC law and medicines policies (part 1). Even the most rights-compliant legislation for access to medicines is subject to the unique and inconsistent interpretation of domestic courts, which may be inconsistent with the right to health in international law (part 2). Many national health systems for which data were available still fail to meet the official targets for eight indicators of access to medicines (part 3).
Conclusions
International human rights law and WHO policy are embedded in national law for essential medicines and practically implemented in national health systems. Law makers can use these findings and the example texts in this thesis as a starting point for writing and monitoring governments' rights-based legal commitments for access to medicines. Future research should study the effect of national law on access to medicines and population health.

Article
Factors contributing to the uptake of childhood vaccination in Galkayo District, Puntland, Somalia
Mohamed Farah Abdullahi , Jennifer Stewart Williams , Klas-Göran Sahlèn , Khalif Bile & John Kinsman
Article: 1803543
Published online: 27 Aug 2020

Global Health: Science and Practice (GHSP)
Vol. 8, No. 3 October 01, 2020
http://www.ghspjournal.org/content/current
[Reviewed earlier]

Global Public Health
Volume 15, 2020 Issue 12
http://www.tandfonline.com/toc/rgph20/current
[Reviewed earlier]

Globalization and Health
http://www.globalizationandhealth.com/
[Accessed 21 Nov 2020]

[No new digest content identified]

Health Affairs
Vol. 39, No. 10 October 2020
https://www.healthaffairs.org/toc/hlthaff/current
Children's Health

Health and Human Rights
Volume 22, Issue 1, June 2020
https://www.hhrjournal.org/volume-22-issue-1-june-2020/
Special Section: Mental Health and Human Rights
[Reviewed earlier]

Health Economics, Policy and Law
Volume 15 - Issue 4 - October 2020
https://www.cambridge.org/core/journals/health-economics-policy-and-law/latest-issue
[Reviewed earlier]

Health Policy and Planning
Volume 35, Issue 8, October 2020
https://academic.oup.com/heapol/issue/35/8
[Reviewed earlier]

Health Research Policy and Systems
http://www.health-policy-systems.com/content
[Accessed 21 Nov 2020]
Commentary
Applying systems thinking to knowledge mobilisation in public health
Knowledge mobilisation (KM) is a vital strategy in efforts to improve public health policy and practice. Linear models describing knowledge transfer and translation have moved towards multi-directional and complexity-attuned approaches where knowledge is produced and becomes meaningful through social processes. There are calls for systems approaches to KM but little guidance on how this can be operationalised. This paper describes the contribution that systems thinking can make to KM and provides guidance about how to put it into action.
Authors: Abby Haynes, Lucie Rychetnik, Diane Finegood, Michelle Irving, Louise Freebairn and Penelope Hawe
17 November 2020

Human Gene Therapy
Volume 31, Issue 21-22 / November 2020
https://www.liebertpub.com/toc/hum/31/21-22
[New issue; No digest content identified]

Humanitarian Exchange Magazine
Number 78, October 2020
https://odihpn.org/magazine/inclusion-of-persons-with-disabilities-in-humanitarian-action-what-now/
Disability inclusion in humanitarian action
by HPN October 2020
The theme of this edition of Humanitarian Exchange, co-edited with Sherin Alsheikh Ahmed from Islamic Relief Worldwide, is disability inclusion in humanitarian action. Persons with disabilities are not only disproportionately impacted by conflicts, disasters and other emergencies, but also face barriers to accessing humanitarian assistance. At the same time, global commitments and standards and the IASC Guidelines on the inclusion of persons with disabilities in humanitarian action all emphasise how persons with disabilities are also active agents of change. Disability and age-focused organisations have led on testing and demonstrating how inclusion can be done better. Yet despite this progress, challenges to effective inclusion remain.

As Kirstin Lange notes in the lead article, chief among these challenges is humanitarian agencies' lack of engagement with organisations of persons with disabilities. Simione Bula, Elizabeth Morgan and Teresa Thomson look at disability inclusion in humanitarian response in the Pacific, and Kathy Al Jubeh and Alradi Abdalla argue for a 'participation revolution', building on learning from the gender movement. Tchaurea Fleury and Sulayman AbdulMumuni Ujah outline how the Bridge Article 11 training initiative is encouraging constructive exchange between humanitarian and disability actors. The lack of good, disaggregated data is highlighted by Sarah Collinson; Frances Hill, Jim Cranshaw and Carys Hughes emphasise the need for training resources in local languages and accessible formats; and Sophie Van Eetvelt and colleagues report on a review of the evidence on inclusion of people with disabilities and older people.

Rebecca Molyneux and co-authors analyse the findings of a review of a DFID programme in north-east Nigeria, while Carolin Funke highlights the importance of strategic partnerships between disability-focused organisations, drawing on her research in Cox's Bazar. Sherin Alsheikh Ahmed describes Islamic Relief Worldwide's approach to mainstreaming protection and inclusion, while Pauline Thivillier and Valentina Shafina outline IRC's Client Responsive Programming. The edition ends with reflections by Mirela Turcanu and Yves Ngunzi Kahashi on CAFOD's SADI approach.

