

Vaccines and Global Health: The Week in Review 22 August 2020 :: Number 565 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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Milestones :: Perspectives :: Research

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Aligning Legislative, Spending Decisions with Climate Action Key to Recovering from COVID-19 Pandemic, Secretary-General Tells Speakers of Parliament

19 August 2020 SG/SM/20213

Following are UN Secretary-General António Guterres' remarks at the opening of the Inter-Parliamentary Union (IPU) World Conference of Speakers of Parliament on the theme: "Parliamentary leadership for more effective multilateralism that delivers peace and sustainable development for the people and planet", in New York:

...First, of course, is the COVID-19 pandemic. We face an unprecedented disaster, from economic wreckage to an education deficit imperiling an entire generation, from the aggravation of humanitarian crises to the deepening of already troubling infringements of human rights. We have surpassed 21 million cases and 770,000 deaths — and the toll continues to grow and even accelerate in some places.

The United Nations family is working across many fronts to save lives, control transmission of the virus, ease the fallout and recover better. We have shipped personal protective equipment and other medical supplies to more than 130 countries. We continue to press for a global ceasefire and to fight the plague of misinformation.

Across the weeks, we have issued analysis and policy recommendations spanning the full range of affected countries, sectors, issues and populations. From the beginning, the United Nations has been calling for massive global support for the most vulnerable people and countries — a rescue package amounting to at least 10 per cent of the global economy. We are also supporting work to accelerate research and development for a people's vaccine, affordable and accessible to all.

As we address the emergency today, we must learn its many lessons for tomorrow. Even before the virus, our societies were on shaky footing, with rising inequalities, worsening degradation of the environment, shrinking civic space, inadequate public health and untenable social frictions rooted in governance failures and a lack of opportunities.

The pandemic has spotlighted these injustices in especially stark terms. It has also exposed the world's fragilities in general. And so, we cannot go back to what was, but rather must turn the recovery into a real opportunity to do things right for the future...

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WHO Emergencies Press Conference on coronavirus disease outbreak - 18 August 2020

Streamed live on Aug 18, 2020 https://www.youtube.com/watch?v=OWTnMdwUkDw [Excerpts]

...00:09:24 [DG - Tedros Adhanom Ghebreyesus]

Sharing finite supplies strategically and globally is actually in each country's national interest. No-one is safe until everyone is safe. No one country has access to research and development, manufacturing and all the supply chain for all essential medicines and materials and if we can work together we can ensure that all essential workers are protected and proven treatments like dexamethasone are available to those who need them.

With PPE and tests a collaboration between the public and private sectors meant supply was increased in order to support fair and equitable use of scarce products.

As new diagnostics, medicines and vaccines come through the pipeline it's critical that countries don't repeat the same mistakes. We need to prevent vaccine nationalism and for this reason WHO is working with governments and the private sector to both accelerate the science through the ACT accelerator and ensure that new innovations are available to everyone everywhere, starting with those at highest risk.

00:10:57

Since May WHO has been in extensive consultations to develop a new framework to guide fair and equitable access to diagnostics, therapeutics and vaccines for COVID-19 across all countries. These cross-cutting principles are key to the promotion of equitable access and fair allocation of these essential health products for the greatest impact globally.

For example once a successful vaccine has been identified WHO's strategic advisory group will provide recommendations for their [sic] appropriate and fair use. The allocation of vaccines is proposed to be rolled out in two phases. In phase one dose will be allocated proportionally to all participating countries simultaneously to reduce overall risk. In phase two consideration will be given to countries in relation to threat and vulnerability. Front-line workers in health and social care settings are prioritised as they are essential to treat and protect the population and come in close contact with high mortality-risk groups.

Initial data has shown that adults over 65 years old and those with certain comorbidities are at the highest risk of dying from COVID-19. For most countries a phase-one allocation that builds up to 20% of the population would cover most of the at-risk groups.

00:12:50

If we don't protect these highest-risk people from the virus everywhere and at the same time we can't stabilise health systems and rebuild the global economy... This is what the first crucial phase of the vaccine allocation mechanism aims to do.

We are all so interconnected. As a small example vaccine developed in one country may need to be filled in vials with stoppers that are produced in another using materials for the high-grade glass that are only available from yet another country.

We will need to quickly manufacture billions of doses to reach all those who need the vaccine, which means hundreds of millions of glass vials and ways to transport them effectively. All this means elite planning at the highest level is needed right now to prepare to vaccinate and treat the world as new technologies come down the pipeline.

00:14:09

As we accelerate the science solidarity is needed to provide a joint solution to the pandemic. The COVAX global vaccines facility is the critical mechanism for joint procurement and pooling risk across multiple vaccines, which is why today I sent a letter to every member state encouraging them to join the COVAX facility.

Like an orchestra we need all instruments to be played in harmony to create music that everyone enjoys. One or two instruments playing by themselves just wouldn't suffice when the world is waiting and listening intently.

We will work to bring the band together, to promote science, solutions and solidarity because we believe to our core that we do it best when we do it together. I thank you...

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EMERGENCIES

Coronavirus [COVID-19]

Public Health Emergency of International Concern (PHEIC)

Editor's Note:

The most recent COVID-19 Situation Report posted is dated 16 August 2020. These daily reports seem to have been replaced with Weekly Epidemiological Updates, the first issue of which is dated 17 August 2020 as just below.

Weekly Epidemiological Update - 1

Coronavirus disease 2019 (COVID-19) 17 August 2020

Confirmed cases :: 22 812 491 [week ago: 21 026 758] Confirmed deaths :: 795 132 [week ago: 755 786]

Key weekly updates

:: "There are two essential elements to addressing the pandemic effectively: leaders must step up to take action and citizens need to embrace new measures...My message is crystal clear: suppress, suppress, suppress the virus."

WHO Director-General Dr Tedros, at his regular media briefing on Monday, 10 August

:: The Access to COVID-19 Tools (ACT) Accelerator, is a global collaboration to accelerate the development, production, and equitable access to COVID-19 tests, treatments, and vaccines. Nine vaccine candidates are currently in the portfolio of the vaccines pillar (called COVAX) and going through phase two or phase three trials. This portfolio, already the broadest in the world, is constantly expanding. The ACT-Accelerator is the only up-and-running global initiative that brings together all the global research and development, manufacturing, regulatory, purchasing and procurement needed for all the tools required to end the pandemic.

- :: Access to basic handwashing facilities is a key condition for schools to be able to operate safely in the midst of the COVID-19 pandemic. Yet the latest data from the WHO/UNICEF Joint Monitoring Programme (JMP) found that 43% of schools worldwide lacked access to basic handwashing with soap and water in 2019. UNICEF and partners have published a Framework for Reopening schools and Guidance on hand hygiene, which compliments Key Messages and Actions for COVID-19 Prevention and Control in Schools and COVID-19.
- :: WHO has published updated <u>guidance on home care for patients with suspected or confirmed COVID-19 and the management of their contacts.</u> The document provides guidance on the issues to be considered when deciding whether or not to provide care for COVID-19 patients at home and offers advice for health workers and caregivers providing that care.
- :: WHO has published the <u>Emergency Global Supply Chain System (COVID-19) catalogue</u>, 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 <u>COVID-19 Supply Portal</u>.

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COVID-19 Vaccines – Discovery/Trials

<u>Pfizer and BioNTech Share Positive Early Data on Lead mRNA Vaccine Candidate</u> <u>BNT162b2 Against COVID-19</u>

August 20, 2020

- :: In a Phase 1 study in the U.S., at 7 days after a second dose of 30µg, BNT162b2 elicited SARS-CoV-2—neutralizing geometric mean titers (GMTs) in younger adults (18-55 years of age) that were 3.8 times the GMT of a panel of 38 sera of SARS-CoV-2 convalescent patients, and in older adults (65-85 years of age) the vaccine candidate elicited a neutralizing GMT 1.6 times the GMT of the same panel, demonstrating strong immunogenicity in younger and older adults.
- :: The companies previously announced that BNT162b2-vaccinated human participants displayed a favorable breadth of epitopes recognized in T cell responses specific to the SARS-CoV-2 spike antigen, and that BNT162b2 demonstrated concurrent induction of high magnitude CD4+ and CD8+ T cell responses against the receptor binding domain (RBD) and against the remainder of the spike glycoprotein
- :: Across all populations, BNT162b2 administration was well tolerated with mild to moderate fever in fewer than 20% of the participants
- :: These results informed the selection of the BNT162b2 candidate for the pivotal Phase 2/3 global study in up to 30,000 participants that started in July 2020, which has to date enrolled more than 11,000 participants, including in areas with significant SARS-CoV-2 transmission
- :: Assuming clinical success, Pfizer and BioNTech are on track to seek regulatory review of BNT162b2 as early as October 2020 and, if regulatory authorization or approval is obtained,

currently plan to supply up to 100 million doses worldwide by the end of 2020 and approximately 1.3 billion doses by the end of 2021

...The totality of the clinical and preclinical data informed Pfizer and BioNTech's decision to select BNT162b2 as the lead candidate to advance into pivotal trials. We are proud to share our findings with the scientific community as we continue our work to deliver a safe and effective vaccine to combat this devastating virus," said Kathrin U. Jansen, Ph.D., Senior Vice President and Head of Vaccine Research & Development, Pfizer. "We are especially pleased to offer these early data showing our vaccine candidate's promising safety and immunogenicity profile from the U.S. trial and we look forward to sharing T cell immune response data from the German trial in the near future."

"It is important to us to continue sharing data and related information on our COVID-19 vaccine lead candidate," said Ugur Sahin, M.D., CEO and Co-Founder of BioNTech. "The favorable safety profile of BNT162b2 and the breadth of T cell responses we previously announced have supported our decision to select this candidate for the pivotal Phase 2/3 study. As of today, we have already dosed more than 11,000 participants with BNT162b2 in that study."...

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Emergencies

POLIO

Public Health Emergency of International Concern (PHEIC)

Polio this week as of 19 August 2020

- :: A cVDPV1 outbreak has been detected in Yemen. WHO and UNICEF are supporting local health authorities to plan and launch an effective outbreak response to limit virus spread. :: Next week the African Regional Certification Committee is anticipated to announce that the African Region has met the required standard to be certified as wild polio free. To mark the occasion, a live stream to the virtual ceremony will be publicly accessible via WHO channels and a dedicated website.
- :: The 18th report of the Independent Monitoring Board has been published on the GPEI website. The report presents an analysis of the current status of eradication efforts and makes recommendations to help accelerate progress toward interruption of wild poliovirus and the absence of all circulating vaccine-derived polioviruses (cVDPVs). The GPEI welcomes the IMB's recommendations, scrutiny and shared commitment to polio eradication, and will continue to work closely with the IMB, polio-affected countries and partners to optimize the polio. [See excerpts below]
- :: Dr Ana Elena Chevez has dedicated over twenty years of her life to protecting children from vaccine preventable diseases. In the <u>latest story</u> in our '<u>Women Leaders</u>' series, she shares advice for the next generation of women leaders.

