**Vaccines and Global Health: The Week in Review**
**3 October 2020 :: Number 573**
**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 evening 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.*

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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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***Milestones :: Perspectives :: Research***

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**Framework for Equitable Allocation of COVID-19 Vaccine**
National Academies of Sciences, Engineering, and Medicine
Committee on Equitable Allocation of Vaccine for the Novel Coronavirus; Helene Gayle, William Foege, Lisa Brown, and Benjamin Kahn, Editors
October 2020
PDF: https://download.nap.edu/cart/download.cgi?record_id=25917
*Description*

In response to the coronavirus disease 2019 (COVID-19) pandemic and the societal disruption it has brought, national governments and the international community have invested billions of dollars and immense amounts of human resources to develop a safe and effective vaccine in an unprecedented time frame. Vaccination against this novel coronavirus, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), offers the possibility of significantly reducing severe morbidity and mortality and transmission when deployed alongside other public health strategies and improved therapies.

Health equity is intertwined with the impact of COVID-19 and there are certain populations that are at increased risk of severe illness or death from COVID-19. In the United States and worldwide, the pandemic is having a disproportionate impact on people who are already disadvantaged by virtue of their race and ethnicity, age, health status, residence, occupation, socioeconomic condition, or other contributing factors.

*Framework for Equitable Allocation of COVID-19 Vaccine* offers an overarching framework for vaccine allocation to assist policy makers in the domestic and global health communities. Built on widely accepted foundational principles and recognizing the distinctive characteristics of COVID-19, this report's recommendations address the commitments needed to implement equitable allocation policies for COVID-19 vaccine.

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**Public consultation for review of draft Considerations for the Assessment of COVID-19 Vaccines for Listing by WHO**
Organizations and individuals are invited to review and provide comments/suggestions on the draft Document "Considerations for the assessment of Covid-19 vaccines"

**Please provide your comments in writing to WHO no later than 08 October 2020, 18:00 CEST by email at the following address WHOEUL@who.int.**

:: CONSIDERATIONS FOR EVALUATION OF COVID19 VACCINES - Points to consider for manufacturers of COVID19 vaccines pdf, 406kb
:: Comments Form doc, 136kb

**This document provides advice to manufacturers on both the process and the criteria that will be used by the World Health Organization (WHO) to evaluate COVID-19 vaccines that are submitted either for prequalification (PQ) or for**

**Emergency Use Listing (EUL).** The current status of development of a candidate Covid-19 vaccine, the extent of the available quality, safety and efficacy data and regulatory approvals by relevant NRAs will guide WHO's decision on which pathway (PQ or EUL) to follow for each vaccine.

The submission and review processes are described. Only vaccines that have undergone phase IIb or phase III studies and have received authorization from a reference NRA should be submitted for consideration. Criteria that will be used to assess clinical trial design, endpoints, and statistical criteria are described. Specific data that should be submitted to answer programmatically relevant questions are outlined. Manufacturing, quality control and labelling requirements are summarized, as are non-clinical data to address the potential for vaccine-associated enhanced disease. Post-authorization commitments are specified.

This document should be read in conjunction with the following:
:: "Procedure for assessing the acceptability, in principle, of vaccines for purchase by United Nations agencies", WHO Technical Report Series 978, Annex 6, 2013 (1)
:: WHO EUL document (2)
:: "Guidelines on clinical evaluation of vaccines: regulatory expectations", WHO Technical Report Series 1004, Annex 9, 2017 (3)
:: COVAX SAGE Compendium of Covid-19 vaccine research questions (4)
:: "Guidelines for assuring the quality, safety, and efficacy of plasmid DNA vaccines" adopted by the Seventy-first Meeting of the World Health Organization Expert Committee on Biological Standardization, 24–28August 2020. (5)
:: "Points to Consider for assuring the quality, safety and efficacy of RNA vaccines" (6)
:: "WHO Target Product Profiles for COVID-19 Vaccines" (7)

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(1) http://www.who.int/immunization_standards/vaccine_quality/TRS_978_61st_report_Annex_6_PQ_vaccine_procedure.pdf
(2) https://www.who.int/medicines/regulation/prequalification/prequal-vaccines/EUL_PQ_Vaccines/en/
(3) http://www.who.int/biologicals/expert_committee/WHO_TRS_1004_web_Annex_9.pdf
(4) COVAX SAGE Compendium of Covid-19 vaccine research questions
(5) https://www.who.int/publications/m/item/DNA-post-ECBS-1-sept-2020
(6) Currently under development and to be published at https://www.who.int/biologicals
(7) https://www.who.int/publications/m/item/who-target-product-profiles-for-covid-19-vaccines

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**Life Science Companies and the Bill & Melinda Gates Foundation: Commitments to Expanded Global Access for COVID-19 Diagnostics, Therapeutics, and Vaccines**
*Joint Communique* 30 September 2020 *[Editor's text bolding]*

COVID-19's existence anywhere poses a threat to communities everywhere. The health, social, and economic impacts can only be addressed through the collective actions of stakeholders across private, public, and philanthropic sectors in partnership with civil society. As organizations dedicated to improving and protecting global health, with our varied skills, roles,

and resources, we remain committed to doing our part in ending this pandemic worldwide. Earlier this year AstraZeneca; Bayer; bioMérieux; Boehringer Ingelheim; Bristol Myers Squibb; Eisai; Eli Lilly; Gilead; GSK; Johnson & Johnson; Merck & Co. (known as MSD outside the U.S. and Canada); Merck KGaA, Darmstadt, Germany; Novartis; Pfizer; Roche; and Sanofi together with the Bill & Melinda Gates Foundation each pledged ourselves to the fight against COVID-19.

**Collectively, we have launched the most expansive and ambitious pandemic R&D response effort in history**, with the promise of a range of interventions that can help end the pandemic. Creating these innovations is not enough, however. **Through partnerships with other stakeholders we are committed to ensuring global access to diagnostics, therapeutics, and vaccines that will help to accelerate the end of the pandemic.**

**To accomplish this critical goal, we will:**
**:: Develop innovations for patients worldwide.** We will continue advancing the research and development of COVID-19 diagnostics, therapeutics, and vaccines that are suitable to meet the needs of populations around the world. To do so, we will work to expand clinical trials to account for diverse representation including lower-income settings and endeavor to address the specific product characteristics needed for use in lower-income settings even after new innovations are brought forward.

**:: Strive for timely availability.** By scaling up manufacturing at unprecedented speed and much earlier than usual, we will bring large quantities of safe and effective innovations to countries around the world for broad distribution as early as possible, no matter their income level. Mechanisms for rapidly escalating supply must be aligned with the specific context of a rapid pandemic response and tailored to each product, with options including early voluntary licensing and appropriate approaches to peer-to-peer innovator company manufacturing agreements.

**:: Enable affordability for lower income countries.** We will pursue a range of approaches to make products we are developing or supporting affordable in lower-income countries. These approaches will be independently determined by each supplier in response to the pandemic to address the significant affordability challenges, including approaches such as donations, not-for-profit supply, or equity-based tiered pricing based on countries' needs and capabilities.

**:: Support effective and equitable distribution of these innovations globally.** We will strive towards equitable allocation of our products and support global mechanisms like COVAX, recognizing the most effective approach to equitable access will vary across vaccines, therapeutics, and diagnostics. We also will use our collective voice alongside other global health stakeholders to advocate for the strengthening of health systems and distribution networks so crucial innovations reach everyone who needs them. In doing so, we support evidence-based prioritization so that health care workers, high-risk individuals, and other priority groups identified by WHO and other health authorities are protected for the duration of the pandemic, regardless of the country they live in. We will advocate for equitable distribution, recognizing that sovereign nations have final decision-making authority.

**:: Maintain public confidence in our innovations.** We will continue making the safety of individuals who receive products we are developing or supporting the highest priority.

Adherence to the strictest scientific and ethical standards in product development and in manufacturing processes will remain the top priority over speed or politics.

Access to interventions to fight COVID-19 on a global scale requires financial resources, assets, infrastructure, and jurisdictional support and collaboration beyond the capacity or role of the signatories to this commitment. **We therefore call on governments, multilateral institutions, companies, NGOs, and others to build on our commitments and efforts already underway to:**

**:: Provide sufficient, dedicated, sustainable, and timely funding** for the procurement and delivery of the tools necessary to end the COVID-19 pandemic.

**:: Diversify representation in critical decision-making and coordination bodies** with special emphasis on voices representing low-income and lower-middle-income countries.

**:: Continue quickly developing and communicating clear guidance** on product needs in lower-resource settings as early as possible as our understanding of COVID-19 and the tools to combat it evolve.

**:: Advance fit-for-purpose regulatory and liability processes** for all stakeholders involved, which prioritize safety while not slowing down access to critical new tools.

**:: Build and maintain public confidence in the approval mechanisms** for diagnostics, therapeutics, and vaccines by ensuring robust safety and efficacy reviews and removing unwarranted political considerations from these discussions and the approval process.

**:: Enhance country readiness and in-country delivery systems** by ensuring adequate expertise and resources are in place for effective country planning, distribution, and follow-up for new diagnostics, therapeutics, and vaccines.

The world's extraordinary situation requires unprecedented collaboration across every part of society. To date, we as life science and philanthropic organizations have risen to this challenge and recognize the need to push further. The commitments above will save lives only if partners across the entire development-to-deployment pathway work together to guarantee products reach the people who need them. The ACT-Accelerator offers a forum for collaboration and action, and the global community must collectively mobilize the resources partners have identified as critical to ending this pandemic for communities everywhere. **By aligning those resources with the commitments above, we believe we will not only enable a faster path out of the current COVID-19 crisis but will also lay the foundation for a strong pandemic preparedness ecosystem the next time a pandemic arises.**

*Pascal Soriot, Executive Director and CEO, AstraZeneca*
*Stefan Oelrich, Member of the Board of Management, President of Pharmaceuticals, Bayer AG*
*Bill Gates, Co-Chair and Trustee, Bill & Melinda Gates Foundation*
*Melinda Gates, Co-Chair and Trustee, Bill & Melinda Gates Foundation*
*Alexandre Mérieux, Chairman and CEO, bioMérieux*
*Hubertus von Baumbach, Chairman, Board of Managing Directors, Boehringer Ingelheim GmbH*
*Giovanni Caforio, Chairman and CEO, Bristol Myers Squibb*
*Haruo Naito, Representative Corporate Officer and CEO, Eisai Co., Ltd.*

*David A. Ricks, Chairman and CEO, Eli Lilly and Company*
*Daniel O'Day Chairman and CEO, Gilead Sciences, Inc.*
*Emma Walmsley, Chief Executive Officer, GSK*
*Alex Gorsky, Chairman of the Board and CEO, Johnson & Johnson*
*Kenneth C. Frazier, Chairman of the Board and CEO, Merck & Co. Inc.*
*Belén Garijo, Vice Chair of the Executive Board, Deputy CEO, Merck KGaA, Darmstadt, Germany*
*Vas Narasimhan, M.D., Chief Executive Officer, Novartis*
*Albert Bourla, DVM, Ph.D., Chairman and CEO, Pfizer Inc.*
*Dr Severin Schwan, Chief Executive Officer, Roche Group*
*Paul Hudson, Chief Executive Officer, Sanofi*

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***Editor's Note:***
*In special circumstances, we will include full strategic announcements and statements such as this one:*

**Pfizer**
*Moving at the Speed of Science*
October 1, 2020
**An open letter from Pfizer Chairman and CEO Albert Bourla to U.S. colleagues**
*[Editor's text bolding]*
Tuesday night I joined the millions of Americans who tuned in to the Presidential debate. Once more, I was disappointed that the prevention for a deadly disease was discussed in political terms rather than scientific facts. People, who are understandably confused, don't know whom or what to believe. Global health has too much at stake, and the public trust and acceptance of a vaccine is so important to me, that I'm writing to explain the principles we are using at Pfizer today.

Remember from the beginning of the year, it was clear that the suffering and destruction from the COVID-19 pandemic would be extreme. In February, cases began spiraling across the globe. Addressing a pandemic requires many simultaneous fronts of attack, but it became obvious that a safe and effective vaccine could be an essential part of the solution. And, it would take a huge effort by a company with scale to achieve that goal. I knew Pfizer had an obligation to step up and lead. That is why in March, I declared a bold ambition: that Pfizer would create a vaccine, and we would devote any and all resources necessary to be successful. I further announced, after consulting with our scientists, that we could have vaccine data ready to submit to the FDA by end of the third quarter, in October, and hopefully a hundred million doses delivered by the end of the year. I knew our goal was ambitious, but it would also be critical to protect against the second wave of cases that could accompany the return of colder weather in the Fall.

Since then, and every day for the last seven months, we've kept our shoulder to that wheel. Our scientists have leveraged our vaccine research and development expertise, our manufacturing team has innovated to solve production and delivery hurdles, and we've recruited more than 35,000 people in clinical trials in multiple countries. Every ounce of our ability has been spent and nearly $2 billion put at risk.

Now, we are approaching our goal and despite not having any political considerations with our pre-announced date, **we find ourselves in the crucible of the U.S. Presidential election. In this hyper-partisan year, there are some who would like us to move more quickly and others who argue for delay. Neither of those options are acceptable to me. Against this backdrop, people need to know three things:**

**First, we are moving at the speed of science.** With a virus this ferocious, time is our enemy. This week, we will hit the grim marker of 1 million deaths globally and the number continues to climb. This danger supersedes any other timing considerations.

**Second, we would never succumb to political pressure**. The only pressure we feel—and it weighs heavy—are the billions of people, millions of businesses and hundreds of government officials that are depending on us. We've engaged with many elected leaders around the globe through this health crisis, but Pfizer took no investment money from any government. Our independence is a precious asset.

**Third, our priority is the development of a safe and effective vaccine to end this pandemic.** I have a duty to Pfizer's 171-year history to honor our legacy of discovering and manufacturing high-quality medicines. We will never cut a corner. Pfizer's purpose is simple: "Breakthroughs that Change Patients' Lives." It's our North Star.

Finally, I enjoy a robust policy debate, but I'm not a politician. I'm a scientist, business leader, husband and father, friend and neighbor who cares deeply about the integrity of this potential vaccine. **The amplified political rhetoric around vaccine development, timing and political credit is undercutting public confidence. I can't predict exactly when, or even if our vaccine will be approved by the FDA for distribution to the public. But I do know that the world will be safer if we stop talking about the vaccines' delivery in political terms and focus instead on a rigorous independent scientific evaluation and a robust independent approval process.**

Let's continue to work together to build trust in the science. That is what we are doing at Pfizer. Imagine the compounded tragedy if we have a safe and effective vaccine that many people didn't trust. That is a risk none of us should accept.

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## EMERGENCIES

### Coronavirus [COVID-19]

*Public Health Emergency of International Concern (PHEIC)*

***Weekly Epidemiological and Operational updates***

last update: 11 September 2020, 20:00 GMT-4
**Confirmed cases** :: 34 495 176 [week ago: 32 429 965]
**Confirmed deaths** :: 1 025 729 [week ago: 985 823]

**Weekly Epidemiological Update**
Coronavirus disease 2019 (COVID-19)
28 September 2020

***Global epidemiological situation***
To date, over 32.7 million COVID-19 cases and 991 000 deaths have been reported to WHO. During the week of 21–27 September, there were more than 2 million new cases and 36 000 new deaths reported, which is similar to the numbers reported the previous week. Cumulative deaths are expected to exceed one million in the coming week.

The Region of the Americas continues to carry the highest incidence of COVID-19 globally (Table 1), reporting similar numbers of new cases and deaths as the previous week. The Region accounts for 38% of all new cases and 52% of all new deaths reported in the past seven days. The Eastern Mediterranean Region showed the greatest increase (9%) in cases in the past week, while the European Region reported a substantial rise in deaths, with a 9% increase compared to the previous week. The WHO African, Western Pacific and South-East Asia Regions reported decreases in the new case and deaths over the past week…

***Key weekly updates***
:: COVID-19: Nearly 33 million cases and one million deaths in 9 months. As Dr Mike Ryan, Executive Director of WHO's Health Emergencies Programme said at the press conference on Friday 25 September, "the realities of getting a vaccine out there in the next nine months is a big task for everyone involved. There is a lot that can be done to save lives, both in terms of disease control, existing life-saving measures and the innovations that are coming down the pipe. Are we willing to make the investments now that are needed in the ACT Accelerator, especially in COVAX?"