Human Vaccines & Immunotherapeutics (formerly Human Vaccines)
Volume 16, Issue 9, 2020
http://www.tandfonline.com/toc/khvi20/current
[Reviewed earlier]

Infectious Agents and Cancer
http://www.infectagentscancer.com/content
[Accessed 21 Nov 2020]
[No new digest content identified]

Infectious Diseases of Poverty

http://www.idpjournal.com/content
[Accessed 21 Nov 2020]
[No new digest content identified]

International Health
Volume 12, Issue 6, November 2020
https://academic.oup.com/inthealth/issue/12/6
[Reviewed earlier]

International Journal of Community Medicine and Public Health
Vol 7, No 11 (2020) November 2020
https://www.ijcmph.com/index.php/ijcmph/issue/view/68
Table of Contents
A cross sectional study on immunization status among children 12 to 24 months of age in urban field practice area of tertiary health care centre, Hyderabad
Arundhathi Baaki, Lavanya Katta, Sreelatha Panuganti, B. Kiranmai
DOI: 10.18203/2394

Review Articles
Vaccine hesitancy in India-the challenges: a review
Gopalakrishnan S., Sujitha P.
DOI: 10.18203/2394-6040.ijcmph20204768
Abstract
Immunization is the most cost-effective scientific method of reducing childhood morbidity and mortality. In India the national immunization programme has not been able to attain complete coverage of the eligible children and hence mortality due to vaccine preventable diseases is approximately 5 lakhs annually. Every year, 89 lakhs children are at risk to develop vaccine preventable diseases due to lack of immunization. While most people vaccinate according to the recommended schedule, this success is challenged by individuals and groups who delay, hesitant or refuse vaccines due to various reasons. Despite the realization of compulsory scheduling of vaccines, there are an alarming number of parents who do not permit the vaccination of their children as scheduled. Vaccine hesitancy refers to a delay in acceptance or refusal of vaccines despite the availability of vaccination services. WHO in 2019 listed vaccine hesitancy as one of the ten global health threats. The recent vaccination coverage evaluation studies have shown that there is a perceptible drop in the vaccine coverage in most parts of India and also that the disparity in the urban-rural coverage is also widening. Hence an evaluation of the reasons for vaccine hesitancy is vital at present to strengthen the universal immunization program. The authors are trying to trace the present status and reasons for vaccine hesitancy reported in recent times, which can lead to outbreaks of already controlled vaccine preventable diseases and to identify strategies which are being implemented to overcome the vaccine hesitancy.

International Journal of Epidemiology
Volume 49, Issue 4, August 2020
https://academic.oup.com/ije/issue/49/4
[Reviewed earlier]

International Journal of Human Rights in Healthcare
Volume 13 Issue 4 2020
https://www.emerald.com/insight/publication/issn/2056-4902/vol/13/iss/4
Table of Contents
[Reviewed earlier]

International Journal of Infectious Diseases
September 2020 Volume 98, p1-502
https://www.ijidonline.com/issue/S1201-9712(20)X0010-5
[Reviewed earlier]

JAMA
November 17, 2020, Vol 324, No. 19, Pages 1925-2006
https://jamanetwork.com/journals/jama/currentissue
Research Letter
Financial Penalties Imposed on Large Pharmaceutical Firms for Illegal Activities
Denis G. Arnold, PhD; Oscar Jerome Stewart, PhD; Tammy Beck, PhD
JAMA. 2020;324(19):1995-1997. doi:10.1001/jama.2020.18740
This study describes financial penalties levied on pharmaceutical companies for illegal activities by type of activity and dollar value between 2003 and 2016.

Viewpoint
Preventing the Spread of SARS-CoV-2 With Masks and Other "Low-tech" Interventions
Andrea M. Lerner, MD, MS; Gregory K. Folkers, MS, MPH; Anthony S. Fauci, MD
free access has active quiz has multimedia has audio
JAMA. 2020;324(19):1935-1936. doi:10.1001/jama.2020.21946
In this Viewpoint, Anthony Fauci and colleagues at NIAID emphasize the continued importance of low-tech public health practices, such as wearing masks, limiting large gatherings, hand washing, and physical distancing, to help control the COVID-19 pandemic even after safe and effective vaccines become available until distribution and uptake of vaccines confer herd immunity on a population level.

Postapproval Vaccine Safety Surveillance for COVID-19 Vaccines in the US
Grace M. Lee, MD, MPH; José R. Romero, MD; Beth P. Bell, MD, MPH
free access has active quiz
JAMA. 2020;324(19):1937-1938. doi:10.1001/jama.2020.19692
This Viewpoint reviews systems in place to monitor postlicensure vaccine safety, and recommends harmonizing end points and protocols across vaccine trials and surveillance systems to enable timely identification and reliable evaluation of potential adverse events.

