



Vaccines and Global Health: The Week in Review
14 July 2018
Center for Vaccine Ethics & Policy (CVEP)

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

*Vaccines and Global Health: The Week in Review is also **posted in pdf form** and as a set of blog posts at <https://centerforvaccineethicsandpolicy.net>. This blog allows full-text searching of over 8,000 entries.*

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

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Milestones :: Perspectives

Explorations of inequality: Childhood immunization

World Health Organization 2018 : 92 pages

ISBN 978-92-4-156561-5

PDF: <http://apps.who.int/iris/bitstream/handle/10665/272864/9789241565615-eng.pdf?ua=1>

Overview

This report takes a detailed look at the current status of childhood immunization in 10 priority countries: Afghanistan, Chad, Democratic Republic of the Congo, Ethiopia, India, Indonesia, Kenya, Nigeria, Pakistan and Uganda.

In each country, childhood immunization coverage is broken down by multiple factors to show inequality according to child, mother, household and geographical characteristics. Then, the report employs multiple regression analysis to identify factors that are associated with immunization coverage. A multicountry assessment illustrates similarities and differences between countries.

The findings of the report show how a child's likelihood of being vaccinated is affected by compounding advantage or vulnerability; they also provide insight into how policies, programmes and practices can be targeted to promote universal childhood immunization coverage. Interactive visuals and tables accompany the report, enabling further exploration of the data.

Key Messages

Across the 10 priority countries, the national DTP3 immunization coverages ranged from 34% in Chad to 90% in Kenya. Evaluating performance based on national averages alone, however, masks the situation in population subgroups. The countries faced distinct patterns of inequality, from Uganda, where inequality tended to be very small for most of the featured characteristics, to Nigeria, where inequality was pronounced for most characteristics.

Despite the uniqueness of each country situation, some commonalities emerged. Inequalities by child's sex tended to be minimal or non-existent, and inequality by subnational region tended to be substantial. All countries reported variation by mother's education and subnational region and all (except Uganda) demonstrated inequality on the basis of household economic status. All 10 priority countries showed a positive association between mother's education level and childhood immunization coverage. Countries that reported low national coverage (e.g. Chad, Ethiopia and Nigeria) tended to demonstrate steep gradients and/or mass deprivation patterns across socioeconomic subgroups; the odds of immunization tended to be significantly higher in more advantaged subgroups in these countries. Countries with higher national coverage (e.g. India, Indonesia, Kenya and Uganda), more often demonstrated marginal exclusion or universal patterns across socioeconomic subgroups, and tended to have lower urban–rural inequality.

When considered alongside knowledge of the country context, the results of this report can be used to inform equity-oriented policies, programmes and practices to promote universal childhood immunization coverage. This report serves as a basis for more detailed explorations at the national and subnational levels, and a baseline for future health inequality monitoring efforts. Monitoring and exploring inequalities in health is essential as countries strive to “leave no one behind” on the path towards sustainable development.

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FDA approves the first drug with an indication for treatment of smallpox

July 13, 2018

The U.S. Food and Drug Administration today approved TPOXX (tecovirimat), the first drug with an indication for treatment of smallpox. Though the World Health Organization declared smallpox, a contagious and sometimes fatal infectious disease, eradicated in 1980, there have been longstanding concerns that smallpox could be used as a bioweapon.

"To address the risk of bioterrorism, Congress has taken steps to enable the development and approval of countermeasures to thwart pathogens that could be employed as weapons. Today's approval provides an important milestone in these efforts. This new treatment affords us an additional option should smallpox ever be used as a bioweapon," said FDA Commissioner Scott Gottlieb, M.D. "This is the first product to be awarded a Material Threat Medical Countermeasure priority review voucher. Today's action reflects the FDA's commitment to ensuring that the U.S. is prepared for any public health emergency with timely, safe and effective medical products."

Prior to its eradication in 1980, variola virus, the virus that causes smallpox, was mainly spread by direct contact between people. Symptoms typically began 10 to 14 days after infection and included fever, exhaustion, headache and backache. A rash initially consisting of small, pink bumps progressed to pus-filled sores before finally crusting over and scarring. Complications of smallpox could include encephalitis (inflammation of the brain), corneal ulcerations (an open sore on the clear, front surface of the eye) and blindness.

TPOXX's effectiveness against smallpox was established by studies conducted in animals infected with viruses that are closely related to the virus that causes smallpox, and was based on measuring survival at the end of the studies. More animals treated with TPOXX lived compared to the animals treated with placebo. TPOXX was approved under the FDA's Animal Rule, which allows efficacy findings from adequate and well-controlled animal studies to support an FDA approval when it is not feasible or ethical to conduct efficacy trials in humans.

The safety of TPOXX was evaluated in 359 healthy human volunteers without a smallpox infection. The most frequently reported side effects were headache, nausea and abdominal pain.

The FDA granted this application Fast Track and Priority Review designations. TPOXX also received Orphan Drug designation, which provides incentives to assist and encourage the development of drugs for rare diseases and a Material Threat Medical Countermeasure Priority Review Voucher, which provides additional incentives for certain medical products intended to treat or prevent harm from specific chemical, biological, radiological and nuclear threats. The FDA granted approval of TPOXX to SIGA Technologies Inc.

TPOXX was developed in conjunction with the U.S. Department of Health and Human Services' Biomedical Advanced Research and Development Authority (BARDA).

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Emergencies

POLIO

Public Health Emergency of International Concern (PHEIC)

[Polio this week as of 10 July 2018](#) [GPEI]

:: A Disease Outbreak News (DON) notification was issued on 10 July on the Democratic Republic of the Congo's three concurrent circulating vaccine-derived poliovirus type 2 (cVDPV2) outbreaks.

:: Papua New Guinea prepares for the launch of large-scale immunization campaigns in Morobe, Madang and Eastern Highlands provinces, set to commence next week..

Summary of new cases this week:

Afghanistan:

:: Last week's advance notification of one wild poliovirus type 1 (WPV1) case in Nad-e-Ali district, Helmand province, has been confirmed. The case had onset of paralysis on 1 June. This brings the total number of WPV1 cases in 2018 (in Afghanistan) to nine.

:: A sub-national immunization days campaign aiming to reach 6.4 million children under five years of age in 225 high risk districts of 27 provinces, primarily in the southern and eastern parts of the country including Kabul city, has concluded.

:: Two new WPV1 positive environmental samples have been reported: one in Kandahar City, Kandahar province, and one in Jalalabad, Nangarhar province.

Pakistan:

:: Four new WPV1 positive environmental samples have been reported this week: one in Peshawar and one in Kohat, Khyber Pakhtunkhwa province (both 26 June), one in Karachi, Sindh province (23 June), and one in Islamabad, Punjab province (24 June).

Somalia:

:: An advance notification has been confirmed of one new cVDPV2 positive contact in Somalia.

DONs

[Circulating vaccine-derived poliovirus type 2 – Democratic Republic of the Congo](#)

10 July 2018

...*WHO risk assessment*

WHO assessed the overall public health risk at the national level to be very high and the risk of international spread to be high. This risk is magnified by known population movements between the affected area of Democratic Republic of the Congo, Uganda, Central African Republic and South Sudan, and the upcoming rainy season which is associated with increased intensity of virus transmission.

The detection of cVDPV2s underscores the importance of maintaining high routine vaccination coverage everywhere to minimize the risk and consequences of any poliovirus circulation. These events also underscore the risk posed by any low-level transmission of the virus. A robust outbreak response is needed to rapidly stop circulation and ensure sufficient vaccination coverage in the affected areas to prevent similar outbreaks in the future. WHO will continue to evaluate the epidemiological situation and outbreak response measures being implemented...

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[WHO Grade 3 Emergencies](#) [to 14 Jul 2018]

The Syrian Arab Republic

:: Southern Syrian Arab Republic Health Cluster report pdf, 82kb 9 - 12 July 2018

:: WHO delivers over 17 tons of life-saving medicines and medical equipment to the newly accessible city of Douma 7 July 2018

Iraq - *No new announcements identified*

Nigeria - *No new announcements identified*

South Sudan - *No new announcements identified*

Yemen - *No new announcements identified*

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WHO Grade 2 Emergencies [to 14 Jul 2018]

[Several emergency pages were not available at inquiry]

Cameroon - *No new announcements identified*

Central African Republic - *No new announcements identified.*

Democratic Republic of the Congo - *No new announcements identified*

Ethiopia - *No new announcements identified.*

Libya - *No new announcements identified.*

Myanmar - *No new announcements identified*

Niger - *No new announcements identified.*

Ukraine - *No new announcements identified.*

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UN OCHA – L3 Emergencies

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

Syrian Arab Republic

:: Syrian Arab Republic: Dar'a, Quneitra, As-Sweida Situation Report No. 2 as of 11 July 2018

Published on 11 Jul 2018

Yemen

:: Yemen Humanitarian Update Covering 12 June - 9 July 2018 | Issue 20

Published on 10 Jul 2018

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UN OCHA – Corporate Emergencies

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

Ethiopia - *No new announcements identified.*

Somalia - *No new announcements identified.*

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Editor's Note:

We will cluster these recent emergencies as below and continue to monitor the WHO webpages for updates and key developments.