:: A total of 67 higher income economies have joined the COVAX Facility, with another 34 expected to sign, joining 92 low- and middle-income economies eligible for support for the procurement of vaccines. **However, so far only a tenth of the $35 billion needed for scale-up and impact have been received**, a small investment considering that the global economy is expected to contract by trillions of US dollars this year alone. WHO's aim is to have two billion doses of vaccine available by the end of 2021.

:: A new report from Every Woman Every Child, "Protect the Progress: Rise, Refocus, Recover, 2020" warns that the COVID-19 crisis is exacerbating existing inequities, with reported disruptions in essential health interventions disproportionately impacting the most vulnerable women and children. "There is no doubt that the pandemic has set back global efforts to improve the health and well-being of women and children, but that should only serve to strengthen our resolve," said Dr Tedros Adhanom Ghebreyesus, WHO Director-General.

:: WHO has released a video series, Science in 5, in which experts explain the science about specific issues related to COVID-19. So far five episodes have been released on subjects including herd immunity, SARS-CoV2, myths vs science, and reopening schools. Watch these short videos on WHO's YouTube, Instagram, Facebook, Twitter, and LinkedIn accounts or listen to the podcasts.

:: On 23 September, WHO together with the UN, specialised agencies and partners called on countries to develop and implement action plans to promote the timely dissemination of science-based information and prevent the spread of false information while respecting freedom of expression.

:: WHO has published the Emergency Global Supply Chain System (COVID-19) catalogue, which lists all medical devices, including personal protective equipment, medical equipment, medical consumables, single use devices, laboratory and test-related devices that may be requested through the COVID-19 Supply Portal.

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## Emergencies

### POLIO

*Public Health Emergency of International Concern (PHEIC)*

**Polio this week as of 30 September 2020**

:: "The more time you can spend getting your shoes dusty walking and working together in the field, the better you will understand the challenges," Says Dr Sue Gerber, a Senior Program Officer at the Bill & Melinda Gates Foundation (BMGF) in our latest Women Leaders in Polio Eradication feature.

:: As part of the GPEI's ongoing research activities to help achieve and sustain polio eradication, in particular to develop Sabin-IPV and polio vaccine-like particle (VLP) development, we have issued a call for nomination of experts to serve on the WHO polio eradication advisory panel on Sabin-IPV and polio VLP vaccine development.

:: **On 19 September 2019, a polio outbreak was declared in the Philippines** after a 3-year-old child and several environmental samples tested positive for polioviruses. Fifteen other children have been paralyzed by polio since the outbreak started. To protect children from lifelong paralysis due to polio, vaccination rounds have been conducted in parts of the country. Meet the #HeroesEndingPolio who have been working to combat polio in the Philippines.

***Summary of new WPV and cVDPV viruses this week*** *(AFP cases and environmental samples):*
**:: Afghanistan**: two WPV1 positive environmental samples
**:: Pakistan:** one WPV1 case, 9 WPV1 positive environmental samples, three cVDPV2 cases and two cVDPV2 positive environmental samples
**:: Cameroon:** one cVDPV2 case and one cVDPV2 positive environmental sample
**:: Democratic Republic of the Congo (DR Congo):** six cVDPV2 cases
**:: Guinea:** seven cVDPV2 cases
**:: Sudan**: one cVDPV2 case and five cVDPV2 positive environmental samples

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**WHO Grade 3 Emergencies** [to 3 Oct 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 3 Oct 2020]
Afghanistan - *No new digest announcements identified*
Angola - *No new digest announcements identified*
Burkina Faso [in French] - *No new digest announcements identified*
Burundi - *No new digest announcements identified*
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*
Iraq - *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 3 Oct 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**

:: Syrian Arab Republic: COVID-19 Humanitarian Update No. 19 As of 29 September 2020

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.*

**COVID-19**

:: Coronavirus disease 2019 (COVID-19) Situation Report 46: occupied Palestinian territory, issued 1 October 2020, information for period: 5 March - 1 October 2020

**East Africa Locust Infestation**

:: Desert Locust situation update - 29 September 2020

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**WHO & Regional Offices** [to 3 Oct 2020]

**The best time to prevent the next pandemic is now: countries join voices for better emergency preparedness**

1 October 2020

*News release*

COVID-19 will not be the world's last health emergency and there is an urgent need for sustainable health emergency preparedness to deal with the next one.

This was the strong sentiment shared by participants of the United Nations General Assembly side-event on 'Sustainable preparedness for health security and resilience: Adopting a whole-of-society approach and breaking the "panic-then-forget" cycle'. The high-level virtual event was co-hosted by Finland, France and Indonesia, along with the World Health Organization (WHO)…

**Global partnership to make available 120 million affordable, quality COVID-19 rapid tests for low- and middle-income countries**

28 September 2020

*News release*

:: A full access package includes WHO policy guidance on the use of antigen-based rapid diagnostic tests, manufacturer volume guarantees for low and middle-income countries, catalytic funding to assist governments to deploy the tests and an initial US$50 million procurement fund

:: Several rapid, point-of-care antigen tests are being assessed by WHO for Emergency Use Listing (EUL)

:: Agreements between the Bill & Melinda Gates Foundation and test manufacturers Abbott and SD Biosensor make available innovative tests priced at a maximum of US$5 for low- and middle-income countries (LMICs)
:: The Global Fund commits an initial US$50 million to enable countries to purchase the new tests, with the first orders expected to be placed this week
:: Expedited market introduction of these tests in multiple LMICs is being supported through the Africa Centres for Disease Control and Prevention (Africa CDC), Unitaid, FIND, CHAI, and their partners
:: This is the latest move from the Access to COVID-19 Tools (ACT) Accelerator to develop, procure and distribute critical new tools to fight the pandemic; new tests are urgently needed to meet the huge unmet needs for testing worldwide

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**Weekly Epidemiological Record, 2 October 2020, vol. 95, 40 (pp. 477–488)**
Maternal and neonatal tetanus eliminated in the south-west geopolitical zone of Nigeria
Progress in eliminating onchocerciasis in the WHO Region of the Americas: advances towards transmission suppression in parts of the Yanomami focus area.

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**WHO Regional Offices**
*Selected Press Releases, Announcements*
**WHO African Region AFRO**
:: Review of maternal deaths and the continuity of essential reproductive, maternal, an...
01 October 2020
In the context of the double burden of COVID-19 and Humanitarian Emergencies in the Sahel region, analysis of data from the official weekly telegram-letter (TLOH) of the Ministry of Health's showed an unusually high number of institutional maternal deaths reported in this region during the four weeks (Week 16 to Week 19) of the year 2020, compared to data from the same period in 2019.
:: Statement from Dr Matshidiso Moeti, WHO Regional Director for Africa, on Sexual Abus...
30 September 2020
Brazzaville – The allegations of sexual exploitation and abuse by aid workers, who identified themselves as working for the World Health Organization (WHO) Ebola response in the Democratic Republic of the Congo are deeply horrific and heartbreaking. All my life as a woman, doctor, leader, mother and health worker, I have fought against gender inequality, as well as sexual harassment and abuse. When I became WHO Regional Director for Africa, I committed to advancing women's careers and interests in the workplace and robustly addressing sexual harassment.
:: African island states launch joint medicines procurement initiative
29 September 2020
Ministers of Health from seven small African island states today signed an agreement to jointly procure drugs and vaccines in a bid to improve quality and access to medicines and other health products.

**WHO Region of the Americas PAHO**
*No new digest content identified*

**WHO South-East Asia Region SEARO**
*No new digest content identified*

**WHO European Region EURO**
:: WHO and European Union support COVID-19 training for medical personnel in Georgia to improve health system readiness 30-09-2020
:: Global solidarity in the fight against COVID-19 takes centre stage during Regional Director's visit to Russian Federation 30-09-2020
:: Tobacco use and exposure to second-hand smoke linked to more than 20% of deaths from coronary heart disease 29-09-2020

**WHO Eastern Mediterranean Region EMRO**
:: WHO Regional Director's press briefing statement on vaccine development and COVAX Facility for COVID-19 30 September 2020

**WHO Western Pacific Region**
*No new digest content identified*

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**CDC/ACIP** [to 3 Oct 2020]
http://www.cdc.gov/media/index.html
https://www.cdc.gov/vaccines/acip/index.html
*Latest News Releases, Announcements*
**Cruise Ship No Sail Order Extended Through October 31, 2020**
Wednesday, September 30, 2020

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**Africa CDC** [to 3 Oct 2020]
http://www.africacdc.org/
*News*
*Press Releases*
**Trade and Development Bank donates half a million dollars to COVID-19 response in Africa**
30 September 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*

**Oct 3: Daily briefing on novel coronavirus cases in China**
On Oct 2, 31 provincial-level regions and the Xinjiang Production and Construction Corps on the Chinese mainland reported 10 new cases of confirmed infections.

**Central authority inspects local COVID-19 prevention**
2020-09-30
China's central authority has sent inspection teams to multiple regions in the country in a supervision campaign to check COVID-19 containment measures and make sure these localities are ready to prevent a resurgence of infections in autumn and winter…

**Macao SAR gov't to buy 1.4 mln COVID-19 vaccines for all residents**
2020-09-29
The Macao Special Administrative Region (SAR) government will buy 1.4 million doses of novel coronavirus (COVID-19) vaccines for all Macao residents, the SAR's COVID-19 response center said here on Sept 28.
The Novel Coronavirus Response and Coordination Center of the Macao SAR told the press that the vaccines will be sent to Macao in different batches, and certain groups such as senior residents, patients with chronic diseases and people working in anti-pandemic frontlines will get vaccinated with priority.
The first batch of COVID-19 vaccines is enough to cover all those priority groups, whose number is estimated at 150,000, the response center added…

**China reports good results on 11 vaccine candidates**
2020-09-28
… A senior official with the Chinese Ministry of Science and Technology, Wu Yuanbin, said on Sept 25 China has registered good results on the safety and efficiency of vaccines in the phase one and two clinical trials. He added that China is among the countries leading in COVID-19 vaccine research and development.
"Eleven vaccine candidates are under clinical trial, and four of them are in phase three trials. Chinese companies are working with related organizations in other countries, including those in the Middle East, South America, and Southeast Asia."
The ministry says the trials are going well, but it's still uncertain when the vaccines will be in the market. It has also outlined how the vaccines will be distributed when ready….

**Expert: Large-scale vaccination will take 1-2 years**
2020-09-27
It will need at least one or two years for mass vaccination to prevent COVID-19, Zhong Nanshan, a leading respiratory disease expert, said on Sept 24, and he called on people to take conventional measures to prevent the disease at present…

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## Announcements

**Paul G. Allen Frontiers Group** [to 3 Oct 2020]
https://alleninstitute.org/what-we-do/frontiers-group/news-press/
*News*

*No new digest content identified.*

**BARDA – U.S. Department of HHS** [to 3 Oct 2020]
https://www.phe.gov/about/barda/Pages/default.aspx
*BARDA News*
**September 30, 2020: Two novel investigational drugs targeting antibiotic-resistant infections move into advanced development with HHS**
:: One drug candidate may restore the body's natural balance of bacteria to prevent Clostridioides difficile (C. difficile) infections, a serious complication of certain antibiotics or long-term antibiotic use
:: Second drug candidate uses CRISPR technology, carried in a virus, to kill Escherichia coli (E. coli) bacteria that cause recurring or drug-resistant urinary tract infections (UTIs)
**...** BARDA will provide an initial $7.36 million and up to a total of $76.9 million over nine-and-a-half years to Vedanta Biosciences, Inc., of Cambridge, Massachusetts, to support development of VE303 to prevent *C. difficile* infections. BARDA also will provide an initial $11 million and up to a total of $77 million over five years to Locus Biosciences of Morrisville, North Carolina, part of a $144 million program to develop LBP-EC01 to treat recurrent UTIs including those caused by antibiotic-resistant *E. coli*...

**BMGF - Gates Foundation** [to 3 Oct 2020]
http://www.gatesfoundation.org/Media-Center/Press-Releases
*Press Releases and Statements*
SEPTEMBER 30, 2020
**Life Science Companies and the Bill & Melinda Gates Foundation: Commitments to Expanded Global Access for COVID-19 Diagnostics, Therapeutics, and Vaccines**
30 September 2020
*[See Milestones above for detail]*

SEPTEMBER 29, 2020
**Statement from CEO Mark Suzman on Momentum in Global COVID-19 Response**
SEATTLE, September 29, 2020 - The death toll from COVID-19 passed one million this week. It is a sobering moment. But there is cause for optimism as recent days have seen a significant surge in momentum around global cooperation, which is our greatest strength when it comes to consigning this pandemic to the history books.

**Bill & Melinda Gates Medical Research Institute** [to 3 Oct 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 3 Oct 2020]
https://carb-x.org/
*CARB-X is a non-profit public-private partnership dedicated to accelerating antibacterial research to tackle the global rising threat of drug-resistant bacteria.*
*No new digest content identified.*

**CEPI – Coalition for Epidemic Preparedness Innovations** [to 3 Oct 2020]
http://cepi.net/
*Latest News*
**Why and how do we harmonise assessment of COVID-19 vaccine trials?**
Valentina Bernasconi, Preclinical and Immunology Scientist at CEPI and Project Leader of the Centralised Laboratory Network, discusses the importance of centralising the analysis of samples obtained...
02 Oct 2020

**CEPI establishes global network of laboratories to centralise assessment of COVID-19 vaccine candidates**
All COVID-19 vaccine developers can use the network of five laboratories working together as part of centralised network to reliably assess and compare immunological responses generated by COVID-19...
02 Oct 2020

**Why we need a "portfolio approach" to COVID-19 vaccine development**
Hundreds of vaccine candidates against COVID-19 are under development. Predicting which of these will be successful is extremely difficult. That's why we need multiple shots at goal, writes Nick...
28 Sep 2020

**EDCTP** [to 3 Oct 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 3 Oct 2020]
http://www.vaccines.emory.edu/
*Vaccine Center News*
*No new digest content identified.*

**European Medicines Agency** [to 3 Oct 2020]
http://www.ema.europa.eu/ema/

*News & Press Releases*

**News: Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 28 September - 1 October 2020**

PRAC, Last updated: 02/10/2020

EMA's safety committee (PRAC) has started a review of a safety signal to assess reports of acute kidney injury in some patients with COVID-19 taking Veklury (remdesivir).

Veklury has been given a 'conditional marketing authorisation' in the EU for the treatment of COVID-19 in adults and adolescents from 12 years of age with pneumonia who require supplemental oxygen, because the benefits to these severely ill patients outweigh the risks of making the medicine available despite having less complete data than normally expected. This means that more evidence is required to be submitted in the post-authorisation phase…

**News: EMA starts first rolling review of a COVID-19 vaccine in the EU**

Last updated: 01/10/2020

EMA's human medicines committee (CHMP) has started the first 'rolling review' of a COVID-19 vaccine, which is being developed by the company AstraZeneca in collaboration with the University of Oxford.

The start of the rolling review means that the committee has started evaluating the first batch of data on the vaccine, which come from laboratory studies (non-clinical data). This does not mean that a conclusion can be reached yet on the vaccine's safety and effectiveness, as much of the evidence is still to be submitted to the committee.

A rolling review is one of the regulatory tools that the Agency uses to speed up the assessment of a promising medicine or vaccine during a public health emergency…

**European Vaccine Initiative** [to 3 Oct 2020]

http://www.euvaccine.eu/

*Latest News*

*No new digest content identified.*

**FDA** [to 3 Oct 2020]

https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/default.htm

*Press Announcements*

**October 2, 2020 - Coronavirus (COVID-19) Update: Daily Roundup October 2, 2020**

**::** The FDA posted a transcript of Dr. Stephen M. Hahn, M.D.'s remarks to the National Consumers League earlier this week about the vaccine review process.

**October 1, 2020 - Coronavirus (COVID-19) Update: Daily Roundup October 1, 2020**

**::** Today, the FDA revised its Emergency Use Authorization (EUA) to reflect changes in the distribution and allocation of the antiviral drug Veklury (remdesivir). More information about the revised EUA can be found here.

**September 30, 2020 - Coronavirus (COVID-19) Update: Daily Roundup September 30, 2020**

:: Today, the U.S. Food and Drug Administration (FDA) updated the SARS CoV-2 reference panel comparative data on FDA's website to reflect the latest information.

