Vaccines and Global Health: The Week in Review
12 September 2020 :: Number 569
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.

Comments and suggestions should be directed to
David R. Curry, MS
Editor and
Executive Director
Center for Vaccine Ethics & Policy
david.r.curry@centerforvaccineethicsandpolicy.org

Request email delivery of the pdf: If you would like to receive the PDF of each edition via email [Constant Contact], please send your request to david.r.curry@centerforvaccineethicsandpolicy.org.

Support this knowledge-sharing service: Your financial support helps us cover our costs and to address a current shortfall in our annual operating budget. Click here to donate and thank you in advance for your contribution.

Contents [click on link below to move to associated content]
A. Milestones :: Perspectives :: Featured Journal Content
B. Emergencies
C. WHO; CDC [U.S., Africa, China]
D. Announcements
E. Journal Watch
F. Media Watch

::::::

::::::
Global collaboration for health: rhetoric versus reality

The Lancet
Sep 12, 2020 Volume 396 Number 10253 p735-798, e25-e29
https://www.thelancet.com/journals/lancet/issue/current

Editorial

The 75th session of the UN General Assembly (UNGA) opens on Sept 15, 2020. Being held remotely for the first time, the meeting will inevitably be dominated by the COVID-19 pandemic, but other issues on the agenda that have resonance for global health include the climate crisis, peace, disarmament, and humanitarian assistance. Underpinning this year’s agenda is the UN theme of multilateralism, under the banner “The future we want, the United Nations we need: reaffirming our collective commitment to multilateralism”. Yet the meeting comes at a time when global collaboration and cooperation are in disarray.

The UNGA is traditionally built on bold rhetoric of global collaboration and exhaustive debate over some of the world’s most intractable problems. But rather than expressing a shared vision for a common future, countries are now undermining global cooperation through rising nationalism, open hostility towards multilateral institutions, and a growing tendency to look after their own interests—eg, rushing to secure supplies of potential COVID-19 vaccines. Health is precariously caught in the middle of these tensions. Science has become increasingly politicised, with multiple and conflicted interests at play, and often little sense of solidarity within or between nations.

An immediate casualty of these opposing forces is the global effort towards vaccines for COVID-19. COVAX, the COVID-19 Global Access Facility, is led by WHO; Gavi, The Vaccine Alliance; and the Coalition for Epidemic Preparedness Innovations, and aims to rapidly develop and equitably distribute effective vaccines. Variable commitment to COVAX reflects the tension between nationalism and collaboration. 170 countries plan to participate, but the USA, for one, is opting not to join COVAX. Instead, the USA has secured bilateral deals with several pharmaceutical companies for millions of doses of promising COVID-19 vaccines. Similar deals have been struck by Australia, the EU, and the UK. In July, Médecins Sans Frontières warned that “These bilateral deals will reduce the initial global vaccine stocks available for vulnerable groups in poorer countries and undermine global efforts to ensure fair allocation”.

Insufficient collaboration is also jeopardising the Pan American Health Organization, with many member states, including Brazil, Venezuela, and Mexico, withholding essential funding at a time when Latin America is under mounting pressure from COVID-19. Meanwhile, the USA continues its deeply disappointing withdrawal from WHO.
The climate emergency is another subject on which rhetoric has fallen flat in the face of nationalistic inaction. The global response to COVID-19 depends heavily on the idea of creating a better future for human and planetary health, and commitment to this approach is non-negotiable for sustainable recovery. It is disappointing that the UNGA's formal general agenda does not more extensively cover climate change beyond the item “Protection of global climate for present and future generations of humankind”, although there is a Summit on Biodiversity on Sept 30, as well as activities across New York City.

Hopefully, the summit will also return the UNGA's focus to the Sustainable Development Goals, which must still be met by 2030, and to defining a post-2020 biodiversity framework. An early indication that nations might work to protect health in the face of climate change as laid out in this year's WHO manifesto for a healthy and green recovery from COVID-19 is seen in the commitment to the Resilient Recovery Platform. Launched in Japan on Sept 3, 2020, the platform is a global sharing of policy and actions to address the response to COVID-19 coupled with the response to the climate emergency, with stakeholders such as governments, businesses, non-governmental organisations, and civil society. The participation of 80 countries shows a willingness to engage in overhauling socioeconomic models towards a sustainable future. But will it be translated into action?

Global solidarity cannot be garnered through rhetoric alone. COVID-19 has brought into clear view that every person's health is interconnected, and the UNGA is a platform with the power to reorientate global interests in such a way as to protect the health and lives of all people in every nation. The need for global cooperation has never been more visible or more crucial. Unfortunately, the UN has so far in 2020 not been able to transform rhetoric into reality. This should give pause for serious reflection. Global crises call for global responses, and we have yet to see them.

COVID-19 Vaccines, Therapeutics, Diagnostics

Statement from the first ACT-Accelerator Facilitation Council meeting
10 September 2020  WHO
As Members and Partners of the Facilitation Council of the ‘Access to COVID-19 Tools Accelerator’ (ACT- Accelerator), on the occasion of the Council’s launch meeting;

We share the vision of the ACT-Accelerator as a unique international collaboration to fast-track the development and equitable deployment of COVID-19 vaccines, therapeutics and diagnostics globally while strengthening related health systems;

We thank the World Health Organization and the European Commission for their leadership in co-convening this first meeting of the Facilitation Council at this crucial time, as the COVID-19 pandemic continues to have a devastating impact on the health, societies and economies of all countries, the consequences of which have disproportionately affected poor and vulnerable populations;

We welcome South Africa and Norway as the Council’s co-chairs;
We recognize that the fastest and most effective solution to the COVID-19 crisis, and the full mitigation of its health, social and economic consequences, is through global multilateral collaboration and international solidarity that supports all countries and populations, including the world’s poorest and at-risk populations such as women and children;

We fully align with the ACT-Accelerator goal of rapidly reducing the risk of severe COVID-19 disease globally, which will in turn bolster the capacity of health systems to safely and effectively manage COVID-19 and restore the global confidence needed to resume economic and societal activity;

We appreciate the leadership and work of the ACT-Accelerator Pillar co-conveners and their partners for the substantial achievements to date, while recognizing the considerable challenges they face to realize the full potential of this unprecedented global collaboration;

We consider the ACT-Accelerator an integral part of the implementation of the World Health Assembly Resolution (WHA73.1(3)) and that it responds fully to the G20 Leaders’ Commitment of 26 March 2020, as both highlighted the need for end-to-end solutions to accelerate the development and equitable, universal deployment of life saving COVID-19 vaccines, therapeutics and diagnostics;

**We acknowledge the urgency of catalysing a step-change in political support and financing for the ACT-Accelerator in order to enable it to deliver on its mission of accelerating the discovery and deployment of new COVID-19 tools to all people, everywhere;**

Accordingly, we will:

[1] **Provide sustained political leadership to galvanize and harness broad international support for the ACT-Accelerator**, including in key upcoming fora such as the UN General Assembly, the G20 and G7 processes, the Paris Peace Forum and IMF/World Bank Group meetings and through our respective regional cooperation groups and national processes;

[2] **Advocate in support of the ACT-Accelerator Investment Case in order to secure as a matter of urgency the financial resources required to scale-up for impact and change the course of the pandemic;**

[3] ** Honour and realize our shared commitment to leave no one behind in this crisis**, by working to ensure that all countries and populations have early, affordable and equitable access to the new vaccines, therapeutics and diagnostics that the ACT-Accelerator is pursuing.

COVID-19 Vaccines – Development Standards/Regulatory Review/Commitments
Press Release

Biopharma Leaders Unite to Stand with Science

Nine CEOs sign historic pledge to continue to make the safety and well-being of vaccinated individuals the top priority in development of the first COVID-19 vaccines

NEW YORK--(BUSINESS WIRE)-- Sep. 8, 2020  The CEOs of AstraZeneca, BioNTech, GlaxoSmithKline plc, Johnson & Johnson, Merck, known as MSD outside the United States and Canada, Moderna, Inc., Novavax, Inc., Pfizer Inc., and Sanofi today announced a historic pledge, outlining a united commitment to uphold the integrity of the scientific process as they work towards potential global regulatory filings and approvals of the first COVID-19 vaccines. All nine CEOs signed the following pledge:

"We, the undersigned biopharmaceutical companies, want to make clear our ongoing commitment to developing and testing potential vaccines for COVID-19 in accordance with high ethical standards and sound scientific principles.

"The safety and efficacy of vaccines, including any potential vaccine for COVID-19, is reviewed and determined by expert regulatory agencies around the world, such as the United States Food and Drug Administration (FDA). FDA has established clear guidance for the development of COVID-19 vaccines and clear criteria for their potential authorization or approval in the US. FDA’s guidance and criteria are based on the scientific and medical principles necessary to clearly demonstrate the safety and efficacy of potential COVID-19 vaccines. More specifically, the agency requires that scientific evidence for regulatory approval must come from large, high quality clinical trials that are randomized and observer-blinded, with an expectation of appropriately designed studies with significant numbers of participants across diverse populations.

" Following guidance from expert regulatory authorities such as FDA regarding the development of COVID-19 vaccines, consistent with existing standards and practices, and in the interest of public health, we pledge to:
:: Always make the safety and well-being of vaccinated individuals our top priority.
:: Continue to adhere to high scientific and ethical standards regarding the conduct of clinical trials and the rigor of manufacturing processes.
:: Only submit for approval or emergency use authorization after demonstrating safety and efficacy through a Phase 3 clinical study that is designed and conducted to meet requirements of expert regulatory authorities such as FDA.
:: Work to ensure a sufficient supply and range of vaccine options, including those suitable for global access.

"We believe this pledge will help ensure public confidence in the rigorous scientific and regulatory process by which COVID-19 vaccines are evaluated and may ultimately be approved.”

Together, these nine companies have collectively developed more than 70 novel vaccines that have helped to eradicate some of the world’s most complex and deadly public health threats, underscoring their experience in clinical development and regulatory rigor, as well as their longstanding commitments to patient safety and public health.
...The FDA’s career scientists and physicians are helping to facilitate the development and evaluation of safe and effective COVID-19 vaccines. These professionals have globally recognized expertise in the complexity of vaccine development and in evaluating the safety and effectiveness of vaccines intended to prevent infectious diseases. They are experts in clinical trial design and analysis and synthesizing and evaluating tremendous amounts of data to determine whether a vaccine has been shown to be safe and effective. These experts are responsible for assessing the adequacy of manufacturing and the facilities where vaccines are made, which are critical to producing high-quality vaccines, and for post-marketing safety surveillance, using a wide variety of surveillance systems and data mining to continually review safety after a vaccine is approved.

The FDA is often held up as the “gold standard” of regulatory agencies around the globe. What’s at the core of these standards are the agency’s regulatory independence and science-based decision-making. As with all products we regulate, we will follow the science and data in our decision making regarding COVID-19 vaccines. It is because the FDA is a science-based agency that we say this with the clarity of conviction. The dedicated career public health professionals who will be involved in evaluating the data submitted to the FDA in requests for Emergency Use Authorization (EUA) and in Biologics License Applications (BLAs) for COVID-19 vaccines are committed to decision making based on science and data. They are fathers, mothers, sisters, brothers, grandparents and more – and they (and their families) are directly impacted by the work they do. They are exactly who you want making decisions regarding vaccine safety and effectiveness.

No time in recent memory has shone as bright a light on the work of FDA review staff as the COVID-19 pandemic. We understand that a lot of people may not have information about vaccine development or how the FDA determines whether or not to approve a vaccine – and may not have given it much thought – at least until now.

With so much at stake, we understand the importance of being as transparent as possible about the work we do, including how we will make decisions regarding COVID-19 vaccines. The publication of our guidance was an important step – we firmly believe that transparency regarding the FDA’s thinking about the scientific data needed to support approval of safe and effective vaccines will help build public confidence in the FDA’s evaluation process, which will be critical in ensuring the use of COVID-19 vaccines once available.

An upcoming key milestone is the meeting of our Vaccines and Related Biological Products Advisory Committee on October 22, at which the committee will discuss publicly the general development of COVID-19 vaccines. While this meeting is not intended to discuss any particular vaccine candidates, the agency is also prepared to rapidly schedule additional meetings of this Committee upon submission of any BLAs or requests for EUAs to further ensure transparency.
The FDA has been asked what regulatory path will be used to make COVID-19 vaccines available (i.e., will there be an EUA, or will the FDA approve a BLA?). The short answer is, taking into consideration input from the FDA, manufacturers decide whether and when to submit an EUA request or BLA to the FDA. The agency will review EUA requests and BLAs received and make appropriate determinations by looking at the totality of the available scientific evidence. For a vaccine for which there is adequate manufacturing information, issuance of an EUA may be appropriate once studies have demonstrated the safety and effectiveness of the vaccine, but before the manufacturer has submitted all of the various data elements normally required and/or the FDA has completed its formal review of the BLA.