Summary of new WPV and cVDPV viruses this week (AFP cases and environmental samples):

:: Afghanistan: three WPV1 cases, one WPV1 positive environmental sample and five cVDPV2 positive environmental samples

:: Pakistan: two WPV1 cases, two WPV1 positive environmental samples and two cVDPV2 positive environmental samples

:: Cote d'Ivoire: four cVDPV2 cases

:: Nigeria: one cVDPV2 case

:: Somalia: two cVDPV2 cases and four cVDPV2 positive environmental samples

:: Sudan: two cVDPV2 cases **:: Yemen:** 15 cVDPV1 cases

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18th report of the Independent Monitoring Board

THE NEW NORMAL. FINDING THE PATH BACK TO ERADICATION IN THE TIME OF CORONAVIRUS

July 2020 :: 60 pages

INTRODUCTION. [excerpts]

...It is essential that the Polio Programme remembers that, by the end of 2019, it stood on very shaky ground. There were massive challenges both in interrupting wild poliovirus transmission in the endemic areas and in managing many vaccine-derived poliovirus outbreaks.

Cases of poliovirus had increased fivefold between 2018 and 2019. There was uncertainty and doubt surrounding the effectiveness of strategies and tools.

At the Polio Oversight Board meeting, that immediately followed the Abu Dhabi Pledging Conference, on 20 November 2019, donor countries made an unprecedented demand that the GPEI should review and reform its governance and accountability structures. This did not reflect a reduced determination by these donors to get the job done, but rather the depth of their concern that there was no clear end in sight for polio eradication, and a lack of clear accountability in a \$1 billion a year spending programme.

Even before COVID-19, many donor countries' overseas aid budgets were being heavily scrutinised. With the coronavirus's savage impact on national economies, the case that polio dollars are safe in GPEI hands will, in future, need to be more convincingly made to the governments and taxpayers of these countries. At the same time, there is greater need for resources than originally planned.

Each year of failure to eradicate polio results in enormous health, opportunity, and economic costs. The budgetary needs of the programme are increasing steeply. They will increase further if vaccine-derived poliovirus outbreaks continue to occur on a wide scale. Also, conducting polio campaigns in a COVID-19 environment will be much slower, will need many more precautions (such as personal protective equipment), and, as a result, will be more expensive.

...Overall, since late February and early March 2020, more than 60 polio vaccination campaigns, of different geographical scales, have been paused in 38 countries. Six million doses of vaccine had been delivered to those countries. They could not be used. Another 100 million doses have been procured, but still await shipment because of air freight disruption. Some of these vaccines have been delivered, in the weeks running up to vaccination campaigns that were resumed in July 2020. However, other batches of vaccines will be nearing the end of their shelf life and the Polio Programme will have to bear the costs of the waste and resupply. Also, some

of the suppliers are reaching storage capacity and may well be forced to stop production, and there may be longer-term implications for manufacturers...

The Polio Programme is now poised for resumption when vaccine rounds can be planned and start again. The GPEI has set up a new committee to oversee this process, to be called the GPEI Continuity Planning and Facilitation Group (PFG). Its objectives include:

- :: To facilitate development and tracking of a comprehensive global level GPEI workplan, in support of regional and country polio eradication activities, to adjust to the COVID-19 pandemic;
- :: To identify any long-term strategic adjustments to the Polio Endgame Strategy 2019–2023 that may be required in the post-emergency phase of the COVID-19 pandemic in order to ensure sustainable, effective programme operations...

CONCLUSIONS. [excerpts]

It remains deeply inspiring to have a global vision of a world free of polio. It is a noble cause. It is important to many dedicated individuals currently working in the Polio Programme, and to others who have given a major part of their professional careers to the endeavour. It is a solemn reminder of front-line workers who lost their lives, and those who still do, to blind hatred for their personification of a humanitarian ideal. Ultimately, it will be a public good for all people of the world.

That vision currently seems a distant pinpoint of light. The Polio Programme is in dire straits. With a worsening epidemiological position, during 2019, for both wild and vaccine-derived poliovirus cases, the world was hit by a devastating pandemic of coronavirus. A yawning funding gap is opening up.

The Polio Programme stands in the middle of 2020 confronted by twin challenges that stand in the way of eradication. The first is the challenge of facing up to the real reasons that it went off track in 2019 into a jaw-dropping slump of performance at a time that the "almost there" narrative was believed by too many people. The phrase now being used to encourage everyone is: "The last mile is always the most difficult". The Polio Programme is too forgiving of itself.

The second is the challenge of making the right choice of paths, emerging from the coronavirus crisis. An oft-repeated phrase at the IMB meeting was that the COVID-19 pandemic has a "silver lining" for the polio eradication programme. What that meant to those at the meeting who referred to it, or what it should mean for everyone involved in the future delivery is less clear.

What is overwhelmingly clear, though, for the Polio Programme at country level, at regional level, and at global level is that to "keep calm and carry on" through this complex situation would be inexcusable.

The criticality of developments over the next several months for polio eradication cannot be overstated. The opportunity of COVID-19 to finally determine innovative and integrated delivery strategies provides a lifeline for polio eradication. The risk of a Polio Programme going back into the field tired and half-hearted about needing new ideas could be the death knell of the programme. The GPEI Strategy Committee, in particular, needs to understand the gravity of the times and treat them as such..

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Emergencies

Ebola - DRC+

Public Health Emergency of International Concern (PHEIC)

Last WHO Situation Report published 23 June 2020

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WHO Director-General's opening remarks at the media briefing on COVID-19 21 August 2020

...I would like to begin today's briefing with an update on the Ebola outbreak in the Equateur province of the Democratic Republic of the Congo.

The outbreak continues to increase and to spread geographically. **Yesterday, the 100th** case was reported, with 43 deaths in 11 health zones across the province.

There is currently a delay of about 5 days from the onset of symptoms to when an alert about a suspected case is raised.

This is concerning, because the longer a patient goes without treatment, the lower their chances of survival, and the longer the virus can spread unseen in communities.

The situation has been further complicated by a strike by health workers, which is affecting activities including vaccination and safe burials.

DRC has the best-trained workforce in the world for Ebola. This situation needs to be resolved as quickly as possible.

WHO and our partners are working intensively in communities to find cases and shorten the delay.

We're also supporting the government of DRC to take a stronger role in the response, and to prepare areas that have not been affected so far.

There continues to be an urgent need for increased human resources and logistics capacity to support an effective response across an ever-expanding geographical area, and to help health officials identify cases earlier.

The government of DRC has developed a plan that needs about US\$40 million. We urge partners to support this plan...

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WHO Grade 3 Emergencies [to 22 Aug 2020]

<u>Democratic Republic of the Congo</u> - No new digest announcements identified <u>Mozambique floods</u> - No new digest announcements identified

Nigeria - No new digest announcements identified

Somalia - No new digest announcements identified

South Sudan - No new digest announcements identified

Syrian Arab Republic - No new digest announcements identified

Yemen - No new digest announcements identified

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WHO Grade 2 Emergencies [to 22 Aug 2020]

<u>Iraq</u>

:: WHO concludes COVID-19 awareness-raising campaign in the south 19 August 2020

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

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

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

Burundi - No new digest announcements identified

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

Central African Republic - No new digest announcements identified

Ethiopia - No new digest announcements identified

Iran floods 2019 - No new digest announcements identified

Libya - No new digest announcements identified

Malawi - No new digest announcements identified

Measles in Europe - No new digest announcements identified

MERS-CoV - No new digest announcements identified

<u>Myanmar</u> - 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 22 Aug 2020]

Chad - No new digest announcements identified

<u>Djibouti</u> – Page not responding at inquiry

Kenya - No new digest announcements identified

Mali - No new digest announcements identified

Namibia - viral hepatitis - No new digest announcements identified

Tanzania - No new digest announcements identified

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UN OCHA – L3 Emergencies

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

Syrian Arab Republic

- :: Recent Developments in Northwest Syria Situation Report No. 19 As of 21 August 2020
- :: Syrian Arab Republic: COVID-19 Response Update No. 09 21 August 2020

Yemen - No new digest announcements identified

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<u>UN OCHA – Corporate Emergencies</u>

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 - No new digest announcements identified

East Africa Locust Infestation - No new digest announcements identified

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WHO & Regional Offices [to 22 Aug 2020]

19 August 2020 News release

World Humanitarian Day 2020: A tribute to aid workers on the front lines

:: Amid a global pandemic, unprecedented needs and growing insecurity, aid workers and health-care responders are staying and delivering to the world's most vulnerable people.

- :: Last year was the most violent on record for humanitarians, with 483 attacked, 125 killed, 234 wounded and 124 kidnapped. The UN condemns all attacks on humanitarians.
- :: OCHA and partners present the inspiring stories of humanitarian #RealLifeHeroes who are stepping up to meet the challenges.

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Weekly Epidemiological Record, 21 August 2020, vol. 95, 34 (pp. 393–408)

Global yellow fever update, 2019

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WHO Regional Offices

Selected Press Releases, Announcements

WHO African Region AFRO

:: Zambia's COVID-19 home-based care relieves health facilities 20 August 2020

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-trained young epidemiologists help fight COVID-19 in the Republic of Moldova 20-08-2020
- :: Risk of #COVID19 resurgence is never far away, but now we know how to target the virus instead of targeting society 20-08-2020

- :: Against the backdrop of a humanitarian crisis, COVID-19 responders carry out heroic work in northwest Syria 19-08-2020
- :: Tailoring health interventions: behavioural and cultural insights for health 19-08-2020
- :: COVID-19 and conflict, a double battle for humanitarian workers 19-08-2020

WHO Eastern Mediterranean Region EMRO

:: Exceptional bravery of Beirut health care workers following blast 19 August 2020

WHO Western Pacific Region

:: <u>Virtual press conference on COVID-19 in the Western Pacific</u> Remarks by Dr Takeshi Kasai 18 August 2020

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CDC/ACIP [to 22 Aug 2020]

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

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

Latest News Releases

<u>CDC data show disproportionate COVID-19 impact in American Indian/Alaska Native populations</u>

Wednesday, August 19, 2020

The Centers for Disease Control and Prevention (CDC) released a <u>new study</u> that specifically examines how COVID-19 is affecting American Indians and Alaska Natives (AI/AN) – one of the racial and ethnic minority groups at highest risk from the disease. CDC found that in 23 selected states, the cumulative incidence of laboratory-confirmed COVID-19 cases among AI/AN was 3.5 times that of non-Hispanic whites.