:: The FDA also posted an infographic that provides a visualization of data associated with CDRH's response to the coronavirus (COVID-19) pandemic.

**Fondation Merieux** [to 3 Oct 2020]
http://www.fondation-merieux.org/
*News, Events*
*Event*
**Let's take a look back on the ACDx webinar on the critical role of diagnostics in the COVID-19 pandemic**
October 1, 2020, Virtual
What is the role of diagnostics in the management of the COVID-19 sanitary crisis around the world? What are the ...

*Project*
**Fight against COVID-19: supporting the Akamasoa association and OSCAPE in Madagascar**
September 29, 2020, Antananarivo (Madagascar)
The Mérieux Foundation in Madagascar acts alongside two partner organizations - the Akamasoa association and OSCAPE - to fight against ...

**Gavi** [to 3 Oct 2020]
https://www.gavi.org/
*News releases*
1 October 2020
**Gavi to provide US$ 150 million to support low- and middle-income countries' readiness to deliver COVID-19 vaccines**
:: The Gavi Board has approved the provision of US$ 150 million in initial funding to jumpstart support COVAX AMC-eligible countries' readiness to deliver COVID-19 vaccines, in the form of planning, technical assistance and cold chain equipment
:: The Board also provisionally approved new governance structures for the COVAX Facility that aim to ensure a voice for all economies and partners engaged in the effort to ensure global, equitable access to safe and effective COVID-19 vaccines
…The Board gave approval for the provisional establishment of governance bodies that will involve all 168 self-financing and AMC-eligible economies engaged in the COVAX Facility. The 76 self-financing economies will form part of the COVAX Shareholders Council, while the 92 economies eligible for the COVAX AMC will form part of the AMC Engagement Group. Both groups will serve a non-technical strategic and advisory function with respect to operational aspects of COVAX Facility implementation, and will be self-organising…

29 September 2020
**New collaboration makes further 100 million doses of COVID-19 vaccine available to low- and middle-income countries**
:: Collaboration among the Serum Institute of India (SII), Gavi, the Vaccine Alliance and the Bill & Melinda Gates Foundation will accelerate manufacturing and delivery of up to an additional 100 million doses of future vaccines, if proven to be safe and effective, for low- and middle-income countries in 2021

:: The expansion follows August's announcement of up to 100 million doses to be delivered by the collaboration, bringing the total now to be delivered by the partnership to up to 200 million doses of COVID-19 vaccines, priced at a maximum of US$ 3 per dose, with an option to secure more
:: Dr Seth Berkley: "This is vaccine manufacturing for the Global South, by the Global South, helping us to ensure no country is left behind when it comes to the race for a COVID-19 vaccine"

29 September 2020
**José Manuel Barroso named as new Chair of the Gavi Board**
:: Gavi Board unanimously approves the selection of former Prime Minister of Portugal and President of the European Commission José Manuel Barroso as its new Chair
:: Barroso will replace Dr Ngozi Okonjo-Iweala, whose term ends in December 2020.
:: Barroso: "The world needs Gavi now more than ever, both to ensure COVID-19 vaccines reach every country, rich and poor, and to press ahead with its core mission to protect hundreds of millions of people from preventable diseases."

**GHIT Fund** [to 3 Oct 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*
September 29, 2020
**GHIT Fund Announces New Investments: A Total of 1.37 Billion Yen in Drugs for Malaria, Chagas Disease, Leishmaniasis, Schistosomiasis, and Soil-Transmitted Helminths, and Diagnostics for Malaria, Buruli Ulcer, and Schistosomiasis**

**Global Fund** [to 3 Oct 2020]
https://www.theglobalfund.org/en/news/
*News/Updates*
**Global partnership to make available 120 million affordable, quality COVID-19 rapid tests for low- and middle-income countries**
28 September 2020
A set of agreements to make available, for low and middle-income countries, affordable, high-quality COVID-19 antigen rapid tests were today announced by the Access to COVID-19 Tools (ACT) Accelerator.

**Global Research Collaboration for Infectious Disease Preparedness [GloPID-R]** [to 3 Oct 2020]
https://www.glopid-r.org/news/
*News*
*No new digest content identified.*

**Hilleman Laboratories** [to 3 Oct 2020]
http://www.hillemanlabs.org/
*No new digest content identified.*

**Human Vaccines Project** [to 3 Oct 2020]
http://www.humanvaccinesproject.org/media/press-releases/
*HVP COVID Report*
**No More Silos – Global Collaboration Should Drive Vaccine Development**
October 1, 2020

**IAVI** [to 3 Oct 2020]
https://www.iavi.org/newsroom
*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*
*No new digest content identified.*

**IFFIm**
http://www.iffim.org/
*Announcements*
*No new digest content identified.*

**IFRC** [to 3 Oct 2020]
http://media.ifrc.org/ifrc/news/press-releases/
*Selected Press Releases, Announcements*
*Guatemala, Honduras*
**Hundreds receive aid as migrants cross into Guatemala**
Geneva/Panama, 2 October 2020 – The Guatemalan and Honduran Red Cross Societies are providing assistance and care to hundreds of migrants who have crossed the border from Honduras to Guatemala. In Guatemala, Red Cross volunteers have been deployed to E …
2 October 2020

*Global*
**"A million individual tragedies" – IFRC statement as official COVID-19 death toll hits 1 million**
Geneva, 28 September 2020 – The following is attributable to Jagan Chapagain, Secretary General of the International Federation of Red Cross and Red Crescent Societies (IFRC): "Today, we stand in grim solidarity with the hundreds of thousands of famili …

28 September 2020

*Indonesia*
**Two years after tsunami, communities tackle COVID-19 crisis**
Palu/Jakarta/Kuala Lumpur, 28 September 2020 – Two years after an earthquake and tsunami struck communities in Central Sulawesi, Indonesia, thousands of survivors face a severe socio-economic crisis caused by the COVID-19 pandemic. The September 28 ear …
28 September 2020

**IRC International Rescue Committee** [to 3 Oct 2020]
http://www.rescue.org/press-release-index
*Media highlights [Selected]*
*Press Release*
**IRC launches response to Ebola outbreak in DRC as new assessment finds massive need amidst COVID pandemic**
September 30, 2020

*Press Release*
**New report reveals how the failures of the international community to combat COVID-19 has led to dire consequences for millions of the most vulnerable**
September 29, 2020

**IVAC** [to 3 Oct 2020]
https://www.jhsph.edu/research/centers-and-institutes/ivac/index.html
*Updates; Events*
*No new digest content identified.*

**IVI** [to 3 Oct 2020]
http://www.ivi.int/
*Selected IVI News, Announcements, Events*
*Event*
**Building Vaccine Diplomacy and Advocacy**
*IVI Virtual State Forum 2020*
Tuesday, October 13, 2020
04:00 New York / 10:00 Geneva, Copenhagen, Oslo / 17:00 Seoul
Watch live: bit.ly/ivi-state-forum-2020
*Registration Required*

**JEE Alliance** [to 3 Oct 2020]
https://www.jeealliance.org/
*Selected News and Events*
*No new digest content identified.*

**MSF/Médecins Sans Frontières** [to 3 Oct 2020]
http://www.msf.org/
*Latest [Selected Announcements]*
*Greece*
**European policies of deterrence and containment degrade human life**
Op-Ed 1 Oct 2020

*South Sudan*
**Young biotechnologists at the forefront of the COVID-19 response**
Project Update 1 Oct 2020

*Women's health*
**Proposed changes to US Global Gag Rule threaten wider harm to women**
Interview 28 Sep 2020

**National Vaccine Program Office -** U.S. HHS [to 3 Oct 2020]
https://www.hhs.gov/vaccines/about/index.html
*No new digest content identified.*

**NIH** [to 3 Oct 2020]
http://www.nih.gov/news-events/news-releases
*Selected News Releases*
**NIH to assess and expand COVID-19 testing for underserved communities**
September 30, 2020 — *RADx-UP program will support projects designed to rapidly implement testing strategies.*
The National Institutes of Health has awarded nearly $234 million to improve COVID-19 testing for underserved and vulnerable populations. A part of the Rapid Acceleration of Diagnostics (RADx) initiative, the RADx Underserved Populations (RADx-UP) program will support 32 institutions across the United States and will focus on populations disproportionately affected by the pandemic. These groups include African Americans, American Indians/Alaskan Natives, Latinos/Latinas, Native Hawaiians, older adults, pregnant women and those who are homeless or incarcerated…

**Investigational COVID-19 vaccine well-tolerated and generates immune response in older adults**
September 29, 2020 — *A Phase 1 clinical trial enrolled 40 healthy volunteers.*
A Phase 1 trial of an investigational mRNA vaccine to prevent SARS-CoV-2 infection has shown that the vaccine is well-tolerated and generates a strong immune response in older adults. A report published today in the New England Journal of Medicine describes the findings from the study, which was supported by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health. SARS-CoV-2 is the virus that causes COVID-19 disease.
*Anderson et al. Safety and immunogenicity of SARS-CoV-2 mRNA-1273 vaccine in older adults. New England Journal of Medicine DOI: 10.1056/NEJMoa2028436 (2020).*

**PATH** [to 3 Oct 2020]
https://www.path.org/media-center/
*Press Releases*
**PATH applauds passage of critical COVID-19 emergency funding legislation in U.S. House of Representatives**
October 1, 2020 by PATH
The newly updated HEROES Act not only proposes support for COVID-19 pandemic response in the United States, but also adds critical emergency funding for global health programs.

**PATH receives grant to combat soil-transmitted helminth infections**
September 30, 2020 by PATH
A grant from the GHIT Fund will support partners in the United States and Japan to develop a new low-cost, broad spectrum anthelmintic protein Cry5B oral treatment option.

**Sabin Vaccine Institute** [to 3 Oct 2020]
http://www.sabin.org/updates/pressreleases
*Statements and Press Releases*
*No new digest content identified.*

**UNAIDS** [to 3 Oct 2020]
http://www.unaids.org/en
*Selected Press Releases/Reports/Statements*
1 October 2020
**Young people discuss innovations to reduce health inequalities**

30 September 2020
**"I want to contribute to creating a world without stigma and discrimination": young women living with HIV in Uzbekistan become activists**

28 September 2020
**New HIV infections increasingly among key populations**

**UNICEF** [to 3 Oct 2020]
https://www.unicef.org/media/press-releases
*Statement*
10/02/2020
**Remarks by Henrietta Fore, UNICEF Executive Director, at press briefing on Education Plus initiative**
As prepared for delivery

*Statement*
10/02/2020
**Remarks by Henrietta Fore, UNICEF Executive Director, at Security Council meeting on universal connectivity & access to digital technology in conflict & post-conflict contexts**

As prepared for delivery

*Statement*
09/30/2020
**UNICEF statement on allegations of sexual exploitation and abuse in the Democratic Republic of the Congo**

*Press release*
09/30/2020
**UN agencies hail milestone as over 1000 asylum seekers relocated from Greece so far this year through EU initiative**

*Statement*
09/30/2020
**Statement by Henrietta H. Fore, UNICEF Executive Director at the high-level side event on the ACT-Accelerator at the 75th session of UN General Assembly**

*Statement*
09/29/2020
**UNICEF condemns the death of four children in Baghdad and calls on all parties to protect children from violence**
Statement attributable to Ms Hamida Lasseko, UNICEF Representative in Iraq

*Statement*
09/29/2020
**Statement by UNICEF Executive Director Henrietta Fore on 30th anniversary of World Summit for Children**

**Unitaid** [to 3 Oct 2020]
https://unitaid.org/
*Featured News*
*No new digest content identified.*

**Vaccination Acceptance Research Network (VARN)** [to 3 Oct 2020]
https://vaccineacceptance.org/news.html#header1-2r
*Announcements*
*No new digest content identified.*

**Vaccine Confidence Project** [to 3 Oct 2020]
http://www.vaccineconfidence.org/
*Research and Reports*
**The Harris Poll: Nearly 80% of Americans think that the speedy approval process of a coronavirus vaccine is driven by politics – NOT by proof that shots work**
1 Oct 2020

**Vaccine Education Center – Children's Hospital of Philadelphia** [to 3 Oct 2020]
http://www.chop.edu/centers-programs/vaccine-education-center
*No new digest content identified.*

**Wellcome Trust** [to 3 Oct 2020]
https://wellcome.ac.uk/news
*Opinion* | 28 September 2020
**Covid-19 in the UK: the hard choices we face**
Jeremy Farrar, Director Wellcome
Six months after lockdown was first announced in the UK, the country is seeing a rise in Covid-19 infections. Jeremy Farrar reflects on the measures we need to take to suppress transmission.

**The Wistar Institute** [to 3 Oct 2020]
https://www.wistar.org/news/press-releases
*Press Releases*
Sep. 30, 2020
**New Mechanism of Cell Survival in Chronic Lymphocytic Leukemia**
Role of STING signaling in normal B cell differentiation suggests that reduced STING expression and activation promotes malignant cell survival through increased B cell receptor signaling.

**WFPHA: World Federation of Public Health Associations** [to 3 Oct 2020]
https://www.wfpha.org/
*Latest News*
*No new digest content identified.*

**World Organisation for Animal Health (OIE)** [to 3 Oct 2020]
https://www.oie.int/en/for-the-media/press-releases/2020/
*Press Releases*
*No new digest content identified.*

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**ARM [Alliance for Regenerative Medicine]** [to 3 Oct 2020]
https://alliancerm.org/press-releases/
*Press Releases*
*No new digest content identified.*

**BIO** [to 3 Oct 2020]
https://www.bio.org/press-releases
*Press Releases*

**BIO's Dr. McMurry-Heath Calls on HHS Sec. Azar to Publicly Release FDA Guidance on Emergency Use Authorization for Covid-19 Vaccines**
October 1, 2020

The Honorable Alex Azar
Secretary of U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Azar:
On behalf of the scientists and researchers the Biotechnology Innovation Organization (BIO) represents, **I am writing to request that you publicly release all new guidance developed by the Food and Drug Administration (FDA) concerning emergency use authorization for vaccines to prevent the spread of COVID-19. The release of FDA guidance would provide scientists and researchers greater regulatory clarity and strengthen public confidence in any future vaccine that may be authorized or approved.**

BIO member companies are leading a global effort to develop vaccines against COVID-19. In fact, more than 180 experimental vaccines for COVID-19 are currently in development, including 10 that now are in Phase 3 clinical trials. The scale and speed of the biopharmaceutical industry's response to the novel coronavirus are unprecedented. These efforts to bring a safe and effective vaccine to the public provide real hope that this pandemic will soon end, and our nation will begin to return to normal.

Our organization and member companies are working closely with FDA scientists and public health experts to achieve our shared commitment to testing and developing vaccines in strict accordance with sound scientific principles and with high ethical and safety standards.

That is why we were encouraged to learn the FDA has been finalizing new guidance to clarify what biopharmaceutical companies will need to demonstrate for safety and efficacy data in order to receive emergency use authorization for COVID-19 vaccines. Insight into FDA's views on clinical and scientific factors underlying emergency use authorization of COVID-19 vaccines would support ongoing research and development.

**All new FDA guidance should be finalized and communicated with those on the frontlines developing potential vaccines. Just as importantly, it must also be shared more broadly with the American public. We cannot allow a lack of transparency to undermine confidence in the vaccine development process**. The public must have full faith in the scientific process and the rigor of FDA's regulatory oversight if we are to end the pandemic. Releasing any additional guidance on granting emergency use authorization for a vaccine will go a long way in accomplishing this critical goal.

On behalf of BIO and its members, I am deeply grateful for the efforts of countless individuals across the federal government in response to this public health crisis. We look forward to continuing to work with key government partners to achieve our shared goal of ending the COVID-19 pandemic quickly and safely.