EBOLA/EVD [to 14 Jul 2018]

<http://www.who.int/ebola/en/>

Ebola virus disease – Democratic Republic of the Congo 6 July 2018

The Ministry of Health and WHO continue to closely monitor the outbreak of Ebola virus disease in the Democratic Republic of the Congo.

Contact tracing activities concluded on 27 June after the last people with potential exposure to the virus completed their 21-day follow-up without developing symptoms. Over 20 000 visits to contacts have been conducted by the field team throughout the outbreak.

On 12 June, the last confirmed Ebola virus disease patient in Équateur Province was discharged from an Ebola treatment centre, following two negative tests on serial laboratory specimens. Before the outbreak can be declared over, a period of 42 days (two incubation periods) following the last possible exposure to a confirmed case must elapse without any new confirmed cases being detected. Until this milestone is reached, it is critical to maintain all key response pillars, including intensive surveillance to rapidly detect and respond to any resurgence.

In light of progress in the response, WHO has revised the risk assessment for this outbreak... there remains a risk of resurgence from potentially undetected transmission chains and possible sexual transmission of the virus by male survivors. It is therefore, critical to maintain all key response pillars until the end of the outbreak is declared. Strengthened surveillance mechanisms and a survivor monitoring program are in place to mitigate, rapidly detect and respond to such events. Based on these factors, WHO considers the public health risk to be moderate at the national level.

In the absence of ongoing transmission, the probability of exported cases is low and diminishing, and has been further mitigated by the undertaking of preparedness activities and establishment of contingency plans in neighbouring countries. WHO has assessed the public health risk to be low at the regional and global levels...

MERS-CoV [to 14 Jul 2018]

<http://who.int/emergencies/mers-cov/en/>

- *No new announcements identified.*

Yellow Fever [to 14 Jul 2018]

<http://www.who.int/csr/disease/yellowfev/en/>

- *No new announcements identified.*

Zika virus [to 14 Jul 2018]

<http://www.who.int/csr/disease/zika/en/>

- *No new announcements identified.*

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WHO & Regional Offices [to 14 Jul 2018]

WHO Regional Offices

Selected Press Releases, Announcements

WHO African Region AFRO

Selected Featured News

- :: Borno targets more than 1 million children with anti-malaria therapy. 13 July 2018
- :: Rising cases of sickle cell disease prompts calls for urgent action 13 July 2018
- :: Adamawa conducts first vaccination campaign in response to cholera outbreak 10 July 2018
- :: Ethiopia launched the 1st round synchronized mOPV2 campaign 10 July 2018
- :: Targeted vaccine campaign underway to interrupt measles outbreak in remote northern Sierra Leone 07 July 2018

WHO Region of the Americas PAHO

- No new announcements identified.

WHO South-East Asia Region SEARO

- No new announcements identified.

WHO European Region EURO

- :: Health ministers of south-eastern Europe meet to share good practices, discuss health challenges 12-07-2018
- :: Twenty years of explaining the evidence – the European Observatory on Health Systems and Policies 12-07-2018
- :: Portugal on fast track to achieve HIV targets ahead of 2020 deadline 11-07-2018
- :: Making the link between transport, health, environment and achieving the SDGs 11-07-2018

WHO Eastern Mediterranean Region EMRO

- :: WHO concerned about access to health services for displaced people in southern Syria
12 July, 2018 – WHO today called for the protection of health facilities and increased access to southern Syria, where recent hostilities have left over 210 000 people displaced and in need of urgent health services. Up to 160 000 displaced Syrians currently seeking safety in Quneitra are inaccessible to health partners, raising concerns for their health. Since the escalation of violence, WHO has provided medicines and supplies to health partners, hospitals, and primary health care centres for almost 200 000 medical treatments...

WHO Western Pacific Region

- No new announcements identified.

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CDC/ACIP [to 14 Jul 2018]

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

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

No new digest content identified.

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Africa CDC [to 14 Jul 2018]

<https://au.int/en/africacdc>

No new digest content identified.

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China CDC

<http://www.chinacdc.cn/en/ne/>

Website not responding at inquiry...no connection since 2 June inquiry

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Announcements

AERAS [to 14 Jul 2018]

<http://www.aeras.org/pressreleases>

JULY 11, 2018)

New England Journal of Medicine Publishes Final Results from Innovative Phase 2 Study Showing Vaccines Can Reduce Rate of Sustained TB Infections in Adolescents at High Risk

Trial offers hope for new revaccination strategies with Bacille Calmette-Guerin (BCG) against Tuberculosis, the world's leading infectious disease killer

ROCKVILLE, MARYLAND (--Aeras, a nonprofit organization dedicated to developing vaccines against tuberculosis (TB), today announced the publication of the full results from a Phase 2, randomized, controlled clinical trial of two TB vaccines— the currently available BCG vaccine and an investigational vaccine, H4:IC31—in the [New England Journal of Medicine](#) (NEJM).

This proof-of-concept study showed that vaccination can reduce the rate of sustained TB infections in a high-transmission setting, such as in uninfected, healthy adolescents in the Western Cape of South Africa where the study was conducted. In the trial, revaccination with BCG significantly reduced sustained TB infections in adolescents with a 45.4% vaccine efficacy. H4:IC31 also reduced sustained infections, although not at statistically significant levels, showing 30.5% vaccine efficacy. However, the trend observed for H4:IC31 is the first time a subunit vaccine has shown any signal that it may be able to protect against TB infection or disease in humans. In the trial, TB infections were measured by a blood test (QuantiFERON-TB Gold In-Tube (QFT)) converting from negative to positive, and sustained infections were defined by a QFT test that remained positive for at least six months.

Jacqueline Shea, PhD, Chief Executive Officer at Aeras, said: "With this study, we showed that vaccines against TB infection can work. The results highlight the importance of investing in new approaches to fighting the leading infectious disease killer and to evaluating new concepts in clinical trials. Further, the collaborative effort established between industry leaders, nonprofits and clinical sites during this trial showed how powerful combining such forces can be for developing new interventions against a global health threat. The BCG results are important findings with significant public health implications that could lead to saving millions of lives. Likewise, the novel prevention-of-infection trial design can be used to inform clinical development of new vaccine candidates before entry into large-scale prevention-of-disease efficacy trials. We are very grateful to the trial participants and our partners and funders who enabled the conduct of this trial."

Initial results from the study were presented at the 5th Global Forum in New Delhi, India in February 2018...

BMGF - Gates Foundation [to 14 Jul 2018]

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

JULY 05, 2018

Gates Foundation Names Carolyn Ainslie as Chief Financial Officer

SEATTLE, July 5, 2018 — The Bill & Melinda Gates Foundation today announced that Carolyn Ainslie has been named chief financial officer, effective October 1, 2018. Currently, Ainslie is Vice President for Finance and Treasurer at Princeton University where she serves as the chief financial officer, responsible for the central financial functions of the University.

Bill & Melinda Gates Medical Research Institute [to 14 Jul 2018]

<https://www.linkedin.com/company/bill-melinda-gates-medical-research-institute/>

The Bill & Melinda Gates Medical Research Institute is a non-profit research organization dedicated to combating diseases that impact the world's poorest. We strive to combat inequities in health by accelerating progress in translational science to ensure life-saving products are available and accessible to everyone. We consider ourselves pioneers dedicated to uncovering radical solutions that will close the gap between cutting-edge scientific innovation and its application to challenges in global health.
No new digest content identified.

CARB-X [to 14 Jul 2018]

<https://carb-x.org/>

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

07.10.2018

CARB-X funds Summit Therapeutics to support development of a new class of antibiotics to treat Gonorrhoea Superbug

CARB-X awards Summit Therapeutics \$2 million in non-dilutive funding, with the possibility of up to \$2.5 million more, to support the development of a new class of antibiotics to treat gonorrhoea. This project bring to 10 the number of new classes in the portfolio; 34 projects to fight superbugs

CEPI – Coalition for Epidemic Preparedness Innovations [to 14 Jul 2018]

<http://cepi.net/>

No new digest content identified.