These data also showed that AI/AN who tested positive for SARS-CoV-2 tended to be younger than white non-Hispanic individuals with COVID-19 infection. Compared to whites, a higher percentage of cases among AI/AN individuals were in people under 18 years of age (12.9 percent AI/AN; 4.3 percent white), and a smaller percentage of cases were among AI/AN 65 years or older (12.6 percent AI/AN; 28.6 percent white). Limited data were available to quantify the disparity in COVID-19 incidence, COVID-19 disease severity, and outcomes among AI/AN persons compared with those among other racial/ethnic groups, reinforcing the need to prioritize improved data collection as a key strategy to understand and improve health outcomes.

Recent CDC studies have shown that AI/AN are among the racial and ethnic minority groups at higher risk for severe COVID-19 outcomes. Persisting racial inequity and historical trauma have contributed to disparities in health and socioeconomic factors between AI/AN and white populations that have adversely affected tribal communities. The elevated incidence within this population might also reflect differences in reliance on shared transportation, limited access to running water, household size, and other factors that might facilitate community transmission...

MMWR News Synopsis Friday, August 21, 2020

National, Regional, State, and Selected Local Area Vaccination Coverage Among Adolescents Aged 13-17 Years - United States, 2019

<u>Disparities in Incidence of COVID-19 Among Underrepresented Racial/Ethnic Groups in Counties Identified as Hotspots During June 5–18, 2020 — 22 States, February–June 2020</u>

<u>Trends in Number and Distribution of COVID-19 Hotspot Counties — United States, March 8—</u> July 15, 2020

Racial and Ethnic Disparities Among COVID-19 Cases in Workplace Outbreaks by Industry Sector — Utah, March 6–June 5, 2020

<u>Mass Testing for SARS-CoV-2 in 16 Prisons and Jails — Six Jurisdictions, United States, April—</u> May 2020

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Africa CDC [to 22 Aug 2020] http://www.africacdc.org/ News No new digest content identified.

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China CDC

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

National Health Commission of the People's Republic of China

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

News

Aug 22: Daily briefing on novel coronavirus cases in China

On Aug 21, 31 provincial-level regions and the Xinjiang Production and Construction Corps on the Chinese mainland reported 22 new cases of confirmed infections.

Mask no longer mandatory for outdoor activities in Beijing 2020-08-21

China capable of containing COVID-19 resurgence in autumn, winter: expert

China is confident of being able to control a COVID-19 epidemic resurgence in autumn and winter based on recent epidemic containment experience over more than six months, a health expert said on Aug 19.

Announcements

Paul G. Allen Frontiers Group [to 22 Aug 2020]

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

News from The Paul G. Allen Frontiers Group: August 2020

August 20, 2020

Highlights include: Testing treatments aimed at Alzheimer's for Covid-19 patients, how funding basic neuroscience research can support Covid-19 research, a new study by AHA-Allen Initiative awardee Tony Wyss-Coray, and more.

BARDA – U.S. Department of HHS [to 22 Aug 2020]

https://www.phe.gov/about/barda/Pages/default.aspx BARDA News No new digest content identified.

BMGF - Gates Foundation [to 22 Aug 2020]

http://www.gatesfoundation.org/Media-Center/Press-Releases No new digest content identified.

Bill & Melinda Gates Medical Research Institute [to 22 Aug 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 22 Aug 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 22 Aug 2020]

http://cepi.net/

Latest News

<u>COVAX seeks civil society representatives to contribute to ensuring equitable global access to COVID-19 vaccines</u>

17 Aug 2020

CEPI, Gavi and the World Health Organization (WHO) are seeking representatives from civil society and community organisations (CSOs) to participate in COVAX – the vaccines pillar of the Access to COVID-19 Tools (ACT) Accelerator – which aims to develop, manufacture and fairly

allocate 2 billion doses of safe and effective COVID-19 vaccine by the end of 2021 to end the acute phase of the COVID-19 pandemic.

CSOs will play a vital role in the development and implementation of the COVAX initiative as well as the deployment of any successful vaccine through COVAX.

Specifically, we are looking for CSO representatives to participate in coordination meetings and a number of specific workstreams of COVAX. We anticipate that the roles of CSOs will include fostering the necessary support at a political and community engagement level to ensure equitable access and delivery of future COVID-19 vaccine; providing in-depth subject matter expertise in one or more areas including vaccine R&D, manufacturing, delivery, demand, access and allocation, policy, governance; and, acting as an advocate for civil society and community perspectives as appropriate. We also seek representatives' input in building public trust and capacity across healthcare systems for COVID-19 vaccination programmes.

In addition to nominated representatives, broader CSOs will also be engaged in COVAX through other forums.'

The deadline for applications is 25 August, 2020.

EDCTP [to 22 Aug 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

19 August 2020

Sir Alimuddin Zumla receives 2020 Mahathir Science Award

On 18 August 2020, the Mahathir Science Award Foundation and the Academy of Sciences Malaysia announced that Professor Sir Alimuddin Zumla is the recipient of the 2020 Mahathir Science Award. It is the most prestigious international science award for tropical sciences. Sir Alimuddin is Professor of Infectious Diseases and International Health at University College London, and a Consultant Infectious Diseases Physician at the UCL Hospitals NHS Foundation Trust in London, the United Kingdom. The Mahathir Science Award comprises a gold medal, a certificate and \$100,000...

Emory Vaccine Center [to 22 Aug 2020]

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

European Medicines Agency [to 22 Aug 2020]

http://www.ema.europa.eu/ema/ News & Press Releases No new digest content identified.

European Vaccine Initiative [to 22 Aug 2020]

http://www.euvaccine.eu/

Latest News

No new digest content identified.

FDA [to 22 Aug 2020]

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

Press Announcements

August 21, 2020 - Coronavirus (COVID-19) Update: Daily Roundup August 21, 2020

August 20, 2020 - Coronavirus (COVID-19) Update: Daily Roundup August 20, 2020

August 19, 2020 - Coronavirus (COVID-19) Update: Daily Roundup August 19, 2020

August 18, 2020 - Coronavirus (COVID-19) Update: Daily Roundup August 18, 2020

August 17, 2020 - Coronavirus (COVID-19) Update: Daily Roundup August 17, 2020

Fondation Merieux [to 22 Aug 2020]

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

News, Events

Project

SEALAB project kicks off in Cambodia to strengthen laboratory systems in Southeast Asia

August 18, 2020 - Cambodia

SEALAB, a project launched to strengthen laboratory networks in Southeast Asia with funding from the Australian Department of Foreign Affairs and Trade (DFAT), was initiated in Cambodia during the first steering committee meeting held on August 7, 2020 in Phnom Penh.

Gavi [to 22 Aug 2020] https://www.gavi.org/

News releases

No new digest content identified.

GHIT Fund [to 22 Aug 2020]

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

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

Global Fund [to 22 Aug 2020]

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

News/Updates

No new digest content identified.

Hilleman Laboratories [to 22 Aug 2020]

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

Human Vaccines Project [to 22 Aug 2020]

http://www.humanvaccinesproject.org/media/press-releases/ Press Release No new digest content identified.

IAVI [to 22 Aug 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 22 Aug 2020]

http://media.ifrc.org/ifrc/news/press-releases/ Selected Press Releases, Announcements

World Humanitarian Day: One million masks produced by Syrian and Turkish volunteers, uniting forces against COVID-19

Ankara, Turkey (19 August 2020): Syrian refugees and Turkish people are coming together to help tackle the COVID-19 pandemic in Turkey and around the world. Since the pandemic began, over 120 volunteers and community members across Turkey have mobilize ... 19 August 2020

Asia Pacific, Indonesia, Timor-Leste

Timor-Leste COVID-19 threats: Red Cross prioritizes border areas

Dili, Timor-Leste, August 17, 2020 – Timor-Leste Red Cross (CVTL) is urgently ramping up COVID-19 prevention in remote areas bordering Indonesia as the country's containment success is threatened after its first new case has been reported in more than ... 17 August 2020 Lebanon

IRC International Rescue Committee [to 22 Aug 2020]

http://www.rescue.org/press-release-index

Media highlights Press Release

NE Syria: 60% increase in COVID-19 cases in past week, IRC calls for increased

health capacity
August 17, 2020

IVAC [to 22 Aug 2020]

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

Updates

No new digest content identified.

IVI [to 22 Aug 2020]

http://www.ivi.int/

Selected IVI News & Announcements

IVI welcomes Finland as 36th member state with flag-raising ceremony

August 10, 2020 – SEOUL, South Korea – The flag of Finland was raised at the International Vaccin e Institute (IVI) Headquarters today during a ceremony welcoming the country's accession to IVI. Finland joined the Seoul-based international organization dedicated to vaccines for global health in response to the COVID-19 pandemic, committing an annual contribution of 500,000 EUR during the period of 2020 – 2025 to support IVI's core operations and 500,000 EUR for COVID-19 vaccine research and development this year...

JEE Alliance [to 22 Aug 2020]

https://www.jeealliance.org/ Selected News and Events No new digest content identified.

MSF/Médecins Sans Frontières [to 22 Aug 2020]

http://www.msf.org/

Latest [Selected Announcements]

Greece

MSF statement on violent 20 August protest in Moria

Statement 21 Aug 2020

South Sudan

A forgotten crisis continues

Project Update 20 Aug 2020

The Jonglei and Greater Pibor administrative areas of South Sudan have seen repeated cycles of bitter inter-communal fighting – some lasting for months at a time – throughout 2020. The latest escalation, from June to mid August saw thousands of people displaced. Many continue to live in the bush without healthcare, food, shelter or water and sanitation.

Spain

MSF calls for urgent measures in care homes to prevent more deaths from COVID-19

Press Release 20 Aug 2020

An MSF report published this week highlights serious problems in Spain's response to COVID-19 in nursing homes across the country, resulting in horrific mortality rates among the elderly.