Best,
Dr. Michelle McMurry-Heath, Ph.D.
President and CEO

**DCVMN – Developing Country Vaccine Manufacturers Network** [to 3 Oct 2020]
http://www.dcvmn.org/
*News; Upcoming events*
*No new digest content identified.*

**ICBA – International Council of Biotechnology Associations** [to 3 Oct 2020]
https://internationalbiotech.org/
*News*
*No new digest content identified.*

**IFPMA** [to 3 Oct 2020]
http://www.ifpma.org/resources/news-releases/
*Selected Press Releases, Statements, Publications*
*No new digest content identified.*

**PhRMA** [to 3 Oct 2020]
http://www.phrma.org/
*Selected Press Releases, Statements*
*No new digest content identified.*

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## *Journal Watch*

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

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

**American Journal of Infection Control**
October 2020 Volume 48, Issue 10, p1133-1286
http://www.ajicjournal.org/current
*Major Articles*

**Mandatory employee vaccination as a strategy for early and comprehensive health care personnel immunization coverage: Experience from 10 influenza seasons**
Christopher Blank, Nancy Gemeinhart, W. Claiborne Dunagan, Hilary M. Babcock
p1133–1138
Published online: March 29, 2020

**Low rates of influenza vaccination uptake among healthcare workers: Distinguishing barriers between occupational groups**
Ana Durovic, Andreas F. Widmer, Marc Dangel, Anja Ulrich, Manuel Battegay, Sarah Tschudin-Sutter
p1139–1143
Published online: March 18, 2020

**American Journal of Preventive Medicine**
October 2020 Volume 59, Issue 4, p469-620
http://www.ajpmonline.org/current
*Research Articles*
**Vaccine Efficacy Needed for a COVID-19 Coronavirus Vaccine to Prevent or Stop an Epidemic as the Sole Intervention**
Sarah M. Bartsch, Kelly J. O'Shea, Marie C. Ferguson, Maria Elena Bottazzi, Patrick T. Wedlock, Ulrich Strych, James A. McKinnell, Sheryl S. Siegmund, Sarah N. Cox, Peter J. Hotez, Bruce Y. Lee
p493–503
Published online: July 15, 2020
This study found that the vaccine has to have an efficacy of at least 70% to prevent an epidemic and of at least 80% to largely extinguish an epidemic without any other measures (e.g., social distancing).

**American Journal of Public Health**
October 2020 110(S3) Supplement 3 2020
http://ajph.aphapublications.org/toc/ajph/current
***Health Misinformation on Social Media***
This special supplement issue features research and perspectives on the dangers—and opportunities—posed by a shift in how modern populations consume health information via social media. Just as the spread of misinformation by malicious and unwitting parties poses a threat to public health and the credibility of institutional knowledge, so too do these platforms offer new approaches to counteract rumors and intentional deception in real time and with targeted strategies.

**A Prologue to the Special Issue: Health Misinformation on Social Media**
Wen-Ying Sylvia Chou PhD, MPH, and Anna Gaysynsky MPHAuthor affiliations, information, and correspondence details
Accepted: August 20, 2020
Published Online: October 01, 2020

**American Journal of Tropical Medicine and Hygiene**

Volume 103, Issue 3, September 2020
http://www.ajtmh.org/content/journals/14761645/103/3
*Editorial*
**Keep Politics out of Funding Decisions for Medical Research and Public Health**
Philip J. Rosenthal, Daniel G. Bausch, Karen A. Goraleski, David R. Hill, Julie A. Jacobson, Chandy C. John and Joel G. Breman
Pages: 931–932
https://doi.org/10.4269/ajtmh.20-0850

***Perspective Piece***
**The Equatoguinean Malaria Vaccine Initiative: From the Launching of a Clinical Research Platform to Malaria Elimination Planning in Central West Africa**
Peter F. Billingsley, Carl D. Maas, Ally Olotu, Christopher Schwabe, Guillermo A. García, Matilde Riloha Rivas, Dianna E. B. Hergott, Claudia Daubenberger, Elizabeth Saverino, Adel Chaouch, Oscar Embon, Mwajuma Chemba, Elizabeth Nyakarungu, Ali Hamad, Carlos Cortes, Tobias Schindler, Maximillian Mpina, Ali Mtoro, B. Kim Lee Sim, Thomas L. Richie, Ken McGhee, Marcel Tanner, Gabriel Mbaga Obiang Lima, Salim Abdulla, Stephen L. Hoffman and Mitoha Ondo'o Ayekaba
Pages: 947–954
https://doi.org/10.4269/ajtmh.19-0966

*Review Article*
**Global Governing Bodies: A Pathway for Gene Drive Governance for Vector Mosquito Control**
Adam Kelsey, Drusilla Stillinger, Thai Binh Pham, Jazmin Murphy, Sean Firth and Rebeca Carballar-Lejarazú
Pages: 976–985
https://doi.org/10.4269/ajtmh.19-0941

**Annals of Internal Medicine**
15 September 2020 Volume 173, Issue 6
http://annals.org/aim/issue
[Reviewed earlier]

**Artificial Intelligence – An International Journal**
Volume 288 November 2020
https://www.sciencedirect.com/journal/artificial-intelligence/vol/288/suppl/C
*Research article Abstract only*
**Combining experts' causal judgments**
Dalal Alrajeh, Hana Chockler, Joseph Y. Halpern
Article 103355
*Abstract*
Consider a policymaker who wants to decide which intervention to perform in order to change a currently undesirable situation. The policymaker has at her disposal a team of experts, each with their own understanding of the causal dependencies between different factors contributing to the outcome. The policymaker has varying degrees of confidence in the experts' opinions.

She wants to combine their opinions in order to decide on the most effective intervention. We formally define the notion of an effective intervention, and then consider how experts' causal judgments can be combined in order to determine the most effective intervention. We define a notion of two causal models being compatible, and show how compatible causal models can be merged. We then use it as the basis for combining experts' causal judgments. We also provide a definition of decomposition for causal models to cater for cases when models are incompatible. We illustrate our approach on a number of real-life example

**BMC Cost Effectiveness and Resource Allocation**
http://resource-allocation.biomedcentral.com/
(Accessed 3 Oct 2020)
[No new digest content identified]

**BMJ Global Health**
October 2020 - Volume 5 - 10
https://gh.bmj.com/content/5/10
*Commentary*
**Symptoms of a broken system: the gender gaps in COVID-19 decision-making**
(1 October, 2020)
Kim Robin van Daalen, Csongor Bajnoczki, Maisoon Chowdhury, Sara Dada, Parnian Khorsand, Anna Socha, Arush Lal, Laura Jung, Lujain Alqodmani, Irene Torres, Samiratou Ouedraogo, Amina Jama Mahmud, Roopa Dhatt, Alexandra Phelan, Dheepa Rajan

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http://www.biomedcentral.com/bmchealthservres/content
(Accessed 3 Oct 2020)
[No new digest content identified]

**BMC Infectious Diseases**
http://www.biomedcentral.com/bmcinfectdis/content
(Accessed 3 Oct 2020)
**Determinants of self-paid rotavirus vaccination status in Kanazawa, Japan, including socioeconomic factors, parents' perception, and children's characteristics**
*Japan's National Immunization Program does not cover rotavirus vaccine and no government subsidies are available. This study aimed to measure the uptake of and determinants that influenced self-paid rotavirus ...*
Authors: Megumi Hara, Rie Koshida, Kaoru Araki, Masahide Kondo and Yoshio Hirota
Citation: BMC Infectious Diseases 2020 20:712
Content type: Research article
Published on: 29 September 2020

**BMC Medical Ethics**
http://www.biomedcentral.com/bmcmedethics/content

(Accessed 3 Oct 2020)
**Researchers' views on, and experiences with, the requirement to obtain informed consent in research involving human participants: a qualitative study**
*Informed consent is often cited as the "cornerstone" of research ethics. Its intent is that participants enter research voluntarily, with an understanding of what their participation entails. Despite agreement on the necessity to obtain informed consent in research, opinions vary on the threshold of disclosure necessary and the best method to obtain consent. We aimed to investigate Australian researchers' views on, and their experiences with, obtaining informed consent.*
Authors: Antonia Xu, Melissa Therese Baysari, Sophie Lena Stocker, Liang Joo Leow, Richard Osborne Day and Jane Ellen Carland
Content type: Research article
2 October 2020

**BMC Medicine**
http://www.biomedcentral.com/bmcmed/content
(Accessed 3 Oct 2020)
[No new digest content identified]

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http://www.biomedcentral.com/bmcpregnancychildbirth/content
(Accessed 3 Oct 2020)
[No new digest content identified]

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http://bmcpublichealth.biomedcentral.com/articles
(Accessed 3 Oct 2020)
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http://www.biomedcentral.com/bmcresnotes/content
(Accessed 3 Oct 2020)
[No new digest content identified]

**BMJ Open**
October 2020 - Volume 10 - 10
https://bmjopen.bmj.com/content/10/10
[New issue; No digest content identified]

**Bulletin of the World Health Organization**
Volume 98, Number 10, October 2020, 645-724
https://www.who.int/bulletin/volumes/98/10/en/

*EDITORIALS*

**COVID-19 and sustainable development goals**

— Kristin Heggen, Tony J Sandset & Eivind Engebretsen

http://dx.doi.org/10.2471/BLT.20.263533

**Child Care, Health and Development**

Volume 46, Issue 5 Pages: 537-649 September 2020

https://onlinelibrary.wiley.com/toc/13652214/current

[Reviewed earlier]

**Clinical Pharmacology & Therapeutics**

Volume 108, Issue 4 Pages: 681-895 October 2020

https://ascpt.onlinelibrary.wiley.com/toc/15326535/current

*Perspectives*

**Pandemic Best Regulatory Practices: An Urgent Need in the COVID-19 Pandemic**

Murray M. Lumpkin, John C. W. Lim

Pages: 703-705

First Published:04 June 2020

*Abstract*

As large numbers of candidate drugs and vaccines for potential use in the coronavirus disease 2019 (COVID-19) pandemic are being investigated, medicine regulators globally must now make urgent, informed, contextually risk-1based decisions regarding clinical trials and marketing authorizations. They must do this with the flexibility demanded by the pandemic while maintaining their core risk assessment and public safety functions. We lay out the critical role of regulators in the current crisis and offer eight "pandemic best regulatory practices." These should support both the regulatory public heath imperative and assure timely patient access to effective, safe, quality products worldwide during this emergency—thus contributing to ending this pandemic as quickly, effectively, and safely as possible.

*Mini-Review Open Access*

**Leading a Digital Transformation in the Pharmaceutical Industry: Reimagining the Way We Work in Global Drug Development**

Luca A. Finelli, Vas Narasimhan

Pages: 756-761

First Published:15 April 2020

*Abstract*

We are experiencing seminal times in computing that seem to define a fourth industrial revolution. This may fundamentally change the way we live, work, and relate to one another. Embracing data and digital information is a top priority for most industries these days, and Life Sciences is no exception. The pharmaceutical industry in particular is fundamentally a data-driven business. Inspired by a desire to "Go Big on Data," we developed a strategic roadmap defining a digital transformation to reimagine the way we work in Novartis Global Drug Development, leveraging data science to generate and inject actionable insights into our best practices. We launched a program called Nerve Live, and built a state-of-the-art data and analytics platform to harness past and present operational data, providing access to decades of drug development "experience" buried across multiple sources. The platform enabled the

systematic application of machine learning and predictive analytics to generate "intelligence": new insights across multiple functional areas. To action the insights and create "value," we crafted skillfully designed end-user applications for domain experts to plan, track, predict, compare and monitor domain activities, optimize costs, and maximize quality. Today, the Nerve Live program enables insights-driven decision making at scale, unlocking productivity, and providing transparency across the Novartis Global Drug Development organization and beyond. We identified three main drivers making the Nerve Live program successful and enabling the associated digital transformation to flourish. We discuss the challenges, highlight the benefits, and see the importance of leading the way to become future proof.

**Clinical Therapeutics**
August 2020 Volume 42, Issue 8, p1425-1624, e115-e160
http://www.clinicaltherapeutics.com/current

*Commentary*

**COVID-19: Regulatory Landscape of Medicinal and Medical Device Products for Human Use**

Paul Beninger
p1444–1450
Published online: June 28, 2020

*Abstract*

Against the backdrop of the COVID pandemic, the scientific and medical communities are working with all deliberate speed with state-of-the-art technologies to develop diagnostic and therapeutic products that can identify, treat, and prevent infection with SARS-CoV-2. These activities may only be legally conducted with the necessary statutes and regulations in place to facilitate the timely development, manufacturing, evaluation, and distribution of products that meet quality standards. The present regulatory landscape for medicinal and medical products for human use has been shaped by nearly 12 decades of statutory history that followed in reaction to disasters and tragedies. Five distinct, closely woven threads of statutory history have led to the regulatory infrastructure we have in place: (1) standardized processes for routine development of medicinal and medical device products for human use; (2) processes for expedited development to shorten time frames and expand patient populations; (3) mechanisms of Expanded Access to make medicinal products available to patients prior to approval of the US Food and Drug Administration; (4) Emergency Use Authorization during public health emergencies; and (5) the development of pathways for bringing generic drugs and biosimilar biologics to market. These mechanisms are being brought to bear to facilitate the defeat of infection with SARS-CoV-2.

**Assessing Participation Burden in Clinical Trials: Introducing the Patient Friction Coefficient**

David Cameron, Cara Willoughby, Denise Messer, Marie Lux, Murray Aitken, Kenneth Getz
e150–e159
Published online: July 31, 2020

*Abstract*

Protocol design complexity, and associated study volunteer burden, negatively impact patient recruitment and retention as well as overall research and development productivity. Complex protocols reduce the willingness of potential clinical trial participants to enroll and reduce retention rates. There have been few systematic assessments of protocol design characteristics

to determine the burden placed on study volunteers, although such an assessment would offer a compelling opportunity to optimize trial designs and improve recruitment and retention performance. To be useful, an assessment would need to be patient-centric, and focused on the factors that influence participation throughout the clinical trial. Such an assessment would also need to accommodate the unique cost-value trade-off compared with current treatment patterns that each participant makes when choosing to participate and remain in a clinical trial. This article proposes a new methodology to quantify patient burden: the clinical trial patient friction coefficient (PFC). A case example is provided to illustrate the utility of the PFC. A number of applications for the PFC are envisioned: standardizing patient burden assessment to evaluate clinical trial design feasibility, shedding light on the impact of patient burden on clinical trial economics and performance, and conducting sensitivity analyses to identify factors that most reduce patient burden and improve the performance and efficiency of clinical trials.

**Clinical Trials**
Volume 17 Issue 5, October 2020
https://journals.sagepub.com/toc/ctja/17/5
*Perspective*
**Clinical trials in the time of a pandemic**
Susan S Ellenberg
First Published July 10, 2020; pp. 467–471
*Abstract*
The first rumblings about a new coronavirus spreading in China were heard in January 2020. By the end of that month, the World Health Organization, recognizing the severity of the disease and the potential for global spread, had declared a public health emergency. By February 2020, cases had been identified in multiple countries, clinical trials of treatments with some biological plausibility had begun in China, and the initial steps of vaccine development were underway. In mid-March, by which time countries around the world were experiencing rapidly increasing numbers of cases and deaths, the World Health Organization categorized the outbreak as a pandemic. This new coronavirus was designated SARS-COV-2 in recognition of its similarity to the coronavirus responsible for the severe acute respiratory syndrome outbreak in 2002–2003. The race is on to develop treatments that can mitigate the severe consequences of infection and vaccines that can prevent infection and/or diminish the severity of disease in those who do get infected. Many challenges face these development efforts. Some are similar to those faced in the past; others are new. The urgency of finding ways to treat, and ultimately prevent, the consequences of this new and potentially deadly infection has led to unprecedented focus on clinical trials.