Postlicensure Evaluation of COVID-19 Vaccines
Manish M. Patel, MD; Michael L. Jackson, PhD; Jill Ferdinands, PhD
free access has active quiz
JAMA. 2020;324(19):1939-1940. doi:10.1001/jama.2020.19328

This Viewpoint explains the "test-negative" modified case-control design commonly used for evaluating vaccine effectiveness, describes why it may be lead to biased estimates of COVID-19 vaccine effectiveness in patients with severe illness more likely to test negative, and proposes potential approaches to correcting the bias, including incorporation of clinical assessment of cases.

Heritable Human Genome EditingThe International Commission Report
Eli Y. Adashi, MD, MS; I. Glenn Cohen, JD
has audio
JAMA. 2020;324(19):1941-1942. doi:10.1001/jama.2020.19059
This Viewpoint summarizes the report of the International Commission on the Clinical Use of Human Germline Genome Editing sponsored by the US National Academy of Medicine and the UK Royal Society, enumerating technical, regulatory, and ethical standards that need to be met before HHGE can be used on human embryos.

Editorial
Bioinformatics, Sequencing Accuracy, and the Credibility of Clinical Genomics
W. Gregory Feero, MD, PhD
Abstract
JAMA. 2020;324(19):1945-1947. doi:10.1001/jama.2020.19939
The adoption of clinical exome and whole-genome sequencing based on next-generation sequencing technologies has increased rapidly over the last decade; this has been accelerated by increasing coverage of these services by private and public insurers.[1,2] Examples of use include tumor and germline sequencing in patients with cancer, rapid turn-around sequencing of the genomes of critically ill neonates to diagnose mendelian conditions, and noninvasive prenatal testing for reproductive decision-making. The accuracy of sequencing results is of paramount importance to patients, clinicians, and those paying for testing services; inaccuracy can affect not only the tested individual, but their extended biological family.[3] Understanding what accuracy means in the context of genome sequencing is a challenge. In the genomics community accuracy is often described using 2 terms: analytic validity, eg, does the sequencing process reliably detect variations that are present in an individual's genome; and clinical validity, eg, are the variants detected reliably related to health outcomes.

JAMA Network
COVID-19 Update November 21, 2020
These articles on COVID-19 were published across the JAMA Network in the last week.
[Reviewed earlier]

JAMA Pediatrics
November 2020, Vol 174, No. 11, Pages 1017-1124
http://archpedi.jamanetwork.com/issue.aspx
[Reviewed earlier]

JBI Evidence Synthesis
November 2020 - Volume 18 - Issue 11
https://journals.lww.com/jbisrir/Pages/currenttoc.aspx
[New issue; No digest content identified]

Journal of Adolescent Health
December 2020 Volume 67Issue 6p733-880
https://www.jahonline.org/current
[New issue; No digest content identified]

Journal of Artificial Intelligence Research
Vol. 69 (2020)
https://www.jair.org/index.php/jair
[Reviewed earlier]

Journal of Community Health
Volume 45, issue 6, December 2020
https://link.springer.com/journal/10900/volumes-and-issues/45-6
Articles
Self-efficacy and HPV Vaccine Attitudes Mediate the Relationship Between Social Norms and Intentions to Receive the HPV Vaccine Among College Students
Authors (first, second and last of 5)
Madison E. Stout, Shannon M. Christy, Catherine E. Mosher
Content type: Original Paper
Published: 16 May 2020
Pages: 1187 – 1195

Identifying Associations Between Influenza Vaccination Status and Access, Beliefs, and Sociodemographic Factors Among the Uninsured Population in Suffolk County, NY
Authors (first, second and last of 4)
George Chen, Masooma Kazmi, Jedan Phillips
Content type: Original Paper
Published: 30 June 2020
Pages: 1236 - 1241

Journal of Development Economics
Volume 147 November 2020
https://www.sciencedirect.com/journal/journal-of-development-economics/vol/147/suppl/C
[Reviewed earlier]

Journal of Empirical Research on Human Research Ethics
Volume 15 Issue 5, December 2020
http://journals.sagepub.com/toc/jre/current
[Reviewed earlier]

Journal of Epidemiology & Community Health

November 2020 - Volume 74 - 11
https://jech.bmj.com/content/74/11
[Reviewed earlier]

Journal of Evidence-Based Medicine
Volume 13, Issue 3 Pages: 179-249 August 2020
https://onlinelibrary.wiley.com/toc/17565391/current
[Reviewed earlier]

Journal of Global Ethics
Volume 16, Issue 2, 2020
http://www.tandfonline.com/toc/rjge20/current
[Reviewed earlier]

Journal of Health Care for the Poor and Underserved (JHCPU)
Volume 31, Number 4, November 2020
https://muse.jhu.edu/issue/42831
Table of Contents
[Reviewed earlier]

Journal of Immigrant and Minority Health
Volume 22, issue 5, October 2020
https://link.springer.com/journal/10903/volumes-and-issues/22-5
[Reviewed earlier]