As we have said, these decisions will be firmly rooted in science. We are committed to expediting the development of COVID-19 vaccines, but not at the expense of sound science and decision making. We will not jeopardize the public's trust in our science-based, independent review of these or any vaccines. There's too much at stake....

COVID-19 Vaccines – Development Status/Scorecard

**IVI**  [to 12 Sep 2020]
http://www.ivi.int/

*Selected IVI News & Announcements*

**IVI to ready clinical trial sites for COVID-19 vaccine efficacy trials in 4 countries**

September 9, 2020 – SEOUL, South Korea – The International Vaccine Institute (IVI) announced today that the Bill & Melinda Gates Foundation awarded close to 1.5 million USD to IVI to support clinical trial site preparedness in four African and Asian countries to potentially support future COVID-19 Phase III efficacy vaccine trials.

Following successful completion of early-stage clinical trials of COVID-19 vaccine candidates, it will be essential to transition to efficacy trials at different sites around the world with high disease burden, including those in resource-limited settings. To ensure these sites are prepared for efficacy trials with the necessary technical capability, trained staff, sufficient trial participants, and a thorough assessment of prevailing COVID-19 burden, IVI aims to bolster in-country capacity at select sites by 4Q2020.

Dr Florian Marks, Deputy Director General of Epidemiology, Public Health, Impact, and Clinical Development at IVI, said: “The COVID-19 threat is worldwide, which means preparations for the development and delivery of safe and effective vaccines must also be a global project. It is imperative that lack of resources does not equate to exclusion, that COVID-19 vaccines be regarded as global public goods from the outset, and that equal access is ensured. We look forward to working with our long-time partners in Africa and Asia to accelerate the global push toward a COVID-19 vaccine solution.”

IVI currently conducts active projects in Africa and Asia, including disease prevention and surveillance for cholera and typhoid in Mozambique and Ghana, respectively, as well as a Phase III clinical trial for a novel typhoid conjugate vaccine in the Philippines. IVI also received funding
from the Swedish International Development Cooperation Agency (Sida) this May to strengthen COVID-19 surveillance in Madagascar and Burkina Faso.

Selected Developer Announcements

**COVID-19 vaccine AZD1222 clinical trials resumed in the UK**
12 September 2020 14:20 BST

Clinical trials for the AstraZeneca Oxford coronavirus vaccine, AZD1222, have resumed in the UK following confirmation by the Medicines Health Regulatory Authority (MHRA) that it was safe to do so.

On 6 September, the standard review process triggered a voluntary pause to vaccination across all global trials to allow review of safety data by independent committees, and international regulators. The UK committee has concluded its investigations and recommended to the MHRA that trials in the UK are safe to resume.

AstraZeneca and the University of Oxford, as the trial sponsor, cannot disclose further medical information. All trial investigators and participants will be updated with the relevant information and this will be disclosed on global clinical registries, according to the clinical trial and regulatory standards...

**Pfizer and BioNTech Propose Expansion of Pivotal COVID-19 Vaccine Trial**
September 12, 2020

NEW YORK & MAINZ, Germany--(BUSINESS WIRE)--Pfizer Inc. (NYSE: PFE) and BioNTech SE (NASDAQ: BNTX) announced today that they have submitted an amended protocol to the U.S. Food and Drug Administration to expand the enrollment of their Phase 3 pivotal COVID-19 vaccine trial to up to approximately 44,000 participants which also allows for the enrollment of new populations...

**Pfizer and BioNTech to Potentially Supply the EU with 200 Million Doses of mRNA-based Vaccine Candidate Against SARS-CoV-2**

::: The proposed agreement is intended to provide a supply of 200 million doses and an option to purchase additional 100 million doses, with deliveries starting by the end of 2020, subject to regulatory approval
::: The vaccine supply for the EU would be produced by BioNTech’s manufacturing sites in Germany and Pfizer’s manufacturing site in Belgium
::: 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

September 09, 2020
Sinovac Reports Preliminary Phase I/II Results of COVID-19 Vaccine in Elderly Volunteers

September 09, 2020

BEIJING--(BUSINESS WIRE)--Sinovac Biotech Ltd. (NASDAQ: SVA) ("Sinovac" or the "Company"), a leading provider of biopharmaceutical products in China, announced that the inactivated COVID-19 vaccine candidate developed by Sinovac Life Sciences (Sinovac LS), or "CoronaVac," shows good safety and immunogenicity on healthy adults aged 60 and above from its phase I/II clinical studies conducted in China, which is comparable to the result in healthy adults aged from 18 to 59 in the earlier studies.

The phase I/II clinical trial on elderly volunteers were randomized, double-blinded and placebo controlled trials with two-dose immunization scheduled at 28 day intervals...

COVID-19 Vaccines – Transport/Logistics

The Time to Prepare for COVID-19 Vaccine Transport is Now

Press release

9 SEPTEMBER/ GENEVA - The International Air Transport Association (IATA) urged governments to begin careful planning with industry stakeholders to ensure full preparedness when vaccines for COVID-19 are approved and available for distribution. The association also warned of potentially severe capacity constraints in transporting vaccines by air.

Preparedness

Air cargo plays a key role in the distribution of vaccines in normal times through well-established global time- and temperature-sensitive distribution systems. This capability will be crucial to the quick and efficient transport and distribution of COVID-19 vaccines when they are available, and it will not happen without careful planning, led by governments and supported by industry stakeholders.

"Safely delivering COVID-19 vaccines will be the mission of the century for the global air cargo industry. But it won’t happen without careful advance planning. And the time for that is now. We urge governments to take the lead in facilitating cooperation across the logistics chain so that the facilities, security arrangements and border processes are ready for the mammoth and complex task ahead,” said IATA’s Director General and CEO, Alexandre de Juniac.

"Delivering billions of doses of vaccine to the entire world efficiently will involve hugely complex logistical and programmatic obstacles all the way along the supply chain. We look forward to working together with government, vaccine manufacturers and logistical partners to ensure an efficient global roll-out of a safe and affordable COVID-19 vaccine,” said Dr Seth Berkley, CEO of Gavi, the Vaccine Alliance.

Facilities: Vaccines must be handled and transported in line with international regulatory requirements, at controlled temperatures and without delay to ensure the quality of the product. While there are still many unknowns (number of doses, temperature sensitivities, manufacturing locations, etc.), it is clear that the scale of activity will be vast, that cold chain
facilities will be required and that delivery to every corner of the planet will be needed. Priorities for preparing facilities for this distribution include:

:: Availability of temperature-controlled facilities and equipment - maximizing the use or re-purposing of existing infrastructure and minimizing temporary builds
:: Availability of staff trained to handle time- and temperature-sensitive vaccines
:: Robust monitoring capabilities to ensure the integrity of the vaccines is maintained

**Security:** Vaccines will be highly valuable commodities. Arrangements must be in place to keep ensure that shipments remain secure from tampering and theft. Processes are in place to keep cargo shipments secure, but the potential volume of vaccine shipments will need early planning to ensure that they are scalable.

**Border Processes:** Working effectively with health and customs authorities will, therefore, be essential to ensure timely regulatory approvals, adequate security measures, appropriate handling and customs clearance. This could be a particular challenge given that, as part of COVID-19 prevention measures, many governments have put in place measures that increase processing times. Priorities for border processes include:

:: Introducing fast-track procedures for overflight and landing permits for operations carrying the COVID-19 vaccine
:: Exempting flight crew members from quarantine requirements to ensure cargo supply chains are maintained
:: Supporting temporary traffic rights for operations carrying the COVID-19 vaccines where restrictions may apply
:: Removing operating hour curfews for flights carrying the vaccine to facilitate the most flexible global network operations
:: Granting priority on arrival of those vital shipments to prevent possible temperature excursions due to delays
:: Considering tariff relief to facilitate the movement of the vaccine

**Capacity**

On top of the transport preparations and coordination needed, governments must also consider the current diminished cargo capacity of the global air transport industry. IATA warned that, with the severe downturn in passenger traffic, airlines have downsized networks and put many aircraft into remote long-term storage. The global route network has been reduced dramatically from the pre-COVID 24,000 city pairs. The WHO, UNICEF and Gavi have already reported severe difficulties in maintaining their planned vaccine programs during the COVID-19 crisis due, in part, to limited air connectivity.

“The whole world is eagerly awaiting a safe COVID vaccine. It is incumbent on all of us to make sure that all countries have safe, fast and equitable access to the initial doses when they are available. As the lead agency for the procurement and supply of the COVID vaccine on behalf of the COVAX Facility, UNICEF will be leading what could possibly be the world’s largest and fastest operation ever. The role of airlines and international transport companies will be critical to this endeavour,” said Henrietta Fore, UNICEF Executive Director.

The potential size of the delivery is enormous. Just providing a single dose to 7.8 billion people would fill 8,000 747 cargo aircraft. Land transport will help, especially in developed economies.
with local manufacturing capacity. But vaccines cannot be delivered globally without the significant use air cargo.

“Even if we assume that half the needed vaccines can be transported by land, the air cargo industry will still face its largest single transport challenge ever. In planning their vaccine programs, particularly in the developing world, governments must take very careful consideration of the limited air cargo capacity that is available at the moment. If borders remain closed, travel curtailed, fleets grounded and employees furloughed, the capacity to deliver life-saving vaccines will be very much compromised,” said de Juniac.

COVID-19 Vaccines Development/Distribution – Ethical Considerations

Vaccine
Volume 38, Issue 41  Pages 6347-6484 (22 September 2020)
https://www.sciencedirect.com/journal/vaccine/vol/38/issue/41
Review article  Full text access

So much at stake: Ethical tradeoffs in accelerating SARS-CoV-2 vaccine development
Christine Grady, Seema Shah, Franklin Miller, Marion Danis, ... Annette Rid
Pages 6381-6387

Abstract
Background
A sense of urgency exists to develop vaccines against SARS-CoV-2, responsible for numerous global cases and deaths, as well as widespread social and economic disruption. Multiple approaches have been proposed to speed up vaccine development, including accelerated randomized controlled trials (RCT), controlled human challenge trials (CHI), and wide distribution through an emergency use authorization after collecting initial data. There is a need to examine how best to accelerate vaccine development in the setting of a pandemic, without compromising ethical and scientific norms.

Methods
Trade-offs in scientific and social value between generating reliable evidence about safety and efficacy while promoting rapid vaccine availability are examined along five ethically relevant dimensions: (1) confidence in and generalizability of data, (2) feasibility, (3) speed and cost, (4) participant risks, and (5) social risks.

Results
Accelerated individually randomized RCTs permit expeditious evaluation of vaccine candidates using established methods, expertise, and infrastructure. RCTs are more likely than other approaches to be feasible, increase speed and reduce cost, and generate reliable data about safety and efficacy without significantly increasing risks to participants or undermining societal trust.

Conclusion
Ethical analysis suggests that accelerated RCTs are the best approach to accelerating vaccine development in a pandemic, and more likely than other approaches to enhance social value without compromising ethics or science. RCTs can expeditiously collect rigorous data about vaccine safety and efficacy. Innovative and flexible designs and implementation strategies to respond to shifting incidence and test vaccine candidates in parallel or sequentially would add
value, as will coordinated data sharing across vaccine trials. CHI studies may be an important complementary strategy when more is known. Widely disseminating a vaccine candidate without efficacy data will not serve the public health nor achieve the goal of identifying safe and effective SARS Co-V-2 vaccines.

Science
11 September 2020 Vol 369, Issue 6509
http://www.sciencemag.org/current.dtl

Policy Forum
An ethical framework for global vaccine allocation
Science11 Sep 2020 : 1309-1312
The Fair Priority Model offers a practical way to fulfill pledges to distribute vaccines fairly and equitably

Summary
Once effective coronavirus disease 2019 (COVID-19) vaccines are developed, they will be scarce. This presents the question of how to distribute them fairly across countries. Vaccine allocation among countries raises complex and controversial issues involving public opinion, diplomacy, economics, public health, and other considerations. Nevertheless, many national leaders, international organizations, and vaccine producers recognize that one central factor in this decision-making is ethics (1, 2). Yet little progress has been made toward delineating what constitutes fair international distribution of vaccine. Many have endorsed “equitable distribution of COVID-19...vaccine” without describing a framework or recommendations (3, 4). Two substantive proposals for the international allocation of a COVID-19 vaccine have been advanced, but are seriously flawed. We offer a more ethically defensible and practical proposal for the fair distribution of COVID-19 vaccine: the Fair Priority Model.