*Research Letter*
**COVID-19 impact on multi-site recruitment and enrollment**
Emma Strujo, Mechelle Sanders, Kevin Fiscella, Marie Thomas, Brent Johnson, Alex Deets, Claudia Sanchez Lucas, Tameir Holder, Nina Johal, Amneris Luque, Andrea Cassells, Stephen Williams, Jonathan N Tobin
First Published August 20, 2020; pp. 501–504

**Conflict and Health**
http://www.conflictandhealth.com/

[Accessed 3 Oct 2020]
[No new digest content identified]

**Contemporary Clinical Trials**
Volume 96  September 2020
https://www.sciencedirect.com/journal/contemporary-clinical-trials/vol/96/suppl/C
[New issue; No digest content identified]

**The CRISPR Journal**
Volume 3, Issue 4 / August 2020
https://www.liebertpub.com/toc/crispr/3/4
[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**
October 2020 - Volume 33 - Issue 5
https://journals.lww.com/co-infectiousdiseases/pages/currenttoc.aspx
[New issue; No digest content identified]

**Developing World Bioethics**
Volume 20, Issue 3  Pages: 115-171  September 2020
https://onlinelibrary.wiley.com/toc/14718847/current
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**Development in Practice**
Volume 30, Issue 6, 2020
http://www.tandfonline.com/toc/cdip20/current
***New sectoral perspectives on international NGOs: scale, dynamics and influences. Guest Editors: Nicola Banks, Lau Schulpen, and Dan Brockington***
[Reviewed earlier]

**Disaster Medicine and Public Health Preparedness**
Volume 14 - Issue 2 - April 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 9 3 September 2020
https://www.embopress.org/toc/14693178/current
[Reviewed earlier]

**Emerging Infectious Diseases**
Volume 26, Number 10—October 2020
http://wwwnc.cdc.gov/eid/
*Research*
**Effectiveness of 23-Valent Pneumococcal Polysaccharide Vaccine against Invasive Pneumococcal Disease in Adults, Japan, 2013–2017**

**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 5 Pages: 1-40 September–October 2020
https://onlinelibrary.wiley.com/toc/25782363/current
***Participants with autism • Big data and pragmatic trials • Covid-19 research***
[Reviewed earlier]

**The European Journal of Public Health**
Volume 30, Issue Supplement_4, September 2020
https://academic.oup.com/eurpub/issue/30/Supplement_4
[Reviewed earlier]

**Expert Review of Vaccines**
Vol 19 (8) 2020

https://www.tandfonline.com/toc/ierv20/current
*Editorial*
**The potential impact of COVID-19 pandemic on the immunization performance in Indonesia**
Auliya A. Suwantika , Cornelis Boersma & Maarten J. Postma
Pages: 687-690
Published online: 06 Aug 2020

Review
**Fifteen years of experience with the oral live-attenuated human rotavirus vaccine: reflections on lessons learned**
Priya Pereira , Volker Vetter , Baudouin Standaert & Bernd Benninghoff
Pages: 755-769
Published online: 04 Sep 2020

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https://gatesopenresearch.org/browse/articles
[Accessed 3 Oct 2020]
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[Accessed 3 Oct 2020]
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**Global Health Action**
Volume 12, 2019 Issue 1
https://www.tandfonline.com/toc/zgha20/12/sup1?nav=tocList
[Reviewed earlier]

**Global Health: Science and Practice (GHSP)**
Vol. 8, No. 3 October 01, 2020
http://www.ghspjournal.org/content/current
*ORIGINAL ARTICLES*
**The Critical Role and Evaluation of Community Mobilizers in Polio Eradication in Remote Settings in Africa and Asia**
Judy Lewis, Karen LeBan, Roma Solomon, Filimona Bisrat, Samuel Usman and Ahmed Arale
Global Health: Science and Practice October 2020, 8(3):396-412;
https://doi.org/10.9745/GHSP-D-20-00024
Critical community health worker criteria are important for all community programs, including those focused on a single disease. Areas of importance include community engagement, local adaptation, and linkage with the health system—critical areas for current and future epidemics.

*Open Access*

**Determinants of Facility-Level Use of Electronic Immunization Registries in Tanzania and Zambia: An Observational Analysis**
Emily Carnahan, Ellen Ferriss, Emily Beylerian, Francis Dien Mwansa, Ngwegwe Bulula, Dafrossa Lyimo, Anna Kalbarczyk, Alain B. Labrique, Laurie Werner and Jessica C. Shearer
Global Health: Science and Practice October 2020, 8(3):488-504;
https://doi.org/10.9745/GHSP-D-20-00134

We provide a framework to quantify the use of electronic immunization registry systems at the facility level and results show the importance of behavioral and organizational factors in explaining their sustained use in Tanzania and Zambia.

*REVIEWS*
*Open Access*
**Factors That Influence Data Use to Improve Health Service Delivery in Low- and Middle-Income Countries**
Nicole Rendell, Kamalini Lokuge, Alexander Rosewell and Emma Field
Global Health: Science and Practice October 2020, 8(3):566-581;
https://doi.org/10.9745/GHSP-D-19-00388

We identified factors that may influence the relationship between information generation and improvement of health service delivery: governance (leadership, participatory monitoring, regular review of data); production of information (presentation of findings, data quality, qualitative data); and health information system resources (electronic health management information systems, organizational structure, training).

**Global Public Health**
Volume 15, 2020 Issue 10
http://www.tandfonline.com/toc/rgph20/current
*Article*
**Medical populism and the COVID-19 pandemic**
Gideon Lasco
Pages: 1417-1429
Published online: 11 Aug 2020
*ABSTRACT*
This paper uses the vocabulary of 'medical populism' to identify and analyse the political constructions of (and responses to) the COVID-19 pandemic in Brazil, the Philippines, and the United States from January to mid-July 2020, particularly by the countries' heads of state: Jair Bolsonaro, Rodrigo Duterte, and Donald Trump. In all three countries, the leaders' responses to the outbreak can be characterised by the following features: simplifying the pandemic by downplaying its impacts or touting easy solutions or treatments, spectacularizing their responses to crisis, forging divisions between the 'people' and dangerous 'others', and making medical knowledge claims to support the above. Taken together, the case studies illuminate the role of individual political actors in defining public health crises, suggesting that medical populism is not an exceptional, but a familiar response to them. This paper concludes by offering recommendations for global health in anticipating and responding to pandemics and infectious disease outbreaks.

**Globalization and Health**

http://www.globalizationandhealth.com/
[No new digest content identified]

**Health Affairs**
Vol. 39, No. 9 September 2020
https://www.healthaffairs.org/toc/hlthaff/current
***Medicare Payment Incentives, Medicaid & More***
[Reviewed earlier]

**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 7, August 2020
https://academic.oup.com/heapol/issue/35/7
*Original Articles*
**Budget line items for immunization in 33 African countries**
Ulla K Griffiths, Jennifer Asman, Alex Adjagba, Marina Yo, James O Oguta ...
Health Policy and Planning, Volume 35, Issue 7, August 2020, Pages 753–764,
https://doi.org/10.1093/heapol/czaa040

**The development of a new accountability measurement framework and tool for global health initiatives**
Adriane Martin Hilber, Patricia Doherty, Andrea Nove, Rachel Cullen, Tunde Segun ...
Health Policy and Planning, Volume 35, Issue 7, August 2020, Pages 765–774,
https://doi.org/10.1093/heapol/czz170
*Abstract*
The Global Strategy for Women's Children's and Adolescents' Health emphasizes accountability as essential to ensure that decision-makers have the information required to meet the health needs of their populations and stresses the importance of tracking resources, results, and rights to see 'what works, what needs improvement and what requires increased attention'. However, results from accountability initiatives are mixed and there is a lack of broadly applicable, validated tools for planning, monitoring and evaluating accountability interventions. This article documents an effort to transform accountability markers—including political will, leadership and the monitor–review–act cycle—into a measurement tool that can be used prospectively or retrospectively to plan, monitor and evaluate accountability initiatives. It describes the

development process behind the tool including the literature review, framework development and subsequent building of the measurement tool itself. It also examines feedback on the tool from a panel of global experts and the results of a pilot test conducted in Bauchi and Gombe states in Nigeria. The results demonstrate that the tool is an effective aid for accountability initiatives to reflect on their own progress and provides a useful structure for future planning, monitoring and evaluation. The tool can be applied and adapted to other accountability mechanisms working in global health.

**Health Research Policy and Systems**
http://www.health-policy-systems.com/content
[Accessed 3 Oct 2020]
[No new digest content identified]

**Human Gene Therapy**
Volume 31, Issue 17-18 / September 2020
https://www.liebertpub.com/toc/hum/31/17-18
***Special Issue on Gene and Cell Therapies for Pulmonary Disorders***
[New issue; No digest content identified]

**Humanitarian Exchange Magazine**
Number 77, March 2020
https://odihpn.org/magazine/responding-to-ebola-in-the-democratic-republic -of-congo/
***Responding to Ebola in the Democratic Republic of Congo***
by Humanitarian Practice Network
This edition of Humanitarian Exchange, co-edited with Anne Harmer, focuses on the response to the Ebola outbreak in the Democratic Republic of Congo (DRC). Although at the time of publication the outbreak appeared to have ended, over its course it claimed 2,200 lives, with more than 3,300 infected, making this the world's second largest outbreak ever.

In the lead article, Natalie Roberts reflects on the extent to which humanitarian actors have applied learning from the outbreak in West Africa in 2014–2016. Richard Kojan and colleagues report on the NGO ALIMA's flexible, patient-centred approach to reducing mortality, Marcela Ascuntar reflects on lessons learned from community feedback and Bernard Balibuno, Emanuel Mbuna Badjonga and Howard Mollett highlight the crucial role faith-based organisations have played in the response. In their article, Theresa Jones, Noé Kasali and Olivia Tulloch outline the work of the Bethesda counselling centre in Beni, which provides support to grieving families. Reflecting on findings from a recent assessment by Translators without Borders, Ellie Kemp describes the challenges involved in providing clear and accessible information on Ebola and the response, and Sung Joon Park and colleagues explain how humane care and treatment can help increase trust and confidence in the response. Stephen Mugamba and his co-authors highlight the importance of community involvement in Ebola research, and Gillian McKay and her co-authors examine the impact of the Ebola outbreak and response on sexual and reproductive health services.

Stacey Mearns, Kiryn Lanning and Michelle Gayer present an Ebola Readiness Roadmap to support NGOs in preparing for an outbreak, while Edward Kumakech, Maurice Sadlier, Aidan Sinnott and Dan Irvine report on a Gap Analysis tool looking at the communication, community engagement and compliance tracking activities that need to be in place before an Ebola vaccine is deployed. Emanuele Bruni and colleagues describe the development of a new monitoring and evaluation framework for strategic response planning. The edition ends with an article by Adelicia Fairbanks, who argues for an acceptance strategy in the DRC to improve security and access for responding agencies.

**Human Vaccines & Immunotherapeutics** (formerly Human Vaccines)
Volume 16, Issue 7, 2020
http://www.tandfonline.com/toc/khvi20/current
[Reviewed earlier]

**Infectious Agents and Cancer**
http://www.infectagentscancer.com/content
[Accessed 3 Oct 2020]
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**Infectious Diseases of Poverty**
http://www.idpjournal.com/content
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Volume 12, Issue 5, September 2020
https://academic.oup.com/inthealth/issue/12/5
[Reviewed earlier]

**International Journal of Community Medicine and Public Health**
Vol 7, No 10 (2020) October 2020
https://www.ijcmph.com/index.php/ijcmph/issue/view/67
[Reviewed earlier]

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Volume 49, Issue 3, June 2020
https://academic.oup.com/ije/issue/49/3
[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
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September 2020 Volume 98, p1-502
https://www.ijidonline.com/issue/S1201-9712(20)X0010-5
[Reviewed earlier]

**JAMA Network**
**COVID-19 Update October 3, 2020**
*These articles on COVID-19 were published across the JAMA Network in the last week.*

**JAMA**
September 22/29, 2020, Vol 324, No. 12, Pages 1123-1255
https://jamanetwork.com/journals/jama/currentissue
[Reviewed earlier]

**JAMA Pediatrics**
September 2020, Vol 174, No. 9, Pages 815-916
http://archpedi.jamanetwork.com/issue.aspx
[Reviewed earlier]

**JBI Database of Systematic Review and Implementation Reports**
September 2020 - Volume 18 - Issue 9
https://journals.lww.com/jbisrir/Pages/currenttoc.aspx
[New issue; No digest content identified]

**Journal of Adolescent Health**
October 2020 Volume 67, Issue 4, p461-622
https://www.jahonline.org/issue/S1054-139X(20)X0008-5
*Editorials*
**HIV Prevention in Adolescents: Removing Obstacles and Protecting Human Rights**
*Obstacles exist to effective HIV prevention for all age groups. For adolescent minors, younger than 18 years, the impediments may include legal constraints. The most common is a requirement of parental consent, which may apply to both clinical care and research, with some important exceptions. Ensuring that young people are able to benefit fully from HIV prevention efforts has important human rights implications.*
Abigail English
p463–464
Published in issue: October 2020

*Original Articles*

**Adolescent Barriers to HIV Prevention Research: Are Parental Consent Requirements the Biggest Obstacle?**

*One third of people newly living with HIV/AIDS are adolescents. Research on adolescent HIV prevention is critical owing to differences between adolescents and adults. Parental permission requirements are often considered a barrier to adolescent enrollment in research, but whether adolescents view this barrier as the most important one is unclear.*

Seema K. Shah, Zaynab Essack, Katherine Byron, Catherine Slack, Daniel Reirden, Heidi van Rooyen, Nathan R. Jones, David S. Wendler

p495–501

Published online: July 5, 2020

**Journal of Artificial Intelligence Research**

Vol. 69 (2020)

https://www.jair.org/index.php/jair

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**Journal of Community Health**

Volume 45, issue 5, October 2020

https://link.springer.com/journal/10900/volumes-and-issues/45-5

*Articles*

[Reviewed earlier]

**Journal of Development Economics**

Volume 146 September 2020

https://www.sciencedirect.com/journal/journal-of-development-economics/vol/146/suppl/C

***Special Section on Child Development in India***

[Reviewed earlier]

**Journal of Empirical Research on Human Research Ethics**

Volume 15 Issue 4, October 2020

http://journals.sagepub.com/toc/jre/current

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**Journal of Epidemiology & Community Health**

September 2020 - Volume 74 - 9

https://jech.bmj.com/content/74/9

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Volume 13, Issue 3 Pages: 179-249 August 2020

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**Journal of Global Ethics**
Volume 16, Issue 1, 2020
http://www.tandfonline.com/toc/rjge20/current
[Reviewed earlier]

**Journal of Health Care for the Poor and Underserved (JHCPU)**
Volume 31, Number 3, August 2020
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**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
[New issue; No digest content identified]

**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**
October 2020 - Volume 46 - 10
http://jme.bmj.com/content/current
[Reviewed earlier]

**Journal of Patient-Centered Research and Reviews**
Volume 7, Issue 3 (2020)
https://digitalrepository.aurorahealthcare.org/jpcrr/
[Reviewed earlier]

**Journal of Pediatrics**
October 2020 Volume 225, p1-288
http://www.jpeds.com/current

Commentary
**Seeking Normalcy as the Curve Flattens: Ethical Considerations for Pediatricians Managing Collateral Damage of Coronavirus Disease-2019**
Dalia M. Feltman, Gregory P. Moore, Andrew F. Beck, Emily Siffermann, Carlo Bellieni, John Lantos
p233–238
Published online: June 26, 2020

**Journal of Pharmaceutical Policy and Practice**
https://joppp.biomedcentral.com/
[Accessed 3 Oct 2020]
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**Journal of Public Health Management & Practice**
September/October 2020 - Volume 26 - Issue 5
https://journals.lww.com/jphmp/pages/currenttoc.aspx
[Reviewed earlier]

**Journal of Public Health Policy**
Volume 41, Issue 3, September 2020
https://link.springer.com/journal/41271/41/3
[Reviewed earlier]

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

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September 2020 Volume 17 Issue 170
https://royalsocietypublishing.org/toc/rsif/current
[Reviewed earlier]

**Journal of Travel Medicine**
Volume 27, Issue 6, August 2020
https://academic.oup.com/jtm/issue/27/6
*Perspectives*
**Assessing US traveller vaccination access: an evaluation of US requirements for healthcare payer coverage of recommended travel vaccines**
Richard Hughes IV, Zach Klein
Journal of Travel Medicine, Volume 27, Issue 6, August 2020, taaa118,
https://doi.org/10.1093/jtm/taaa118

*Original Article*
**Safety of yellow fever vaccination in pregnancy: findings from a cohort of active duty US military women**
Clinton Hall, PhD, Zeina G Khodr, PhD, Richard N Chang, MPH, Anna T Bukowinski, MPH, Gia R Gumbs, MPH ...
Journal of Travel Medicine, Volume 27, Issue 6, August 2020, taaa138,
https://doi.org/10.1093/jtm/taaa138

**Journal of Virology**
September 2020; Volume 94,Issue 18
http://jvi.asm.org/content/current
[Reviewed earlier]

**The Lancet**
Oct 03, 2020 Volume 396 Number 10256 p935-1044, e53-e56
https://www.thelancet.com/journals/lancet/issue/current
*Comment*
**Offline: Science and the breakdown of trust**
Richard Horton

*Articles*
**Azithromycin in addition to standard of care versus standard of care alone in the treatment of patients admitted to the hospital with severe COVID-19 in Brazil (COALITION II): a randomised clinical trial**
Remo H M Furtado, et al for the COALITION COVID-19 Brazil II Investigators
The efficacy and safety of azithromycin in the treatment of COVID-19 remain uncertain. We assessed whether adding azithromycin to standard of care, which included hydroxychloroquine, would improve clinical outcomes of patients admitted to the hospital with severe COVID-19…
In patients with severe COVID-19, adding azithromycin to standard of care treatment (which included hydroxychloroquine) did not improve clinical outcomes. Our findings do not support the routine use of azithromycin in combination with hydroxychloroquine in patients with severe COVID-19.