EDCTP [to 14 Jul 2018]

<http://www.edctp.org/>

The European & Developing Countries Clinical Trials Partnership (EDCTP) aims to accelerate the development of new or improved drugs, vaccines, microbicides and diagnostics against

HIV/AIDS, tuberculosis and malaria as well as other poverty-related and neglected infectious diseases in sub-Saharan Africa, with a focus on phase II and III clinical trials

10 July 2018

MTBVAC in Newborns: kick-off meeting in South Africa

The kick-off meeting of the EDCTP-funded project MTBVAC in Newborns took place in Cape Town, South Africa on 6-7 June 2018. The candidate TB vaccine MTBVAC was developed by researchers from the University of Zaragoza, Spain, and the Institut Pasteur...

Emory Vaccine Center [to 14 Jul 2018]

<http://www.vaccines.emory.edu/>

No new digest content identified.

European Medicines Agency [to 14 Jul 2018]

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

13/07/2018

Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 9-12 July 2018

European Vaccine Initiative [to 14 Jul 2018]

<http://www.euvaccine.eu/news-events>

No new digest content identified.

FDA [to 14 Jul 2018]

<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/default.htm>

July 13, 2018 –

FDA approves the first drug with an indication for treatment of smallpox

[See Milestones above for more detail]

July 11, 2018 –

Statement from FDA Commissioner Scott Gottlieb, M.D. on agency's efforts to advance development of gene therapies

Chemistry, Manufacturing, and Control (CMC) Information for Human Gene Therapy

Investigational New Drug Applications (INDs); Draft Guidance for Industry (PDF - 486KB) July 2018

Long Term Follow-up After Administration of Human Gene Therapy Products; Draft Guidance for Industry (PDF - 294KB) July 2018

Testing of Retroviral Vector-Based Human Gene Therapy Products for Replication Competent Retrovirus During Product Manufacture and Patient Follow-up; Draft Guidance for Industry (PDF - 124KB) July 2018

Human Gene Therapy for Hemophilia; Draft Guidance for Industry (PDF - 371KB) July 2018

Human Gene Therapy for Rare Diseases; Draft Guidance for Industry (PDF - 136KB) July 2018

Human Gene Therapy for Retinal Disorders; Draft Guidance for Industry (PDF - 172KB) July 2018

Fondation Merieux [to 14 Jul 2018]

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

Project

Launch of a study on lower acute respiratory infections in Rohingya refugee camps to improve and adapt patient care in a humanitarian crisis

July 12, 2018 - Cox's Bazar (Bangladesh)

The Mérieux Foundation is conducting a new study to identify the pathogens at the onset of Lower Acute Respiratory Infections (LARI) in the context of a humanitarian crisis and to determine the healthcare interventions needed to improve patient care in such a setting.

Gavi [to 14 Jul 2018]

<http://www.gavi.org/library/news/press-releases/>

11 July 2018

Shifo & Gavi join hands to help make vaccines work for every child

The Shifo Foundation, in collaboration with Gavi and other key partners will work to strengthen registration and data quality across The Gambia and ensure no child misses out on life-saving vaccines.

GHIT Fund [to 14 Jul 2018]

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

*GHIT was set up in 2012 with the aim of developing new tools to tackle infectious diseases that devastate the world's poorest people. Other funders include six Japanese pharmaceutical
No new digest content identified.*

Global Fund [to 14 Jul 2018]

<http://www.theglobalfund.org/en/news/?topic=&type=NEWS;&country=>

News

Global Fund Appoints Philippe François as Head of Sourcing & Supply Chain

09 July 2018

Peter Sands, Executive Director of the Global Fund to Fight AIDS, Tuberculosis and Malaria, today named Philippe François as Head of Sourcing & Supply Chain, bringing a recognized track record of innovation in supplying healthcare products and services worldwide.

Hilleman Laboratories [to 14 Jul 2018]

<http://www.hillemanlabs.org/>

No new digest content identified.

Human Vaccines Project [to 14 Jul 2018]

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

No new digest content identified.

IAVI [to 14 Jul 2018]

<https://www.iavi.org/>

No new digest content identified.

IFFIm

<http://www.iffim.org/library/news/press-releases/>

No new digest content identified.

IVAC [to 14 Jul 2018]

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

No new digest content identified.

IVI [to 14 Jul 2018]

<http://www.ivi.int/>

No new digest content identified.

JEE Alliance [to 14 Jul 2018]

<https://www.jeealliance.org/>

No new digest content identified.

MSF/Médecins Sans Frontières [to 14 Jul 2018]

<http://www.msf.org/>

Selected Press Releases/Statements

DRC 2018 Ebola outbreak

["Congolese health workers have shown an amazing commitment to fighting Ebola"](#)

Voices from the Field 11 Jul 2018

NIH [to 14 Jul 2018]

<http://www.nih.gov/news-events/news-releases>

July 12, 2018

[Imaging technique illuminates immune status of monkeys with HIV-like virus](#)

— Approach could improve understanding of immune system recovery in people treated for HIV infection

[NIAID scientists create 3D structure of 1918 influenza virus-like particles](#)

July 11, 2018 — Details could advance vaccine development for several human diseases.

NIH researchers identify sequence leading to release of malaria parasites from red blood cells

July 11, 2018 — Findings could inform the development of new antimalarial drugs.

NIH and VA collaborate to boost veterans' access to cancer clinical trials

July 10, 2018 — NAVIGATE will launch at 12 VA facilities across the nation.

PATH [to 14 Jul 2018]

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

No new digest content identified.

Sabin Vaccine Institute [to 14 Jul 2018]

<http://www.sabin.org/updates/pressreleases>

No new digest content identified.

UNAIDS [to 14 Jul 2018]

<http://www.unaids.org/en>

Feature story

Monaco becomes a Fast-Track city

09 July 2018

Monaco has joined a network of more than 250 cities worldwide by signing the Paris Declaration, making a commitment to Fast-Track its response to the HIV epidemic and adopt the 90–90–90 targets.

The 90-90-90 targets are that, by 2020, 90% of all people living with HIV will know their HIV status, 90% of all people living with HIV will have access to antiretroviral therapy and 90% of all people on antiretroviral therapy will have viral suppression...

UNICEF [to 14 Jul 2018]

<https://www.unicef.org/media/press-releases>

Selected Press Releases/Reports/Statements

Press release

UNICEF Executive Director to serve as board chair of Global Partnership to End Violence Against Children

12/07/2018

Vaccine Confidence Project [to 14 Jul 2018]

<http://www.vaccineconfidence.org/>

No new digest content identified.

Vaccine Education Center – Children's Hospital of Philadelphia [to 14 Jul 2018]

<http://www.chop.edu/centers-programs/vaccine-education-center>

No new digest content identified.

Wellcome Trust [to 14 Jul 2018]

<https://wellcome.ac.uk/news>

Published: 10 July 2018

Director's update: taking risks on bold ideas

Today we're announcing a new £250m Leap Fund to back bold ideas. Director Jeremy Farrar explains how it will accelerate discovery and innovation.

...Today we're announcing a new £250m not-for-profit fund: the Wellcome Leap Fund. The Leap Fund will accelerate discovery and innovation, with the aim of delivering breakthroughs over a five- to ten-year horizon.

It will draw inspiration from the technology and venture capital sectors – taking on early stage, high-risk ideas and funding at scale – and apply these principles to charitable programme investments in the health and life sciences. It will run for an initial five years from 2020 and will account for around 5% of our total charitable spend during this time.

We think this addresses a gap in funding in the health and life sciences, where venture capital is often injected in the later stages of translation and restricted to investments that will guarantee financial returns. As an independent charitable foundation, Wellcome is well placed to offer something different. We can take an unconventional approach by taking risks on things we know may not succeed, but would be transformational if they did.

The Leap Fund will not replace or duplicate any of our current research funding schemes. We'll continue to support these through our Primary Fund to the tune of over £900m a year, rising with inflation.

Leap funding will instead come from the separate [Reserve Fund](#), which was established last year to support ambitious programmes where Wellcome has the capacity to drive significant progress towards addressing a global health challenge, or to advance science in a specific space within five to ten years...

The Wistar Institute [to 14 Jul 2018]

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

No new digest content identified.

World Organisation for Animal Health (OIE) [to 14 Jul 2018]

<http://www.oie.int/en/for-the-media/press-releases/2018/>

No new digest content identified.

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BIO [to 14 Jul 2018]

<https://www.bio.org/insights/press-release>

No new digest content identified.

DCVMN – Developing Country Vaccine Manufacturers Network [to 14 Jul 2018]

<http://www.dcvmn.org/>

No new digest content identified.

IFPMA [to 14 Jul 2018]

<http://www.ifpma.org/resources/news-releases/>

No new digest content identified.