EMERGENCIES

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

Weekly Epidemiological and Operational updates
last update: 11 September 2020, 20:00 GMT-4
Confirmed cases :: 28 329 790 [week ago: 26 468 031]
Confirmed deaths :: 911 877 [week ago: 871 166]

Weekly Operational Update
Coronavirus disease 2019 (COVID-19)
9 September 2020
Weekly Epidemiological Update
Coronavirus disease 2019 (COVID-19)
7 September 2020

Emergencies

POLIO
Public Health Emergency of International Concern (PHEIC)

Polio this week as of 09 September 2020

Summary of new WPV and cVDPV viruses this week (AFP cases and environmental samples):
:: Afghanistan: Four WPV1 cases
:: Pakistan: Three WPV1 cases and 17 WPV1 positive environmental samples
:: Chad: three cVDPV2 cases
:: Democratic Republic of the Congo (DR Congo): 15 cVDPV2 cases
:: Sudan: eight cVDPV2 case

Statement
Polio programme accelerates efforts to respond to new polio outbreaks in Sudan and Yemen

Joint statement by WHO Regional Director for the Eastern Mediterranean Region Dr Ahmed Al Mandhari and UNICEF Regional Director for the Middle East and North Africa Region Ted Chaiban

AMMAN/CAIRO, 11 September 2020 - "The recent vaccine-derived polio outbreaks confirmed in Yemen and Sudan are consequences of increasingly low levels of immunity among children. Each outbreak has paralysed children in areas that have been extremely difficult if not impossible to reach with routine or supplementary polio vaccination for extended periods of time.

"These outbreaks do not come as a total surprise. In Sudan, extensive population movement by nomadic communities, people displaced by conflict, frequent movement between neighbouring countries and restricted access in some areas have made it enormously difficult to reach every child with vaccines. The cases in Yemen are clustered in the Sa’adah Governorate in the war-ravaged country’s north-west, an area that has very low routine immunization levels and has been inaccessible to the polio programme for more than two years. The last house-to-house campaigns in this area were in November 2018...

...The outbreaks in Sudan and Yemen are the first new polio outbreaks in the COVID-19 era in our region. WHO’s Eastern Mediterranean Region is also responding to circulating vaccine-derived poliovirus outbreaks in Somalia, Afghanistan and Pakistan. We know that when national
authorities, communities and polio programme partners pull together, we can end outbreaks – just as we did in Syria in 2018. But if we cannot reach every child across these regions with life-saving vaccine, we fear that even more countries will see children tragically and permanently paralysed by a disease that can – and must – be stopped...

Emergencies

Ebola – DRC+
Last *WHO Situation Report* published 23 June 2020
Last *WHO DON* published 3 July 2020

WHO Grade 3 Emergencies  [to 12 Sep 2020]
Democratic Republic of the Congo  - No new digest announcements identified
Mozambique floods  - No new digest announcements identified
Nigeria  - No new digest announcements identified
Somalia  - No new digest announcements identified
South Sudan  - No new digest announcements identified
Syrian Arab Republic  - No new digest announcements identified
Yemen  - No new digest announcements identified

WHO Grade 2 Emergencies  [to 12 Sep 2020]
Iraq
:: WHO Iraq frontline workers tackling COVID-19 with community sensitizations and engagements
9 September 2020

Niger
:: L’Afrique certifiée libre du poliovirus sauvage : un évènement historique suivi au N...
07 septembre 2020

Afghanistan  - No new digest announcements identified
Angola  - No new digest announcements identified
Burkina Faso  [in French]  - No new digest announcements identified
Burundi  - No new digest announcements identified
Cameroon  - No new digest announcements identified
Central African Republic  - No new digest announcements identified
Ethiopia  - No new digest announcements identified
Iran floods 2019  - No new digest announcements identified
Libya  - No new digest announcements identified
Malawi Floods  - No new digest announcements identified
Measles in Europe - No new digest announcements identified
MERS-CoV - No new digest announcements identified
Mozambique - No new digest announcements identified
Myanmar - No new digest announcements identified
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

::::::

WHO Grade 1 Emergencies [to 12 Sep 2020]

Chad - No new digest announcements identified
Djibouti – Page not responding at inquiry
Kenya - No new digest announcements identified
Mali - No new digest announcements identified
Namibia - viral hepatitis - No new digest announcements identified
Tanzania - No new digest announcements identified

::::::

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. 20 - As of 9 September 2020

Yemen

::::::

UN OCHA – Corporate Emergencies

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

COVID-19

East Africa Locust Infestation
- No new digest announcements identified
**WHO & Regional Offices** [to 12 Sep 2020]

10 September 2020

**Statement**

**Statement from the first ACT-Accelerator Facilitation Council meeting**

[See Milestones above for detail]

**News release**

**Coronavirus Global Response: Access to COVID-19 Tools-Accelerator Facilitation Council holds inaugural meeting**

:: United Nations Secretary General António Guterres appeals for a quantum leap in funding for the ACT-Accelerator, a global solution to get the world moving, working and prospering again
:: H.E. Cyril Ramaphosa, President of South Africa, and H.E. Erna Solberg, Prime Minister of Norway, co-chair the ACT-Acceleration Facilitation Council
:: Global leaders – including over 30 heads of state and ministers – release statement of commitment to galvanizing support for the ACT-Accelerator and the need for the financial resources required to leave no one behind
:: ACT-Accelerator calculates that $35 billion is still required to give all countries the tools needed to end the pandemic as quickly as possible

9 September 2020  **News release**

**COVID-19 could reverse decades of progress toward eliminating preventable child deaths, agencies warn**

9 September 2020  **News release**

**More than 3 billion people protected from harmful trans fat in their food**

8 September 2020  **News release**

**WHO calls for global action on sepsis - cause of 1 in 5 deaths worldwide**

**Weekly Epidemiological Record, 11 September 2020, vol. 95, 37 (pp. 441–448)**

Cholera 2019

**WHO Regional Offices**

Selected Press Releases, Announcements

**WHO African Region AFRO**

:: COVID-19 genome sequencing laboratory network launches in Africa  10 September 2020
:: Noncommunicable diseases increase risk of dying from COVID-19 in Africa  10 September 2020

**WHO Region of the Americas PAHO**

No new digest content identified
CDC/ACIP [to 12 Sep 2020]

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

Latest News Releases

**Federal Government Adjusts COVID-19 Entry Strategy for International Air Passengers**

Wednesday, September 9, 2020

As the COVID-19 pandemic continues, the United States Government (USG) is innovating and taking a new approach to help keep international air passengers healthy. The new, more effective strategy focuses on the continuum of travel and the individual passenger, including pre-departure and post-arrival education, efforts to develop a potential testing framework with international partners, and illness response. This strategy is consistent with the current phase of the pandemic and more effectively protects the health of the American public.

Beginning September 14, 2020, the USG will remove requirements for directing all flights carrying airline passengers arriving from, or recently had a presence in, certain countries to land at one of 15 designated airports and halt enhanced entry health screening for these passengers. Currently, enhanced entry health screening is conducted for those arriving from, or with recent presence in, China (excluding the Special Administrative Regions of Hong Kong and Macau), Iran, the Schengen region of Europe, the United Kingdom (excluding overseas territories outside of Europe), Ireland, and Brazil.

We now have a better understanding of COVID-19 transmission that indicates symptom-based screening has limited effectiveness because people with COVID-19 may have no symptoms or fever at the time of screening, or only mild symptoms. Transmission of the virus may occur.
from passengers who have no symptoms or who have not yet developed symptoms of infection. Therefore, CDC is shifting its strategy and prioritizing other public health measures to reduce the risk of travel-related disease transmission...

---

**MMWR News Synopsis Friday, September 11, 2020**
*Delay or Avoidance of Medical Care Because of COVID-19–Related Concerns — United States, June 2020*

Community and Close Contact Exposures Associated with COVID-19 Among Symptomatic Adults >18 years in 11 Outpatient Health Care Facilities — United States, July 2020

---

**Africa CDC** [to 12 Sep 2020]
http://www.africacdc.org/
*News*  
*Press Releases*  
*Africa CDC, FIND partner to build capacity for COVID-19 rapid diagnostic tests in Africa*
11 September 2020  
:: Strategic partnership between Africa CDC and FIND builds on long-standing relationship and newly signed Memorandum of Understanding to drive access to essential diagnostics across Africa in collaboration with local partners  
:: Work to ensure readiness to roll out critical antigen RDTs for COVID-19 is being conducted as part of the Access to COVID-19 Tools (ACT) Accelerator Diagnostics Pillar

*Press Releases*  
*COVID-19 genome sequencing laboratory network launches in Africa*
   Addis Ababa/Brazzaville, 10 September 2020 – With several African countries now expanding COVID-19 testing, the World Health Organization (WHO) and the Africa Centres for Disease Control and Prevention (Africa CDC) have launched a network of laboratories to reinforce genome sequencing of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes COVID-19, in Africa...

---

**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*  
*Sept 12: Daily briefing on novel coronavirus cases in China*
On Sept 11, 31 provincial-level regions and the Xinjiang Production and Construction Corps on the Chinese mainland reported *6 new cases of confirmed infections.*
Xi presents medals to role models in China's COVID-19 fight
2020-09-08
BEIJING -- China held a meeting on Sept 8 at the Great Hall of the People in Beijing to commend role models in the country’s fight against the COVID-19 epidemic.

Vaccines for COVID-19 available by year's end, says developer
2020-09-08
Two inactivated vaccines for COVID-19 under clinical trial in China are likely to provide immunity for up to three years and may be available on the market by the end of this year, according to their developer.

The candidate vaccines, which are already approved for emergency use and are undergoing phase three clinical trials, have proved to be safe and able to cause production of antibodies in all volunteers that are effective enough to protect them from the novel coronavirus 28 days after they received a second dose, said Zhou Song, chief legal adviser of China National Biotec Group, which is a subsidiary of China National Pharmaceutical Group Corporation...

China Injects Hundreds of Thousands With Experimental Covid-19 Vaccines
Chinese pharmaceutical companies administer newly developed inoculations outside of clinical trials, despite dangers
By Chao Deng
Wall Street Journal, Sept. 11, 2020 10:20 am ET

A Chinese pharmaceutical company has injected hundreds of thousands of people with experimental Covid-19 vaccines, as its Western counterparts warn against administering mass vaccinations before rigorous scientific studies are complete.

China National Biotec Group Co., a subsidiary of state-owned Sinopharm, has given two experimental vaccine candidates to hundreds of thousands of people under an emergency-use condition approved by Beijing in July, the company said this week. Separately, Chinese drugmaker Sinovac Biotech Ltd. said it has inoculated around 3,000 of its employees and their family members, including the firm’s chief executive, with its experimental coronavirus vaccine.

The three vaccine candidates are still undergoing Phase 3 clinical trials, which involve testing a vaccine’s safety and effectiveness on thousands of people. Six other leading Covid-19 vaccine candidates are also in this final phase, according to the World Health Organization...

Announcements

Paul G. Allen Frontiers Group [to 12 Sep 2020]
News
No new digest content identified.

BARDA – U.S. Department of HHS [to 12 Sep 2020]
European Medicines Agency [to 12 Sep 2020]
News & Press Releases
No new digest content identified.

European Vaccine Initiative [to 12 Sep 2020]
http://www.euvaccine.eu/
Latest News
No new digest content identified.

FDA [to 12 Sep 2020]
https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/default.htm
Press Announcements
September 11, 2020 - Coronavirus (COVID-19) Update: Daily Roundup September 11, 2020
... In a new FDA Voices entitled, The FDA’s Scientific and Regulatory Oversight of Vaccines is Vital to Public Health, agency leaders explain that they are committed to making decisions that are guided by science and data regarding the authorization or approval of COVID-19 vaccines. ... FDA issued a temporary guidance, “Resuming Normal Drug and Biologics Manufacturing Operations During the COVID-19 Public Health Emergency,” to help drug and biological product manufacturers (including animal drug manufacturers) transition from operations impacted by the COVID-19 public health emergency to normal manufacturing operations.


September 8, 2020 - Coronavirus (COVID-19) Update: Daily Roundup September 8, 2020
...The FDA has deactivated the FDA registration for 340 foreign establishments that failed to identify a U.S. Agent as required by FDA’s regulations. Of these, 131 establishments list devices that are essential to the COVID-19 pandemic response. ...Testing updates: To date, the FDA has currently authorized 243 tests under EUAs; these include 195 molecular tests, 44 antibody tests, and 4 antigen tests.

Fondation Merieux [to 12 Sep 2020]
http://www.fondation-merieux.org/
News, Events
Mérieux Foundation co-organized event
ACDX Webinar focused on the critical role of diagnostics in the COVID-19 pandemic – 4 regional perspectives
September 15, 2020 - Webinar 3:00pm to 5:00pm (CET)
The COVID-19 pandemic has highlighted the major role of diagnostics in the patient’s management. Around the globe, the regions and countries have put in place different diagnostics strategies and policies to tackle this COVID-19 sanitary crisis.

The Mérieux Foundation and the London School of Hygiene & Tropical Medicine (LSHTM) are jointly organizing a 2 hour webinar on September 15 at 3pm (CET) on the critical role of diagnostics in the COVID-19 crisis management to share best practices & lessons learnt from experiences around the world.

Gavi [to 12 Sep 2020]
https://www.gavi.org/
News releases
No new digest content identified.