National Vaccine Program Office - U.S. HHS [to 22 Aug 2020]

https://www.hhs.gov/vaccines/about/index.html

NVAC Meetings

September 23-24, 2020 Meeting (Virtual)

February 4-5, 2021 NVAC Meeting

June 16-17, 2021 NVAC Meeting

NIH [to 22 Aug 2020] http://www.nih.gov/news-events/news-releases Selected News Releases No new digest content identified.

PATH [to 22 Aug 2020]

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

Aug. 19, 2020

PATH congratulates India on approving first locally produced pneumococcal vaccine

Serum Institute of India's pneumococcal conjugate vaccine, PNEUMOSIL®, has received marketing authorization in India—adding a quality-certified and more affordable option to the country's pneumonia prevention toolkit.

Aug. 12, 2020

PATH CEO announces global leadership changes

August 12, 2020 - PATH announced the creation of four new executive leadership positions that will support the global organization's next strategy toward a more equitable organization and advance a sustainability agenda.

...The four new Executive Team positions are as follows:

Chief of the Africa Region - Nanthalile Mugala, MD, MMed

The position of Chief of the Africa Region, to be filled by Dr. Nanthalile Mugala, will lead a newly created Africa Region Division. This new executive role, effective October 1, 2020, provides strategic leadership and guidance, overseeing program activities in the region. This is a demonstration of an intentional shift in power to leaders who will advance locally designed

solutions for the communities PATH serves, always in alignment with national partners and national plans...

Chief of Asia/Middle East/Europe (AMEE) Region – to be hired

All country programs in Asia and Europe will become part of the Asia/Middle East/Europe (AMEE) Region, to be led by a Chief of the Asia/Middle East/Europe (AMEE) Region. This role is similar to the Chief of the Africa Region and PATH will be filling this position in the near future. Recruitment for this position will begin in the coming weeks.

<u>David Fleming, MD</u>, VP of Global Health Programs, who currently leads the organization's public health and country programs, is stepping into a new role, Senior Vice President of Public Health, to make room for regional leadership positions at the executive level. "Our next step toward equity is to elevate country leadership to our Executive Team and to no longer have our non-US programs represented by a Seattle-based leader," said Dr. Fleming. In this new role, Dr. Fleming will serve as Chief Medical Officer and Public Health Officer for the organization.

Chief of Business and Financial Operations - Philippe Guinot

PATH's Operations and Finance divisions will merge into a single new division focused on optimizing global business activities and revenue generation and will be led by the Chief of Business and Financial Operations, a new position to be filled by Philippe Guinot, effective October 1, 2020. This move is designed to create greater alignment around revenue generation and donor partnerships...

Chief of External Affairs – Carla Costa Sandine

To oversee institutional marketing and communications, advocacy and public policy, and philanthropy, and to co-lead PATH's institutional diversity, equity, and inclusion initiative, Carla Costa Sandine has been promoted to Chief of External Affairs, a new position leading the External Affairs division. Ms. Sandine's promotion was effective on August 1, 2020...

Sabin Vaccine Institute [to 22 Aug 2020] http://www.sabin.org/updates/pressreleases Statements and Press Releases No new digest content identified.

UNAIDS [to 22 Aug 2020]
http://www.unaids.org/en
Selected Press Releases/Reports/Statements
19 August 2020

On World Humanitarian Day, UNAIDS celebrates the work of #RealLifeHeroes

UNICEF [to 22 Aug 2020]
https://www.unicef.org/media/press-releases
Selected Press releases/Announcements
News note
08/21/2020

Children affected by Beirut explosions in need of psychological support as 50 per cent show signs of trauma

This is a summary of what was said by Marixie Mercado, UNICEF spokesperson in Geneva – to whom guoted text may be attributed – at today's press briefing at the Palais des Nations in Geneva.

Press release 08/17/2020

COVID-19 causes disruptions to child protection services in more than 100 countries, UNICEF survey finds

Unitaid [to 22 Aug 2020] https://unitaid.org/ Featured News No new digest content identified.

Vaccination Acceptance Research Network (VARN) [to 22 Aug 2020]

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

Vaccine Confidence Project [to 22 Aug 2020]

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

Vaccine Education Center – Children's Hospital of Philadelphia [to 22 Aug 2020]

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

Wellcome Trust [to 22 Aug 2020]

https://wellcome.ac.uk/news No new digest content identified.

The Wistar Institute [to 22 Aug 2020]

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

No new digest content identified.

WFPHA: World Federation of Public Health Associations [to 22 Aug 2020]

https://www.wfpha.org/

Latest News No new digest content identified.

World Organisation for Animal Health (OIE) [to 22 Aug 2020]

https://www.oie.int/en/for-the-media/press-releases/2020/18/08/20

Required competences of Veterinary Services for international trade

Veterinary Services play a critical role in facilitating the international trade of animals and animal products by preventing the spread of diseases. In the current changing world, they face numerous challenges. To better identify and address them, the OIE Technical Item for 2020 provides an evaluation of current challenges and demonstrates how the OIE's diverse programmes are instrumental in building targeted capacities amongst national Veterinary Services.

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ARM [Alliance for Regenerative Medicine] [to 22 Aug 2020]

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

BIO [to 22 Aug 2020]

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

Press Releases

BIO: FDA Oversight of Animal Biotechnology Must Be Changed

America's position as an innovation leader is at stake

Washington, D.C. (August 19, 2020) – The U.S. government's system for regulating animal biotechnology – currently under the U.S. Food and Drug Administration (FDA) – is broken and is driving beneficial innovations to other countries, according to discussions taking place this week as part of the Animal Health in the Heartland virtual symposium.

Dr. Clint Nesbitt, Senior Director of Science and Regulatory Affairs for Food & Agriculture at the Biotechnology Innovation Organization (BIO), addressed symposium participants this morning during the presentation, "U.S. Oversight of Animal Biotechnology and the Need for Change."

"Animal biotechnology holds tremendous potential for improving animal health and well-being, transforming our farming and food systems, boosting our bioeconomy, and even helping to prevent and respond to zoonotic diseases such as COVID-19," said Nesbitt. "But these breakthroughs are dependent on a clear, timely, and science-based approval process that includes a viable path to market."...

DCVMN – Developing Country Vaccine Manufacturers Network [to 22 Aug 2020]

http://www.dcvmn.org/
News; Upcoming events

<u>Webinar on Tools for COVID-19 Vaccine Safety Assessment developed by the Safety Platform for Emergency vACcines (SPEAC)</u>

27 August 2020
Organized by Vaccine Safety Working Group
Thursday, August 27th at
11 AM - 12:30 PM EDT |
5 PM - 6:30 PM CEST.
In order to register, kindly click on the following link:
https://attendee.gotowebinar.com/register/1832853306915777038

ICBA – International Council of Biotechnology Associations [to 22 Aug 2020]

https://internationalbiotech.org/ News No new digest content identified.

IFPMA [to 22 Aug 2020]

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

PhRMA [to 22 Aug 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

August 2020 Volume 48, Issue 8, p859-974 http://www.ajicjournal.org/current [Reviewed earlier]

American Journal of Preventive Medicine

August 2020 Volume 59, Issue 2, p149-308 http://www.ajpmonline.org/current [Reviewed earlier]

American Journal of Public Health

August 2020 110(8) http://ajph.aphapublications.org/toc/ajph/current [Reviewed earlier]

American Journal of Tropical Medicine and Hygiene

Volume 103, Issue 2, August 2020 http://www.ajtmh.org/content/journals/14761645/103/2 [Reviewed earlier]

Annals of Internal Medicine

18 August 2020 Volume 173, Issue 4 http://annals.org/aim/issue
Original Research

<u>Risk for Subdeltoid Bursitis After Influenza Vaccination - A Population-Based Cohort Study</u>

Elisabeth M. Hesse, MD, MTM&H, Ronald A. Navarro, MD, Matthew F. Daley, MD, ... et al. Shoulder bursitis has been reported as an adverse event after intramuscular vasculitis. This study estimated the risk for subdeltoid bursitis after influenza vaccination using data from the Vaccine Safety Datalink, which contains encounter information from 10.2 million members seen in 7 U.S. health care organizations.

Editorials

Vaccination-Induced Bursitis: Technique Matters

Sandra Adamson Fryhofer, MD and George W. Fryhofer, MD, MTR

In this issue, a Centers for Disease Control and Prevention–funded Vaccine Safety Datalink study of 2943493 vaccinated persons reported an additional 7.78 cases of subdeltoid bursitis per 1 million influenza vaccinations. The editorialists discuss the findings and describe vaccination techniques to prevent vaccine-associated bursitis.

History of Medicine

Biomedical Research in Times of Emergency: Lessons From History

Deborah Doroshow, MD, PhD, Scott Podolsky, MD, and Justin Barr, MD, PhD COVID-19 has disrupted the lives of billions of people worldwide. Emergencies can stimulate substantial investment of resources that catalyze impressive scientific accomplishments but can also lead to false promises and ethical breaches. The authors discuss how history shows the importance of treating early results with caution, given that we are only beginning to understand SARS-CoV-2.

Artificial Intelligence – An International Journal

Volume 286 September 2020 https://www.sciencedirect.com/journal/artificial-intelligence/vol/286/suppl/C [Reviewed earlier]

BMC Cost Effectiveness and Resource Allocation

http://resource-allocation.biomedcentral.com/ (Accessed 22 Aug 2020) [No new digest content identified]

BMJ Global Health

August 2020 - Volume 5 - 8 https://gh.bmj.com/content/5/8 [Reviewed earlier]

BMC Health Services Research

http://www.biomedcentral.com/bmchealthservres/content (Accessed 22 Aug 2020)

<u>Factors related to the adoption of the Brazilian National Immunization Program</u> Information System

One way to optimize the adoption and use of technological innovations is to understand how those involved perceive, assess and decide to use them. This study aims to analyze the attributes that influence the a...

Authors: Valéria Conceição de Oliveira, Eliete Albano de Azevedo Guimarães, Gilberto Perez, Fabiana Costa Machado Zacharias, Ricardo Bezerra Cavalcante, Tarcísio Laerte Gontijo, Humberto Ferreira de Oliveira Quites, Gabriela Gonçalves Amaral, Brener Santos Silva and Ione Carvalho Pinto

Citation: BMC Health Services Research 2020 20:759

Content type: Research article Published on: 17 August 2020

BMC Infectious Diseases

http://www.biomedcentral.com/bmcinfectdis/content (Accessed 22 Aug 2020) [No new digest content identified]

BMC Medical Ethics

http://www.biomedcentral.com/bmcmedethics/content (Accessed 22 Aug 2020) [No new digest content identified]

BMC Medicine

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

(Accessed 22 Aug 2020)

Compassionate drug (mis)use during pandemics: lessons for COVID-19 from 2009

Patients were frequently treated for pandemic influenza with drugs not registered for this indication, but rarely under circumstances of high-quality data capture. The result was a reliance on use under compassionate circumstances, resulting in continued uncertainty regarding the potential benefits and harms of anti-viral treatment. Rapid scaling of clinical trials is critical for generating a quality evidence base during pandemics.