PhRMA [to 14 Jul 2018]

<http://www.phrma.org/press-room>

July 12, 2018

PhRMA Statement on Efforts to Support Real-World Evidence

WASHINGTON, D.C. (July 12, 2018) – Pharmaceutical Research and Manufacturers of America (PhRMA) spokesperson Andrew Powaleny issued the following statement on comments made by U.S. Food and Drug Administration Commissioner Scott Gottlieb:

"We agree with Commissioner Gottlieb that the use of real-world evidence and innovative clinical trial designs hold great promise for enhancing the drug development process. When leveraged with the latest science and methodologies, these approaches can lead to more efficient drug development programs, provide more robust information about the benefits and risks of new medicines and can ultimately lead to more timely access to innovative, safe and effective medicines for patients...

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Reports/Research/Analysis/Commentary/Conferences/Meetings/Book Watch/Tenders

Vaccines and Global Health: The Week in Review has expanded its coverage of new reports, books, research and analysis published independent of the journal channel covered in Journal Watch below. Our interests span immunization and vaccines, as well as global public health, health governance, and associated themes. If you would like to suggest content to be included in this service, please contact David Curry at: david.r.curry@centerforvaccineethicsandpolicy.org

MEDICINE AND VACCINE SHORTAGES – WHAT IS THE ROLE OF GLOBAL REGULATORY COMPLEXITY FOR POST APPROVAL CHANGES?

The Economist Intelligence Unit Limited 2018 :: 35 pages

Executive summary

This study aims to explore whether the varying regulatory requirements for pharmaceutical products across the world are associated with medicine and vaccine shortages. This research project included a rapid literature review involving database and grey literature searches and a series of interviews with representatives of academia, industry, regulatory authorities, international organisations and global non-governmental organisations.

Key messages from the findings of the literature review and insights from the expert interviews are presented below.

:: Medicine and vaccine shortages are a global problem affecting rich and poor countries alike

Medicines and vaccines shortages are a global problem with significant impact on populations and health care systems. Shortages continue to persist, despite increased efforts from a range of stakeholders including international organisations, governments, regulators, healthcare providers, pharmacists and industry over the past decade. Vaccines shortages in particular are a

serious public health issue, as they can lead to reduced population coverage and delays in prevention and control programmes for infectious diseases.

:: Causes for shortages are complex, multifaceted and not well understood

Causes for shortages are complex and interrelated, and vary for different products and countries. To channel the activities for prevention and mitigation of shortages, we need more research into the interplay of related causes, with a particular emphasis on economic and market-related causes. There is a need to identify critical products such as vaccines and risk factors that could affect the uninterrupted supply of these products to the people who need them.

:: This study found little evidence for the existence of a direct correlation between the global complexity of regulatory requirements for post approval changes and shortages

This study explored the question of whether the global complexity of regulatory requirements for post approval changes (PACs) to the terms of marketing authorisation could be a contributing factor for medicine and vaccine shortages; however we found little evidence in support of this hypothesis. In situations of shortages however, the regulatory complexity for PACs on a global scale could be an aggravating factor that delays or hinders mitigation actions.

:: There is a universal agreement that regulatory convergence and harmonisation are beneficial to all stakeholders

Regulatory harmonisation has been supported by the World Health Organization (WHO) since the 1980s. Numerous global and regional initiatives have been set up, including the European Regulatory System for medicines and the International Council on Harmonisation (ICH). There is a trend towards greater co-operation and regulatory convergence in the Americas, Asia-Pacific and South-East Asia, which could only be positive in terms of strengthening the regulatory systems in these regions and building trust between national regulatory authorities (RAs). The developments in Africa leading towards the establishment of an African Medicines Agency that follows the European model will also have a positive effect on the processes and timelines for PACs. © The Economist Intelligence Unit Limited 2018 4

:: Trust and strong political will are required for harmonisation and convergence initiatives to succeed

It is important to develop an understanding of the expectations and priorities of all stakeholders, and to pursue the harmonisation goal, even though progress may seem slow at times. A look at the history of the European Medicines Agency (EMA) since its establishment in 1995 shows that it has taken decades of work and strong political will to achieve the current level of harmonisation. The recent increase in mutual recognition agreements between the EMA and other RAs shows that regulators can work together to avoid duplication in effort and rely on each other's expertise in challenging areas for regulatory science. The adoption of WHO guidelines for procedures and data requirements for changes to approved vaccines by national RAs, and further developments related to ICH quality guideline proposals for product lifecycle management, would help to reduce the complexity of requirements for the same changes across different jurisdictions.

:: Finding a permanent solution for shortages is critical for achieving global health goals

We hope that this report will help to raise awareness about the global impact of medicine and vaccine shortages, and the need for coordinated action from multiple stakeholders at international and national level. Finding a permanent solution for shortages is crucial for achieving the UN Sustainable Development Goal for health, including access to “safe, effective, quality and affordable essential medicines and vaccines for all” by 2030.^{1, 2}

* * * *

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

July 2018 Volume 46, Issue 7, p733-850, e43-e64

<http://www.ajicjournal.org/current>

[Reviewed earlier]

American Journal of Preventive Medicine

July 2018 Volume 55, Issue 1, p1-132, e1-e18

<http://www.ajpmonline.org/current>

[Reviewed earlier]

American Journal of Public Health

July 2018 108(7)

<http://ajph.aphapublications.org/toc/ajph/current>

[Reviewed earlier]

American Journal of Tropical Medicine and Hygiene

Volume 98, Issue 6, 2018

<http://www.ajtmh.org/content/journals/14761645/98/6>

[Reviewed earlier]

Annals of Internal Medicine

3 July 2018 Vol: 169, Issue 1

<http://annals.org/aim/issue>

[Reviewed earlier]

BMC Cost Effectiveness and Resource Allocation

<http://resource-allocation.biomedcentral.com/>

(Accessed 14 Jul 2018)

[No new digest content identified]

BMJ Global Health

July 2018 - Volume 3 - 4

<https://gh.bmj.com/content/3/4>

[Reviewed earlier]

BMC Health Services Research

<http://www.biomedcentral.com/bmchealthservres/content>

(Accessed 14 Jul 2018)

Research article

[Preparedness and response against diseases with epidemic potential in the European Union: a qualitative case study of Middle East Respiratory Syndrome \(MERS\) and poliomyelitis in five member states](#)

EU Decision 1082/2013/EU on serious cross-border health threats provides a legal basis for collaboration between EU Member States, and between international and European level institutions on preparedness, pre...

Authors: John Kinsman, John Angrén, Fredrik Elgh, Maria Furberg, Paola A. Mosquera, Laura Otero-García, René Snacken, Tarik Derrough, Paloma Carrillo Santistevé, Massimo Ciotti and Svetla Tsoleva

Citation: BMC Health Services Research 2018 18:528

Published on: 6 July 2018

BMC Infectious Diseases

<http://www.biomedcentral.com/bmcinfectdis/content>

(Accessed 14 Jul 2018)

[No new digest content identified]

BMC Medical Ethics

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

(Accessed 14 Jul 2018)

Research article

[Standards of practice in empirical bioethics research: towards a consensus](#)

This paper reports the process and outcome of a consensus finding project, which began with a meeting at the Brocher Foundation in May 2015. The project sought to generate and reach consensus on standards of practice for Empirical Bioethics research. The project involved 16 academics from 5 different European Countries, with a range of disciplinary backgrounds.

Authors: Jonathan Ives, Michael Dunn, Bert Molewijk, Jan Schildmann, Kristine Bærøe, Lucy Frith, Richard Huxtable, Elleke Landeweer, Marcel Mertz, Veerle Provoost, Annette Rid, Sabine Salloch, Mark Sheehan, Daniel Strech, Martine de Vries and Guy Widdershoven

Citation: BMC Medical Ethics 2018 19:68

Published on: 10 July 2018

The [Correspondence to this article](#) has been published in BMC Medical Ethics 2018 19:67

The [Correspondence to this article](#) has been published in BMC Medical Ethics 2018 19:69

The [Correspondence to this article](#) has been published in BMC Medical Ethics 2018 19:66

BMC Medicine

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

(Accessed 14 Jul 2018)

Research article

[Modelling population-level impact to inform target product profiles for childhood malaria vaccines](#)

The RTS,S/AS01 vaccine for Plasmodium falciparum malaria demonstrated moderate efficacy in 5–17-month-old children in phase 3 trials, and from 2018, the vaccine will be evaluated through a large-scale pilot imple...