GHIT Fund [to 12 Sep 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 12 Sep 2020]
News/Updates
COVID-19 Response: Corticosteroids
08 September 2020
Following the World Health Organization guidance Corticosteroids for COVID-19 from 2 September, the Global Fund has confirmed that corticosteroids can be funded through Global Fund grants.

Global Research Collaboration for Infectious Disease Preparedness [GloPID-R] [to 12 Sep 2020]
https://www.glopid-r.org/news/
News
Mérieux Foundation seeks Scientific and Advocacy Director for the GloPID-R Secretariat
01/09/2020
Since 2015, the GloPID-R alliance has been pursuing its objectives to increase preparedness and facilitate rapid research response to outbreaks...

Hilleman Laboratories [to 12 Sep 2020]
http://www.hillemanlabs.org/
No new digest content identified.

Human Vaccines Project [to 12 Sep 2020]
IAVI  [to 12 Sep 2020]
https://www.iavi.org/newsroom
FEATURES
September 8, 2020
IAVI Researchers Publish Study on Antibody Responses to HIV Immunogen in Non-human Primates
Researchers at IAVI’s Neutralizing Antibody Center (NAC), Scripps Research, and other partner organizations have identified and isolated a suite of neutralizing HIV antibodies that develop in rhesus macaques in response to immunization with BG505 SOSIP. This immunogen is the basis of several HIV vaccine candidates now in Phase I clinical trials, including the IAVI W001 trial. Their findings were published in Cell Reports on September 8, 2020...

International Coalition of Medicines Regulatory Authorities [ICMRA]
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 12 Sep 2020]
Selected Press Releases, Announcements
Europe, Greece
Residents of Moria camp must be moved now – Red Cross head
Around 13,000 people are lacking food, water and shelter, after devastating fires on Tuesday and Wednesday this week. At the time of the first fire the camp was under lockdown due to more than 30 COVID19 positive cases.
11 September 2020
Africa, Sudan
Red Cross launches Emergency Appeal for Sudan as deadly flooding leaves thousands homeless

Nairobi/Geneva, 11 September 2020 — The International Federation of Red Cross and Red Crescent Societies (IFRC) today launched an additional funds appeal for 12 million Swiss Francs to support the Sudanese Red Crescent Society (SRCS) in delivering assi ...

11 September 2020

Global

Red Cross Red Crescent turns to Rakuten Viber to fight COVID-19 infodemic

Geneva, 10 September 2020 – The International Federation of Red Cross and Red Crescent Societies (IFRC) and the Croatian Red Cross today signed a new partnership agreement with global messaging app Rakuten Viber to engage new online audiences with trus ...

10 September 2020

Global

Migrants and refugees “least protected, most affected” in COVID crisis, warns IFRC President

Geneva, 10 September 2020 – The COVID-19 pandemic has been a disaster for people from all walks of life, but an absolute “catastrophe” for the world’s vulnerable migrants, people seeking asylum and refugees. Already weak social safety nets are eroding, ...

10 September 2020

Global

IFRC’s first ever virtual climate summit, Climate:Red, is happening everywhere on 9-10 September

Geneva, 8 September 2020 – Climate:Red, a fully virtual and truly global climate change summit, is bringing youth champions, activists, indigenous leaders, scientists and government ministers together on 9 – 10 September 2020 for 30 hours of innovation ...

8 September 2020

IRC International Rescue Committee [to 12 Sep 2020]


Media highlights {Selected}

Press Release

As the threat of resettlement postponement looms, IRC urges the Trump Administration to set refugee admissions cap to at least 95,000 by September 30

September 11, 2020

Press Release

International Rescue Committee’s Pakistan Reading Project Wins 2020 International Prize from the Library of Congress

September 10, 2020

Statement

New UN report details ongoing atrocities in Yemen; IRC calls for immediate ceasefire

September 10, 2020
Press Release

**New Research Finds Lack of Access to Adequate Child Care As One of the Top Barriers to Economic Empowerment for Refugee Women**
September 10, 2020

Press Release

**Over 12,000 people left stranded in Lesvos after a fire engulfs Moria reception centre; IRC providing mental health support to survivors**
September 9, 2020

**IVAC** [to 12 Sep 2020]
https://www.jhsphealth.edu/research/centers-and-institutes/ivac/index.html

*Updates; Events*

**Webinar: Avoiding Barriers to Access for a COVID-19 Vaccine**

Register: The International Vaccine Access Center (IVAC) on September 16, 2020 at 8:00 EDT/21:00 KST will host a 60-minute webinar, “Avoiding Barriers to Access for a COVID-19 Vaccine.”

Description: Even before the COVID-19 pandemic, countries worked to overcome a myriad of challenges when introducing new safe and effective vaccines. While policy makers and health advocates addressed barriers, from understanding disease burden and cost effectiveness to establishing cold chain systems, preventable diseases spread, sicken populations, and cost lives. Learning from the past failures of vaccine introductions will be crucial for ensuring equitable access to a COVID-19 vaccine. Leaders and scientists in the international vaccine field will discuss the barriers to vaccine access we must overcome to avoid and the role the international community will play in promoting equity in delivering a COVID-19 vaccine.

**IVI** [to 12 Sep 2020]
http://www.ivi.int/

*Selected IVI News & Announcements*

**IVI to ready clinical trial sites for COVID-19 vaccine efficacy trials in 4 countries**
September 9, 2020 – SEOUL, South Korea – The International Vaccine Institute (IVI) announced today that the Bill & Melinda Gates Foundation awarded close to 1.5 million USD to IVI to support clinical trial site preparedness in four African and Asian countries to potentially support future COVID-19 Phase III efficacy vaccine trials.

[See COVID-19 above for detail]

**JEE Alliance** [to 12 Sep 2020]
https://www.jeealliance.org/

*Selected News and Events*

No new digest content identified.

**MSF/Médecins Sans Frontières** [to 12 Sep 2020]
http://www.msf.org/
Latest [Selected Announcements]

Myanmar
MSF hands over long-running HIV project in Yangon to ministry of ...
Project Update 10 Sep 2020

Greece
All people in Moria camp must be evacuated to safety in wake of destru...
Project Update 9 Sep 2020

Pakistan
Meeting regular health needs amid the COVID-19 pandemic in...
Project Update 8 Sep 2020

Nigeria
“Children can draw assault rifles better than a football” in Borno state
Interview 8 Sep 2020

National Vaccine Program Office - U.S. HHS [to 12 Sep 2020]
https://www.hhs.gov/vaccines/about/index.html
NVAC Meetings
September 23-24, 2020 Meeting (Virtual)
Selected Agenda Topics:
:: Serving Up Equity: Health-In-All Approaches for COVID-19 Vaccination [Panel]
:: Allocation and Prioritization: Considerations and Recommendations for the Distribution of COVID-19 Vaccines [Dr. Ezekiel Emanuel, University of Pennsylvania; CDC tbd]
:: Perspectives from the Field: Operation Warp Speed [Dr. Moncef Slaoui, HHS]
:: The Infodemic, COVID-19 Immunization, and the Public's Health [Panel]
:: Immunization Information Systems to Support the COVID-19 Response [Panel]

NIH [to 12 Sep 2020]
Selected News Releases

NIH ACTIV initiative launches adaptive clinical trials of blood-clotting treatments for COVID-19
September 10, 2020

The National Institutes of Health has launched two of three adaptive Phase 3 clinical trials evaluating the safety and effectiveness of varying types of blood thinners to treat adults diagnosed with COVID-19. Part of the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) initiative, these trials will be conducted at more than 100 sites around the world and will involve patients in various clinical settings — those who have not been hospitalized, those currently hospitalized and those discharged after hospitalization for moderate to severe disease.

Collectively known as ACTIV-4 Antithrombotics, the trials will provide critical insights that could help guide the care of patients with COVID-19, particularly those who suffer from life-threatening blood clots. The trial for hospitalized COVID-19 patients and the trial for patients with COVID-19 who have not been hospitalized are now underway. A third trial to start later will
focus on patients discharged after hospitalization for moderate to severe COVID-19 disease. All three clinical trials will be coordinated and overseen by the National Heart, Lung, and Blood Institute (NHLBI), part of NIH, and funded through Operation Warp Speed...

**PATH** [to 12 Sep 2020]
https://www.path.org/media-center/
*Press Releases*
No new digest content identified.

**Sabin Vaccine Institute** [to 12 Sep 2020]
http://www.sabin.org/updates/pressreleases
*Statements and Press Releases*
No new digest content identified.

**UNAIDS** [to 12 Sep 2020]
http://www.unaids.org/en
*Selected Press Releases/Reports/Statements*
9 September 2020
Cash donations for people who use drugs during COVID-19 in Bangladesh

**UNICEF** [to 12 Sep 2020]
https://www.unicef.org/media/press-releases
*Selected Press releases/Announcements*
Statement
09/11/2020
**UNICEF statement on children affected by the Moria camp fire on Lesvos Island, Greece**
Statement
09/11/2020
**Polio programme accelerates efforts to respond to new polio outbreaks in Sudan and Yemen**
Joint statement by WHO Regional Director for the Eastern Mediterranean Region Dr Ahmed Al Mandhari and UNICEF Regional Director for the Middle East and North Africa Region Ted Chaiban
Statement
09/10/2020
**UNICEF Executive Director Henrietta Fore’s remarks at the UN Security Council Open Debate on Children and Armed Conflict: Attacks against schools as a grave violation of children’s rights**
This is a summary of what was said by Henrietta Fore, UNICEF Executive Director – to whom quoted text may be attributed – at today’s Security Council Open Debate at the United Nations in New York. Checked against delivery.
Press release
09/10/2020
**The Time to Prepare for COVID-19 Vaccine Transport is Now**
[See COVID-19 above for detail]

Statement
09/10/2020
**Remarks by UNICEF Executive Director Henrietta Fore at the 2020 Executive Board Session**

Press release
09/09/2020
**More than half a million children under five in Burkina Faso are acutely malnourished – UNICEF**

Statement
09/09/2020
**UNICEF statement on fire at Moria Camp in Lesvos, Greece**

Press release
09/08/2020
**COVID-19 could reverse decades of progress toward eliminating preventable child deaths, agencies warn**
With the number of under-five deaths at an all-time recorded low of 5.2 million in 2019, disruptions in child and maternal health services due to the COVID-19 pandemic are putting millions of additional lives at stake

**Unitaid** [to 12 Sep 2020]
https://unitaid.org/
Featured News
No new digest content identified.

**Vaccination Acceptance Research Network (VARN)** [to 12 Sep 2020]
https://vaccineacceptance.org/news.html#header1-2r
Announcements
No new digest content identified.

**Vaccine Confidence Project** [to 12 Sep 2020]
http://www.vaccineconfidence.org/
Research and Reports
No new digest content identified.

**Vaccine Education Center – Children’s Hospital of Philadelphia** [to 12 Sep 2020]
Wellcome Trust  [to 12 Sep 2020]
https://wellcome.ac.uk/news
Explainer | 11 September 2020
Safety first: how to run a Covid-19 vaccine clinical trial
The world is waiting eagerly for Covid-19 vaccines to be developed as quickly as possible. But to make sure they are safe and effective, the clinical trials that test them have to be robust. So how do trials achieve this?

Opinion | 7 September 2020
The first Covid-19 vaccine may not be the magic bullet that returns life to 'normal'
Jeremy Farrar
Director Wellcome
As we'll soon start to see the results of the first vaccines coming through late-stage clinical trials, Jeremy Farrar explains why we should be cautiously optimistic.

The Wistar Institute  [to 12 Sep 2020]
Press Releases
Sep. 10, 2020
Scientists Engineer DNA-based Nanotechnology to Stimulate Potent Antitumor Immune Responses in Preclinical Models
Synthetic DNA nanovaccines enhance killer T cell immunity resulting in tumor control in preclinical studies.

Press Release
Sep. 7, 2020
The BEAT-HIV Martin Delaney Collaboratory Issues Recommendations on Measuring Persistent HIV Reservoirs in Cure-directed Clinical Trials
The consortium provides first authoritative viewpoint on which viral measurements to prioritize when evaluating the impact of potential therapeutic strategies to eradicate HIV.

WFPHA: World Federation of Public Health Associations  [to 12 Sep 2020]
https://www.wfpha.org/
Latest News
No new digest content identified.