Journal of Immigrant & Refugee Studies
Volume 18, 2020_ Issue 4
https://www.tandfonline.com/toc/wimm20/current
[Reviewed earlier]

Journal of Infectious Diseases
Volume 222, Issue 3, 1 August 2020
https://academic.oup.com/jid/issue/222/3
[Reviewed earlier]

Journal of Medical Ethics
November 2020 - Volume 46 - 11
http://jme.bmj.com/content/current
[Reviewed earlier]

Journal of Patient-Centered Research and Reviews
Volume 7, Issue 4 (2020)
https://digitalrepository.aurorahealthcare.org/jpcrr/
[Reviewed earlier]

Journal of Pediatrics
November 2020 Volume 226 p1-322
http://www.jpeds.com/current
[Reviewed earlier]

Journal of Pharmaceutical Policy and Practice
https://joppp.biomedcentral.com/
[Accessed 21 Nov 2020]
[No new digest content identified]

Journal of Public Health Management & Practice
November/December 2020 - Volume 26 - Issue 6
https://journals.lww.com/jphmp/pages/currenttoc.aspx
[Reviewed earlier]

Journal of Public Health Policy
Volume 41, issue 4, December 2020
https://link.springer.com/journal/41271/volumes-and-issues/41-4
Original Article
Infectious disease, public health, and politics: United States response to Ebola and Zika
Phillip M. Singer, Charley E. Willison, Scott L. Greer
Published: 03 August 2020
Pages: 399 - 409

Viewpoint
Leveraging media and health communication strategies to overcome the COVID-19 infodemic
Nour Mheidly, Jawad Fares
Published: 21 August 2020
Pages: 410 - 420

Journal of Refugee & Global Health
Volume 3, Issue 1 (2020)
https://ir.library.louisville.edu/rgh/
[Reviewed earlier]

Journal of the Royal Society – Interface

November 2020 Volume 17 Issue 172
https://royalsocietypublishing.org/toc/rsif/current
[Reviewed earlier]

Journal of Travel Medicine
Volume 27, Issue 7, October 2020
https://academic.oup.com/jtm/issue/27/7
[Reviewed earlier]

Journal of Virology
November 2020; Volume 94,Issue 21
http://jvi.asm.org/content/current
[Reviewed earlier]

The Lancet
Nov 21, 2020 Volume 396 Number 10263 p1607-1702, e89
https://www.thelancet.com/journals/lancet/issue/current
Editorial
COVID-19 vaccines: no time for complacency
The Lancet
"Yes. Yes. Yes." That was the response of John Bell, Regius Professor of Medicine at the University of Oxford, when asked whether we could be confident that life will be returning to normal by spring. He was being interviewed by the BBC shortly after the announcement last week by Pfizer and BioNTech that their COVID-19 vaccine candidate had 90% efficacy in clinical trials. Similar announcements about the Russian Sputnik V and Moderna vaccines followed soon after. The prospect of preventing illness and death, and avoiding the harm and misery of extended restrictions, is a cause for optimism. But although it is right to be hopeful and encouraged, we are far from ending COVID-19 as a public health issue.

Unfortunately, the trials' results were announced via press releases, leaving many scientific uncertainties that will dictate how the vaccines will affect the course of the pandemic. Little safety data are available. How well the vaccines work in older people or those with underlying conditions and their efficacy in preventing severe disease are still unclear. Peer-reviewed publication should resolve these issues, but other questions will not be answerable for some time. For one, the duration of protection is unknown and will have a huge bearing on the practicalities and logistics of immunisation (will boosters be needed? How often?).

Whether the vaccines prevent transmission of SARS-CoV-2 or mainly just protect against illness is largely unknown too. If the latter, achieving herd immunity through immunisation becomes a difficult prospect. Pfizer and Moderna together project that there will be enough vaccine for 35 million individuals in 2020, and perhaps up to 1 billion in 2021. As a result, many millions of people at high risk of disease will not be immunised any time soon, necessitating the continued use of non-pharmaceutical interventions. There is a danger that the public might become complacent following the news of promising vaccines, but how much more difficult will it be to ensure adherence to guidance and restrictions when a vaccine is available to many but others remain unprotected? Vaccine hesitancy is

also a clear threat to COVID-19 control. New data show that willingness to take a COVID-19 vaccine is far from universal. When even wearing a face mask can be painted as a political act rather than a public health measure, responsible leadership and careful public communications will be essential.

These concerns will be irrelevant in places where a vaccine is unavailable entirely. Leaving aside the huge logistical challenges of manufacturing and roll-out (including onerous cold-chain requirements for some candidates), vaccine nationalism remains a major threat to equitable access. COVAX, the GAVI-led financing mechanism to provide COVID vaccines to low-income and middle-income countries, has raised US$2 billion, but needs $5 billion more for 2021. Pfizer and Moderna have not yet reached agreements with COVAX to supply vaccines; Pfizer has issued an expression of interest. By contrast, a handful of high-income countries have already secured the option to buy hundreds of millions of doses. Although some vaccine developers have promised to limit profits from the COVID-19 pandemic, Pfizer and Moderna have made no such commitments.