Authors: Amanda M. Rojek, Genevieve E. Martin and Peter W. Horby

Citation: BMC Medicine 2020 18:265

Content type: Research article Published on: 21 August 2020

<u>Seasonal influenza vaccination in Kenya: an economic evaluation using dynamic transmission modelling</u>

There is substantial burden of seasonal influenza in Kenya, which led the government to consider introducing a national influenza vaccination programme. Given the cost implications of a nationwide programme, I...

Authors: Jeanette Dawa, Gideon O. Emukule, Edwine Barasa, Marc Alain Widdowson, Omu Anzala, Edwin van Leeuwen, Marc Baguelin, Sandra S. Chaves and Rosalind M. Eggo

Citation: BMC Medicine 2020 18:223

Content type: Research article Published on: 20 August 2020

BMC Pregnancy and Childbirth

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

(Accessed 22 Aug 2020)

[No new digest content identified]

BMC Public Health

http://bmcpublichealth.biomedcentral.com/articles

(Accessed 22 Aug 2020)

A systematic review of studies that measure parental vaccine attitudes and beliefs in childhood vaccination

Acceptance of vaccines is an important predictor of vaccine uptake. This has public health implications as those who are not vaccinated are at a higher risk of infection from vaccine preventable diseases. We a...

Authors: Amalie Dyda, Catherine King, Aditi Dey, Julie Leask and Adam G. Dunn

Citation: BMC Public Health 2020 20:1253

Content type: Research article Published on: 17 August 2020

<u>Bibliometric analysis of global scientific literature on vaccine hesitancy in peer-reviewed journals (1990–2019)</u>

Vaccine hesitancy is a growing threat to national and global health security. The current study was undertaken to provide insights into the global scientific literature on vaccine hesitancy in peer-reviewed jo...

Authors: Waleed M. Sweileh

Citation: BMC Public Health 2020 20:1252

Content type: Research article Published on: 17 August 2020

BMC Research Notes

http://www.biomedcentral.com/bmcresnotes/content (Accessed 22 Aug 2020) [No new digest content identified]

BMJ Open

August 2020 - Volume 10 - 8 https://bmjopen.bmj.com/content/10/8?current-issue=y [Reviewed earlier]

Bulletin of the World Health Organization

Volume 98, Number 8, August 2020, 509-580 https://www.who.int/bulletin/volumes/98/8/en/ [Reviewed earlier]

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 1 Pages: 1-161 July 2020 https://ascpt.onlinelibrary.wiley.com/toc/15326535/2020/108/1 [Reviewed earlier]

Clinical Therapeutics

July 2020 Volume 42, Issue 7, p1137-1424 http://www.clinicaltherapeutics.com/current Original Research

<u>The Evolution of Master Protocol Clinical Trial Designs: A Systematic Literature</u> Review

Recent years have seen a change in the way that clinical trials are being conducted. There has been a rise of designs more flexible than traditional adaptive and group sequential trials which allow the investigation of multiple substudies with possibly different objectives, interventions,

and subgroups conducted within an overall trial structure, summarized by the term master protocol. This review aims to identify existing master protocol studies and summarize their characteristics. The review also identifies articles relevant to the design of master protocol trials, such as proposed trial designs and related methods.

Elias Laurin Meyer, Peter Mesenbrink, Cornelia Dunger-Baldauf, Hans-Jürgen Fülle, Ekkehard Glimm, Yuhan Li, Martin Posch, Franz König

p1330-1360

Published online: July 1, 2020

Clinical Trials

Volume 17 Issue 4, August 2020 https://journals.sagepub.com/toc/ctja/17/4 [Reviewed earlier]

Conflict and Health

http://www.conflictandhealth.com/ [Accessed 22 Aug 2020] [No new digest content identified]

Contemporary Clinical Trials

Volume 95 August 2020

https://www.sciencedirect.com/journal/contemporary-clinical-trials/vol/95/suppl/C Research article Abstract only

Advances and challenges in conducting ethical trials involving populations lacking capacity to consent: A decade in review

Victoria Shepherd Article 106054 Abstract

Informed consent is an essential requirement prior to clinical trial participation, however some 'vulnerable' groups, such as people with cognitive impairments and those in medical emergency situations, may lack decisional capacity to consent. This raises ethical and practical challenges when designing and conducting clinical trials involving these populations, who are frequently excluded as a result. Despite recent advances in improving informed consent processes, there has been far less attention paid to the enrolment of adults lacking capacity.

Exclusion criteria are an important determinant of the external validity of clinical trial results. The exclusion of these populations, and consent-based recruitment biases which arise from the challenges of identifying and involving surrogate decision-makers, leads to trials which are not representative of the clinical population.

This article discusses the involvement of adults who lack decisional capacity to consent in clinical trials and presents the advances over the previous decade and the remaining ethical challenges for the inclusion of this under-represented population in research.

The CRISPR Journal

Volume 3, Issue 3 / June 2020

https://www.liebertpub.com/toc/crispr/3/3

[Reviewed earlier]

Current Genetic Medicine Reports

Volume 8, issue 3, September 2020 https://link.springer.com/journal/40142/volumes-and-issues/8-3 [New issue; No digest content identified]

Current Opinion in Infectious Diseases

August 2020 - Volume 33 - Issue 4 https://journals.lww.com/co-infectiousdiseases/pages/currenttoc.aspx [Reviewed earlier]

Developing World Bioethics

Volume 20, Issue 2 Pages: 61-114 June 2020 https://onlinelibrary.wiley.com/toc/14718847/current [Reviewed earlier]

Development in Practice

Volume 30, Issue 5, 2020 http://www.tandfonline.com/toc/cdip20/current [New issue; No digest content identified]

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 3 Pages: 433-618 July 2020 https://onlinelibrary.wiley.com/toc/14677717/current [Reviewed earlier]

EMBO Reports

Volume 21 Issue 8 5 August 2020 https://www.embopress.org/toc/14693178/current [Reviewed earlier]

Emerging Infectious Diseases

Volume 26, Number 8—August 2020 http://wwwnc.cdc.gov/eid/ [Reviewed earlier]

Epidemics

Volume 32 September 2020

https://www.sciencedirect.com/journal/epidemics/vol/32/suppl/C

Research article Open access

<u>Influencing public health policy with data-informed mathematical models of infectious diseases:</u> Recent developments and new challenges

Amani Alahmadi, Sarah Belet, Andrew Black, Deborah Cromer, ... Alexander E. Zarebski Article 100393

Special Issue Articles

Research article Open access

Tooling-up for infectious disease transmission modelling

Marc Baguelin, Graham F. Medley, Emily S. Nightingale, Kathleen M. O'Reilly, ... Moritz Wagner Article 100395

Abstract

In this introduction to the Special Issue on methods for modelling of infectious disease epidemiology we provide a commentary and overview of the field. We suggest that the field has been through three revolutions that have focussed on specific methodological developments; disease dynamics and heterogeneity, advanced computing and inference, and complexity and application to the real-world. Infectious disease dynamics and heterogeneity dominated until the 1980s where the use of analytical models illustrated fundamental concepts such as herd immunity. The second revolution embraced the integration of data with models and the increased use of computing. From the turn of the century an emergence of novel datasets enabled improved modelling of real-world complexity. The emergence of more complex data that reflect the real-world heterogeneities in transmission resulted in the development of improved inference methods such as particle filtering. Each of these three revolutions have always kept the understanding of infectious disease spread as its motivation but have been developed through the use of new techniques, tools and the availability of data. We conclude by providing a commentary on what the next revoluition in infectious disease modelling may be.

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 4 Pages: 1-40 July–August 2020 https://onlinelibrary.wiley.com/toc/25782363/current

Pregnant Women Covid-19 Vaccine Challenge Trials Lotteries

[Reviewed earlier]

The European Journal of Public Health

Volume 30, Issue Supplement_2, June 2020 https://academic.oup.com/eurpub/issue/30/Supplement_2 [Reviewed earlier]

Expert Review of Vaccines

Vol 19 (6) 2020 https://www.tandfonline.com/toc/ierv20/current [Reviewed earlier]

Gates Open Research

https://gatesopenresearch.org/browse/articles [Accessed 22 Aug 2020] [No new digest content identified]

Genome Medicine

https://genomemedicine.biomedcentral.com/articles [Accessed 22 Aug 2020] [No new digest content identified]

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)

2020 | Volume 8 | Number 2 June 30, 2020 http://www.ghspjournal.org/content/current [Reviewed earlier]

Global Public Health

Volume 15, 2020 Issue 8 http://www.tandfonline.com/toc/rgph20/current [Reviewed earlier]

Globalization and Health

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

Health Affairs

Vol. 39, No. 7 July 2020 https://www.healthaffairs.org/toc/hlthaff/current Food, Income, Work & 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 3 - July 2020 https://www.cambridge.org/core/journals/health-economics-policy-and-law/latest-issue [Reviewed earlier]

Health Policy and Planning

Volume 35, Issue 6, July 2020 https://academic.oup.com/heapol/issue/35/6 [Reviewed earlier]

Health Research Policy and Systems

http://www.health-policy-systems.com/content [Accessed 22 Aug 2020] [No new digest content identified]

Human Gene Therapy

Volume 31, Issue 13-14 / July 2020 https://www.liebertpub.com/toc/hum/31/13-14 **Focus on Retinal Gene Therapy**[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 22 Aug 2020] [No new digest content identified]

Infectious Diseases of Poverty

http://www.idpjournal.com/content [Accessed 22 Aug 2020] [No new digest content identified]

International Health

Volume 12, Issue 4, July 2020 https://academic.oup.com/inthealth/issue/12/4 [Reviewed earlier]

International Journal of Community Medicine and Public Health

Vol 7, No 7 (2020) July 2020 https://www.ijcmph.com/index.php/ijcmph/issue/view/64 [Reviewed earlier]

International Journal of Epidemiology

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 3 2020 https://www.emerald.com/insight/publication/issn/2056-4902/vol/13/iss/3 Table of Contents [Reviewed earlier]

International Journal of Infectious Diseases

August 2020 Volume 97, p1-404 https://www.ijidonline.com/issue/S1201-9712(20)X0009-9 [Reviewed earlier]

JAMA Network

COVID-19 Update August 22, 2020

These articles on COVID-19 were published across the JAMA Network in the last week.