*The Lancet Commissions*
**The Lancet NCDI Poverty Commission: bridging a gap in universal health coverage for the poorest billion**
Gene Bukhman, et al for the Lancet NCDI Poverty Commission Study Group
*Key messages*
:: For the poorest of our world, non-communicable diseases and injuries (NCDIs) account for more than a third of their burden of disease; this burden includes almost 800 000 deaths annually among those aged younger than 40 years, more than HIV, tuberculosis, and maternal deaths combined
:: Despite already living in abject poverty, between 19 million and 50 million of the poorest billion spend a catastrophic amount of money each year in direct out-of-pocket costs on health care as a :: :: :: Progressive implementation of affordable, cost-effective, and equitable NCDI

interventions between 2020 and 2030 could save the lives of more than 4·6 million of the world's poorest, including 1·3 million who would otherwise die before the age of 40 years
:: To avoid needless death and suffering, and to reduce the risk of catastrophic health spending, essential NCDI services must be financed through pooled, public resources, either from increased domestic funding or external funds
:: National governments should set and adjust priorities based on the best available local data on NCDIs and the specific needs of the worst off
:: International development assistance for health should be augmented and targeted to ensure that the poorest families affected by NCDIs are included in progress towards universal health care

**The Lancet Child & Adolescent Health**
Oct 2020 Volume 4 Number 10 p709-794, e36-e39
https://www.thelancet.com/journals/lanchi/issue/current
[Reviewed earlier]

**Lancet Digital Health**
Oct 2020 Volume 2 Number 10 e493-e560
https://www.thelancet.com/journals/landig/issue/current
*Editorial*
**Guiding better design and reporting of AI-intervention trials**
The Lancet Digital Health

*Review*
**Reporting guidelines for clinical trial reports for interventions involving artificial intelligence: the CONSORT-AI extension**
Xiaoxuan Liu, Samantha Cruz Rivera, David Moher, Melanie J Calvert, Alastair K Denniston and the SPIRIT-AI and CONSORT-AI Working Group
*Summary*
The CONSORT 2010 statement provides minimum guidelines for reporting randomised trials. Its widespread use has been instrumental in ensuring transparency in the evaluation of new interventions. More recently, there has been a growing recognition that interventions involving artificial intelligence (AI) need to undergo rigorous, prospective evaluation to demonstrate impact on health outcomes. The CONSORT-AI (Consolidated Standards of Reporting Trials-Artificial Intelligence) extension is a new reporting guideline for clinical trials evaluating interventions with an AI component. It was developed in parallel with its companion statement for clinical trial protocols: SPIRIT-AI (Standard Protocol Items: Recommendations for Interventional Trials-Artificial Intelligence). Both guidelines were developed through a staged consensus process involving literature review and expert consultation to generate 29 candidate items, which were assessed by an international multi-stakeholder group in a two-stage Delphi survey (103 stakeholders), agreed upon in a two-day consensus meeting (31 stakeholders), and refined through a checklist pilot (34 participants). The CONSORT-AI extension includes 14 new items that were considered sufficiently important for AI interventions that they should be routinely reported in addition to the core CONSORT 2010 items. CONSORT-AI recommends that investigators provide clear descriptions of the AI intervention, including instructions and skills required for use, the setting in which the AI intervention is integrated, the handling of inputs

and outputs of the AI intervention, the human–AI interaction and provision of an analysis of error cases. CONSORT-AI will help promote transparency and completeness in reporting clinical trials for AI interventions. It will assist editors and peer reviewers, as well as the general readership, to understand, interpret, and critically appraise the quality of clinical trial design and risk of bias in the reported outcomes.

**Guidelines for clinical trial protocols for interventions involving artificial intelligence: the SPIRIT-AI extension**

Samantha Cruz Rivera, Xiaoxuan Liu, An-Wen Chan, Alastair K Denniston, Melanie J Calvert and The SPIRIT-AI and CONSORT-AI Working Group

*Summary*

The SPIRIT 2013 statement aims to improve the completeness of clinical trial protocol reporting by providing evidence-based recommendations for the minimum set of items to be addressed. This guidance has been instrumental in promoting transparent evaluation of new interventions. More recently, there has been a growing recognition that interventions involving artificial intelligence (AI) need to undergo rigorous, prospective evaluation to demonstrate their impact on health outcomes. The SPIRIT-AI (Standard Protocol Items: Recommendations for Interventional Trials-Artificial Intelligence) extension is a new reporting guideline for clinical trial protocols evaluating interventions with an AI component. It was developed in parallel with its companion statement for trial reports: CONSORT-AI (Consolidated Standards of Reporting Trials-Artificial Intelligence). Both guidelines were developed through a staged consensus process involving literature review and expert consultation to generate 26 candidate items, which were consulted upon by an international multi-stakeholder group in a two-stage Delphi survey (103 stakeholders), agreed upon in a consensus meeting (31 stakeholders) and refined through a checklist pilot (34 participants). The SPIRIT-AI extension includes 15 new items that were considered sufficiently important for clinical trial protocols of AI interventions. These new items should be routinely reported in addition to the core SPIRIT 2013 items. SPIRIT-AI recommends that investigators provide clear descriptions of the AI intervention, including instructions and skills required for use, the setting in which the AI intervention will be integrated, considerations for the handling of input and output data, the human–AI interaction and analysis of error cases. SPIRIT-AI will help promote transparency and completeness for clinical trial protocols for AI interventions. Its use will assist editors and peer reviewers, as well as the general readership, to understand, interpret, and critically appraise the design and risk of bias for a planned clinical trial.

**Lancet Global Health**

Oct 2020 Volume 8 Number 10 e1242-e1351

http://www.thelancet.com/journals/langlo/issue/current

*Editorial*

**A historic achievement in a year of turmoil**

The Lancet Global Health

On World Polio Day 6 years ago, we wrote in an Editorial that "2014 has not felt like a good year for infectious disease control". Little did we know what lay ahead. Yet in 2020—a year of unprecedented disruption at the hands of a new human pathogen—the transmission of an old and more deadly and disabling virus was formally declared over on a continent with some of the weakest health systems in the world.

The certification on Aug 25 that the African region is now free of wild poliovirus was a truly historic moment. Back in 2014, WHO declared a Public Health Emergency of International Concern over markedly increased international spread, including from Africa, and in 2016 WHO revoked Nigeria's recently achieved polio-free status after several cases of wild poliovirus were discovered in Borno state. Genetic analysis pointed to long-term undetected transmission—a devastating setback borne of prolonged conflict that had destroyed health-care delivery infrastructure and severely restricted surveillance…

*Comment*

**Launching the Kofi Annan Global Health Leadership Programme**
John N Nkengasong, Edem Adzogenu, Amira E M Elfadil, Kwesi T Quartey

**Leadership training to accelerate progress in public health in sub-Saharan Africa: time for action**
Yukari C Manabe, Yohana Mashalla, Carey Farquhar, Nelson K Sewankambo

**The SickleGenAfrica Network**
Solomon F Ofori-Acquah on behalf of the SickleGenAfrica Network

*Articles*

**Routine childhood immunisation during the COVID-19 pandemic in Africa: a benefit–risk analysis of health benefits versus excess risk of SARS-CoV-2 infection**
Kaja Abbas, et al LSHTM CMMID COVID-19 Working Group

National immunisation programmes globally are at risk of suspension due to the severe health system constraints and physical distancing measures in place to mitigate the ongoing COVID-19 pandemic. We aimed to compare the health benefits of sustaining routine childhood immunisation in Africa with the risk of acquiring severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection through visiting routine vaccination service delivery points.

**The allocation of US$105 billion in global funding from G20 countries for infectious disease research between 2000 and 2017: a content analysis of investments**
Michael G Head, et al

**Domestic HPV vaccine price and economic returns for cervical cancer prevention in China: a cost-effectiveness analysis**
Zhuoru Zou, et al.

*Health Policy*

**Certifying the interruption of wild poliovirus transmission in the WHO African region on the turbulent journey to a polio-free world**
The Africa Regional Commission for the Certification of Poliomyelitis Eradication

*Summary*

On Aug 25 2020, the Africa Regional Commission for the Certification of Poliomyelitis Eradication declared that the WHO African region had interrupted transmission of all indigenous wild polioviruses. This declaration marks the African region as the fifth of the six WHO regions to celebrate this extraordinary achievement. Following the Yaoundé Declaration on Polio Eradication in Africa by heads of state and governments in 1996, Nelson Mandela launched the Kick Polio out of Africa campaign. In this Health Policy paper, we describe the long and

turbulent journey to the certification of the interruption of wild poliovirus transmission, focusing on 2016–20, lessons learned, and the strategies and analyses that convinced the Regional Commission that the African region is free of wild polioviruses. This certification of the WHO African region shows the feasibility of polio eradication in countries with chronic insecurity, inaccessible and hard-to-reach populations, and weak health systems. Challenges have been daunting and the sacrifices enormous—dozens of health workers and volunteers have lost their lives in the pursuit of a polio-free Africa.

**Lancet Infectious Diseases**
Sep 2020 Volume 20 Number 9 p993-1100, e215-e249
http://www.thelancet.com/journals/laninf/issue/current

*Editorial*

**Curing COVID-19**

The Lancet Infectious Diseases

As the COVID-19 pandemic moves into its 10th month, greater patient survival suggests that treatment of severe disease has improved. How much of this improvement is due to better supportive care and how much to pharmaceuticals is a matter of debate. Given the huge effort that the biomedical community has put into finding drugs to treat COVID-19, with thousands of trials completed and ongoing, it's worth taking stock of the evidence for what has worked and what has not…

*Personal View*

**Need for sustainable biobanking networks for COVID-19 and other diseases of epidemic potential**

Rosanna W Peeling, Debrah Boeras, Annelies Wilder-Smith, Amadou Sall, John Nkengasong

**Vaccinology: time to change the paradigm?**

Christine Stabell Benn, Ane B Fisker, Andreas Rieckmann, Signe Sørup, Peter Aaby

*Summary*

The existing vaccine paradigm assumes that vaccines only protect against the target infection, that effective vaccines reduce mortality corresponding to the target infection's share of total mortality, and that the effects of vaccines are similar for males and females. However, epidemiological vaccine research has generated observations that contradict these assumptions and suggest that vaccines have important non-specific effects on overall health in populations. These include the observations that several live vaccines reduce the incidence of all-cause mortality in vaccinated compared with unvaccinated populations far more than can be explained by protection against the target infections, and that several non-live vaccines are associated with increased all-cause mortality in females. In this Personal View we describe current observations and contradictions and define six emerging principles that might explain them. First, that live vaccines enhance resistance towards unrelated infections. Second, non-live vaccines enhance the susceptibility of girls to unrelated infections. Third, the most recently administered vaccination has the strongest non-specific effects. Fourth, combinations of live and non-live vaccines given together have variable non-specific health effects. Fifth, vaccinating children with live vaccines in the presence of maternal immunity enhances beneficial non-specific effects and reduces mortality. Finally, vaccines might interact with other co-administered health interventions, for example vitamin A supplementation. The potential implications for child health are substantial. For example, if BCG vaccination was given to

children at birth, if higher measles vaccination coverage could be obtained, if diphtheria, tetanus, and pertussis-containing vaccines were not given with or after measles vaccine, or if the BCG strain with the best non-specific effects could be used consistently, then child mortality could be considerably lower. Pursuing these emerging principles could improve our understanding and use of vaccines globally.

**Lancet Public Health**
Oct 2020 Volume 5 Number 10 e512-e567
https://www.thelancet.com/journals/lanpub/issue/current
*Editorial*
**Public health must be a priority in the 2020 US election**
The Lancet Public Health

**Lancet Respiratory Medicine**
Oct 2020 Volume 8 Number 10 p935-1060, e73-e77
http://www.thelancet.com/journals/lanres/issue/current
[New issue; No digest content identified]

**Maternal and Child Health Journal**
Volume 24, issue 10, October 2020
https://link.springer.com/journal/10995/volumes-and-issues/24-10
[Reviewed earlier]

**Medical Decision Making (MDM)**
Volume 40 Issue 6, August 2020
http://mdm.sagepub.com/content/current
[Reviewed earlier]

**The Milbank Quarterly**
*A Multidisciplinary Journal of Population Health and Health Policy*
Volume 98, Issue 3 Pages: 619-1020 September 2020
[Reviewed earlier]

**Nature**
Volume 585 Issue 7826, 24 September 2020
http://www.nature.com/nature/current_issue.html
*Editorial* | 29 September 2020
**COVID vaccine confidence requires radical transparency**
*Public trust in a potential vaccine is under threat. Drug companies and their academic partners must disclose protocols and results data.*
…History has shown that once public trust in vaccines has been compromised it is difficult to win back — and that distrust in one vaccine can fuel concerns about others. People wary of a

COVID-19 vaccine might be less likely to get vaccinated against other ailments, fuelling the vaccine-hesitancy movement that has already led to dangerous resurgences of diseases such as measles that were once largely contained. The causes of vaccine hesitancy are complex. But delays and reluctance in communicating results, or outright secrecy, do not help. Researchers, publishers, regulators, policymakers — and especially pharmaceutical companies — need to accept this if we are to succeed in quickly disrupting the path of the pandemic.

**Nature Biotechnology**
Volume 38 Issue 9, 1 September 2020
https://www.nature.com/nbt/volumes/38/issues/9
[Reviewed earlier]

**Nature Communications**
https://www.nature.com/subjects/health-sciences/ncomms
(Accessed 3 Oct 2020)
[No new digest content identified]

**Nature Genetics**
Volume 52 Issue 10, October 2020
https://www.nature.com/ng/volumes/52/issues/10
*Comment* | 09 September 2020
**Exploring the coronavirus pandemic with the WashU Virus Genome Browser**
The WashU Virus Genome Browser is a web-based portal for efficient visualization of viral 'omics' data in the context of a variety of annotation tracks and host infection responses. The browser features both a phylogenetic-tree-based view and a genomic-coordinate, track-based view in which users can analyze the sequence features of viral genomes, sequence diversity among viral strains, genomic sites of diagnostic tests, predicted immunogenic epitopes and a continuously updated repository of publicly available genomic datasets.
Jennifer A. Flynn, Deepak Purushotham[…] & Ting Wang

*Comment* | 09 September 2020
**The UCSC SARS-CoV-2 Genome Browser**
The UCSC SARS-CoV-2 Genome Browser ( https://genome.ucsc.edu/covid19.html ) is an adaptation of our popular genome-browser visualization tool for this virus, containing many annotation tracks and new features, including conservation with similar viruses, immune epitopes, RT–PCR and sequencing primers and CRISPR guides. We invite all investigators to contribute to this resource to accelerate research and development activities globally.
Jason D. Fernandes, Angie S. Hinrichs[…] & Maximilian Haeussler

*Comment* | 09 September 2020
**Exploring the structural distribution of genetic variation in SARS-CoV-2 with the COVID-3D online resource**
The emergence of the COVID-19 pandemic has spurred a global rush to uncover basic biological mechanisms to inform effective vaccine and drug development. Despite the novelty of the virus, global sequencing efforts have already identified genomic variation across isolates. To

enable easy exploration and spatial visualization of the potential implications of SARS-CoV-2 mutations in infection, host immunity and drug development, we have developed COVID-3D ( http://biosig.unimelb.edu.au/covid3d/ ).
Stephanie Portelli, Moshe Olshansky[…] & David B. Ascher

*Perspective* | 14 September 2020
**Treating medical data as a durable asset**
This Perspective discusses important aspects of data generation, infrastructure and management that affect how the research community uses medical data, including genetic and genomic information.
Amalio Telenti & Xiaoqian Jiang
*Abstract*
Access to medical data is central for conducting research on genomics. However, to tap these metadata (observable traits and phenotypes, diagnoses and medication, and labels), researchers must grapple with the complex and sensitive nature of the information. In this Perspective, we argue that, at this exciting time for genomics and artificial intelligence, several critical aspects of data generation, infrastructure and management are pillars of a modern data ecosystem. Many risks to privacy and many obstacles to medical research can be eliminated or mitigated by new secure data analytics. Finally, we discuss the potential consequences of medical data exiting the institutions and being managed by individuals. These shifts in data ownership have the potential for profound disruption and opportunity across many fields.