What does the long-term future look like? Will SARS-CoV-2 become endemic, in a post-pandemic phase? It is likely, but it is too early to be sure what form this endemicity will take. Vaccines will be just one determinant. Reinfections are another: they appear rare so far, but the pandemic is still young. The nature and length of immune responses, and the characteristics of the virus and infection play a role too. Can infection provide sterilising immunity? How quickly does protective immunity wane? How severe might reinfection be? How does immunity vary by sex, ethnicity, and age? Will we have annual seasonal outbreaks? Or longer spells of quiescence punctuated by re-emergence? And how will health systems have to adapt accordingly? These issues and many others will determine the continuing impacts of COVID-19 on health and all are still poorly understood.

2020 has been a year of incredible scientific achievement. In less than 12 months, researchers have characterised a novel illness, sequenced a new virus's genome, developed diagnostics, produced treatment protocols, and established the efficacy of drugs and vaccines in randomised controlled trials. Many people are feeling hopeful for the first time in a long time. But there is still much to learn and many barriers to overcome. On Nov 14, 5 days after the announcement by Pfizer, 663 772 new cases of COVID-19 were recorded, the largest number in a single day. It is a dangerous moment to be complacent.

Comment

Maintaining confidentiality of emerging results in COVID-19 vaccine trials is essential
Philip R Krause, Thomas R Fleming, Susan S Ellenberg, Ana Maria Henao-Restrepo on behalf of the WHO Ad Hoc Clinical Trial Expert Group

Challenges in creating herd immunity to SARS-CoV-2 infection by mass vaccination
Roy M Anderson, Carolin Vegvari, James Truscott, Benjamin S Collyer

The Lancet Child & Adolescent Health
Nov 2020 Volume 4 Number 11 p795-852, e40-e44
https://www.thelancet.com/journals/lanchi/issue/current
[Reviewed earlier]

Lancet Digital Health

Nov 2020 Volume 2 Number 11 e561-e628
https://www.thelancet.com/journals/landig/issue/current
[Reviewed earlier]

Lancet Global Health
Nov 2020 Volume 8 Number 11 e1352-e1443
http://www.thelancet.com/journals/langlo/issue/current
[Reviewed earlier]

Lancet Infectious Diseases
Nov 2020 Volume 20 Number 11 p1217-1348, e275-e297
http://www.thelancet.com/journals/laninf/issue/current
[Reviewed earlier]

Lancet Public Health
Nov 2020 Volume 5 Number 11 e568-e627
https://www.thelancet.com/journals/lanpub/issue/current
[Reviewed earlier]

Lancet Respiratory Medicine
Nov 2020 Volume 8 Number 11 p1061-1158, e78-e86
http://www.thelancet.com/journals/lanres/issue/current
[Reviewed earlier]

Maternal and Child Health Journal
Volume 24, issue 11, November 2020
https://link.springer.com/journal/10995/volumes-and-issues/24-11
Special Issue : Deaf Child Health in an International Context
[Reviewed earlier]

Medical Decision Making (MDM)
Volume 40 Issue 8, November 2020
http://mdm.sagepub.com/content/current
[New issue; No digest content identified]

The Milbank Quarterly
A Multidisciplinary Journal of Population Health and Health Policy
Volume 98, Issue 3 Pages: 619-1020 September 2020
https://onlinelibrary.wiley.com/toc/14680009/current
[Reviewed earlier]

Nature
Volume 587 Issue 7834, 19 November 2020
http://www.nature.com/nature/current_issue.html
Editorial | 17 November 2020
Europe must think more globally in crafting its pandemic response
The EU has struggled to find a unified voice in the pandemic. A new plan is a strong start, but needs to be more outward-looking.

Editorial | 18 November 2020
Facial-recognition research needs an ethical reckoning
The fields of computer science and artificial intelligence are struggling with the ethical challenges of biometrics. Researchers, funders and institutions must respond.

Nature Biotechnology
Volume 38 Issue 11, November 2020
https://www.nature.com/nbt/volumes/38/issues/11
[Reviewed earlier]

Nature Communications
https://www.nature.com/subjects/health-sciences/ncomms
(Accessed 21 Nov 2020)
[No new digest content identified]

Nature Genetics
Volume 52 Issue 11, November 2020
https://www.nature.com/ng/volumes/52/issues/11
[Reviewed earlier]

Nature Medicine
Volume 26 Issue 11, November 2020
https://www.nature.com/nm/volumes/26/issues/11
[New issue; No digest content identified]

Nature Reviews Genetics
Volume 21 Issue 11, November 2020
https://www.nature.com/nrg/volumes/21/issues/11
[Reviewed earlier]

Nature Reviews Immunology
Volume 20 Issue 11, November 2020
https://www.nature.com/nri/volumes/20/issues/11