World Organisation for Animal Health (OIE)  [to 12 Sep 2020]
Press Releases
No new digest content identified.
PhRMA member companies invested $83 billion in research and development last year
Tim McClung | September 10, 2020 |
PhRMA member companies invested $83 billion in research and development (R&D) in 2019, the highest level of investment on record, according to the 2020 PhRMA member annual survey. Over the past two decades, PhRMA member companies have invested a grand total of nearly $1 trillion in the search for and development of new and better treatments and cures. America’s biopharmaceutical companies are at the heart of a robust R&D ecosystem that develops more innovative medicines than any other country in the world. There are nearly 260 vaccines in development for the treatment or prevention of disease, including numerous different types of potential vaccines that target COVID-19...
**Journal Watch**

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

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

---

**American Journal of Infection Control**
September 2020 Volume 48, Issue 9, p975-1132
[Reviewed earlier]

[http://www.ajicjournal.org/current](http://www.ajicjournal.org/current)

---

**American Journal of Preventive Medicine**
September 2020 Volume 59, Issue 3, p309-468
[Reviewed earlier]

[http://www.ajpmonline.org/current](http://www.ajpmonline.org/current)

---

**American Journal of Public Health**
September 2020 110(9)
[Reviewed earlier]


---

**American Journal of Tropical Medicine and Hygiene**
Volume 103, Issue 3, September 2020
[Reviewed earlier]

[http://www.ajtmh.org/content/journals/14761645/103/3](http://www.ajtmh.org/content/journals/14761645/103/3)

---

**Annals of Internal Medicine**
1 September 2020 Volume 173, Issue 5
[Reviewed earlier]

[http://annals.org/aim/issue](http://annals.org/aim/issue)

---

**Artificial Intelligence – An International Journal**
Volume 287  October 2020
Human germline editing in the era of CRISPR-Cas: risk and uncertainty, inter-generational responsibility, therapeutic legitimacy

Authors: Sebastian Schleidgen, Hans-Georg Dederer, Susan Sgodda, Stefan Cravcisin, Luca Lüneburg, Tobias Cantz and Thomas Heinemann

11 September 2020

Abstract

Background

Clustered Regularly Interspaced Short Palindromic Repeats-associated (CRISPR-Cas) technology may allow for efficient and highly targeted gene editing in single-cell embryos. This possibility brings human germline editing into the focus of ethical and legal debates again.

Main body

Against this background, we explore essential ethical and legal questions of interventions into the human germline by means of CRISPR-Cas: How should issues of risk and uncertainty be handled? What responsibilities arise regarding future generations? Under which conditions can germline editing measures be therapeutically legitimized? For this purpose, we refer to a scenario anticipating potential further development in CRISPR-Cas technology implying...
improved accuracy and exclusion of germline transmission to future generations. We show that, if certain concepts regarding germline editing are clarified, under such conditions a categorical prohibition of one-generation germline editing of single-cell embryos appears not to be ethically or legally justifiable.

Conclusion
These findings are important prerequisites for the international debate on the ethical and legal justification of germline interventions in the human embryo as well as for the harmonization of international legal standards.

BMC Medicine
http://www.biomedcentral.com/bmcmed/content
(Accessed 12 Sep 2020)
Preparing for a pandemic: highlighting themes for research funding and practice—perspectives from the Global Research Collaboration for Infectious Disease Preparedness (GloPID-R)
The Global Research Collaboration for Infectious Disease Preparedness (GloPID-R) is an international network of global health funders and stakeholders formed in 2013 to ensure preparedness for a coordinated research response to epidemics and pandemics [1]. GloPID-R aims to address challenges to effective research in epidemics and pandemics, through both preparedness and response activities.
Authors: Alice Norton, Louise Sigfrid, Adeniyi Aderoba, Naima Nasir, Peter G. Bannister, Shelui Collinson, James Lee, Geneviève Boily-Larouche, Josephine P. Golding, Evelyn Depoortere, Gail Carson, Barbara Kerstiens and Yazdan Yazdanpanah
Citation: BMC Medicine 2020 18:273
Content type: Commentary
Published on: 8 September 2020

BMC Pregnancy and Childbirth
http://www.biomedcentral.com/bmcpregnancychildbirth/content
(Accessed 12 Sep 2020)
[No new digest content identified]

BMC Public Health
http://bmcpublichealth.biomedcentral.com/articles
(Accessed 12 Sep 2020)
Targeted vaccination campaigns of teenagers after two clusters of B invasive meningococcal disease in Brittany, France, 2017
In December 2016, three cases of serogroup B invasive meningococcal disease, including two children from the same middle school (11 to 15 years old pupils), occurred in the department (administrative district)...
Authors: Mathilde Pivette, Muhamed-Kheir Taha, Anne-Sophie Barret, Elisabeth Polard, Marie-Bernadette Hautier, Jean-Benoît Dufour, Marlène Faisant, Lisa Antoinette King, Denise Antona, Daniel Levy-Bruhl, Hélène Tillaut, Alexandre Scanff, Camille Morival, José-Hector Aranda Grau, Pierre Guillaumot and Bertrand Gagnière
Citation: BMC Public Health 2020 20:1382
Impact of an influenza information pamphlet on vaccination uptake among Polish pupils in Edinburgh, Scotland and the role of social media in parental decision making

In Edinburgh, Scotland, lower influenza vaccine uptake has been observed in primary school children in the Polish community.

Authors: K. Bielecki, J. Craig, L. J. Willocks, K. G. Pollock and D. R. Gorman
Citation: BMC Public Health 2020 20:1381
Content type: Research article
Published on: 10 September 2020

Impact of quadrivalent influenza vaccines in Brazil: a cost-effectiveness analysis using an influenza transmission model

Influenza epidemics significantly weight on the Brazilian healthcare system and its society. Public health authorities have progressively expanded recommendations for vaccination against influenza, particular...

Authors: Pascal Crépey, Louis Boiron, Rafael Rodrigo Araujo, Juan Guillermo Lopez, Audrey Petitjean and Expedito José de Albuquerque Luna
Citation: BMC Public Health 2020 20:1374
Content type: Research article
Published on: 9 September 2020

BMC Research Notes
http://www.biomedcentral.com/bmcresnotes/content
(Accessed 12 Sep 2020)
[No new digest content identified]

BMJ Open
August 2020 - Volume 10 – 8-9
https://bmjopen.bmj.com/content/10/8?current-issue=y
[Reviewed earlier]

Bulletin of the World Health Organization
Volume 98, Number 9, September 2020, 581-644
https://www.who.int/bulletin/volumes/98/9/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]
Conflict and Health
http://www.conflictandhealth.com/
[Accessed 12 Sep 2020]

Addressing COVID-19 in humanitarian settings: a call to action
Authors: Jude Alawa, Nawara Alawa, Adam Coutts, Richard Sullivan, Kaveh Khoshnood and Fouad M. Fouad
Citation: Conflict and Health 2020 14:64
Content type: Commentary
Published on: 10 September 2020

Abstract
Refugees and internally displaced persons in humanitarian settings are particularly susceptible to the spread of infectious illnesses such as COVID-19 due to overcrowding and inadequate access to clean water, sanitation, and hygiene facilities. Countries facing conflict or humanitarian emergencies often have damaged or fragmented health systems and little to no capacity to test, isolate, and treat COVID-19 cases. Without a plan to address COVID-19 in humanitarian settings, host governments, aid agencies, and international organizations risk prolonging the spread of the virus across borders, threatening global health security, and devastating vulnerable populations. Stakeholders must coordinate a multifaceted response to address COVID-19 in humanitarian settings that incorporates appropriate communication of risks, sets forth resource-stratified guidelines for the use of limited testing, provides resources to treat affected patients, and engages displaced populations.
The CRISPR Journal
Volume 3, Issue 4 / August 2020
https://www.liebertpub.com/toc/crispr/3/4
[Reviewed earlier]

Current Genetic Medicine Reports
Volume 8, issue 3, September 2020
[Reviewed earlier]

Current Opinion in Infectious Diseases
October 2020 - Volume 33 - Issue 5
https://journals.lww.com/co-infectiousdiseases/pages/currenttoc.aspx
[New issue; No digest content identified]

Developing World Bioethics
Volume 20, Issue 3 Pages: 115-171 September 2020
https://onlinelibrary.wiley.com/toc/14718847/current
[New issue; No digest content identified]

Development in Practice
Volume 30, Issue 5, 2020
http://www.tandfonline.com/toc/cdip20/current
[Reviewed earlier]

Disaster Medicine and Public Health Preparedness
Volume 14 - Issue 2 - April 2020
https://www.cambridge.org/core/journals/disaster-medicine-and-public-health-preparedness/latest-issue
[Reviewed earlier]

Disasters
Volume 44, Issue 4 Pages: 619-752 October 2020
https://onlinelibrary.wiley.com/toc/14677717/current
[New issue; No digest content identified]

EMBO Reports
Volume 21 Issue 9 3 September 2020
https://www.embopress.org/toc/14693178/current
[Reviewed earlier]
Emerging Infectious Diseases
Volume 26, Number 9—September 2020
http://wwwnc.cdc.gov/eid/
[Reviewed earlier]

Epidemics
Volume 32   September 2020
[Reviewed earlier]

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

Ethics & Human Research
Volume 42, Issue 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 4, August 2020
https://academic.oup.com/eurpub/issue/30/4
[Reviewed earlier]

Expert Review of Vaccines
Vol 19 (7) 2020
https://www.tandfonline.com/toc/ierv20/current
[Reviewed earlier]

Gates Open Research
https://gatesopenresearch.org/browse/articles
[Accessed 12 Sep 2020]
[No new digest content identified]

Genome Medicine
https://genomemedicine.biomedcentral.com/articles
[Accessed 12 Sep 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 9
http://www.tandfonline.com/toc/rgph20/current
[Reviewed earlier]

Globalization and Health
http://www.globalizationandhealth.com/
Articles
Disease burden metrics and the innovations of leading pharmaceutical companies: a global and regional comparative study
The recent innovation activities of global top-tier pharmaceutical companies in accordance with global and regional health concerns were investigated in order to identify their innovations contributing to popu...
Authors: Ye Lim Jung, JeeNa Hwang and Hyoung Sun Yoo
Citation: Globalization and Health 2020 16:80
Content type: Research
Published on: 10 September 2020

Health Affairs
Vol. 39, No. 9 September 2020
https://www.healthaffairs.org/toc/hlthaff/current
Medicare Payment Incentives, Medicaid & More
Research Article Global Health Policy
Restrictions On US Global Health Assistance Reduce Key Health Services In Supported Countries
Jennifer Sherwood, Matthea Roemer, Brian Honermann, Austin Jones, Greg Millett, and Michele R. Decker
Research Article COVID-19
Designing Pull Funding For A COVID-19 Vaccine
Christopher M. Snyder, Kendall Hoyt, Dimitrios Gougias, Thomas Johnston, and James Robinson
Health and Human Rights
Volume 22, Issue 1, June 2020

Special Section: Mental Health and Human Rights
[Reviewed earlier]

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

Article

Andrew J. Leidner, Harrell W. Chesson, Makram Talih

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 12 Sep 2020]
[No new digest content identified]

Human Gene Therapy
Volume 31, Issue 15-16 / August 2020
https://www.liebertpub.com/toc/hum/31/15-16
[Reviewed earlier]

Humanitarian Exchange Magazine
Number 77, March 2020

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 Asuncar 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 12 Sep 2020]
[No new digest content identified]

**Infectious Diseases of Poverty**
http://www.idpjournal.com/content
[Accessed 12 Sep 2020]
[No new digest content identified]

**International Health**
Volume 12, Issue 5, September 2020
https://academic.oup.com/inthealth/issue/12/5
[Reviewed earlier]

**International Journal of Community Medicine and Public Health**
JAMA Network  
**COVID-19 Update September 12, 2020**  
These articles on COVID-19 were published across the JAMA Network in the last week.

**JAMA**  
September 8, 2020, Vol 324, No. 10, Pages 919-1016  
https://jamanetwork.com/journals/jama/currentissue  

**Preliminary Communication**  
**Effect of an Inactivated Vaccine Against SARS-CoV-2 on Safety and Immunogenicity Outcomes - Interim Analysis of 2 Randomized Clinical Trials**  
Shengli Xia, BS; Kai Duan, PhD; Yuntao Zhang, PhD; et al.  
free access has active quiz  
This interim analysis of 2 randomized trials compares adverse reactions and neutralizing antibody responses to inactivated coronavirus disease 2019 (COVID-19) vs adjuvant-only control vaccination, and compares the outcomes at varying vaccine doses among healthy adults in China.  
...Conclusions and Relevance In this interim report of the phase 1 and phase 2 trials of an inactivated COVID-19 vaccine, patients had a low rate of adverse reactions and demonstrated immunogenicity; the study is ongoing. Efficacy and longer-term adverse event assessment will require phase 3 trials.  
Trial Registration Chinese Clinical Trial Registry Identifier: ChiCTR2000031809
Editorial

An Inactivated Virus Candidate Vaccine to Prevent COVID-19
Mark J. Mulligan, MD

... In summary, this preliminary report by Xia et al10 provides important interim safety, tolerability, and immune response results for a β-propiolactone–inactivated whole-virus vaccine against COVID-19. These interim data are of interest given the urgent global need for protective COVID-19 vaccines. With 7.8 billion individuals worldwide at risk for SARS-CoV-2 infection and COVID-19 morbidity and mortality, humanity needs as many safe and protective COVID-19 vaccines as possible.