**Nature Medicine**
Volume 26 Issue 9, 1 September 2020
https://www.nature.com/nm/volumes/26/issues/9
***Guidelines for AI in clinical trials***
[Reviewed earlier]

**Nature Reviews Genetics**
Volume 21 Issue 10, October 2020
https://www.nature.com/nrg/volumes/21/issues/9
*Comment* | 07 August 2020
**The Human Genome Project changed everything**
Thirty years on from the launch of the Human Genome Project, Richard Gibbs reflects on the promisesthat this voyage of discovery bore. Its success should be measured by how this project transformed the rules of research, the way of practising biological discovery and the ubiquitous digitization of biological science.
Richard A. Gibbs

*Viewpoint* | 24 August 2020
**The road ahead in genetics and genomics**
To celebrate the first 20 years of Nature Reviews Genetics, we asked 12 leading scientists to reflect on the key challenges and opportunities faced by the field of genetics and genomics.
Amy L. McGuire, Stacey Gabriel[…] & Jin-Soo Kim

*Review Article* | 21 July 2020

**Responsible, practical genomic data sharing that accelerates research**

Data sharing can maximize the benefit and reach of genomics research. However, sharing must occur in a responsible manner, particularly when there are privacy risks to human participants. In this Review, the authors discuss the principles of data sharing, strategies for assessing and mitigating privacy risks, as well as practical guidelines for researchers and wider stakeholders.

James Brian Byrd, Anna C. Greene[…] & Casey S. Greene

**Nature Reviews Immunology**

Volume 20 Issue 10, October 2020

https://www.nature.com/nri/volumes/20/issues/10

*Review Article* | 04 September 2020

**Immunological considerations for COVID-19 vaccine strategies**

This Review outlines the guiding immunological principles for the design of coronavirus disease 2019 (COVID-19) vaccine strategies and analyses the current COVID-19 vaccine landscape and the challenges ahead.

Mangalakumari Jeyanathan, Sam Afkhami[…] & Zhou Xing

**Nature Reviews Drug Discovery**

Volume 19 Issue 10, October 2020

https://www.nature.com/nrd/volumes/19/issues/10

*Comment* | 03 September 2020

**COVID-19 must catalyse changes to clinical development**

The response to the COVID-19 pandemic has shown that exceptional efforts can dramatically accelerate the clinical development of vaccines. We propose that it is time to also take immediate actions to improve clinical trials in other areas to better serve all patients.

Rod MacKenzie, Peter Honig[…] & Marie-Pierre Hellio

**New England Journal of Medicine**

October 1, 2020 Vol. 383 No. 14

http://www.nejm.org/toc/nejm/medical-journal

*Perspective*

**Ensuring Uptake of Vaccines against SARS-CoV-2**

Michelle M. Mello, J.D., Ph.D., Ross D. Silverman, J.D., M.P.H., and Saad B. Omer, M.B., B.S., M.P.H., Ph.D.

As Covid-19 continues to exact a heavy toll, development of a vaccine appears the most promising means of restoring normalcy to civil life. Perhaps no scientific breakthrough is more eagerly anticipated. But bringing a vaccine to market is only half the challenge; also critical is ensuring a high enough vaccination rate to achieve herd immunity. Concerningly, a recent poll found that only 49% of Americans planned to get vaccinated against SARS-CoV-2.1

One option for increasing vaccine uptake is to require it. Mandatory vaccination has proven effective in ensuring high childhood immunization rates in many high-income countries. However, except for influenza vaccination of health care workers, mandates have not been widely used for adults.

Although a vaccine remains months to years away, developing a policy strategy to ensure uptake takes time. We offer a framework that states can apply now to help ensure uptake of the vaccine when it becomes available — including consideration of when a mandate might become appropriate. Our approach is guided by lessons from U.S. experiences with vaccines for the 1976 "swine flu," H1N1 influenza, smallpox, and human papillomavirus (HPV).

**We believe that six substantive criteria should be met before a state imposes a SARS-CoV-2 vaccine mandate (see box).** The first is the existence of evidence that Covid-19 is inadequately controlled in the state by other measures, such as testing, contact tracing, and isolation and quarantine — as indicated by sustained, troubling trends in new cases, hospitalizations, or deaths. Principles of public health law and ethics require that interventions that impinge on autonomy be reasonable and necessary; therefore, Covid-19 must present an ongoing threat. By the time a vaccine is available, more will be known about natural immunity in the population, the consequences of relaxing community mitigation measures, and the feasibility of scaling up test-and-trace strategies. There should be a reasonable indication as to whether further measures are needed.

***Six Trigger Criteria for State Covid-19 Vaccination Mandates.***
:: Covid-19 is not adequately contained in the state.
:: The Advisory Committee on Immunization Practices has recommended vaccination for the groups for which a mandate is being considered.
:: The supply of vaccine is sufficient to cover the population groups for which a mandate is being considered.
:: Available evidence about the safety and efficacy of the vaccine has been transparently communicated.
:: The state has created infrastructure to provide access to vaccination without financial or logistic barriers, compensation to workers who have adverse effects from a required vaccine, and real-time surveillance of vaccine side effects.
:: In a time-limited evaluation, voluntary uptake of the vaccine among high-priority groups has fallen short of the level required to prevent epidemic spread.

**The second criterion is that the Advisory Committee on Immunization Practices (ACIP), after reviewing the safety and efficacy evidence, has recommended vaccination for the persons who would be covered by a mandate**. Currently available evidence suggests that the elderly, health professionals working in high-risk situations or working with high-risk patients (e.g., nursing home residents and patients with severe respiratory symptoms), and persons with certain underlying medical conditions may be high-priority groups for the ACIP's consideration, along with other workers with frequent, close, on-the-job contacts and persons living in high-density settings such as prisons and dormitories. When a vaccine nears approval, the ACIP should review the updated evidence and develop recommendations. Only recommended groups should be considered for a vaccination mandate, though health officials can encourage voluntary uptake for others, using means such as public education campaigns and free vaccination.

The fact that a vaccine has received Food and Drug Administration (FDA) approval — whether under an Emergency Use Authorization (EUA) or ordinary review processes — is an insufficient basis on which to conclude that it should be required. FDA approval reflects a determination

that clinical trial evidence shows that the benefits of a vaccine outweigh its risks. ACIP recommendations reflect broader considerations, including values and preferences of affected groups, implementation issues, and health economic analyses. Overweighting FDA decisions would be particularly problematic for SARS-CoV-2 vaccines because EUAs may be based on very limited evidence and consciously or unconsciously influenced by the intense pressure to speed countermeasures to market.2

**The third criterion is that there is an adequate supply of vaccine to cover the groups for which a mandate is being considered**. Initially, global demand for SARS-CoV-2 vaccines will outstrip supply, making the salient question not who must get them but who will be granted access to them. New York State's unsuccessful attempt to mandate H1N1 influenza vaccination for health care workers demonstrates that imposing requirements before adequate supply has been secured needlessly provokes controversy and alienates people who have already made sacrifices to fight an epidemic.3

**The fourth criterion is that there has been transparent communication of the best available evidence about the vaccine's safety and efficacy.**4 Particularly given the possibility that the evidence underlying FDA approval of SARS-CoV-2 vaccines may be more modest than usual, policymakers and the public will need to understand the limits of what is known. Public trust has already been compromised by federal officials' endorsement of hydroxychloroquine as a Covid-19 treatment without evidentiary support; the same must not occur for vaccines.

**The fifth criterion is that the government has put in place certain support mechanisms for persons required to receive the vaccine**. Lessons from past vaccination campaigns suggest that a generous compensation program for people who have serious vaccine side effects should be a centerpiece of these efforts. A federal compensation fund like the Smallpox Vaccine Injury Compensation Program is one attractive model, although identifying compensable injuries may be challenging with a novel vaccine. States will also have to create distribution systems to provide SARS-CoV-2 vaccine to high-priority groups with near-zero financial and logistic barriers — for example, bringing free vaccine to points of care, pharmacies, and work sites. It is equally critical to have a safety-assessment plan in place before vaccines are widely distributed to enable health officials to evaluate safety evidence in real time. States should work with health systems to ensure that reporting systems for vaccine-related adverse events are consistently used and specify a process for reconsidering mandate decisions as evidence evolves.

**The last criterion is that vaccination mandates are imposed only after a time-limited trial of voluntary vaccine provision has proved unsuccessful**. Principles of public health ethics support trying less burdensome policies before moving to more burdensome ones whenever possible. In this case, the costs of a failed voluntary scheme are sufficiently high that the attempt should be limited to a matter of weeks. States should implement a system for measuring vaccine uptake within each high-priority group against a set of coverage targets. Ensuring that the economic and logistic supports described above are in place will maximize the chances for success.

If the proposed trigger criteria were met, what might a vaccination mandate look like? Because the constitutional power to protect public health rests primarily with states, each state will need

to adopt its own legislation. Proposed legislation should be supported by attestations from the state health officer, the ACIP, or another expert committee that all trigger criteria have been met. Targeted SARS-CoV-2 vaccination mandate policies may also be appropriate in certain federal contexts, including high-risk groups in active-duty military environments, Veterans Affairs facilities, federal prisons, and immigration detention centers.

Although state vaccination mandates are usually tied to school and day care entry, that approach is not appropriate for SARS-CoV-2 because children won't be a high-priority group. In addition, state mandates should not be structured as compulsory vaccination (absolute requirements); instead, noncompliance should incur a penalty. Nevertheless, because of the infectiousness and dangerousness of the virus, relatively substantive penalties could be justified, including employment suspension or stay-at-home orders for persons in designated high-priority groups who refuse vaccination. Neither fines nor criminal penalties should be used, however; fines disadvantage the poor, and criminal penalties invite legal challenges on procedural due-process grounds. Both are bad public health policy for a Covid-19 vaccine because they may stoke distrust without improving uptake.

The need to build public trust requires that state officials implement vaccination policy through a transparent and inclusive process, working closely with stakeholder groups such as local health officers, health professional and hospital associations, representatives of high-risk population groups, and groups concerned about vaccine safety. States' experience with HPV vaccination mandates offers another process tip: vaccine manufacturers should stay on the sidelines. The HPV vaccine manufacturer's direct involvement in crafting and lobbying for mandate legislation raised suspicion that profit rather than public health motives lay behind such proposals, undercutting support for vaccination even without a mandatory regime.[5]

As with social distancing orders, we can expect that the advent of SARS-CoV-2 vaccines will spark intense clashes of feeling about what people owe to one another in the fight against the pandemic. In contrast to earlier phases of the pandemic, though, we currently have some time on our side. Careful deliberation now about state vaccination policy can help ensure that we have a strategy when the breakthrough comes.

*Original Article  Free Preview*
**HPV Vaccination and the Risk of Invasive Cervical Cancer**
Jiayao Lei, Ph.D., et al.
The efficacy and effectiveness of the quadrivalent human papillomavirus (HPV) vaccine in preventing high-grade cervical lesions have been shown. However, data to inform the relationship between quadrivalent HPV vaccination and the subsequent risk of invasive cervical cancer are lacking.

**Pediatrics**
Vol. 146, Issue 4  1 Oct 2020
https://pediatrics.aappublications.org/
*Articles*
**Trends in Human Papillomavirus Vaccination in Commercially Insured Children in the United States**
Szu-Ta Chen, Krista F. Huybrechts, Brian T. Bateman, Sonia Hernández-Díaz

Pediatrics, Oct 2020, 146 (4) e20193557

*Commentaries*
**Learning More About Ways to Improve Adolescent HPV Coverage**
Amanda F. Dempsey
Pediatrics, Oct 2020, 146 (4) e2020005454

*Ethics Rounds*
**A Complicated Case of Vaccine Refusal**
Rebecca Rossi, Neil Rellosa, Robin Miller, Corinna L. Schultz, Jonathan M. Miller, Loren Berman, Elissa G. Miller
Pediatrics, Oct 2020, 146 (4) e20200768

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

**PharmacoEconomics**
Volume 38, issue 10, October 2020
https://link.springer.com/journal/40273/volumes-and-issues/38-10
[Reviewed earlier]

**PLoS Genetics**
https://journals.plos.org/plosgenetics/
(Accessed 3 Oct 2020)
[No new digest content identified]

**PLoS Medicine**
http://www.plosmedicine.org/
(Accessed 3 Oct 2020)
[No new digest content identified]

**PLoS Neglected Tropical Diseases**
http://www.plosntds.org/
(Accessed 3 Oct 2020)
[No new digest content identified]

**PLoS One**
http://www.plosone.org/
*Research Article*

**Trend and determinants of complete vaccination coverage among children aged 12-23 months in Ghana: Analysis of data from the 1998 to 2014 Ghana Demographic and Health Surveys**
Eugene Budu, Eugene Kofuor Maafo Darteh, Bright Opoku Ahinkorah, Abdul-Aziz Seidu, Kwamena Sekyi Dickson
| published 01 Oct 2020 PLOS ONE
https://doi.org/10.1371/journal.pone.0239754

**Incidence of invasive pneumococcal disease after introduction of the 13-valent conjugate pneumococcal vaccine in British Columbia: A retrospective cohort study**
Nirma Khatri Vadlamudi, David M. Patrick, Linda Hoang, Manish Sadarangani, Fawziah Marra
Research Article | published 30 Sep 2020 PLOS ONE
https://doi.org/10.1371/journal.pone.0239848

**PLoS Pathogens**
http://journals.plos.org/plospathogens/
[Accessed 3 Oct 2020]
*Opinion*
**Translational Research in the Time of COVID-19—Dissolving Boundaries**
Jonathan D. Edgeworth, Rahul Batra, Gaia Nebbia, Karen Bisnauthsing, Eithne MacMahon, Malur Sudhanva, Sam Douthwaite, Simon Goldenberg, Geraldine O'Hara, Manu Shankar-Hari, Katie J. Doores, Rocio Martinez-Nunez, Carolyn Hemsley, Nicholas M. Price, Jill Lockett, Robert I. Lechler, Stuart J. D. Neil, Michael H. Malim
| published 30 Sep 2020 PLOS Pathogens
https://doi.org/10.1371/journal.ppat.1008898

**PNAS - Proceedings of the National Academy of Sciences of the United States of America**
http://www.pnas.org/content/early/
*Article*
**Global COVID-19 pandemic demands joint interventions for the suppression of future waves**
Ruiyun Li, Bin Chen, Tao Zhang, Zhehao Ren, Yimeng Song, Yixiong Xiao, Lin Hou, Jun Cai, Bo Xu, Miao Li, Karen Kie Yan Chan, Ying Tu, Mu Yang, Jing Yang, Zhaoyang Liu, Chong Shen, Che Wang, Lei Xu, Qiyong Liu, Shuming Bao, Jianqin Zhang, Yuhai Bi, Yuqi Bai, Ke Deng, Wusheng Zhang, Wenyu Huang, Jason D. Whittington, Nils Chr. Stenseth, Dabo Guan, Peng Gong, and Bing Xu
PNAS first published September 28, 2020. https://doi.org/10.1073/pnas.2012002117
*Abstract*
Emerging evidence suggests a resurgence of COVID-19 in the coming years. It is thus critical to optimize emergency response planning from a broad, integrated perspective. We developed a mathematical model incorporating climate-driven variation in community transmissions and movement-modulated spatial diffusions of COVID-19 into various intervention scenarios. We find that an intensive 8-wk intervention targeting the reduction of local transmissibility and international travel is efficient and effective. Practically, we suggest a tiered implementation of this strategy where interventions are first implemented at locations in what we call the Global

Intervention Hub, followed by timely interventions in secondary high-risk locations. We argue that thinking globally, categorizing locations in a hub-and-spoke intervention network, and acting locally, applying interventions at high-risk areas, is a functional strategy to avert the tremendous burden that would otherwise be placed on public health and society.