JAMA

August 18, 2020, Vol 324, No. 7, Pages 617-718 https://jamanetwork.com/journals/jama/currentissue Viewpoint

<u>Evidence-Based Practice for Public Health Emergency Preparedness and Response - Recommendations From a National Academies of Sciences, Engineering, and Medicine Report</u>

Ned Calonge, MD; Lisa Brown, MPH; Autumn Downey, PhD JAMA. 2020;324(7):629-630. doi:10.1001/jama.2020.12901

This Viewpoint summarizes recommendations from a 2020 National Academies of Sciences, Engineering, and Medicine (NASEM) report on transforming the infrastructure, funding, and methods of public health emergency preparedness and response (PHEPR) research to ensure it is grounded in the best science about what works where, why, and for whom.

<u>Integrating Personalized Medicine With Population Health Management - The Path</u>
Forward

David C. Grossman, MD, MPH; Eric B. Larson, MD, MPH; Harold C. Sox, MD Abstract Full Text

free access

JAMA. 2020;324(7):631-632. doi:10.1001/jama.2020.1406

This Viewpoint discusses genome-wide sequencing (GWS) as a potential pathway not only to personalized medicine but also to population health, and proposes 5 dimensions health care organizations might consider when deciding on markers to screen for as they move toward genomic approaches to caring for their patient populations.

JAMA Pediatrics

August 2020, Vol 174, No. 8, Pages 741-812 http://archpedi.jamanetwork.com/issue.aspx [Reviewed earlier]

JBI Database of Systematic Review and Implementation Reports

August 2020 - Volume 18 - Issue 8 https://journals.lww.com/jbisrir/Pages/currenttoc.aspx [New issue; No digest content identified]

Journal of Adolescent Health

August 2020 Volume 67, Issue 2, p145-308 https://www.jahonline.org/issue/S1054-139X(20)X0007-3 [Reviewed earlier]

Journal of Artificial Intelligence Research

Vol. 68 (2020) https://www.jair.org/index.php/jair [Reviewed earlier]

Journal of Community Health

Volume 45, Issue 4, August 2020 https://link.springer.com/journal/10900/45/4 [Reviewed earlier]

Journal of Development Economics

Volume 146 September 2020 https://www.sciencedirect.com/journal/journal-of-development-economics/vol/146/suppl/C [New issue; No digest content identified]

Journal of Empirical Research on Human Research Ethics

Volume 15 Issue 3, July 2020

http://journals.sagepub.com/toc/jre/current [Reviewed earlier]

Journal of Epidemiology & Community Health

August 2020 - Volume 74 - 8 https://jech.bmj.com/content/74/8 [Reviewed earlier]

Journal of Evidence-Based Medicine

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

Journal of Global Ethics

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

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

Volume 31, Number 2, May 2020 https://muse.jhu.edu/issue/42391 [Reviewed earlier]

Journal of Immigrant and Minority Health

Volume 22, Issue 4, August 2020 https://link.springer.com/journal/10903/22/4 [Reviewed earlier]

Journal of Immigrant & Refugee Studies

Volume 18, 2020_ Issue 3 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

August 2020 - Volume 46 - 8

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

August 2020 Volume 223, p1-236 http://www.jpeds.com/current [Reviewed earlier]

Journal of Pharmaceutical Policy and Practice

https://joppp.biomedcentral.com/ [Accessed 22 Aug 2020] [Reviewed earlier]

Journal of Public Health Management & Practice

July/August 2020 - Volume 26 - Issue 4 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 2, Issue 2 (2019) https://ir.library.louisville.edu/rgh/ [Reviewed earlier]

Journal of the Royal Society – Interface

August 2020 Volume 17 Issue 169 https://royalsocietypublishing.org/toc/rsif/current [Reviewed earlier]

Journal of Travel Medicine

Volume 27, Issue 5, July 2020

https://academic.oup.com/jtm/issue/27/5

Editorial

Health diplomacy across borders: the case of yellow fever and COVID-19

Samantha Vanderslott, PhD, Tatjana Marks, BA Hons

Journal of Travel Medicine, Volume 27, Issue 5, July 2020, taaa112,

https://doi.org/10.1093/jtm/taaa112

We provide an overview of disease control across borders through the example of yellow fever, exploring different public health interventions and arrangements for international cooperation. From quarantine to country vaccine entry requirements our paper discusses the implications for health diplomacy in the context of COVID-19.

Perspectives

Combat COVID-19 with artificial intelligence and big data

Leesa Lin, PhD, Zhiyuan Hou, PhD

Journal of Travel Medicine, Volume 27, Issue 5, July 2020, taaa080,

https://doi.org/10.1093/jtm/taaa080

To combat COVID-19, at least 29 countries/regions have resorted to digital technology; some embedded it with strict containment measures and achieved great success. We need to improve cryptography and regulations that would enable contact-tracing systems without mass surveillance in order to attain the benefits of location-tracking while protecting individual privacy.

Journal of Virology

July 2020; Volume 94,Issue 14 http://jvi.asm.org/content/current [Reviewed earlier]

The Lancet

Aug 22, 2020 Volume 396 Number 10250 p513-582 https://www.thelancet.com/journals/lancet/issue/current World Report

COVID-19 and readjusting clinical trials

Aaron van Dorn

The COVID-19 pandemic has disrupted clinical trials worldwide, with long-lasting effects on medical science. Aaron van Dorn reports.

The COVID-19 pandemic has created massive disruptions to clinical trial research across the world. As in other aspects of life, the virus has severely affected the ability to conduct trials in safe and effective ways. This is especially true when considering that trials often deal with vulnerable populations who are most at risk from exposure to COVID-19. Thousands of trials have been suspended or stopped because of the difficulties in continuing under lockdown conditions, even as those restrictions have begun to ease in parts of the world. At the same time, the pandemic has seen an unprecedented reorientation in clinical trials research towards COVID-19. Both of those aspects—the disruption and the fast, effective readjustment to address a new challenge—ensure that the effects of the COVID-19 pandemic will be felt in clinical trials research long after the initial effects have faded.

Clinical trials have long been a premier method of testing and validating new drugs and therapies. New drug approval is predicated on successful trials into the safety and efficacy of new treatments. Trials can involve hundreds of different sites around the world, all with different conditions and facing different effects and government regulations on what is permissible. Once you start looking at the number of people involved in a clinical trial, the scope of the problem begins to seem daunting. In addition to researchers who formulate the protocol for the trial and work to secure funding (either from governments, foundations, pharmaceutical or device manufacturers, or a combination of the above), clinical trials include clinical caregivers and nurses who work with patients at clinical trial sites, postgraduate researchers, postdoctoral fellows, research scientists, and others who work on the analysis of data generated by the trial, some of whom may or may not interact with patients, but all of whom are essential to the final result.

Trials that were stopped, in many cases, were stopped from enrolling new patients. Patients who were already enrolled mostly continued to receive treatment as institutions and researchers worked to make changes to how care was provisioned to deal with the reality of COVID-19. Fergus Sweeney, head of clinical studies and manufacturing at the European Medicines Agency, told The Lancet that one of the key parts of their guidance has been physical distancing to protect patients and clinic staff, but ensuring the safety of patients in testing and treatment is also important. "If people can't come in to a clinic or their hospital at the usual, regular intervals, it may be that they need to be provided with a medication for a longer period of time, or indeed that medication is distributed to their home by a distributor", Sweeney said. To that end, many trials have shifted from the distribution of drugs at the trial site to direct-to-patient courier services, whereby trial drugs are distributed and administered to patients in their homes, eliminating the need for at-risk patients to visit trial sites. Many in-person visits for checkups and other aspects of trials were shifted to teleconferencing services. In March, 2020 (and revised again in July), the US Food and Drug Administration (FDA) also issued guidance on protecting patient safety during the COVID-19 pandemic. The FDA guidelines called on researchers and trial sponsors to "determine that the protection of a participant's safety, welfare, and rights is best served by continuing a study participant in the trial as per the protocol or by discontinuing the administration or use of the investigational product or even participation in the trial". The guidance also calls on investigators and sponsors to coordinate with institutional review boards and ethics committees on potential changes to protocol as early as possible. But for many patients who have turned to clinical trials as a last resort for cardiovascular conditions, who have cancer, or other life-threatening conditions, the eventual resumption of non-COVID-19 trials could come too late.

The Lancet Child & Adolescent Health

Aug 2020 Volume 4 Number 8 p555-640, e26-e34 https://www.thelancet.com/journals/lanchi/issue/current [Reviewed earlier]

Lancet Digital Health

Aug 2020 Volume 2 Number 8e380-e440 https://www.thelancet.com/journals/landig/issue/current

[Reviewed earlier]

Lancet Global Health

Aug 2020 Volume 8 Number 8 e973-e1100 http://www.thelancet.com/journals/langlo/issue/current [Reviewed earlier]

Lancet Infectious Diseases

Aug 2020 Volume 20 Number 8 p875-992, e180-e214 http://www.thelancet.com/journals/laninf/issue/current [Reviewed earlier]

Lancet Public Health

Aug 2020 Volume 5 Number 8 e414-e459 https://www.thelancet.com/journals/lanpub/issue/current [Reviewed earlier]

Lancet Respiratory Medicine

Aug 2020 Volume 8 Number 8 p743-830, e67-e69 http://www.thelancet.com/journals/lanres/issue/current [Reviewed earlier]

Maternal and Child Health Journal

Volume 24, Issue 8, August 2020 https://link.springer.com/journal/10995/24/8 [Reviewed earlier]

Medical Decision Making (MDM)

Volume 40 Issue 5, July 2020 http://mdm.sagepub.com/content/current [Reviewed earlier]

The Milbank Quarterly

A Multidisciplinary Journal of Population Health and Health Policy Volume 98, Issue 2 Pages: 223-617 June 2020 https://onlinelibrary.wiley.com/toc/14680009/current [Reviewed earlier]

Nature

Volume 584 Issue 7821, 20 August 2020

http://www.nature.com/nature/current_issue.html

Editorial | 19 August 2020

Progress report on the coronavirus pandemic

In the first of a series of editorials, we look back at some of the key findings from scientists' race to demystify SARS-CoV-2.