Viewpoint

Unwavering Regulatory Safeguards for COVID-19 Vaccines
Anand Shah, MD; Peter W. Marks, MD, PhD; Stephen M. Hahn, MD

This Viewpoint from the FDA reviews the minimum safety and efficacy standards COVID-19 vaccine candidates would need to meet to be considered for approval, and affirms its commitments to evaluating both in diverse populations and to postmarketing surveillance as means to ensure that approval will meet the highest safety and regulatory standards based on science and evidence, not politics.

Improving Physician Communication About Treatment Decisions - Reconsideration of “Risks vs Benefits”
Daniel J. Morgan, MD; Laura D. Scherer, PhD; Deborah Korenstein, MD

This Viewpoint emphasizes the importance of precise language to help patients make evidence-informed decisions in shared decision-making, and argues that references to “chances of harms and benefits” will be more understandable to patients than discussions of “probabilities of risks and benefits.”

Conversations with Dr Bauchner: Changing Language to Improve Physician Communication About Treatment Decisions

JAMA Pediatrics

September 2020, Vol 174, No. 9, Pages 815-916
http://archpedi.jamanetwork.com/issue.aspx

Viewpoint

Inclusion of Children in Clinical Trials of Treatments for Coronavirus Disease 2019 (COVID-19)
Thomas J. Hwang, AB; Adrienne G. Randolph, MD, MSc; Florence T. Bourgeois, MD, MPH

This Viewpoint discusses the exclusion of children from coronavirus disease 2019 (COVID-19) clinical trials and why that could harm treatment options for children.

Original Investigation
Incidence of Meningococcal Disease Before and After Implementation of Quadrivalent Meningococcal Conjugate Vaccine in the United States
Sarah Mbaeyi, MD, MPH; Tracy Pondo, MSPH; Amy Blain, MPH; et al.
This cohort study examines the association between quadrivalent meningococcal conjugate vaccination and the incidence of meningococcal disease in US adolescents.

Association Between Human Papillomavirus Vaccination School-Entry Requirements and Vaccination Initiation
Jamie S. Ko, MPH; Cameron S. Goldbeck, MS; Eleonore B. Baughan, BS; et al.
This cross-sectional study examines initiation of human papillomavirus vaccination in US jurisdictions with vs those without policies requiring vaccination for school entry.

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
https://www.jahonline.org/issue/S1054-139X(20)X0009-7
[New issue; No digest content identified]

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
Special Section on Child Development in India
[Reviewed earlier]

Journal of Empirical Research on Human Research Ethics
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
September 2020 - Volume 46 - 9
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
September 2020 Volume 224, p1-194
http://www.jpeds.com/current
The Editors' Perspectives
COVID-19: A teachable moment for vaccines and trust
Sarah S. Long
Published in issue: September 2020

Original Articles
Evaluation of a Vaccine-Communication Tool for Physicians
Julia R. Glanternik, Julia C. McDonald, Arnold H. Yee, Amanda Howell BA, Katrina N. Saba, R. Grant Mellor, Bruce Fireman, Nicola P. Klein
p72–78.e1
Published online: June 6, 2020

Commentary
Caring for the Vaccine-Hesitant Family: Evidence-Based Alternatives to Dismissal
Joshua T.B. Williams, Sean T. O'Leary, Abraham M. Nussbaum
p137–140
Published online: May 21, 2020

Journal of Pharmaceutical Policy and Practice
https://joppp.biomedcentral.com/
[Accessed 12 Sep 2020]
Commentary
The Urgent Need for Transparent and Accountable Procurement of Medicine and Medical Supplies in Times of COVID-19 Pandemic
Authors: Jillian Clare Kohler and Tom Wright
11 September 2020

Abstract
The COVID-19 pandemic has unleashed unprecedented and complex public policy issues. One that has emerged as a challenge for many countries globally is how to ensure the efficient and effective procurement of quality medical supplies. Existing corruption pressures on procurement—everything from undue influence to the outright bribery of public officials—has been amplified by the pandemic, and thus demands commensurate policy responses. We argue that transparency and accountability in procurement are essential to preventing the corruption risks that threaten the health and well-being of populations.

Journal of Public Health Management & Practice
September/October 2020 - Volume 26 - Issue 5
https://journals.lww.com/jphmp/pages/currenttoc.aspx
[Reviewed earlier]

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

Journal of Refugee & Global Health
https://ir.library.louisville.edu/rgh/
[Reviewed earlier]

Journal of the Royal Society – Interface
September 2020 Volume 17 Issue 170
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
[Reviewed earlier]

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

Global collaboration for health: rhetoric versus reality
The Lancet
[See Milestones above for full text]

Comment

COVID-19 vaccine trials should seek worthwhile efficacy
Philip Krause, Thomas R Fleming, Ira Longini, Ana Maria Henao-Restrepo, Richard Peto for the World Health Organization Solidarity Vaccines Trial Expert Group

The Lancet Child & Adolescent Health
Aug 2020 Volume 4 Number 8 p555-640, e26-e34
https://www.thelancet.com/journals/lanchi/issue/current

Review

Chronic comorbidities in children and adolescents with perinatally acquired HIV infection in sub-Saharan Africa in the era of antiretroviral therapy
Lisa J Frigati, et al

Lancet Digital Health
Sep 2020 Volume 2 Number 9 e441-e492
https://www.thelancet.com/journals/landig/issue/current

Comment

Approaching autonomy in medical artificial intelligence
Danielle S Bitterman, Hugo J W L Aerts, Raymond H Mak

Viewpoint

The myth of generalisability in clinical research and machine learning in health care
Joseph Futoma, Morgan Simons, Trishan Panch, Finale Doshi-Velez, Leo Anthony Celi

Lancet Global Health
Sep 2020 Volume 8 Number 9 e1101-e1241
http://www.thelancet.com/journals/langlo/issue/current

Editorial

Water and sanitation in a post-COVID world
The Lancet Global Health

Articles

Potential impact of the COVID-19 pandemic on HIV, tuberculosis, and malaria in low-income and middle-income countries: a modelling study
Alexandra B Hogan, et al
Summary

Background
COVID-19 has the potential to cause substantial disruptions to health services, due to cases overburdening the health system or response measures limiting usual programmatic activities. We aimed to quantify the extent to which disruptions to services for HIV, tuberculosis, and malaria in low-income and middle-income countries with high burdens of these diseases could lead to additional loss of life over the next 5 years.

Methods
Assuming a basic reproduction number of 3·0, we constructed four scenarios for possible responses to the COVID-19 pandemic: no action, mitigation for 6 months, suppression for 2 months, or suppression for 1 year. We used established transmission models of HIV, tuberculosis, and malaria to estimate the additional impact on health that could be caused in selected settings, either due to COVID-19 interventions limiting activities, or due to the high demand on the health system due to the COVID-19 pandemic.

Findings
In high-burden settings, deaths due to HIV, tuberculosis, and malaria over 5 years could increase by up to 10%, 20%, and 36%, respectively, compared with if there was no COVID-19 pandemic. The greatest impact on HIV was estimated to be from interruption to antiretroviral therapy, which could occur during a period of high health system demand. For tuberculosis, the greatest impact would be from reductions in timely diagnosis and treatment of new cases, which could result from any prolonged period of COVID-19 suppression interventions. The greatest impact on malaria burden could be as a result of interruption of planned net campaigns. These disruptions could lead to a loss of life-years over 5 years that is of the same order of magnitude as the direct impact from COVID-19 in places with a high burden of malaria and large HIV and tuberculosis epidemics.

Interpretation
Maintaining the most critical prevention activities and health-care services for HIV, tuberculosis, and malaria could substantially reduce the overall impact of the COVID-19 pandemic.

Funding
Bill & Melinda Gates Foundation, Wellcome Trust, UK Department for International Development, and Medical Research Council.

Mapping geographical inequalities in access to drinking water and sanitation facilities in low-income and middle-income countries, 2000–17
Local Burden of Disease WaSH Collaborators

Real-world effectiveness of rotavirus vaccines, 2006–19: a literature review and meta-analysis
Eleanor Burnett, Umesh D Parashar, Jacqueline E Tate

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

Editorial
Air travel in the time of COVID-19
The Lancet Infectious Diseases
Comment

**Vaccine development during global epidemics: the Zika experience**
Priscila M S Castanha, Ernesto T A Marques

**Sequential inactivated and oral poliovirus vaccine schedules: a balancing act**
Khalequ Zaman, Abhijeet Anand

Articles

**Safety and immunogenicity of a Zika purified inactivated virus vaccine given via standard, accelerated, or shortened schedules: a single-centre, double-blind, sequential-group, randomised, placebo-controlled, phase 1 trial**
Kathryn E Stephenson, et al

**Immunogenicity of three sequential schedules with Sabin inactivated poliovirus vaccine and bivalent oral poliovirus vaccine in Zhejiang, China: an open-label, randomised, controlled trial**
Hanqing He, et al

**Lancet Public Health**
Sep 2020 Volume 5 Number 9 e460-e511
https://www.thelancet.com/journals/lanpub/issue/current

**Editorial**

**Will the COVID-19 pandemic threaten the SDGs?**
The Lancet Public Health

Comment

**Communications to improve intention to receive HPV vaccine**
Robert A Bednarczyk

Articles

**Parental intent to initiate and complete the human papillomavirus vaccine series in the USA: a nationwide, cross-sectional survey**
Kalyani Sonawane, Yenan Zhu, Jane R Monteagle, David R Lairson, Cici Bauer, Lindy U McGee, Anna R Giuliano, Ashish A Deshmukh

**Lancet Respiratory Medicine**
Sep 2020 Volume 8 Number 9 p831-934, e70-e72
http://www.thelancet.com/journals/lanres/issue/current

[New issue; No digest content identified]

**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 6, August 2020
http://mdm.sagepub.com/content/current
[Reviewed earlier]

The Milbank Quarterly
A Multidisciplinary Journal of Population Health and Health Policy
Volume 98, Issue 3 Pages: 619-1020 September 2020
https://onlinelibrary.wiley.com/toc/14680009/current
Perspectives  Free Access
Population Health in the Time of COVID-19: Confirmations and Revelations
ANA V. DIEZ ROUX
Pages: 629-640
First Published: 18 August 2020
Milbank Quarterly Classics

Revisiting Compression of Morbidity and Health Disparities in the 21st Century
PAULA M. LANTZ
Pages: 664-667
First Published: 18 August 2020

Nature
Volume 585 Issue 7824, 10 September 2020
http://www.nature.com/nature/current_issue.html
Comment / 08 September 2020
Don’t ignore genetic data from minority populations
Efforts to build representative studies are defeated when scientists discard data from certain groups. Instead, researchers should work to balance statistical needs with fairness.
Chief Ben-Eghan, Rosie Sun[...]
Simon Gravel

Review Article | 09 September 2020
Illuminating the dark spaces of healthcare with ambient intelligence
Albert Haque, Arnold Milstein & Li Fei-Fei
Abstract
Advances in machine learning and contactless sensors have given rise to ambient intelligence—physical spaces that are sensitive and responsive to the presence of humans. Here we review how this technology could improve our understanding of the metaphorically dark, unobserved spaces of healthcare. In hospital spaces, early applications could soon enable more efficient clinical workflows and improved patient safety in intensive care units and operating rooms. In daily living spaces, ambient intelligence could prolong the independence of older individuals and improve the management of individuals with a chronic disease by understanding everyday behaviour. Similar to other technologies, transformation into clinical applications at scale must overcome challenges such as rigorous clinical validation, appropriate data privacy and model
transparency. Thoughtful use of this technology would enable us to understand the complex interplay between the physical environment and health-critical human behaviours.

**Nature Biotechnology**
Volume 38 Issue 9, 1 September 2020  
https://www.nature.com/nbt/volumes/38/issues/9  
*Editorial* | 28 August 2020  
Thank you for sharing  
The pandemic has highlighted long-standing, deep-rooted challenges to the sharing of biological samples. Greater attention is needed to mechanisms for incentivizing materials transfer.

**News** | 04 September 2020  
Massive data initiatives and AI provide testbed for pandemic forecasting  
Initiatives to gather massive epidemiological datasets aim to cut through national COVID-19 stats in a bid to understand the new coronavirus and aid public health policymakers.  
Cormac Sheridan

**Nature Communications**  
https://www.nature.com/subjects/health-sciences/ncomms  
(Accessed 12 Sep 2020)  
[No new digest content identified]

**Nature Genetics**  
Volume 52 Issue 9, 1 September 2020  
https://www.nature.com/ng/volumes/52/issues/9  
[New issue; No digest content identified]

**Nature Medicine**  
Volume 26 Issue 9, 1 September 2020  
https://www.nature.com/nm/volumes/26/issues/9  
*Guidelines for AI in clinical trials*  
The image on the cover illustrates the potential of artificial intelligence (AI) to enhance healthcare delivery. In this issue, new extensions of SPIRIT and CONSORT guidelines dedicated to randomized clinical trials involving AI delineate the reporting standards for these interventions, and Nimri and colleagues report the results of a randomized clinical trial evaluating the performance of an AI for optimizing insulin dosing in patients with type 1 diabetes.