**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
*Review article Abstract only*
**Impact of school-based educational interventions in middle adolescent populations (15-17yrs) on human papillomavirus (HPV) vaccination uptake and perceptions/knowledge of HPV and its associated cancers: A systematic review**
Terri Flood, Iseult M. Wilson, Gillian Prue, Marian McLaughlin, Ciara M. Hughes
Article 106168

*Research article Abstract only*
**A quality improvement collaborative to increase human papillomavirus vaccination rates in local health department clinics**
Rachel Wallace-Brodeur, Rui Li, Wendy Davis, Sharon Humiston, ... Cynthia M. Rand
Article 106235

**Proceedings of the Royal Society B**
30 September 2020 Volume 287 Issue 1935
https://royalsocietypublishing.org/toc/rspb/current
[New issue; No digest content identified]

**Public Health**
Volume 186 Pages A1-A2, 1-304 (September 2020)
https://www.sciencedirect.com/journal/public-health/vol/185/suppl/C
[New issue; No digest content identified]

**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 5, September/October 2020
https://journals.sagepub.com/toc/phrg/135/5
[Reviewed earlier]

**Qualitative Health Research**
Volume 30 Issue 12, October 2020
http://qhr.sagepub.com/content/current
[New issue; No digest content identified]

**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 3 Oct 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*
28 Sep 2020
**Antimicrobial resistance: time for action***
Editorial | English |

28 Sep 2020
**Adequate, reliable and timely information in times of the COVID-19 pandemic**
Current topic | Portuguese |

28 Sep 2020
**Health working conditions and environment: conceptual model for remote and rural areas**
Special report | Spanish |

**Risk Analysis**
Volume 40, Issue 9 Pages: 1691-1886 September 2020
https://onlinelibrary.wiley.com/toc/15396924/current
[New issue; No digest content identified]

**Risk Management and Healthcare Policy**
https://www.dovepress.com/risk-management-and-healthcare-policy-archive56
[Accessed 3 Oct 2020]
[No new digest content identified]

**Science**
02 October 2020  Vol 370, Issue 6512
http://www.sciencemag.org/current.dtl
*Feature*
**Official inaction**
By Charles Piller
Science02 Oct 2020 : 24-29
A Science investigation shows that FDA oversight of clinical trials is lax, slow moving, and secretive—and that enforcement is declining.
*Summary*
The U.S. Food and Drug Administration (FDA) oversees most clinical research in the United States, ensuring the integrity of trial data and the safety of study participants. This Science investigation, which evaluated FDA's clinical trial enforcement for the past 11 years, suggests the agency's enforcement of clinical research regulations is often light-handed, slow moving, and secretive—even when clinical trial practices were deemed dangerous or unlawful. The investigation, which included a review of nearly 1600 FDA inspection and enforcement documents for clinical trials, found that FDA rarely levels sanctions. When it does, follow-ups are either slow or neglected, and cases are frequently resolved based on unverified claims. And the agency has become less and less aggressive in its enforcement. It issued 99 and 36 warning letters for serious clinical trial transgressions during the first and last 3 years of the Obama administration, respectively, and only 12 were issued during the first 3 years under President Donald Trump. Disqualifications of egregious offenders also plummeted under Trump. The Science findings provide a cautionary tale as FDA oversees numerous fast-moving trials of vaccines and drugs for COVID-19.

*Books et al.*
**Flawed research and its enduring repercussions**
By Paul A. Offit
Science02 Oct 2020 : 43
A journalist recounts how he exposed problems with a study linking vaccines and autism

*Policy Forum*
**How to fix the GDPR's frustration of global biomedical research**
By Jasper Bovenberg, David Peloquin, Barbara Bierer, Mark Barnes, Bartha Maria Knoppers
Science02 Oct 2020 : 40-42
*Sharing of data for research beyond the EU must improve*
*Summary*
Since the advent of the European Union (EU) General Data Protection Regulation (GDPR) in 2018, the biomedical research community has struggled to share data with colleagues and consortia outside the EU, as the GDPR limits international transfers of personal data. A July 2020 ruling of the Court of Justice of the European Union (CJEU) reinforced obstacles to sharing, and even data transfer to enable essential research into coronavirus disease 2019

(COVID-19) has been restricted in a recent Guidance of the European Data Protection Board (EDPB). We acknowledge the valid concerns that gave rise to the GDPR, but we are concerned that the GDPR's limitations on data transfers will hamper science globally in general and biomedical science in particular (see the text box) (1)—even though one stated objective of the GDPR is that processing of personal data should serve humankind, and even though the GDPR explicitly acknowledges that the right to the protection of personal data is not absolute and must be considered in relation to its function in society and be balanced against other fundamental rights. We examine whether there is room under the GDPR for EU biomedical researchers to share data from the EU with the rest of the world to facilitate biomedical research. We then propose solutions for consideration by either the EU legislature, the EU Commission, or the EDPB in its planned Guidance on the processing of health data for scientific research. Finally, we urge the EDPB to revisit its recent Guidance on COVID-19 research.

**Science Translational Medicine**
30 September 2020 Vol 12, Issue 563
https://stm.sciencemag.org/
*Editorial*
**Global approaches to genomic medicine implementation**
By Andrea Belcher, Geoffrey S. Ginsburg, Robyn Ward
Science Translational Medicine30 Sep 2020
A snapshot of implementation initiatives worldwide illustrates the need for collaboration to realize the full potential of genomic medicine.

**Social Science & Medicine**
Volume 261 September 2020
https://www.sciencedirect.com/journal/social-science-and-medicine/vol/261/suppl/C
[New issue; No digest content identified]

**Systematic Reviews**
https://systematicreviewsjournal.biomedcentral.com/articles
[Accessed 3 Oct 2020]
[No new digest content identified]

**Travel Medicine and Infectious Diseases**
Volume 36 July–August 2020
https://www.sciencedirect.com/journal/travel-medicine-and-infectious-disease/vol/36/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
[New issue; No digest content identified]

**Vaccine**
Volume 38, Issue 44 Pages 6859-6966 (14 October 2020)
https://www.sciencedirect.com/journal/vaccine/vol/38/issue/44
*Research article Full text access*
**Caregiver and service provider vaccine confidence following the Changchun Changsheng vaccine incident in China: A cross-sectional mixed methods study**
Shiyi Tu, Fiona Yueqian Sun, Tracey Chantler, Xuan Zhang, ... Heidi Larson
Pages 6882-6888

*Research article Full text access*
**Pregnant women's perceptions of risks and benefits when considering participation in vaccine trials**
Elana Jaffe, Anne Drapkin Lyerly, Ilona Telefus Goldfarb
Pages 6922-6929

*Research article Abstract only*
**Effective vaccine management through social behavior change communication: Exploring solutions using a participatory action research approach in the Solomon Islands**
Ibrahim Dadari, Jude Ssenyonjo, Jenniffer Anga
Pages 6941-6953

**Vaccines — Open Access Journal**
http://www.mdpi.com/journal/vaccines
(Accessed 3 Oct 2020)
*Open Access Article*
**Influences on Attitudes Regarding Potential COVID-19 Vaccination in the United States**
by Kendall Pogue , Jamie L. Jensen , Carter K. Stancil , Daniel G. Ferguson , Savannah J. Hughes , Emily J. Mello , Ryan Burgess , Bradford K. Berges , Abraham Quaye and Brian D. Poole
Vaccines 2020, 8(4), 582; https://doi.org/10.3390/vaccines8040582 - 03 Oct 2020
*Abstract*
The COVID-19 pandemic continues to ravage the world, with the United States being highly affected. A vaccine provides the best hope for a permanent solution to controlling the pandemic. However, to be effective, a vaccine must be accepted and used by a large majority of the population. The aim of this study was to understand the attitudes towards and obstacles facing vaccination with a potential COVID-19 vaccine. To measure these attitudes a survey was administered to 316 respondents across the United States by a survey corporation. Structural equation modeling was used to analyze the relationships of several factors with attitudes toward potential COVID-19 vaccination. Prior vaccine usage and attitudes predicted attitudes towards COVID-19 vaccination. Assessment of the severity of COVID-19 for the United States was also predictive. Approximately 68% of all respondents were supportive of being vaccinated for COVID-19, but side effects, efficacy and length of testing remained concerns. Longer testing, increased efficacy and development in the United States were significantly associated with increased vaccine acceptance. Messages promoting COVID-19 vaccination should seek to

alleviate the concerns of those who are already vaccine-hesitant. Messaging directed at the benefits of vaccination for the United States as a country would address the second predictive factor. Enough time should be taken to allay concerns about both short- and long-term side effects before a vaccine is released.

*Open Access Article*
**Impact of the COVID-19 Pandemic on Routine Childhood Immunization in Saudi Arabia**
by Mohammed Alsuhaibani and Aqeel Alaqeel
Vaccines 2020, 8(4), 581; https://doi.org/10.3390/vaccines8040581 - 03 Oct 2020
*Abstract*
The COVID-19 pandemic is impacting national and international public health. Routine childhood immunization may be adversely affected by COVID-19 mitigation measures. We aimed to identify the prevalence of delayed immunization and explore the reasons and barriers for delayed immunization during the COVID-19 pandemic

*Open Access Article*
**Relationship between Citizens' Health Engagement and Intention to Take the COVID-19 Vaccine in Italy: A Mediation Analysis**
by Guendalina Graffigna , Lorenzo Palamenghi , Stefania Boccia and Serena Barello
Vaccines 2020, 8(4), 576; https://doi.org/10.3390/vaccines8040576 - 01 Oct 2020
*Abstract*
The actual effectiveness of the still-to-come vaccination against the coronavirus SARS-CoV-2 might be challenged by vaccine hesitancy, a rather common and known phenomenon whose psychological predictors are, nevertheless, still largely debated. Our study aims at understanding how adult citizens' health engagement, perceived COVID-19

*Open Access Review*
**Measuring the Benefits of Mass Vaccination Programs in the United States**
by Hector Magno and Beatrice Golomb
Vaccines 2020, 8(4), 561; https://doi.org/10.3390/vaccines8040561 - 29 Sep 2020
*Abstract*
Since the late 1940s, mass vaccination programs in the USA have contributed to the significantly reduced morbidity and mortality of infectious diseases. To assist the evaluation of the benefits of mass vaccination programs, the number of individuals who would have suffered death or…

**Value in Health**
September 2020 Volume 23, Issue 9, p1119-1280
https://www.valueinhealthjournal.com/issue/S1098-3015(20)X0011-8
[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 3 Oct 2020*
[No new, unique, relevant content]

**BBC**
http://www.bbc.co.uk/
*Accessed 3 Oct 2020*
*Health*
**UN's Guterres makes Covid vaccine donation appeal**

The UN secretary general says richer countries need to take a global view as "their citizens will not be safe until every citizen in the world is safe".

António Guterres has called on countries such as the US, China and Russia to guarantee fair access to a successful vaccine.

**The Economist**
http://www.economist.com/
*Accessed 3 Oct 2020*
[No new, unique, relevant content]

**Financial Times**
https://www.ft.com/
*Accessed 3 Oct 2020*
[No new, unique, relevant content]

**Forbes**
http://www.forbes.com/
*Accessed 3 Oct 2020*
Oct 1, 2020
**Trump Is 'Single Largest Driver' Of Covid-19 Misinformation, Cornell Study Finds**
Trump declared hydroxychloroquine a "game-changer" and once suggested injecting Covid-19 patients with disinfectants such as bleach.
By Tommy Beer Forbes Staff

*Editors' Pick*/ Sep 30, 2020,10:54am EDT

**Operation Warp Speed Has Over $6 Billion In Secret Covid-19 Vaccine Contracts Evading Scrutiny**
Robert Hart Forbes Staff
*Topline*
Billions of dollars' worth of coronavirus vaccine contracts have avoided usual mechanisms of transparency and regulatory oversight with Operation Warp Speed - the Trump administration's project to develop a Covid-19 vaccine - which is funneling money through a nongovernmental intermediary, a move that is likely to reignite worries over the project's opaque nature.
*Key Facts*
:: Rather than entering into contracts with vaccine makers directly, NPR reports that more than $6 billion in Operation Warp Speed funding has been routed through an intermediary nongovernmental firm, thereby avoiding the usual requirements for regulatory oversight and transparency that accompany federal contracting as well as many public records request requirements.
:: NPR reports that funding is directed through the defense contract management firm Advance Technologies International, Inc., (ATI) who go on to award contracts to companies developing vaccines for Covid-19.
:: Some of the contracts for the most high-profile vaccine candidates have been awarded by ATI in this way, including $1 billion for Johnson & Johnson, $1.79 billion for Sanofi, $1.6 billion for Novavax, and $1.95 billion for Pfizer.
:: Since its inception, Operation Warp Speed has repeatedly come under fire over its opaque nature, including from Senate critics who accused officials of making major decisions behind closed doors; it is likely that the revelation in the way the project issues its contracts will reignite this debate.

**Foreign Affairs**
http://www.foreignaffairs.com/
*Accessed 3 Oct 2020*
[No new, unique, relevant content]

**Foreign Policy**
http://foreignpolicy.com/
*Accessed 3 Oct 2020*
[No new, unique, relevant content]

**The Guardian**
http://www.guardiannews.com/
[No new, unique, relevant content]

**New Yorker**
http://www.newyorker.com/
*News Desk*
**Chinese Citizens Are Already Receiving a Coronavirus Vaccine**
The pandemic has only increased the battle with the U.S. for scientific and political supremacy.
By Peter Hessler
September 29, 2020

**New York Times**

http://www.nytimes.com/
*Accessed 3 Oct 2020*
*Politics*
**Biotech Industry Pushes Trump Administration to Release New Vaccine Guidelines**
The BIO trade group, whose members include most of the vaccine makers, asked the health secretary to make the new vaccine guidelines public.
By Sheryl Gay Stolberg

**Washington Post**
https://www.washingtonpost.com/
*Accessed 3 Oct 2020*
**CDC's credibility is eroded by internal blunders and external attacks as coronavirus vaccine**
Lena H. Sun and Joel Achenbach · Health · Sep 28, 2020

**At UN, India vows to help produce virus vaccine for world**
· Sep 27, 2020

**Black doctors want to vet vaccine process, worried about mistrust from years of medical racism**
Meryl Kornfield · National · Sep 26, 2020

**Trump, White House demand FDA justify tough standards for coronavirus vaccine, raising concerns**
Laurie McGinley, Yasmeen Abutaleb and Josh Dawsey · Politics · Sep 25, 2020

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## ***Think Tanks et al***

**Brookings**
http://www.brookings.edu/
*Accessed 3 Oct 2020*
[No new relevant content]

**Center for Global Development** [to 3 Oct 2020]
http://www.cgdev.org/page/press-center
*Accessed 3 Oct 2020*
October 2, 2020
**Vaccine Experts Speak Out on COVID-19 Vaccines and How to Prepare**
As the world awaits the results of COVID-19 vaccine clinical trials, we have interviewed sixteen vaccine experts from the vaccine industry, academic, and regulatory agencies. Their overall message: the time to prepare is now.
Laura Subramanian et al.

**COVID-19 Vaccine Predictions: Using Mathematical Modelling and Expert Opinions to Estimate Timelines and Probabilities of Success of COVID-19 Vaccines**
*Publication* 10/1/20
We collected publicly available information, interviewed experts, and used our diverse range of expertise to analyse and model the COVID-19 vaccine portfolio in order to generate predictions about the vaccine portfolio's timeline.

**Chatham House** [to 3 Oct 2020]
https://www.chathamhouse.org/
*Webinar:*
**Webinar: Living with COVID-19: Opportunism and International Security**
14 October 2020 - 11:00am to 12:00pm
(London, GMT)

**CSIS**
https://www.csis.org/
*Accessed 3 Oct 2020*
[No new relevant content]

**Council on Foreign Relations**
http://www.cfr.org/
*Accessed 3 Oct 2020*
October 1, 2020
*Pharmaceuticals and Vaccines*
**What Is the World Doing to Create a COVID-19 Vaccine?**
The search to find a vaccine for the new coronavirus is well underway. Governments and researchers are aiming to provide billions of people with immunity in eighteen months or less, which would be un…
Backgrounder by Claire Felter

**Kaiser Family Foundation**
https://www.kff.org/search/?post_type=press-release
*Accessed 3 Oct 2020*
[No new relevant content]

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

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

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

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