Authors: Alexandra B. Hogan, Peter Winskill, Robert Verity, Jamie T. Griffin and Azra C. Ghani

Citation: BMC Medicine 2018 16:109

Published on: 13 July 2018

BMC Pregnancy and Childbirth

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

(Accessed 14 Jul 2018)

[No new digest content identified]

BMC Public Health

<http://bmcpublichealth.biomedcentral.com/articles>

(Accessed 14 Jul 2018)

Research article

[Vaccine wastage in The Gambia: a prospective observational study](#)

Vaccination is a cost-effective and life-saving intervention. Recently several new, but more expensive vaccines have become part of immunization programmes in low and middle income countries (LMIC). Monitoring...

Authors: Effua Usuf, Grant Mackenzie, Lamin Ceesay, Dawda Sowe, Beate Kampmann and Anna Roca

Citation: BMC Public Health 2018 18:864

Published on: 11 July 2018

BMC Research Notes

<http://www.biomedcentral.com/bmcresnotes/content>

(Accessed 14 Jul 2018)

[No new digest content identified]

BMJ Open

July 2018 - Volume 8 - 7

<http://bmjopen.bmj.com/content/current>

[Reviewed earlier]

Bulletin of the World Health Organization

Volume 96, Number 7, July 2018, 441-512

<http://www.who.int/bulletin/volumes/96/7/en/>

[Reviewed earlier]

Child Care, Health and Development

Volume 44, Issue 4 Pages: 507-658 July 2018

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

[Reviewed earlier]

Clinical and Experimental Vaccine Research

Volume 7(1); January 2018

<http://ecevr.org/>

[Reviewed earlier]

Clinical Therapeutics

June 2018 Volume 40, Issue 6, p813-1048

<http://www.clinicaltherapeutics.com/current>

[Reviewed earlier]

Clinical Trials

Volume: 15, Number: 3 (June 2018)

<http://journals.sagepub.com/toc/ctja/15/3>

[Reviewed earlier]

Conflict and Health

<http://www.conflictandhealth.com/>

[Accessed 14 Jul 2018]

[No new digest content identified]

Contemporary Clinical Trials

Volume 70 Pages 1-138 (July 2018)

<https://www.sciencedirect.com/journal/contemporary-clinical-trials/vol/70/suppl/C>

[Reviewed earlier]

Current Opinion in Infectious Diseases

August 2018 - Volume 31 - Issue 4

<http://journals.lww.com/co-infectiousdiseases/pages/currenttoc.aspx>

[Reviewed earlier]

Developing World Bioethics

Volume 18, Issue 2 Pages: 65-203 June 2018

<https://onlinelibrary.wiley.com/toc/14718847/current>

[Reviewed earlier]

Development in Practice

Volume 28, Issue 5, 2018

<http://www.tandfonline.com/toc/cdip20/current>

[Reviewed earlier]

Disaster Medicine and Public Health Preparedness

Volume 12 - Issue 2 - April 2018

<https://www.cambridge.org/core/journals/disaster-medicine-and-public-health-preparedness/latest-issue>

[Reviewed earlier]

Disasters

Volume 42, Issue 3 Pages: 405-612 July 2018

<https://onlinelibrary.wiley.com/toc/14677717/current>

[Reviewed earlier]

EMBO Reports

01 June 2018; volume 19, issue 6

<http://embor.embopress.org/content/19/6?current-issue=y>

[Reviewed earlier]

Emerging Infectious Diseases

Volume 24, Number 7—July 2018

<http://wwwnc.cdc.gov/eid/>

[Reviewed earlier]

Epidemics

Volume 23 Pages 1-120 (June 2018)

<https://www.sciencedirect.com/journal/epidemics/vol/23/suppl/C>

[Reviewed earlier]

Epidemiology and Infection

Volume 146 - Issue 8 - June 2018

<https://www.cambridge.org/core/journals/epidemiology-and-infection/latest-issue>

[Reviewed earlier]

The European Journal of Public Health

Volume 28, Issue 3, 1 June 2018

<https://academic.oup.com/eurpub/issue/28/3>

[Reviewed earlier]

Global Health Action

Volume 11, 2018 – Issue 1

<https://www.tandfonline.com/toc/zgha20/11/1?nav=tocList>

[Reviewed earlier]

Global Health: Science and Practice (GHSP)

June 2018 | Volume 6 | Number 2

<http://www.ghspjournal.org/content/current>

[Reviewed earlier]

Global Public Health

Volume 13, 2017 Issue 8

<http://www.tandfonline.com/toc/rgph20/current>

Special Symposium: Critical Perspectives on the 'End of AIDS'.

Guest Editors: Nora Kenworthy, Matthew Thomann, and Richard Parker

[Reviewed earlier]

Globalization and Health

<http://www.globalizationandhealth.com/>

[Accessed 14 Jul 2018]

[No new digest content identified]

Health Affairs

Vol. 37 , No. 7 July 2018

<https://www.healthaffairs.org/toc/hlthaff/current>

Chronic Care, Prescription Drugs & More

[New issue; No digest content identified]

Health and Human Rights

Volume 20, Issue 1, June 2018

<http://www.hhrjournal.org/>

[Reviewed earlier]

Health Economics, Policy and Law

Volume 13 - Special Issue 3-4 - July 2018

<https://www.cambridge.org/core/journals/health-economics-policy-and-law/latest-issue>

SPECIAL ISSUE: Canadian Medicare: Historical Reflections, Future Directions

[Reviewed earlier]

Health Equity

Volume 2 Issue 1 Jun 2018

<https://www.liebertpub.com/toc/heq/2/1>

[Reviewed earlier]

Health Policy and Planning

Volume 33, Issue 6, 1 July 2018

<http://heapol.oxfordjournals.org/content/current>

[Reviewed earlier]

Health Research Policy and Systems

<http://www.health-policy-systems.com/content>

[Accessed 14 Jul 2018]

[No new digest content identified]

Humanitarian Exchange Magazine

Number 72 July 2018

<https://odihpn.org/magazine/mental-health-and-psychosocial-support-in-humanitarian-crises/>

[Mental health and psychosocial support in humanitarian crises](#)

by Humanitarian Practice Network July 2018

Human Vaccines & Immunotherapeutics (formerly Human Vaccines)

Volume 14, Issue 6 2018

<http://www.tandfonline.com/toc/khvi20/current>

[Reviewed earlier]

Infectious Agents and Cancer

<http://www.infectagentscancer.com/content>

[Accessed 14 Jul 2018]

[No new digest content identified]

Infectious Diseases of Poverty

<http://www.idpjournal.com/content>

[Accessed 14 Jul 2018]

[No new digest content identified]

International Health

Volume 10, Issue 4, 1 July 2018

<http://inthehealth.oxfordjournals.org/content/current>

[Reviewed earlier]

International Journal of Community Medicine and Public Health

Vol 5, No 7 (2018) July 2018

<http://www.ijcmph.com/index.php/ijcmph/issue/view/40>

[Reviewed earlier]

International Journal of Epidemiology

Volume 47, Issue 3, 1 June 2018

<https://academic.oup.com/ije/issue/47/2>

[Reviewed earlier]

International Journal of Human Rights in Healthcare

Volume 11 Issue 3 2018

<https://www.emeraldinsight.com/toc/ijhrh/11/3>

[Reviewed earlier]

International Journal of Infectious Diseases

July 2018 Volume 72, p1-72

[https://www.ijidonline.com/issue/S1201-9712\(18\)X0006-X](https://www.ijidonline.com/issue/S1201-9712(18)X0006-X)

[Reviewed earlier]

JAMA

July 10, 2018, Vol 320, No. 2, Pages 109-212

<http://jama.jamanetwork.com/issue.aspx>

Editorial

[Evaluating Health Technology Through Pragmatic Trials Novel Approaches to Generate High-Quality Evidence](#)

Eric D. Peterson, MD, MPH; Robert A. Harrington, MD

Abstract

Information technology (IT), including digital technologies, wearable sensors, and advanced computational methods, is rapidly transforming the world. From banking, shopping, socializing,

and even driving, IT is disrupting nearly every facet of modern life. Despite initial resistance, medical care is finally, albeit slowly, bending to the transformative power of technological innovations. Investments in health technology have increased substantially; in 2017, an estimated \$6 billion was invested in digital health IT companies, and an estimated \$40 billion was spent by consumers on wearables and health monitoring devices.[1](#),[2](#)

JAMA Pediatrics

July 2018, Vol 172, No. 7, Pages 605-708
<http://archpedi.jamanetwork.com/issue.aspx>
[Reviewed earlier]

JBIR Database of Systematic Review and Implementation Reports

July 2018 - Volume 16 - Issue 7
<http://journals.lww.com/jbisrir/Pages/currenttoc.aspx>
[New issue; No digest content identified]