[Reviewed earlier]

Nature Reviews Drug Discovery
Volume 19 Issue 11, November 2020
https://www.nature.com/nrd/volumes/19/issues/11
[Reviewed earlier]

New England Journal of Medicine
November 19, 2020 Vol. 383 No. 21
http://www.nejm.org/toc/nejm/medical-journal
[New issue; No digest content identified]

Pediatrics
Vol. 146, Issue 5 1 Nov 2020
https://pediatrics.aappublications.org/
[Reviewed earlier]

Pharmaceutics
Volume 12, Issue 7 (July 2020) – 97 articles
https://www.mdpi.com/1999-4923/12/7
[Reviewed earlier]

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Volume 38, issue 11, November 2020
https://link.springer.com/journal/40273/volumes-and-issues/38-11
[Reviewed earlier]

PLoS Genetics
https://journals.plos.org/plosgenetics/
(Accessed 21 Nov 2020)
[No new digest content identified]

PLoS Medicine
http://www.plosmedicine.org/
(Accessed 21 Nov 2020)
[No new digest content identified]

PLoS Neglected Tropical Diseases
http://www.plosntds.org/
(Accessed 21 Nov 2020)

[No new digest content identified]

PLoS One
http://www.plosone.org/
Research Article
[No new digest content identified]

PLoS Pathogens
http://journals.plos.org/plospathogens/
[Accessed 21 Nov 2020]
[No new digest content identified]

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http://www.pnas.org/content/early/
[No new digest content identified]

Prehospital & Disaster Medicine
Volume 35 - Issue 5 - October 2020
https://www.cambridge.org/core/journals/prehospital-and-disaster-medicine/latest-issue
[Reviewed earlier]

Preventive Medicine
Volume 139 October 2020
https://www.sciencedirect.com/journal/preventive-medicine/vol/139/suppl/C
[Reviewed earlier]

Proceedings of the Royal Society B
11 November 2020 Volume 287 Issue 1938
https://royalsocietypublishing.org/toc/rspb/current
[New issue; No digest content identified]

Public Health
Volume 188 Pages A1-A2, 1-54 (November 2020)
https://www.sciencedirect.com/journal/public-health/vol/188/suppl/C
[Reviewed earlier]

Public Health Ethics
IN PROGRESS
Volume 13, Issue 1, April 2020

http://phe.oxfordjournals.org/content/current
[Reviewed earlier]

Public Health Reports
Volume 135 Issue 6, November/December 2020
https://journals.sagepub.com/toc/phrg/135/6
[Reviewed earlier]

Qualitative Health Research
Volume 30 Issue 14, December 2020
http://qhr.sagepub.com/content/current
[Reviewed earlier]

Research Ethics
Volume 16 Issue 3-4, July-October 2020
http://journals.sagepub.com/toc/reab/current
[Reviewed earlier]

Reproductive Health
http://www.reproductive-health-journal.com/content
[Accessed 21 Nov 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
20 Nov 2020
Maternal and child health inequalities among migrants: the case of Haiti and the Dominican Republic
Original research | English |

20 Nov 2020
The effect of early-stage public health policies in the transmission of COVID-19 for South American countries
Original research | English |

20 Nov 2020
Ambient air pollutants and their effect on COVID-19 mortality in the United States of America
Original research | English |

20 Nov 2020

The HIV epidemic in Jamaica: a need to strengthen the National HIV Program
Special report | English |

20 Nov 2020
Emerging mental health challenges, strategies, and opportunities in the context of the COVID-19 pandemic: Perspectives from South American decision-makers
Current topic | English |

16 Nov 2020
Antimicrobial resistance: time for action
Editorial | English |

Risk Analysis
Volume 40, Issue 10 Pages: 1887-2111 October 2020
https://onlinelibrary.wiley.com/toc/15396924/current
[Reviewed earlier]

Risk Management and Healthcare Policy
https://www.dovepress.com/risk-management-and-healthcare-policy-archive56
[Accessed 21 Nov 2020]
[No new digest content identified]

Science
20 November 2020 Vol 370, Issue 6519
http://www.sciencemag.org/current.dtl
[New issue; No digest content identified]

Science Translational Medicine
18 November 2020 Vol 12, Issue 570
https://stm.sciencemag.org/
[New issue; No digest content identified]

Social Science & Medicine
Volume 264 November 2020
https://www.sciencedirect.com/journal/social-science-and-medicine/vol/264/suppl/C
[Reviewed earlier]

Systematic Reviews
https://systematicreviewsjournal.biomedcentral.com/articles
[Accessed 21 Nov 2020]
https://stm.sciencemag.org/