World View | 18 August 2020

How we accelerated clinical trials in the age of coronavirus

The United Kingdom's RECOVERY trial shows a way to benefit patients faster. Nicole Mather

Nature Biotechnology

Volume 38 Issue 8, August 2020 https://www.nature.com/nbt/volumes/38/issues/8 [Reviewed earlier]

Nature Communications

https://www.nature.com/subjects/health-sciences/ncomms (Accessed 22 Aug 2020) [No new digest content identified]

Nature Genetics

Volume 52 Issue 8, August 2020 https://www.nature.com/ng/volumes/52/issues/8 [Reviewed earlier]

Nature Medicine

Volume 26 Issue 8, August 2020 https://www.nature.com/nm/volumes/26/issues/8

Focus on COVID-19 and digital privacy

The COVID-19 pandemic has necessitated the acceleration of the development of digital technologies to monitor the spread of the outbreak. Emergency powers are being used to track not just individuals' health data, but other personal information. The image shows the data that are being monitored on people's cell phones, and the effects on healthcare are discussed in this focus issue on COVID-19 and digital privacy. [Reviewed earlier]

Nature Reviews Genetics

Volume 21 Issue 8, August 2020 https://www.nature.com/nrg/volumes/21/issues/8 [Reviewed earlier]

Nature Reviews Immunology

Volume 20 Issue 8, August 2020 https://www.nature.com/nri/volumes/20/issues/8 [Reviewed earlier]

Nature Reviews Drug Discovery

Volume 19 Issue 8, August 2020 https://www.nature.com/nrd/volumes/19/issues/8 [Reviewed earlier]

New England Journal of Medicine

August 20, 2020 Vol. 383 No. 8 http://www.nejm.org/toc/nejm/medical-journal [New issue; No digest content identified]

Pediatrics

Vol. 146, Issue 2 22 Aug 2020 https://pediatrics.aappublications.org/ [Reviewed earlier]

Pharmaceutics

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

PharmacoEconomics

Volume 38, Issue 8, August 2020 https://link.springer.com/journal/40273/38/8 [Reviewed earlier]

PLoS Genetics

https://journals.plos.org/plosgenetics/ (Accessed 22 Aug 2020) [No new digest content identified]

PLoS Medicine

http://www.plosmedicine.org/ (Accessed 22 Aug 2020)

Evaluation of a city-wide school-located influenza vaccination program in Oakland, California, with respect to vaccination coverage, school absences, and laboratory-confirmed influenza: A matched cohort study

It is estimated that vaccinating 50%-70% of school-aged children for influenza can produce population-wide indirect effects. We evaluated a city-wide school-located influenza vaccination (SLIV) intervention that aimed to increase influenza vaccination coverage. The intervention was implemented in ≥95 preschools and elementary schools in northern California from 2014 to 2018. Using a matched cohort design, we estimated intervention impacts on student influenza vaccination coverage, school absenteeism, and community-wide indirect effects on laboratoryconfirmed influenza hospitalizations.

Jade Benjamin-Chung, Benjamin F. Arnold, Chris J. Kennedy, Kunal Mishra, Nolan Pokpongkiat, Anna Nguyen, Wendy Jilek, Kate Holbrook, Erica Pan, Pam D. Kirley, Tanya Libby, Alan E. Hubbard, Arthur Reingold, John M. Colford Jr.

Research Article | published 18 Aug 2020 PLOS Medicine

https://doi.org/10.1371/journal.pmed.1003238

PLoS Neglected Tropical Diseases

http://www.plosntds.org/ (Accessed 22 Aug 2020) [No new digest content identified]

PLoS One

http://www.plosone.org/

Research Article

A qualitative exploration of using financial incentives to improve vaccination uptake via consent form return in female adolescents in London

Lauren Rockliffe, Selma Stearns, Alice S. Forster | published 21 Aug 2020 PLOS ONE https://doi.org/10.1371/journal.pone.0237805

Assessment of missed opportunities for vaccination in Kenyan health facilities, 2016

Anyie J. Li, Collins Tabu, Stephanie Shendale, Kibet Sergon, Peter O. Okoth, Isaac K. Mugoya, Zorodzai Machekanyanga, Iheoma U. Onuekwusi, Colin Sanderson, Ikechukwu Udo Ogbuanu Research Article | published 20 Aug 2020 PLOS ONE

https://doi.org/10.1371/journal.pone.0237913

A systematic review of trial registry entries for randomized clinical trials investigating COVID-19 medical prevention and treatment

Anders Peder Højer Karlsen, Sebastian Wiberg, Jens Laigaard, Casper Pedersen, Kim Zillo Rokamp, Ole Mathiesen

Research Article | published 20 Aug 2020 PLOS ONE

https://doi.org/10.1371/journal.pone.0237903

Inferring antenatal care visit timing in low- and middle-income countries: Methods to inform potential maternal vaccine coverage

Ranju Baral, Jessica Fleming, Sadaf Khan, Deborah Higgins, Nathaniel Hendrix, Clint Pecenka Research Article | published 20 Aug 2020 PLOS ONE https://doi.org/10.1371/journal.pone.0237718

PLoS Pathogens

http://journals.plos.org/plospathogens/ [Accessed 22 Aug 2020] [No new digest content identified]

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

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

Prehospital & Disaster Medicine

Volume 35 - Issue 4 - August 2020 https://www.cambridge.org/core/journals/prehospital-and-disaster-medicine/latest-issue [Reviewed earlier]

Preventive Medicine

Volume 137 August 2020 https://www.sciencedirect.com/journal/preventive-medicine/vol/137/suppl/C [Reviewed earlier]

Proceedings of the Royal Society B

12 August 2020 Volume 287 Issue 1932 https://royalsocietypublishing.org/toc/rspb/current [Reviewed earlier]

Public Health

Volume 184, Pages 1-112 (July 2020) https://www.sciencedirect.com/journal/public-health/vol/184/suppl/C [Reviewed earlier]

Public Health Ethics

IN PROGRESS
Volume 13, Issue 1, April 2020
http://phe.oxfordjournals.org/content/current
[Reviewed earlier]

Public Health Reports

Volume 135 Issue 4, July/August 2020 https://journals.sagepub.com/toc/phrg/135/4 [Reviewed earlier]

Qualitative Health Research

Volume 30 Issue 11, September 2020 http://qhr.sagepub.com/content/current **Special Issue: International Health**

[Reviewed earlier]

Research Ethics

Volume 16 Issue 1-2, January-April 2020 http://journals.sagepub.com/toc/reab/current [Reviewed earlier]

Reproductive Health

http://www.reproductive-health-journal.com/content [Accessed 22 Aug 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 17 Aug 2020

Epidemic trends, public health response and health system capacity: the Chilean experience in four months of the COVID-19 pandemic

Original research | English |

17 Aug 2020

<u>Leveraging household survey data to measure barriers to health services access in the Americas</u>

Original research | English |

Risk Analysis

Volume 40, Issue 7 Pages: 1321-1506 July 2020 https://onlinelibrary.wiley.com/toc/15396924/current [Reviewed earlier]

Risk Management and Healthcare Policy

https://www.dovepress.com/risk-management-and-healthcare-policy-archive56 [Accessed 22 Aug 2020] [No new digest content identified]

Science

21 August 2020 Vol 369, Issue 6506 http://www.sciencemag.org/current.dtl

Editorial

A dangerous rush for vaccines

By H. Holden Thorp Science 21 Aug 2020: 885

Summary

The chasm between science and politics continues to grow, with Russian President Putin announcing this week that a fast-tracked vaccine for coronavirus disease 2019 (COVID-19) is ready for use, and President Trump indicating days earlier that a vaccine could be ready in the United States before the 3 November presidential election. There's been a dangerous rush to get to the vaccine finish line first. In a race of "Sputnik" proportions (as Putin puts it), quick approval by regulatory agencies is needed to "win." This is dangerous thinking, driven by political goals and instant gratification: Shortcuts in testing for vaccine safety and efficacy endanger millions of lives in the short term and will damage public confidence in vaccines and in science for a long time to come.

Policy Forum

Knowledge transfer for large-scale vaccine manufacturing

By W. Nicholson Price II, Arti K. Rai, Timo Minssen

Science21 Aug 2020 : 912-914 Full Access

Massive, rapid production will require firms to share know-how not just about what to make but how to make it

Summary

As the world rushes to identify safe and effective vaccines and therapeutics to counter the coronavirus disease 2019 (COVID-19) pandemic, attention is turning to the next step: manufacturing these products at enormous scale. To speed up the process, firms are even establishing manufacturing capacity "at risk," before products receive regulatory approval (1). Yet for at least some complex COVID-19 vaccines and biological therapeutics, fast manufacturing, particularly of products originally developed by other firms, will require not only physical capacity but also access to knowledge not contained in patents or in other public disclosures; one reason for the expense and delay historically associated with entry of biosimilars into the market has been the cost and time associated with reverse engineering originator firms' manufacturing processes (2). But a change may be coming. A group of six biopharmaceutical firms researching monoclonal antibody (mAb) candidates recently sought [and the U.S. Department of Justice (DOJ) granted] permission under antitrust law to exchange "technical information" on each other's manufacturing processes and platforms (but not information on cost or price) (3). A focus on rapid information exchange of the sort recently encouraged by the DOJ will not only be critical for the current crisis but could also create the foundation for fewer siloes, improved standardization, and less secrecy over manufacturing information in the future.