*Editorial* | 09 September 2020  
Setting guidelines to report the use of AI in clinical trials  
Delivering the potential of artificial intelligence in clinical decision-making will require testing interventions in well-designed randomized clinical trials and reporting these results in a standardized and transparent fashion.
Artificial intelligence (AI) methods developed in the past decades have made invaluable contributions to biomedical research. Recent technological progress in machine learning and deep learning algorithms, and their application in solving clinical questions, are expanding the possibilities for enhancing healthcare delivery and hold great promise for transforming clinical research. Several proof-of-concept studies have illustrated the capacity of these models, when trained on sufficiently large datasets, to attain image-based diagnosis accuracy compatible with clinical applications or to select optimal treatment regimens for hospitalized patients, among other tasks. However, the utility of most of these algorithms remain largely theoretical, and they have mostly been tested in controlled settings that cannot recapitulate the complexities of the real world.

At this crossroads, when the value of AI approaches for patient management is put to the test, it is crucial that steps be taken to ensure the highest quality in the reporting of prospective randomized clinical trials that involve AI-based interventions. With this goal in mind, the CONSORT-AI and SPIRIT-AI Steering Groups coordinated a Delphi process involving multiple stakeholders — trialists, statisticians, clinical and translational researchers, patients, regulators and editors — to elaborate specific guidelines aimed at increasing transparency of study protocols and reporting for randomized clinical trials involving AI. The resulting checklists, CONSORT-AI and SPIRIT-AI, published in this issue along with their respective explanatory documents, represent an extension to the parental CONSORT and SPIRIT guidelines that have raised the impact and quality of study protocols and reporting for randomized clinical trials.

The new extensions incorporate a series of items that were inadequately covered or not covered at all by current guidance, such as how AI is integrated in the clinical pathway or aspects related to code availability or assessment of performance. As with the original clinical guidelines, the CONSORT-AI and SPIRIT-AI extensions provide a set of principles in a burgeoning field of research, and will evolve and be revised as technological advances and clinical needs require. We at Nature Medicine consider it crucial to follow a standardized, transparent and rigorous report procedure for AI interventions in clinical research to ensure the correct steps are taken and the field advances in the right direction. Therefore, consistent with our mission to nurture high-quality reporting of clinical research, we endorse the CONSORT-AI and SPIRIT-AI guidelines and will require that submissions of manuscripts describing the results of clinical trials using AI algorithms in the clinical decision-making process be reported in accordance with these standards. An example using the CONSORT-AI extension can be seen in the ADVICE4U study in this issue — a randomized non-inferiority trial comparing insulin dosing for youths with type 1 diabetes calculated by an AI-based decision-support system with that of physicians. The study has been reported in accordance with the new guidelines, including completion of the CONSORT-AI checklist.

In the process of elaborating the extensions, it became clear that the incorporation of AI technologies in clinical care also creates new challenges that will need to be overcome to narrow the gap between simulated and real-world medical AI. Some of these challenges are tackled in a series of commissioned Comments in this issue. Eric Topol provides a snapshot of where medical AI stands and highlights the limitations and challenges that these algorithms and study designs need to overcome to be effectively implemented in clinical care. Melissa McCradden and colleagues propose a step-wise process to ensure a positive impact of this technology in patient care, which includes considerations of data access and protection, model performance and deployment, and oversight. For these models to ensure safety and fairness in
clinical care, it is also essential that the design of algorithms be devoid of any bias that might introduce structural inequity in the predictions, as Kellie Owens and Alexis Walker write. Similarly, Atul Butte and colleagues also propose a framework, the MICLAIM guidelines, describing the minimal reporting elements that are required for ensuring the transparency, reproducibility and utility of AI algorithms in medicine.

Clinical research is on the brink of a new phase where innovation has enormous potential to bring new opportunities for advancing healthcare delivery. There are, however, risks that need to be anticipated, and necessary steps must be taken to ensure that AI-enabled solutions prioritize the needs of all patients and, in doing so, earn the trust of users. The CONSORT-AI and SPIRIT-AI guidelines lay the foundation for a responsible and transparent evaluation of these tools, and we look forward to seeing how the promise of AI-enhanced healthcare will be fulfilled.

Comment | 09 September 2020
Welcoming new guidelines for AI clinical research
With only a limited number of clinical trials of artificial intelligence in medicine thus far, the first guidelines for protocols and reporting arrive at an opportune time. Better protocol design, along with consistent and complete data presentation, will greatly facilitate interpretation and validation of these trials, and will help the field to move forward.
Eric J. Topol

Comment | 09 September 2020
Minimum information about clinical artificial intelligence modeling: the MI-CLAIM checklist
Here we present the MI-CLAIM checklist, a tool intended to improve transparent reporting of AI algorithms in medicine.
Beau Norgeot, Giorgio Quer[...] & Atul J. Butte

Comment | 09 September 2020
Clinical research underlies ethical integration of healthcare artificial intelligence
Familiar concepts from research ethics can guide the meaningful and rigorous translation of artificial intelligence (AI) tools into clinical practice.
Melissa D. McCradden, Elizabeth A. Stephenson & James A. Anderson

Comment | 09 September 2020
Those designing healthcare algorithms must become actively anti-racist
Many widely used health algorithms have been shown to encode and reinforce racial health inequities, prioritizing the needs of white patients over those of patients of color. Because automated systems are becoming so crucial to access to health, researchers in the field of artificial intelligence must become actively anti-racist. Here we list some concrete steps to enable anti-racist practices in medical research and practice.
Kellie Owens & Alexis Walker

Comment | 10 July 2020
The ethics of deferred consent in times of pandemics
In the current COVID-19 pandemic, many researchers are applying to research ethics committees for deferred-consent procedures for protocols that aim either to test treatments or
to obtain tissue or samples from research participants. However, the deferred-consent procedure has not been developed for pandemics. In this Comment, we interpret existing guidance documents and argue when and under which conditions deferred consent can be considered ethically acceptable in a pandemic.
Rieke van der Graaf, Marie-Astrid Hoogerwerf & Martine C. de Vries

**Consensus Statements**

Consensus Statement | 09 September 2020 | Open Access

**Guidelines for clinical trial protocols for interventions involving artificial intelligence: the SPIRIT-AI extension**
The CONSORT-AI and SPIRIT-AI extensions improve the transparency of clinical trial design and trial protocol reporting for artificial intelligence interventions.
Samantha Cruz Rivera, Xiaoxuan Liu & Samuel Rowley

Consensus Statement | 09 September 2020 | Open Access

**Reporting guidelines for clinical trial reports for interventions involving artificial intelligence: the CONSORT-AI extension**
The CONSORT-AI and SPIRIT-AI extensions improve the transparency of clinical trial design and trial protocol reporting for artificial intelligence interventions.
Xiaoxuan Liu, Samantha Cruz Rivera & Samuel Rowley

**Nature Reviews Genetics**

Volume 21 Issue 9, 1 September 2020
https://www.nature.com/nrg/volumes/21/issues/9

**Comment | 29 June 2020**

**How digital tools can advance quality and equity in genomic medicine**
As highlighted by the COVID-19 pandemic, digital solutions are becoming essential for the provision of clinical genetics services. However, as this Comment emphasizes, the use of digital tools alone can exacerbate genomic and technological disparities and must be balanced with the merits of face-to-face interactions.
Yvonne Bombard & Robin Z. Hayeems

**Nature Reviews Immunology**

Volume 20 Issue 9, 1 September 2020
https://www.nature.com/nri/volumes/20/issues/9

**Research Highlight | 04 August 2020**

**An RNA vaccine for advanced melanoma**
An RNA vaccine targeting tumour-associated antigens promotes T cell immunity in patients with advanced melanoma.
Yvonne Bordon

**Nature Reviews Drug Discovery**

Volume 19 Issue 9, 1 September 2020
https://www.nature.com/nrd/volumes/19/issues/9

**Perspective | 06 August 2020**
**Antitumour dendritic cell vaccination in a priming and boosting approach**

Dendritic cell vaccines have been widely investigated as a type of cancer immunotherapy, but their promise has not yet been realized. Kandalaft and colleagues propose that a prime and boost approach — primed with either standard therapies or dendritic cell vaccines and boosted with a personalized synthetic vaccine — could help fulfil the potential of such vaccines. They discuss improvements in dendritic cell vaccines that have enabled prime–boost approaches, as well as challenges for adoption.

Alexandre Harari, Michele Graciotti [...] & Lana E. Kandalaft

---

**New England Journal of Medicine**

September 10, 2020  Vol. 383 No. 11

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

*Perspective*

Fundamentals of U.S. Health Policy

**Health Equity — Are We Finally on the Edge of a New Frontier?**

Michele K. Evans, M.D.

---

**Pediatrics**

Vol. 146, Issue 3  1 Sep 2020

https://pediatrics.aappublications.org/

*Pediatrics Perspectives*

**Interference With Pertussis Vaccination in Infants After Maternal Pertussis Vaccination**

Bahaa Abu-Raya, Kathryn M. Edwards

Pediatrics, Sep 2020, 146 (3) e20193579

---

**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 12 Sep 2020)

[No new digest content identified]

---

**PLoS Medicine**
Changes in the HIV continuum of care following expanded access to HIV testing and treatment in Indonesia: A retrospective population-based cohort study
Yane N. Tarigan, Richard J. Woodman, Emma R. Miller, Rudi Wisaksana, F. Stephen Wignall, Paul R. Ward
Research Article | published 11 Sep 2020 PLOS ONE
https://doi.org/10.1371/journal.pone.0239041

Bringing the path toward an HIV-1 vaccine into focus
Cesar J. Lopez Angel, Georgia D. Tomaras
Pearls | published 10 Sep 2020 PLOS Pathogens
https://doi.org/10.1371/journal.ppat.1008663

Improving data access democratizes and diversifies science
Abhishek Nagaraj, Esther Shears, and Mathijs de Vaan
PNAS first published September 8, 2020.
https://doi.org/10.1073/pnas.2001682117
Social media engagement association with human papillomavirus and vaccine awareness and perceptions: Results from the 2017 US Health Information National Trends Survey
Brittany L. Rosen, Christopher Wheldon, Erika L. Thompson, Sarah Maness, Philip M. Massey
Article 106151

Proceedings of the Royal Society B
09 September 2020 Volume 287 Issue 1934
https://royalsocietypublishing.org/toc/rspb/current

Review article   Abstract only
The promise of big data for precision population health management in the US
A. Han, A. Isaacson, P. Muennig

Public Health Ethics
IN PROGRESS
Volume 13, Issue 1, April 2020
http://phe.oxfordjournals.org/content/current

Public Health Reports
Volume 135 Issue 5, September/October 2020
https://journals.sagepub.com/toc/phrg/135/5

Trends in Childhood Influenza Vaccination Coverage, United States, 2012-2019
Tammy A. Santibanez, PhD, Anup Srivastav, PhD, Yusheng Zhai, MSPH, James A. Singleton, PhD
First Published August 12, 2020; pp. 640–649

Qualitative Health Research
The panorama of human phenotypes arises from a mix of common and rare genetic variants, some of which affect how genes are expressed and spliced throughout the body. More than a decade ago, scientists aiming to better understand the effects of genetic diversity in healthy individuals launched the Genotype-Tissue Expression (GTEx) Consortium. Here, Science unveils
the third and final phase of the project, presenting the results from the analysis of the version 8 (v8) GTEx release.

The v8 data release includes an increased number of tissues and individuals, which allows for more accurate mapping of putatively causal variants and identifies cell type–specific differences in gene expression. The increased size of the study also provides the power to link genetic variation to gene expression, both proximally and distally in the genome, so that cis and trans effects as well as population- and sex-specific differences in gene expression can be detected.

The efforts of the GTEx Consortium have led to the development of numerous tools, including Watershed, and have provided a comprehensive resource for the scientific community. The GTEx project has established a foundation to elucidate how genetic variants affect gene regulation and quantitative traits in humans. Such studies of genetic variation and tissue specificity inform on properties of the genome—including noncoding elements and the telomeres found at chromosome ends—and help us understand how gene variants influence aging and disease. This work sets the stage for future exploration into the effects of the common and rare variants that underlie the gamut of humanity.

Policy Forum
An ethical framework for global vaccine allocation
Science11 Sep 2020 : 1309-1312

The Fair Priority Model offers a practical way to fulfill pledges to distribute vaccines fairly and equitably

Summary
Once effective coronavirus disease 2019 (COVID-19) vaccines are developed, they will be scarce. This presents the question of how to distribute them fairly across countries. Vaccine allocation among countries raises complex and controversial issues involving public opinion, diplomacy, economics, public health, and other considerations. Nevertheless, many national leaders, international organizations, and vaccine producers recognize that one central factor in this decision-making is ethics (1, 2). Yet little progress has been made toward delineating what constitutes fair international distribution of vaccine. Many have endorsed “equitable distribution of COVID-19...vaccine” without describing a framework or recommendations (3, 4). Two substantive proposals for the international allocation of a COVID-19 vaccine have been advanced, but are seriously flawed. We offer a more ethically defensible and practical proposal for the fair distribution of COVID-19 vaccine: the Fair Priority Model.