Journal of Adolescent Health

June 2018 Volume 62, Issue 6, p633-754
[https://www.jahonline.org/issue/S1054-139X\(17\)X0021-9](https://www.jahonline.org/issue/S1054-139X(17)X0021-9)
[Reviewed earlier]

Journal of Community Health

Volume 43, Issue 4, August 2018
<https://link.springer.com/journal/10900/43/4/page/1>
[Reviewed earlier]

Journal of Empirical Research on Human Research Ethics

Volume 13, Issue 3, July 2018
<http://journals.sagepub.com/toc/jre/current>
[Reviewed earlier]

Journal of Epidemiology & Community Health

July 2018 - Volume 72 - 7
<http://jech.bmj.com/content/current>
[New issue; No digest content identified]

Journal of Evidence-Based Medicine

Volume 11, Issue 2 Pages: 69-129 May 2018
<https://onlinelibrary.wiley.com/toc/17565391/current>
[Reviewed earlier]

Journal of Global Ethics

Volume 13, Issue 3, 2017

<http://www.tandfonline.com/toc/rjge20/current>

[Reviewed earlier]

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

Volume 29, Number 2, May 2018

<https://muse.jhu.edu/issue/38537>

[Reviewed earlier]

Journal of Humanitarian Logistics and Supply Chain Management

Volume 8 Issue 1 2018

<https://www.emeraldinsight.com/toc/jhlscm/8/1>

[Reviewed earlier]

Journal of Immigrant and Minority Health

Volume 20, Issue 4, August 2018

<https://link.springer.com/journal/10903/20/4/page/1>

[Reviewed earlier]

Journal of Immigrant & Refugee Studies

Volume 16, 2018_ Issue 4

<http://www.tandfonline.com/toc/wimm20/current>

[Reviewed earlier]

Journal of Infectious Diseases

Volume 217, Issue 11, 14 Jul 2018

<https://academic.oup.com/jid/issue/217/1>

[Reviewed earlier]

Journal of Medical Ethics

July 2018 - Volume 44 - 7

<http://jme.bmj.com/content/current>

[Reviewed earlier]

Journal of Medical Internet Research

Vol 20, No 6 (2018): June

<http://www.jmir.org/2018/6>

[Reviewed earlier]

Journal of Medical Microbiology

Volume 67, Issue 6, June 2018

<http://jmm.microbiologyresearch.org/content/journal/jmm/67/6>

[Reviewed earlier]

Journal of Patient-Centered Research and Reviews

Volume 5, Issue 2 (2018)

<https://digitalrepository.aurorahealthcare.org/jpcrr/>

[Reviewed earlier]

Journal of the Pediatric Infectious Diseases Society (JPIDS)

Volume 7, Issue 2 June 2018

<https://academic.oup.com/jpids/issue>

[Reviewed earlier]

Journal of Pediatrics

July 2018 Volume 198, p1-330

<http://www.jpeds.com/current>

[New issue; No digest content identified]

Journal of Pharmaceutical Policy and Practice

<https://joppp.biomedcentral.com/>

[Accessed 14 Jul 2018]

[No new digest content identified]

Journal of Public Health Management & Practice

July/August 2018 - Volume 24 - Issue 4

<https://journals.lww.com/jphmp/pages/currenttoc.aspx>

[Reviewed earlier]

Journal of Public Health Policy

Volume 39, Issue 2, May 2018

<https://link.springer.com/journal/41271/39/2/page/1>

[Reviewed earlier]

Journal of the Royal Society – Interface

May 2018; volume 15, issue 142

<http://rsif.royalsocietypublishing.org/content/current>

[Reviewed earlier]

Journal of Travel Medicine

Volume 25, Issue suppl_1, 1 May 2018

https://academic.oup.com/jtm/issue/25/suppl_1

Asian travel: from the rare to the difficult

[Reviewed earlier]

Journal of Virology

July 2018, volume 92, issue 14

<http://jvi.asm.org/content/current>

[Reviewed earlier]

The Lancet

Jul 14, 2018 Volume 392 Number 10142 p95-186 e1-e3

<https://www.thelancet.com/journals/lancet/issue/current>

[New issue; No digest content identified]

Lancet Global Health

Jul 2018 Volume 6 Number 7 e703-e810

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

[Reviewed earlier]

Lancet Infectious Diseases

Jul 2018 Volume 18 Number 7 p697-812 e183-e227

<http://www.thelancet.com/journals/laninf/issue/current>

[Reviewed earlier]

Lancet Respiratory Medicine

Jul 2018 Volume 6 Number 7 p479-566 e28-e35

<http://www.thelancet.com/journals/lanres/issue/current>

[Reviewed earlier]

Maternal and Child Health Journal

Volume 22, Issue 7, July 2018

<https://link.springer.com/journal/10995/22/6/page/1>

[Reviewed earlier]

Medical Decision Making (MDM)

Volume 38, Issue 5, July 2018

<http://mdm.sagepub.com/content/current>

[Reviewed earlier]

The Milbank Quarterly

A Multidisciplinary Journal of Population Health and Health Policy

Volume 96, Issue 2 Pages: 215-408 June 2018

<https://onlinelibrary.wiley.com/toc/14680009/current>

[Reviewed earlier]

Nature

Volume 559 Issue 7713, 12 July 2018

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

[New issue; No digest content identified]

Nature Medicine

Volume 24 Issue 7, July 2018

<https://www.nature.com/nm/volumes/24/issues/7>

[New issue; No digest content identified]

Nature Reviews Immunology

Volume 18 Issue 7, July 2018

<https://www.nature.com/nri/volumes/18/issues/7>

[Reviewed earlier]

New England Journal of Medicine

July 12, 2018 Vol. 379 No. 2

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

Perspective

[A Parallel Universe of Clinical Trials](#)

Bernard Lo, M.D.

A recent clinical trial of a herpes simplex virus vaccine allegedly violated fundamental scientific, regulatory, and ethical safeguards. This case opens a window into a parallel universe that spurns the current system of clinical trial oversight in the United States and supports broad right-to-try laws allowing patients access to experimental therapies...

Original Articles

[Prevention of M. tuberculosis Infection with H4:IC31 Vaccine or BCG Revaccination](#)

E. Nemes and Others

Recent Mycobacterium tuberculosis infection confers a predisposition to the development of tuberculosis disease, the leading killer among global infectious diseases. H4:IC31, a candidate subunit vaccine, has shown protection against tuberculosis disease in preclinical models, and observational studies have indicated that primary bacille Calmette–Guérin (BCG) vaccination may offer partial protection against infection.

Pediatrics

July 2018, VOLUME 142 / ISSUE 1

<http://pediatrics.aappublications.org/content/142/1?current-issue=y>

[Reviewed earlier]

Pharmaceutics

Volume 36, Issue 7, July 2018

<https://link.springer.com/journal/40273/36/7/page/1>

Editorial

Should Low- and Middle-Income Countries Adopt Clinical Guidelines Developed in 'Rich' Countries?

Alan Haycox

PharmacoEconomics

Volume 36, Issue 6, June 2018

<https://link.springer.com/journal/40273/36/6/page/1>

[Reviewed earlier]

PLOS Currents: Disasters

<http://currents.plos.org/disasters/>

[Accessed 14 Jul 2018]

Development and Implementation of the World Health Organization Emergency Medical Teams: Minimum Technical Standards and Recommendations for Rehabilitation

July 9, 2018 · *Discussion*

Emergency medical teams provide urgent medical and surgical care in emergencies characterized by a surge in trauma or disease. Rehabilitation has historically not been included in the acute phase of care, as teams have either not perceived it as their responsibility or have relied on external providers, including local services and international organizations, to provide services. Low- and middle-income countries, which often have limited rehabilitation capacity within their health system, are particularly vulnerable to disaster and are usually ill-equipped to address the increased burden of rehabilitation needs that arise. The resulting unmet needs for rehabilitation culminate in unnecessary complications for patients, delayed recovery, reduced functional outcomes, and often impede return to daily activities and life roles. Recognizing the systemic neglect of rehabilitation in global emergency medical response, the World Health Organization, in collaboration with key operational partners and experts, developed technical standards and recommendations for rehabilitation which are integrated into the WHO verification process for EMTs. This protocol report presents: 1) the rationale for the development of the standards and accompanying recommendations; 2) the methodology of the development process; 3) the minimum standards and other significant content included in the document; 4) challenges encountered during development and implementation; and 5) current and next steps to continue strengthening the inclusion of rehabilitation in emergency medical response

PLoS Currents: Outbreaks

<http://currents.plos.org/outbreaks/>

[Accessed 14 Jul 2018]

[No new digest content identified]

PLoS Medicine

<http://www.plosmedicine.org/>

(Accessed 14 Jul 2018)

[No new digest content identified]