Science Translational Medicine

19 August 2020 Vol 12, Issue 557 https://stm.sciencemag.org/
[New issue; No digest content identified]

Social Science & Medicine

Volume 258 August 2020

https://www.sciencedirect.com/journal/social-science-and-medicine/vol/258/suppl/C [Reviewed earlier]

Systematic Reviews

https://systematicreviewsjournal.biomedcentral.com/articles [Accessed 22 Aug 2020] [No new digest content identified]

Travel Medicine and Infectious Diseases

Volume 35 May–June 2020

https://www.sciencedirect.com/journal/travel-medicine-and-infectious-disease/vol/35/suppl/C [Reviewed earlier]

Tropical Medicine & International Health

Volume 25, Issue 8 Pages: i-iv, 905-1042 August 2020 https://onlinelibrary.wiley.com/toc/13653156/current [New issue; No digest content identified]

Vaccine

Volume 38, Issue 37 Pages 5877-5962 (18 August 2020) https://www.sciencedirect.com/journal/vaccine/vol/38/issue/37 Research article Abstract only

<u>Maternal and infant outcomes following exposure to quadrivalent human</u> papillomavirus vaccine during pregnancy

Anna T. Bukowinski, Clinton Hall, Richard N. Chang, Gia R. Gumbs, Ava Marie S. Conlin Pages 5933-5939

Research article Abstract only

<u>Cost analysis of supplemental immunization activities to deliver measles immunization to children in Anambra state, south-east Nigeria</u>
Florence Tochukwu Sibeudu, Obinna E. Onwujekwe, Ijeoma L. Okoronkwo

Vaccine

Volume 38, Issue 39, 3 September 2020, Pages Discussion Full text access

Ensuring access and affordability through COVID-19 vaccine research and development investments: A proposal for the options market for vaccines Rebecca Forman, Michael Anderson, Mark Jit, Elias Mossialos

Pages 6075-6077

Highlights

- :: Currently, unconditional investment is being made into COVID-19 vaccine R&D COVID-19 vaccine R&D investments should also ensure access and affordability.
- :: The options market for antibiotics, could be adapted for use with COVID-19 vaccines.
- :: This could help fund R&D, boost manufacturing capacity and secure fair prices.
- :: Further research on the OMV model in the current COVID-19 crisis is warranted.

Vaccines — Open Access Journal

http://www.mdpi.com/journal/vaccines (Accessed 22 Aug 2020) [No new digest content]

Value in Health

August 2020 Volume 23, Issue 8, p979-1118 https://www.valueinhealthjournal.com/issue/S1098-3015(20)X0010-6 ECONOMIC EVALUATION

<u>Value of a QALY for France: A New Approach to Propose Acceptable Reference</u> Values

Bertrand Téhard, Bruno Detournay, Isabelle Borget, Stéphane Roze, Gérard De Pouvourville p985–993

Published online: May 30, 2020

Highlights

:: Cost-effectiveness thresholds are used in many countries to inform reimbursement and pricing decisions, although no such reference threshold has yet been proposed in France.

- :: The value of statistical life (VSL) is an interesting metric for evaluating cost-effectiveness thresholds in healthcare because (1) it can be tailored for individual countries using local utility data, (2) it provides a unique measure to avoid inequity in access to healthcare between different therapeutic domains, and (3) it can be benchmarked against other social domains, where it is used to assess public policies and investments that affect mortality risk.
- :: We propose VSL-based breakeven values for a QALY of €147 093 to €201 398, which could be used to qualify incremental cost-effectiveness ratios in health-economic assessment in France and to address whether a medical intervention at a requested price may or may not be efficient.

* * * * *

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 22 Aug 2020 [No new, unique, relevant content]

BBC

http://www.bbc.co.uk/ Accessed 22 Aug 2020

Coronavirus vaccine: Short cuts and allegations of dirty tricks in race to be first
By Gordon Corera Security correspondent
22 Aug 2020

When Moscow announced on 11 August it had registered the first vaccine against Covid-19 and was naming it Sputnik V, the message was hard to miss. Back in 1957, the Soviet Union had launched the Sputnik satellite and won the race for space. Now, Russia was saying it was pushing the boundaries of medical science.

But critics claimed it was pushing too hard. And the scepticism with which the announcement was met is a reminder of intense international competition. In this race, there have been accusations of short-cuts, espionage, unethical risk-taking and jealousy, amid talk of "vaccine nationalism"...

The Economist

http://www.economist.com/ Accessed 22 Aug 2020

<u>A mixed prognosis - The covid-19 pandemic will be over by the end of 2021, says Bill Gates</u>

But millions of deaths are yet to come in poor countries
Aug 18th 2020

MILLIONS MORE are going to die before the covid-19 pandemic is over. That is the stark message of Bill Gates, a co-founder of Microsoft and one of the world's largest philanthropists via the Bill & Melinda Gates Foundation, in an interview with Zanny Minton Beddoes, The Economist's editor-in-chief, in early August. Most of these deaths, he said, would be caused not by the disease itself, but by the further strain on health-care systems and economies that were already struggling. He also lamented the politicisation of the response to the virus in America, and the spread of conspiracy theories—some implicating him—both of which have slowed efforts to contain the disease's spread. But he offered reasons for hope in the medium term, predicting that by the end of 2021 a reasonably effective vaccine would be in mass production, and a large enough share of the world's population would be immunised to halt the pandemic in its tracks...

Financial Times

http://www.ft.com/home/uk Accessed 22 Aug 2020 Coronavirus treatment

CureVac vows 'ethical margin' on price of Covid-19 vaccine

Pharma group plans to make mRNA-based inoculation in Germany and ship it worldwide August 16, 2020

CureVac, one of the pharmaceutical groups developing a potential vaccine for Covid-19, has ruled out selling its inoculation at cost, arguing instead for an "ethical margin" for shareholders. The German company raised \$213m in a US stock market listing on Friday and will put the money towards conducting trials for the vaccine.

CureVac's approach uses messenger RNA technology, which aims to transcribe some of the pathogen's genetic code into human cells in order to help them detect it. No mRNA vaccine has been approved by regulators, though rivals Moderna and Pfizer, along with the latter's German partner BioNTech, are betting on it. CureVac says its jab could require lower doses.

"That would allow us to give a competitive price while still preserving some ethical margin," said Pierre Kemula, the company's chief financial officer, in an interview with the Financial Times...

Forbes

http://www.forbes.com/ Accessed 22 Aug 2020 Editors' Pick / 9 hours ago

<u>Trump Suggests 'Deep State' At FDA Is Delaying Covid-19 Coronavirus Vaccine</u> Testing

Trump also tweeted about the FDA's hydroxychloroquine decision.

By Bruce Y. Lee Senior Contributor

Foreign Affairs

http://www.foreignaffairs.com/ Accessed 22 Aug 2020

Essay September/October 2020

The Tragedy of Vaccine Nationalism

Global cooperation on vaccine allocation would be the most efficient way to disrupt the spread of the virus

Thomas J. Bollyky and Chad P. Bown

Foreign Policy

http://foreignpolicy.com/ Accessed 22 Aug 2020 | [No new, unique, relevant content]

The Guardian

http://www.guardiannews.com/

Covid-19 will be around for ever, says former UK chief scientific ...

14 hours ago ... Prof Mark Walport says regular **vaccinations** are likely to be required to control coronavirus.

New Yorker

http://www.newyorker.com/ Accessed 22 Aug 2020 [No new, unique, relevant content]

New York Times

http://www.nytimes.com/ Accessed 22 Aug 2020 Europe

Exclusive: Nearly a Fifth of Enrollees in Pfizer, BioNTech COVID-19 Vaccine Study Are Black or Latino

Nearly a fifth of 11,000 people enrolled so far in a 30,000-volunteer U.S. trial testing a COVID-19 vaccine from Pfizer and German partner BioNTech are Black or Latino, groups among the hardest hit by the coronavirus virus pandemic, a top Pfizer executive said. By Reuters Aug 22

U.S.

<u>China Giving Experimental Coronavirus Vaccines to High-Risk Groups Since July, Says Official</u>

China has been giving experimental coronavirus vaccines to groups facing high infection risks since July, a health official told state media.

By Reuters Aug 22

World

Argentina Joins Chinese Coronavirus Vaccine Trial, Maker Says

Argentina joined Peru, Morocco and the United Arab Emirates in approving Phase 3 clinical trials for a coronavirus vaccine developed by China National Biotec Group (CNBG), the company said late Friday.

By Reuters Aug 22

Europe

Russia Approves Trial of AstraZeneca COVID-19 Vaccine: Registry Filing

Britain's AstraZeneca has received regulatory approval to conduct part of a Phase III trial of its potential COVID-19 vaccine in Russia, a filing in the Russian registry of clinical trials showed on Friday.

By Reuters Aug 21

Politics

Australia's Prime Minister Announces Coronavirus Vaccine Deal

Prime Minister Scott Morrison of Australia signed a deal with the drugmaker AstraZeneca to manufacture a coronavirus vaccine and provide it free to 25 million Australians. By The Associated Press Aug 19

Health

New Measures Aim to Boost Vaccine Rates for Flu and Children's Shots

Pharmacists may now vaccinate young children under a new federal emergency rule aimed at helping families who missed well-child visits during the pandemic.

By Jan Hoffman PRINT EDITION | August 21, 2020, Page A7

Americas

Coronavirus Crisis Has Made Brazil an Ideal Vaccine Laboratory

Widespread contagion, a deep bench of scientists and a robust vaccine-making infrastructure have made Brazil an important player in the quest to find a vaccine.

By Manuela Andreoni and Ernesto Londoño

PRINT EDITION August 16, 2020,

Washington Post

https://www.washingtonpost.com/

Accessed 22 Aug 2020

<u>Trump without evidence accuses 'deep state' at FDA of slow-walking coronavirus</u> vaccines

Laurie McGinley, Carolyn Y. Johnson and Josh Dawsey · Health · Aug 22, 2020

<u>Think Tanks et al</u>

Brookings

http://www.brookings.edu/ Accessed 22 Aug 2020 Coronavirus (COVID-19)

Want herd immunity? Pay people to take the vaccine

Robert E. Litan

Tuesday, August 18, 2020

Center for Global Development [to 22 Aug 2020]

http://www.cgdev.org/page/press-center

Accessed 22 Aug 2020

August 20, 2020

Bringing a COVID-19 Vaccine to Market: Where Do We Go from Here?

In this blog, we review the good and the bad about where the world now stands in efforts to bringing a vaccine to market, from the perspective of payers, national governments, and country coalitions, as well as development partners.

Kalipso Chalkidou, Adrian Towse and Rachel Silverman

August 19, 2020

Modelling the Manufacturing Process for COVID-19 Vaccines: Our Approach

We are developing a system of interconnected models which represent global manufacturing capability from the start of clinical trials to secondary vaccine manufacture; that is, time from first human trials to finished product ready to be shipped.

David Reader et al.

Chatham House [to 22 Aug 2020]

https://www.chathamhouse.org/

[No new relevant content]

CSIS

https://www.csis.org/ Accessed 22 Aug 2020 Transcript

Online Event: The Scramble for Vaccines and the COVAX Facility

August 19, 2020

Council on Foreign Relations

http://www.cfr.org/ Accessed 22 Aug 2020 [No new relevant content]

Kaiser Family Foundation

https://www.kff.org/search/?post_type=press-release Accessed 22 Aug 2020 [No new relevant content]

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