Science Translational Medicine
09 September 2020 Vol 12, Issue 560
https://stm.sciencemag.org/

[New issue; No digest content identified]

Social Science & Medicine
The ethics of AI in health care: A mapping review
Jessica Morley, Caio C.V. Machado, Christopher Burr, Josh Cowls, ... Luciano Floridi
Article 113172

Abstract
This article presents a mapping review of the literature concerning the ethics of artificial intelligence (AI) in health care. The goal of this review is to summarise current debates and identify open questions for future research. Five literature databases were searched to support the following research question: how can the primary ethical risks presented by AI-health be categorised, and what issues must policymakers, regulators and developers consider in order to be ‘ethically mindful? A series of screening stages were carried out—for example, removing articles that focused on digital health in general (e.g. data sharing, data access, data privacy, surveillance/nudging, consent, ownership of health data, evidence of efficacy)—yielding a total of 156 papers that were included in the review.

We find that ethical issues can be (a) epistemic, related to misguided, inconclusive or inscrutable evidence; (b) normative, related to unfair outcomes and transformative effectives; or (c) related to traceability. We further find that these ethical issues arise at six levels of abstraction: individual, interpersonal, group, institutional, and societal or sectoral. Finally, we outline a number of considerations for policymakers and regulators, mapping these to existing literature, and categorising each as epistemic, normative or traceability-related and at the relevant level of abstraction. Our goal is to inform policymakers, regulators and developers of what they must consider if they are to enable health and care systems to capitalise on the dual advantage of ethical AI; maximising the opportunities to cut costs, improve care, and improve the efficiency of health and care systems, whilst proactively avoiding the potential harms. We argue that if action is not swiftly taken in this regard, a new ‘AI winter’ could occur due to chilling effects related to a loss of public trust in the benefits of AI for health care.

The influence of local political trends on childhood vaccine completion in North Carolina
Cierra Buckman, Indran C. Liu, Lindsay Cortright, Dmitry Tumin, Salma Syed
Article 113187

Systematic Reviews
https://systematicreviewsjournal.biomedcentral.com/articles
[Accessed 12 Sep 2020]
[No new digest content identified]
Ziad A. Memish, Yusuf Ahmed, Saleh A. Alqahtani, Shahul H. Ebrahim
Article 101817

Research article  Abstract only
Measles immunity gaps in an era of high vaccination coverage: A serology study from Taiwan
Yi-Chen Lee, Yi-Hsuan Lee, Chia-Wen Lu, Shao-Yi Cheng, ... Kuo-Chin Huang
Article 101804

Tropical Medicine & International Health
Volume 25, Issue 9  Pages: i-iv, 1043-1165  September 2020
https://onlinelibrary.wiley.com/toc/13653156/current
Original Research Papers
Regional variations of childhood immunisations in Senegal: a multilevel analysis
Sébastien Cortaredona, Rokhaya Diop, Valérie Seror, Luis Sagaon-Teyssier, Patrick Peretti-Watel
Pages: 1122-1130
First Published: 28 June 2020

Vaccine
Volume 38, Issue 41  Pages 6347-6484 (22 September 2020)
https://www.sciencedirect.com/journal/vaccine/vol/38/issue/41
Discussion  Abstract only
Measles immunity in emergency medical providers
AlleaBelle Gongola, Rebecca Reif, Hanna Jensen, Mack Hutchison, ... Kevin W. Sexton
Pages 6350-6351

'Closing the gap': Evaluating the success of non-mandatory strategies for influenza vaccination of Victorian healthcare workers
N. Bennett, S. Crouch, A. Hoskins, M.J. Malloy, ... L.J. Worth

Review article  Full text access
So much at stake: Ethical tradeoffs in accelerating SARSCoV-2 vaccine development
Christine Grady, Seema Shah, Franklin Miller, Marion Danis, ... Annette Rid
Pages 6381-6387

Review article  Full text access
The effect of Bacillus Calmette–Guérin (BCG) vaccination in preventing severe infectious respiratory diseases other than TB: Implications for the COVID-19 pandemic
Kiddus Yitbarek, Gelila Abraham, Tsinuel Girma, Tizta Tilahun, Mirkuzie Woldie

Research article  Abstract only
Evaluating the health literacy demand and cultural appropriateness of online immunisation information available to refugee and migrant communities in Australia
Ikram Abdi, Bernice Murphy, Holly Seale

Research article  Open access  Long-term effectiveness of pentavalent and monovalent rotavirus vaccines against hospitalization in Taiwan children
Yhu-Chering Huang, Fang-Tzy Wu, Yi-Chuan Huang, Ching-Chun Liu, ... Chao A. Hsiung

Research article  Open access  Efficacy after 1 and 2 doses of CYD-TDV in dengue endemic areas by dengue serostatus
Gustavo H. Dayan, Edith Langevin, Remi Forrat, Betzana Zambrano, ... Carlos A. DiazGranados

Research article  Open access  Immunogenicity of influenza vaccines administered to pregnant women in randomized clinical trials in Mali and South Africa
Avnika B. Amin, Marta C. Nunes, Milagritos D. Tapia, Shabir A. Madhi, ... Saad B. Omer

Pages 6478-6483

Vaccines — Open Access Journal
http://www.mdpi.com/journal/vaccines
(Accessed 12 Sep 2020)
Open Access Article  Trends, Spatial Disparities, and Social Determinants of DTP3 Immunization Status in Indonesia 2004–2016
by Holipah Holipah, Asri Maharani, Sujarwoto Sujarwoto, Takuji Hinoura and Yoshiki Kuroda
Vaccines 2020, 8(3), 518; https://doi.org/10.3390/vaccines8030518 - 10 Sep 2020
Viewed by 162
Abstract
Although 91% of 12–23-month-old children in Indonesia received at least one immunization in 2013, only 76% completed DTP3 immunization. This percentage is below the UNICEF and WHO recommended standards. Thus, this study aims to investigate trends, spatial disparities, and social determinants related to

Open Access Article  Healthcare Workers Training Courses on Vaccinations: A Flexible Format Easily Adaptable to Different Healthcare Settings
by Laura Serino, Massimo Maurici, Gian Loreto D’Alò, Fabiana Amadori, Elisa Terracciano, Laura Zaratti, Elisabetta Franco and Local Health Units Vaccination Group
Vaccines 2020, 8(3), 514; https://doi.org/10.3390/vaccines8030514 - 08 Sep 2020
Viewed by 144
Abstract
Since 2017, Italy has expanded the compulsory vaccination from 4 to 10 for those aged 0 to 16 years. Because of the great organizational effort required for the immunization services, minor attention was given to the vaccinations not included among the mandatory ones. This situation led to a real difficulty in harmonizing the vaccination procedures even inside a single region. In the Lazio region, the Laboratory of Vaccinology of the University of Rome Tor Vergata established a working group to create a new training model for healthcare professionals
**Open Access Article**

**Increasing Measles Seroprevalence in a Sample of Pediatric and Adolescent Population of Tuscany (Italy): A Vaccination Campaign Success**

by Beatrice Zanella, Sara Boccalini, Benedetta Bonito, Marco Del Riccio, Emilia Tiscione, Paolo Bonanni, Working Group DHS, Working Group AOU Meyer, Working Group AUSL Tuscany, and Angela Bechini

Vaccines 2020, 8(3), 512; [https://doi.org/10.3390/vaccines8030512](https://doi.org/10.3390/vaccines8030512) - 08 Sep 2020

Viewed by 168

**Abstract**

Background: Despite the National Plan for the Elimination of Measles and congenital Rubella (NPEmCr), in 2017, a measles outbreak occurred in Italy, due to sub-optimal vaccination coverage (<95%) for many years. Since that year, the anti-measles vaccination became compulsory in minors (0–16

---

**Value in Health**

August 2020 Volume 23, Issue 8, p979-1118

[https://www.valueinhealthjournal.com/issue/S1098-3015(20)X0010-6](https://www.valueinhealthjournal.com/issue/S1098-3015(20)X0010-6)

[Reviewed earlier]

---

**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**


*Accessed 12 Sep 2020*

[No new, unique, relevant content]

**BBC**

[http://www.bbc.co.uk/](http://www.bbc.co.uk/)

*Accessed 12 Sep 2020*

[No new, unique, relevant content]
The Economist
http://www.economist.com/
Accessed 12 Sep 2020
International
*Covid-19 and beyond*
**The world needs a better World Health Organisation**
The WHO has done well against covid-19. But it needs more muscle and more money
Sep 12th 2020 edition

Forbes
http://www.forbes.com/
Accessed 12 Sep 2020
**Breaking | 9 hours ago**
**AstraZeneca Coronavirus Vaccine Trials Back On In U.K. After Abrupt Halt**
After an investigation, the vaccine candidate was deemed safe by regulars, the company said.
By Carlie Porterfield Forbes Staff

Forbes
http://www.forbes.com/
Accessed 12 Sep 2020
[No new, unique, relevant content]

Foreign Policy
http://foreignpolicy.com/
Accessed 12 Sep 2020
**Exclusive**
**Trump Administration Orders U.S. Diplomats to Curtail Contact With WHO**
While Trump burns bridges with the World Health Organization, U.S. officials strain to preserve American influence in an institution that is critical to global health challenges.
Colum Lynch, Robbie Gramer, Allison Meakem
September 9, 2020, 4:41 PM

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

New Yorker
http://www.newyorker.com/
**Medical Dispatch**
**It Will Take More Than a Vaccine to Beat COVID-19**
Vaccines are making progress, but they may not defeat the virus completely. Luckily, other therapies are on the way, too.
By Dhruv Khullar
September 8, 2020

New York Times
http://www.nytimes.com/
Accessed 12 Sep 2020
Health

**AstraZeneca Partly Resumes Coronavirus Vaccine Trial After Halting It for Safety**

The company said tests of its vaccine would start up again in Britain while remaining suspended in the U.S. and other countries. Pfizer, a competitor, announced an expansion of its trials.

By Carl Zimmer, Katie Thomas and Benjamin Mueller

Sep 12

Politics

**Trump Pressed for Plasma Therapy. Officials Worry, Is an Unvetted Vaccine Next?**

New details of how the president has demanded faster action from health agencies help explain the intensifying concern that he could demand pre-Election Day approval of a vaccine.

By Sharon LaFraniere, Noah Weiland and Michael D. Shear

Sep 12

Canada

**The Vaccine Challenge: ’Not Putting All Our Eggs in One Basket’**

Anita Anand is out shopping for millions of doses of a coronavirus vaccine that isn’t yet approved to make sure Canada is ready when it finally is.

By Ian Austen

Sept. 11

Business

**How China is using promises of a vaccine as a diplomatic carrot.**

With pledges of a coronavirus vaccine, China is on a charm offensive to repair strained diplomatic ties and bolster engagement with other countries.

By Sui-Lee Wee

---

**Washington Post**

http://www.washingtonpost.com/

Accessed 12 Sep 2020

National

**Most Americans worry coronavirus vaccine will be rushed by political pressure, new poll finds**

...Confidence in a coronavirus vaccine that the Trump administration said could be ready before Election...

Teo Armus, Jennifer Hassan, Marisa Iati, Paulina Villegas, Miriam Berger, Hamza Shaban, Meryl Kornfield, Paulina Firozi and Darren Sands · Sep 10, 2020

---

**Think Tanks et al**

Brookings

http://www.brookings.edu/

Accessed 12 Sep 2020

[No new relevant content]
We gather to discuss with Dr. Heidi Larson about her new book, *Stuck: How Vaccine Rumors Start – and Why they Don’t Go Away*, a wake-up call and appeal to re-think what drives popular distrust in science and rising levels of vaccine refusal and hesitancy. As the world strives to develop safe and effective vaccines...

*Transcript*

**Online Event: The Scramble for a Vaccine: Putin’s Sputnik V— “Trust me!”**
September 10, 2020

Beijing has increased its manipulation of information as well as disinformation efforts around COVID-19 to damage democracies and boost itself, but its strategies have had mixed results.

In Brief by Joshua Kurlantzick

**Poll: Most Americans Worry Political Pressure Will Lead to Premature Approval of a COVID-19 Vaccine; Half Say They Would Not Get a Free Vaccine Approved Before Election Day**

Republican and Independent Voters See the Economy as Their Top Issue; Coronavirus and Race Relations Top Democrats’ List Most Americans (62%) worry that the political pressure
from the Trump administration will lead the Food and Drug Administration to rush to approve a coronavirus vaccine without making sure that it is...

* * * *
* * * *

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

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

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

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

* * * *
* * * *