PLoS Neglected Tropical Diseases

<http://www.plosntds.org/>

(Accessed 14 Jul 2018)

[No new digest content identified]

PLoS One

<http://www.plosone.org/>

[Accessed 14 Jul 2018]

Research Article

[**The effect of maternal decisional authority on children's vaccination in East Asia**](#)

Minsoo Jung

Research Article | published 12 Jul 2018 PLOS ONE

<https://doi.org/10.1371/journal.pone.0200333>

PLoS Pathogens

<http://journals.plos.org/plospathogens/>

[Accessed 14 Jul 2018]

[No new digest content identified]

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

<http://www.pnas.org/content/early/>

[Accessed 14 Jul 2018]

[No new digest content identified]

Prehospital & Disaster Medicine

Volume 33 - Issue 3 - June 2018

<https://www.cambridge.org/core/journals/prehospital-and-disaster-medicine/latest-issue>

[Reviewed earlier]

Preventive Medicine

Volume 112 Pages 1-222 (July 2018)

<https://www.sciencedirect.com/journal/preventive-medicine/vol/112/suppl/C>

[Reviewed earlier]

Proceedings of the Royal Society B

16 May 2018; volume 285, issue 1878

<http://rspb.royalsocietypublishing.org/content/285/1878?current-issue=y>

[Reviewed earlier]

Public Health

July 2018 Volume 160, p1-166

<http://www.publichealthjrnal.com/current>

[Reviewed earlier]

Public Health Ethics

Volume 11, Issue 2, 1 July 2018

<http://phe.oxfordjournals.org/content/current>

Special Symposium on Public Mental Health Ethics

Original Articles

[The Acceptability of Online Consent in a Self-Test Serosurvey of Responders to the 2014–2016 West African Ebola Outbreak](#)

Catherine R McGowan; Catherine F Houlihan; Patricia Kingori; Judith R Glynn

Public Health Ethics, Volume 11, Issue 2, 1 July 2018, Pages 201–212,

<https://doi.org/10.1093/phe/phx027>

Abstract

Online participation in research is used increasingly to recruit geographically dispersed populations. Obtaining online consent is convenient, yet we know little about the acceptability of this practice. We carried out a serostudy among personnel returning to the UK/Ireland following deployment to West Africa during the 2014–2016 Ebola epidemic. We used an online procedure for consenting returnees and designed a small descriptive study to understand: how much of the consent material they read, how informed they felt and if they preferred online to traditional face-to-face consent. Of 261 returnees, 111 (43 per cent) completed the consent survey. Participants indicated a high level of engagement with the consent materials, with 67 per cent reporting having read all and 20 per cent having read 'most' of the materials. All participants indicated feeling completely (78 per cent) or mostly (22 per cent) informed about the purpose, methods and intended uses of the research, as well as what participation was required and what risks were involved. Only three participants indicated a preference for face-to-face consent. Free-text comments suggested that online consent may be an acceptable modality for uncomplicated and low-risk studies. The study sample was largely composed of health professionals, suggesting acceptability of online consent within this population.

[Influenza Vaccination Strategies Should Target Children](#)

Ben Bamberg; Thomas Douglas; Michael J Selgelid; Hannah Maslen; Alberto Giubilini ...

Public Health Ethics, Volume 11, Issue 2, 1 July 2018, Pages 221–234,

<https://doi.org/10.1093/phe/phx021>

Abstract

Strategies to increase influenza vaccination rates have typically targeted healthcare professionals (HCPs) and individuals in various high-risk groups such as the elderly. We argue that they should (instead or as well) focus on increasing vaccination rates in children. Because children suffer higher influenza incidence rates than any other demographic group, and are major drivers of seasonal influenza epidemics, we argue that influenza vaccination strategies that serve to increase uptake rates in children are likely to be more effective in reducing influenza-related morbidity and mortality than those targeting HCPs or the elderly. This is true even though influenza-related morbidity and mortality amongst children are low, except in the very young. Further, we argue that there are no decisive reasons to suppose that children-focused strategies are less ethically acceptable than elderly or HCP-focused strategies.

Public Health Reports

Volume 133 Issue 4, July/August 2018

<http://phr.sagepub.com/content/current>

[Reviewed earlier]

Qualitative Health Research

Volume 28 Issue 9, July 2018

<http://qhr.sagepub.com/content/current>

[Reviewed earlier]

Research Ethics

Volume 14, Issue 1, Jan - Mar 2018

<http://journals.sagepub.com/toc/reab/current>

[Reviewed earlier]

Reproductive Health

<http://www.reproductive-health-journal.com/content>

[Accessed 14 Jul 2018]

[No new digest content identified]

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

http://www.paho.org/journal/index.php?option=com_content&view=featured&Itemid=101

Thematic issue: Economics of NCDs

The global health burden of noncommunicable diseases (NCDs) is large and growing, as this group of diseases already accounts for 70% of total deaths. Global evidence indicates that the high health burden of NCDs translates into significant economic and social costs that threaten to diminish the quality of life of millions of individuals, impoverish families, jeopardize universal health coverage, and increase health disparities within and between countries. Evidence consistently shows that the NCD epidemic cannot be tackled through interventions and policies in the health sector alone. In particular, prevention measures that address NCD risk factors

involve a range of sectors including finance, trade, education, agriculture, and transportation. As economics has become the common language among decision makers across sectors, it is imperative that health authorities leverage economic information to more effectively communicate the urgency of tackling NCDs and related risk factors.

This thematic issue of the Pan American Journal of Public Health is part of a continued collaboration between the Public Health Agency of Canada (PHAC) and PAHO/WHO to facilitate intragovernmental dialogue for a better understanding of NCD issues by making economic evidence available in the Americas, and to assist countries in integrating economic approaches into their NCD prevention and control policies.

[Reviewed earlier]

Risk Analysis

Volume 38, Issue 7 Pages: 1319-1518 July 2018

<https://onlinelibrary.wiley.com/toc/15396924/current>

[New issue; No digest content identified]

Risk Management and Healthcare Policy

Volume 10, 2017

<https://www.dovepress.com/risk-management-and-healthcare-policy-archive56>

[Reviewed earlier]

Science

13 July 2018 Vol 361, Issue 6398

<http://www.sciencemag.org/current.dtl>

Policy Forum

Citizen science, public policy

By Christi J. Guerrini, Mary A. Majumder, Meaganne J. Lewellyn, Amy L. McGuire

Science 13 Jul 2018 : 134-136 Full Access

Summary

Citizen science initiatives that support collaborations between researchers and the public are flourishing. As a result of this enhanced role of the public, citizen science demonstrates more diversity and flexibility than traditional science and can encompass efforts that have no institutional affiliation, are funded entirely by participants, or continuously or suddenly change their scientific aims. But these structural differences have regulatory implications that could undermine the integrity, safety, or participatory goals of particular citizen science projects. Thus far, citizen science appears to be addressing regulatory gaps and mismatches through voluntary actions of thoughtful and well-intentioned practitioners. But as citizen science continues to surge in popularity and increasingly engage divergent interests, vulnerable populations, and sensitive data, it is important to consider the long-term effectiveness of these private actions and whether public policies should be adjusted to complement or improve on them. Here, we focus on three policy domains that are relevant to most citizen science projects: intellectual property (IP), scientific integrity, and participant protections.

Science Translational Medicine

11 July 2018 Vol 10, Issue 449
<http://stm.sciencemag.org/>
[New issue; No digest content identified]

Social Science & Medicine

Volume 208 Pages 1-208 (July 2018)
<https://www.sciencedirect.com/journal/social-science-and-medicine/vol/208/suppl/C>
[New issue; No digest content identified]

Systematic Reviews

<https://systematicreviewsjournal.biomedcentral.com/articles>
[Accessed 14 Jul 2018]
[No new digest content identified]

Travel Medicine and Infectious Diseases

July-August, 2018 Volume 24
<http://www.travelmedicinejournal.com/>
Systematic review

[A systematic review of emerging respiratory viruses at the Hajj and possible coinfection with *Streptococcus pneumoniae*](#)

The annual Hajj to the Kingdom of Saudi Arabia attracts millions of pilgrims from around the world. International health community's attention goes towards this mass gathering and the possibility of the development of any respiratory tract infections due to the high risk of acquisition of respiratory viruses... Well conducted multinational follow-up studies using the same methodology of testing are necessary for accurate surveillance of respiratory viral infections among Hajj pilgrims. Post-Hajj cohort studies would further evaluate the impact of the Hajj on the acquisition of respiratory viruses.