Vaccines to prevent COVID-19: a protocol for a living systematic review with network meta-analysis including individual patient data (The LIVING VACCINE Project)
Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) causes coronavirus disease 2019 (COVID-19) which has rapidly spread worldwide. Several human randomized clinical trials assessing potential vaccines...
Authors: Steven Kwasi Korang, Sophie Juul, Emil Eik Nielsen, Joshua Feinberg, Faiza Siddiqui, Giok Ong, Sarah Klingenberg, Areti Angeliki Veroniki, Fanlong Bu, Lehana Thabane, Allan Randrup Thomsen, Janus C. Jakobsen and Christian Gluud
Citation: Systematic Reviews 2020 9:262
Content type: Protocol
Published on: 20 November 2020

Travel Medicine and Infectious Diseases
Volume 37 September–October 2020
https://www.sciencedirect.com/journal/travel-medicine-and-infectious-disease/vol/37/suppl/C
[Reviewed earlier]

Tropical Medicine & International Health
Volume 25, Issue 10 Pages: i-iv, 1167-1305 October 2020
https://onlinelibrary.wiley.com/toc/13653156/current
[Reviewed earlier]

Vaccine
Volume 38, Issue 50 Pages 7877-8054 (25 November 2020)
https://www.sciencedirect.com/journal/vaccine/vol/38/issue/50
Discussion Abstract only
A clinical perspective of the U.S. anti-vaccination epidemic: Considering marginal costs and benefits, CDC best practices guidelines, free riders, and herd immunity
Michael G. Anderson, Eric A. Ballinger, David Benjamin, Lawrence D. Frenkel, ... Karin W. Zucker
Pages 7877-7879

Discussion Full text access
Expanding global and national influenza vaccine systems to match the COVID-19 pandemic response
Bruce A. Ruscio, Peter Hotez
Pages 7880-7882

Discussion Full text access
India's cost-effective COVID-19 vaccine development initiatives
Chiranjib Chakraborty, Govindasamy Agoramoorthy
Pages 7883-7884

Research article Abstract only
Cost-effectiveness of HPV vaccination for adults through age 45 years in the United States: Estimates from a simplified transmission model

Harrell W. Chesson, Elissa Meites, Donatus U. Ekwueme, Mona Saraiya, Lauri E. Markowitz
Pages 8032-8039

Research article Open access
Does education about local vaccination rates and the importance of herd immunity change US parents' concern about measles?
Bridget C. Griffith, Angela K. Ulrich, Andy B. Becker, Dawn Nederhoff, ... Nicole E. Basta
Pages 8040-8048

Japanese Society for Vaccinology paper
Research article Abstract only
Effect of a vaccine information statement (VIS) on immunization status and parental knowledge, attitudes, and beliefs regarding infant immunization in Japan
Aya Saitoh, Akihiko Saitoh, Tomohiro Katsuta, Mahito Mine, ... Kenji Okada
Pages 8049-8054

Vaccines — Open Access Journal
http://www.mdpi.com/journal/vaccines
(Accessed 21 Nov 2020)
Open Access Article
Vaccination Attitude and Communication in Early Settings: An Exploratory Study
by Noemi Mereu et al
Vaccines 2020, 8(4), 701; https://doi.org/10.3390/vaccines8040701 - 20 Nov 2020
Abstract
Background: This study assesses attitudes towards vaccination in mothers of new-born babies and explores its association with different exposures to communication. Methods: Data were collected through questionnaires administered by means of interviews. Results: Data highlighted that 20% of mothers showed an orientation towards [...]

Open Access Article
Strategies to Improve Coverage of Typhoid Conjugate Vaccine (TCV) Immunization Campaign in Karachi, Pakistan
by Farah Naz Qamalar et al
Vaccines 2020, 8(4), 697; https://doi.org/10.3390/vaccines8040697 - 19 Nov 2020
Abstract
The emergence and spread of extensively drug-resistant (XDR) typhoid in Karachi, Pakistan led to an outbreak response in Lyari Town, Karachi utilizing a mass immunization campaign with typhoid conjugate vaccine (TCV), Typbar TCV®. The mass immunization campaign, targeted Lyari Town, Karachi, one of [...]

Open Access Article
Understanding How Adolescents Think about the HPV Vaccine
by Robyn A. Pennella et al
Vaccines 2020, 8(4), 693; https://doi.org/10.3390/vaccines8040693 - 18 Nov 2020
Abstract
Despite educational efforts, Tennessee human papillomavirus (HPV) vaccination rates are 43%, among the lowest in the United States. This study examined how adolescents think about the HPV vaccine to

identify patterns and misconceptions to enhance educational efforts. Adolescents (ages 11–12) (N = [...]

Open Access Article
Parental Vaccine Preferences for Their Children in China: A Discrete Choice Experiment
by Tiantian Gong et al
Vaccines 2020, 8(4), 687; https://doi.org/10.3390/vaccines8040687 - 16 Nov 2020
Viewed by 276
Abstract
Background: Vaccination is one of the most cost-effective health investments to prevent and control communicable diseases. Improving the vaccination rate of children is important for all nations, and for China in particular since the advent of the two-child policy. This study aims to [...]