Jaffar A. Al-Tawfiq, Samir Benkouiten, Ziad A. Memish
Vol. 23, p6–13
Published online: April 16, 2018

Tropical Medicine & International Health

Volume 23, Issue 7 Pages: i-iv, 691-813 July 2018
<https://onlinelibrary.wiley.com/toc/13653156/current>
[Reviewed earlier]

Vaccine

Volume 36, Issue 31 Pages 4589-4758 (25 July 2018)
<https://www.sciencedirect.com/journal/vaccine/vol/36/issue/31>
Short communication

[Lack of impact of rotavirus vaccination on childhood seizure hospitalizations in England – An interrupted time series analysis](#)

Pages 4589-4592

Rachael Biggart, Adam Finn, Robin Marlow

Reviews

Meningococcal disease burden and transmission in crowded settings and mass gatherings other than Hajj/Umrah: A systematic review

Review article

Pages 4593-4602

Al-Mamoon Badahdah, Harunor Rashid, Ameneh Khatami, Robert Booy

Prevention of meningococcal disease at mass gatherings: Lessons from the Hajj and Umrah

Review article

Pages 4603-4609

Saber Yezli, Philippe Gautret, Abdullah M. Assiri, Bradford D. Gessner, Badriah Alotaibi

Regular papers

Potential cost-effectiveness of adjuvanted herpes zoster subunit vaccine for older adults in Hong Kong

Original research article

Pages 4610-4620

Joyce H.S. You, Wai-kit Ming, Chak-fei Lee, Owen Tak-yin Tsang, Paul Kay-sheung Chan

Tailoring immunisation programmes: Using behavioural insights to identify barriers and enablers to childhood immunisations in a Jewish community in London, UK

Original research article

Pages 4687-4692

Louise Letley, Vanessa Rew, Rehana Ahmed, Katrine Bach Habersaat, ... Robb Butler

Threats to oral polio vaccine acceptance in Somalia: Polling in an outbreak

Original research article

Pages 4716-4724

Gillian K. SteelFisher, Robert J. Blendon, Rustam Haydarov, William Lodge, ... Christoph Sahm

Socioeconomic drivers of vaccine uptake: An analysis of the data of a geographically defined cluster randomized cholera vaccine trial in Bangladesh

Open access - Original research article

Pages 4742-4749

Amit Saha, Andrew Hayen, Mohammad Ali, Alexander Rosewell, ... Firdausi Qadri

Vaccine: Development and Therapy

<https://www.dovepress.com/vaccine-development-and-therapy-archive111>

(Accessed 14 Jul 2018)

[No new digest content identified]

Vaccines — Open Access Journal

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

(Accessed 14 Jul 2018)
[No new digest content identified]

Value in Health

July 2018 Volume 21, Issue 7, p759-896
<http://www.valueinhealthjournal.com/current>
[New issue; No digest content identified]

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From Google Scholar & other sources: Selected Journal Articles, Newsletters, Dissertations, Theses, Commentary

Clinical Infectious Diseases (CID)

Published: 07 July 2018

Accepted Manuscript

[The Efficacy of the Quadrivalent Human Papillomavirus Vaccine in Girls and Women Living with HIV](#)

E McClymont, M Lee, J Raboud, F Coutlée, S Walmsley... -

Abstract

Background

Human papillomavirus (HPV) vaccination is safe and efficacious in women without HIV. While good immunogenicity has been observed in women living with HIV (WLWH), efficacy data in this population are needed.

Methods

We enrolled 420 females aged ≥ 9 years (range: 9-65) living with HIV. Participants were to receive 3 doses of qHPV vaccine (0/2/6 months). The main endpoint was vaccine failure (i.e., incident persistent qHPV infection, cervical intraepithelial neoplasia of grade 2 or higher (CIN2+), or genital warts). We compared these rates to published rates in vaccinated and unvaccinated women without HIV as well as unvaccinated WLWH.

Results

Among 279 eligible women, median follow-up was 2 years. In the intention-to-treat population, the incidence rate (IR) of persistent qHPV (HPV6/11/16/18) was 2.3 per 100 person-years (/100PY) (95% confidence interval [CI]=1.1-4.1) and IR of genital warts was 2.3/100PY (95% CI=1.2-4.1). In the per-protocol efficacy population, IR of persistent qHPV was 1.0/100PY (95% CI=0.3-2.6) and of genital warts was 1.0/100PY (95% CI=0.3-2.5). No cases of CIN2+ occurred. Reported rates of qHPV-related infection and disease within the vaccinated women without HIV, unvaccinated women without HIV, and the vaccinated WLWH: 0.1 (95% CI=0.02-0.03), 1.5 (95% CI=1.1-2.0), and 1.2 (95% CI=0.2-3.4) /100PY, respectively. The rate of persistent qHPV among vaccinated WLWH was lower than among unvaccinated WLWH (2.3 vs. 6.0/100PY).

Conclusions

Vaccinated WLWH may be at higher risk for vaccine failure than vaccinated women without HIV. However, overall rates of vaccine failure were low and rates of persistent qHPV were lower than in unvaccinated WLWH.

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Media/Policy Watch

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

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

The Atlantic

<http://www.theatlantic.com/magazine/>

Accessed 14 Jul 2018

The Next Plague Is Coming. Is America Ready?

The epidemics of the early 21st century revealed a world unprepared, even as the risks continue to multiply. Much worse is coming.

Ed Yong July/August 2018 Issue

BBC

<http://www.bbc.co.uk/>

Accessed 14 Jul 2018

[No new, unique, relevant content]

The Economist

<http://www.economist.com/>

Accessed 14 Jul 2018

MEDICINE AND VACCINE SHORTAGES – WHAT IS THE ROLE OF GLOBAL REGULATORY COMPLEXITY FOR POST APPROVAL CHANGES?

[See Research above for more detail]

Financial Times

<http://www.ft.com/home/uk>

Accessed 14 Jul 2018

[No new, unique, relevant content]

Forbes

<http://www.forbes.com/>

Accessed 14 Jul 2018

[No new, unique, relevant content]

Foreign Affairs

<http://www.foreignaffairs.com/>

Accessed 14 Jul 2018

[No new, unique, relevant content]

Foreign Policy

<http://foreignpolicy.com/>

Accessed 14 Jul 2018

[No new, unique, relevant content]

The Guardian

<http://www.guardiannews.com/>

Accessed 14 Jul 2018

Italy

Rise of Italian populist parties buoys anti-vaccine movement

Backlash against sportsman's post about his young daughter highlights lingering distrust

When Ivan Zaytsev, a volleyball player with Italy's national team and an Olympic medallist, posted a picture of himself alongside his child on social media last week, it wasn't intended to be a political statement.

His seven-month-old daughter had just received a vaccine and Zaytsev wanted to celebrate her bravery. But within seconds he was hit with a deluge of abuse from anti-vaccine activists. The attacks ranged from accusations of being bankrolled by pharmaceutical companies to chilling messages wishing for his child to contract a disease.

"I wanted to share this moment as a parent and congratulate my daughter – she smiled during the entire process – as well as reassure other parents," Zaytsev, who also has a son, told the Guardian. "I realise that I'm a public figure and everything I do has consequences, but I didn't expect this. When it touches me it's one thing, but when they wish illness for your children then you become very angry."...

New Yorker

<http://www.newyorker.com/>

Accessed 14 Jul 2018

[No new, unique, relevant content]

New York Times

<http://www.nytimes.com/>

Accessed 14 Jul 2018

Asia Pacific

Despite Detente, Sanctions on North Korea Fan TB Epidemic

Wall Street Journal

http://online.wsj.com/home-page?_wsjregion=na_us&_homepage=/home/us

Accessed 14 Jul 2018

[No new, unique, relevant content]

Washington Post

<http://www.washingtonpost.com/>

Accessed 14 Jul 2018

If we really want to eradicate diseases such as Ebola, we need a new strategy

Infrastructure isn't sexy, but it's the best way to fight disease [cold chain]

9 July 2018

by Heidi Morefiel

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Think Tanks et al

Brookings

<http://www.brookings.edu/>

Accessed 14 Jul 2018

[No new relevant content]

Center for Global Development

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

Accessed 14 Jul 2018

What You Should Know About Global Health Financing Transitions: Five Key Takeaways

12 July 2018

In recent years many global health institutions—particularly Gavi and the Global Fund—have adopted eligibility and transition frameworks for the countries they support. These frameworks lay out criteria under which countries will lose eligibility for their support, and, typically, a gradual timeframe to phase out external financing. The question of how these transitions will play out in practice—and whether global health progress will be put at risk through premature or poorly planned transitions—is a hot topic in global health.

CSIS

<https://www.csis.org/>

Accessed 14 Jul 2018

[No new relevant content]

Council on Foreign Relations

<http://www.cfr.org/>

Accessed 14 Jul 2018

[No new relevant content]

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

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

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

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