Value in Health
November 2020 Volume 23Issue 11p1403-1522
https://www.valueinhealthjournal.com/current
[Reviewed earlier]

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Media/Policy Watch

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 21 Nov 2020
[No new, unique, relevant content]

BBC
http://www.bbc.co.uk/
Accessed 21 Nov 2020
[No new, unique, relevant content]

The Economist
http://www.economist.com/
Accessed 21 Nov 2020

[No new, unique, relevant content]

Financial Times
https://www.ft.com/
Accessed 21 Nov 2020
Hungary
Brussels warns Hungary on Russian Covid jab
Brussels has warned that Hungary would risk undermining public confidence in coronavirus vaccinations should it bypass the EU medicines regulator and roll out the Russian jab Budapest plans to trial. The European Commission said on Thursday mass Covid-19 inoculation would become "much harder" if citizens began to question a vaccine because it had not been approved as safe and effective. The comments highlight tensions over Budapest's decision to run clinical trials next month of the Russian Sputnik V drug, which has not yet been assessed by the European Medicines Agency. While the Brussels statement did not mention Hungary or Sputnik V by name, no other EU member state has announced plans for such a radical move outside the bloc-wide vaccination programme overseen by the commission….
November 19, 2020

Forbes
http://www.forbes.com/
Accessed 21 Nov 2020
[No new, unique, relevant content]

Foreign Affairs
http://www.foreignaffairs.com/
Accessed 21 Nov 2020
[No new, unique, relevant content]

Foreign Policy
http://foreignpolicy.com/
Accessed 21 Nov 2020[No new, unique, relevant content]

The Guardian
http://www.guardiannews.com/
Accessed 21 Nov 2020
[No new, unique, relevant content]

New Yorker
http://www.newyorker.com/
Accessed 21 Nov 2020
[No new, unique, relevant content]

New York Times
http://www.nytimes.com/
Accessed 21 Nov 2020
Health
F.D.A. Grants Emergency Authorization of Antibody Treatment Given to Trump

The treatment, made by the biotech company Regeneron, is a cocktail of two powerful antibodies that have shown promise for people who get it early in the course of the disease.
By Katie Thomas and Noah Weiland
Nov 21

Washington Post
https://www.washingtonpost.com/
Middle East
Group of 20 leaders call for global coronavirus vaccine access as U.S. labs near approval
By Miriam Berger
November 21, 2020 at 6:12 p.m. EST

BEIRUT — Leaders from the Group of 20 nations urged greater global cooperation Saturday to ensure coronavirus vaccines reach beyond the wealthiest regions as promising U.S. vaccines appear closer to approval.

The comments draw clear contrasts with the Trump administration's go-it-alone approach, including its break with the World Health Organization. The appeals also struck at questions over whether U.S.-made vaccines would become widely available beyond commercial deals once President-elect Joe Biden takes office — even as the United States struggles with the world's highest death toll from the coronavirus.

With leaders connecting by video link — and Saudi Arabia as the host — attention quickly turned to vaccines as promising results from U.S.-based labs Pfizer and Moderna raise hopes of additional weapons soon against the pandemic, with China and Russia planning expansion beyond trials of their vaccines…

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Think Tanks et al

Brookings
http://www.brookings.edu/
Accessed 21 Nov 2020
[No new relevant content]

Center for Global Development [to 21 Nov 2020]
http://www.cgdev.org/page/press-center
November 18, 2020
A Platform to Support the Researchers and Decision-makers Generating and Using Health Economics Research to Tackle COVID-19

Since the beginning of the outbreak, the scientific community has worked around the clock to produce evidence to support decision-makers in all aspects of COVID management. However, health economics research has been largely missing from this growing literature. The C19economics.org platform has been launched to support policymakers (and their advisers) and researchers working on health economics for COVID, with a focus on LMICs.
Y-Ling Chi et al.

Chatham House [to 21 Nov 2020]
https://www.chathamhouse.org/
Event
Members Event The Virus, the Vaccine and Violence
23 November 2020 — 4:00PM TO 5:15PM
This webinar assesses the potential for conflict-sensitive approaches to COVID-19 with a focus on vaccines.

CSIS
https://www.csis.org/
Accessed 21 Nov 2020
[No new relevant content]

Council on Foreign Relations
http://www.cfr.org/
Accessed 21 Nov 2020
[No new relevant content]

Kaiser Family Foundation
https://www.kff.org/search/?post_type=press-release
Accessed 21 Nov 2020
November 18, 2020 *News Release*
What Do State Plans Reveal About Their Readiness to Distribute COVID-19 Vaccines?
With hopes that a COVID-19 vaccine or vaccines will be proven safe and effective soon, state and local public health authorities will play a critical role in ensuring the efficient distribution and administration of the vaccine. To assess the readiness of these local governments to take on these responsibilities, KFF…

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Support for this service is provided by the Bill & Melinda Gates Foundation; PATH, and industry resource members Janssen/J&J, Pfizer, Sanofi Pasteur U.S.,Takeda, (list in formation).

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

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